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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD-9726]

RIN 1545-BJ58, 1545-BM37, 1545-BM39

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2510 and 2590

RIN 1210-AB67

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS-9940-F]

RIN 0938-AS50

Coverage of Certain Preventive Services Under the Affordable Care Act

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

ACTION: Final rules.

SUMMARY: This document contains final regulations regarding coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. These regulations finalize provisions from three rulemaking actions: interim final regulations issued in July 2010 related to coverage of preventive services, interim final regulations issued in August 2014 related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, and proposed regulations issued in August 2014 related to the definition of “eligible organization,” which would expand the set of entities that may avail themselves of an accommodation with respect to the coverage of contraceptive services.

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

Applicability Date: These final regulations are applicable beginning on the first day of the first plan year (or, for individual health insurance coverage, the first day of the first policy year) that begins on or after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT:

David Mlawsky, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786-1565; Amy Turner or Elizabeth Schumacher, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; or Karen Levin, Internal Revenue Service (IRS), Department of the Treasury, at (202) 927-9639.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's web site (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS's web site (www.cms.gov/ccio), and information on health care reform can be found at 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 of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. These statutes 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 Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide

coverage of certain specified preventive services without cost sharing. These preventive services include:

- Evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (Task Force) with respect to the individual involved.
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved. A recommendation of the Advisory Committee is considered to be “in effect” after it has been adopted by the Director of the Centers for Disease Control and Prevention (CDC). A recommendation is considered to be for “routine use” if it appears on the Immunization Schedules of the CDC.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- With respect to women, preventive care and screenings provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force), including all Food and Drug Administration (FDA)-approved contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).¹

The complete list of recommendations and guidelines that are required to be covered under these final regulations can be found at: <https://www.healthcare.gov/preventive-care->

¹ The HRSA Guidelines exclude services relating to a man’s reproductive capacity, such as vasectomies and condoms.

benefits. Together, the items and services described in these recommendations and guidelines are referred to in this preamble as “recommended preventive services.”

The Departments of Labor, Health and Human Services, and the Treasury (the Departments)² have issued rulemaking to implement these requirements:

- Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations), implemented the preventive services requirements of PHS Act section 2713;
- Interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621, provided HRSA with the authority to exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with those plans) from the requirement to cover contraceptive services consistent with the HRSA Guidelines;³
- Final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations), finalized the definition of religious employer in the 2011 amended interim final regulations without modification;⁴

² Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

³ On the same date, HRSA exercised this authority in the HRSA Guidelines to exempt group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) from the HRSA Guidelines with respect to contraceptive services.

⁴ Contemporaneous with the issuance of the 2012 final regulations, HHS, with the agreement of the Departments of Labor and the Treasury, issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments for group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans) originally issued on February 10, 2012, and reissued on August 15, 2012, and June 28, 2013; available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf>. The guidance clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See Student Health Insurance Coverage, 77 FR 16457 (Mar. 21, 2012).

- An advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501, solicited comments on how to provide for coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously ensuring that certain nonprofit organizations with religious objections to contraceptive coverage would not be required to contract, arrange, pay, or refer for that coverage;
- Proposed regulations on February 6, 2013, at 78 FR 8456, proposed to simplify and clarify the definition of “religious employer” for purposes of the religious employer exemption, and proposed accommodations for group health plans established or maintained by certain nonprofit religious organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with those plans) and for insured student plans arranged by certain nonprofit religious organizations that are institutions of higher education with religious objections to contraceptive coverage;
- Final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations), simplified and clarified the definition of religious employer for purposes of the religious employer exemption and established accommodations for health coverage established or maintained or arranged by eligible organizations;⁵
- Interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations), amended the July 2013 final regulations in light of the United States Supreme

⁵ A contemporaneously re-issued HHS guidance document extended the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This guidance included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary enforcement safe harbor. In addition, HHS and the Department of Labor (DOL) issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under the July 2013 final regulations. This self-certification form was provided for use with the accommodation under the July 2013 final regulations, after the expiration of the temporary enforcement safe harbor (that is, for plan years beginning on or after January 1, 2014). See <http://www.cms.gov/CCIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf>.

Court's interim order in connection with an application for an injunction in Wheaton College v. Burwell (Wheaton interim order),⁶ and provided an alternative process that an eligible organization may use to provide notice of its religious objection to the coverage of contraceptive services; and

- Proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations), proposed potential changes to the definition of "eligible organization" in light of the United States Supreme Court's decision in Burwell v. Hobby Lobby Stores, Inc.⁷

In addition to these regulations, the Departments released six sets of Frequently Asked Questions (FAQs) regarding the preventive services coverage requirements. The Departments released FAQs about Affordable Care Act Implementation Parts II, V, XII, XIX, XX, and XXVI to answer outstanding questions, including questions related to the coverage of preventive services. These FAQs provided guidance related to compliance with the 2010 and 2014 interim final regulations, and addressed issues related to specific services required to be covered without cost sharing, subject to reasonable medical management, under recommendations and guidelines specified in section 2713 of the PHS Act. Information on related safe harbors, forms, and model notices is available at <http://www.dol.gov/ebsa/healthreform> and <http://www.cms.gov/cciio/resources/regulations-and-guidance/index.html>.

After consideration of the comments and feedback received from stakeholders, the Departments are publishing these final regulations⁸, which finalize the July 2010 interim final

⁶ 134 S. Ct. 2806 (2014).

⁷ 134 S. Ct. 2751 (2014).

⁸ The Department of the Treasury/Internal Revenue Service published temporary regulations and proposed regulations with the text of the temporary regulations serving as the text of the proposed regulations as part of each of the joint rulemaking interim final rules listed above. The Departments of Labor and HHS published their rules as

regulations related to coverage of recommended preventive services, the August 2014 interim final regulations related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, and the August 2014 proposed regulations related to the definition of eligible organization.

II. Overview of the Final Regulations

A. Coverage of Recommended Preventive Services under 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130.

(i) Scope of recommended preventive services

Section 2713 of the PHS Act, as added by the Affordable Care Act, requires that a non-grandfathered group health plan or a health insurance issuer offering non-grandfathered group or individual health insurance coverage provide, without cost sharing, coverage for recommended preventive services, as outlined above. The July 2013 final regulations finalized the requirement to provide coverage without cost sharing with respect to those preventive services provided for in the HRSA Guidelines for women. These regulations finalize the requirement to provide coverage without cost sharing with respect to the other three categories of recommendations and guidelines specified in section 2713 of the PHS Act: evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the Task Force, immunizations for routine use that have in effect a recommendation from the Advisory Committee, and evidence-informed preventive care and screenings for infants, children, and adolescents, provided for in guidelines supported by HRSA. The complete list of recommendations and guidelines can be found at: <https://www.healthcare.gov/preventive-care-benefits>.

interim final rules and are finalizing their interim final rules. The Department of the Treasury/Internal Revenue Service is finalizing its proposed rules.

Commenters requested additional clarity on the specific items and services required to be covered without cost sharing. The Departments previously released FAQs about Affordable Care Act Implementation Parts XII⁹ and XIX¹⁰ to provide guidance related to the scope of coverage required under the recommendations and guidelines, including coverage of aspirin and other over-the-counter medication, colonoscopies, BRCA testing, well-woman visits, screening and counseling for interpersonal and domestic violence, HIV and HPV testing, contraception, breastfeeding and lactation counseling, and tobacco cessation interventions. Moreover, on May 11, 2015, the Departments issued FAQs about Affordable Care Act Implementation¹¹ to address specific coverage questions related to BRCA testing, contraception, sex-specific recommended preventive services, services for dependents covered under the plan or policy, and colonoscopies. If additional questions arise regarding the application of the preventive services coverage requirements, the Departments may issue additional subregulatory guidance.

(ii) Office visits

The July 2010 interim final regulations clarified the cost-sharing requirements applicable when a recommended preventive service is provided during an office visit through the use of the “primary purpose” test: First, if a recommended preventive service is billed separately (or is tracked as individual encounter data separately) from an office visit, a plan or issuer may impose cost sharing with respect to the office visit. Second, if a recommended preventive service is not

⁹ See FAQs about Affordable Care Act Implementation Part XII, available at <http://www.dol.gov/ebsa/faqs/aca12.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

¹⁰ See FAQs about Affordable Care Act Implementation Part XIX, available at <http://www.dol.gov/ebsa/faqs/aca19.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.

¹¹ See FAQs about Affordable Care Act Implementation Part XXVI, available at www.dol.gov/ebsa/faqs/FAQs/Downloads/aca_implementatton_faqs26.pdf, and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of the recommended preventive service, a plan or issuer may not impose cost sharing with respect to the office visit. Finally, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of the recommended preventive service, a plan or issuer may impose cost sharing with respect to the office visit. The reference to tracking individual encounter data was included to provide guidance with respect to plans and issuers that use capitation or similar payment arrangements that do not bill individually for items and services.

Several commenters supported the primary purpose test, while other commenters were concerned that the test provides too much discretion to providers or issuers to determine the primary purpose of the visit. Some commenters stated that many individuals only seek medical care from their physician when they are sick, and physicians must be able to provide preventive services, along with other treatment, in a single office visit. Other commenters recommended that the Departments eliminate the primary purpose test. Some of these commenters recommended that cost sharing be prohibited if any recommended preventive service is provided during the visit.

These final regulations continue to provide that when a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit, plans and issuers must look to the primary purpose of the office visit when determining whether they may impose cost sharing with respect to the office visit. Nothing in these requirements precludes a health care provider from providing preventive services, along with other treatment, in a single office visit. These rules only establish the circumstances under which

an office visit that includes a recommended preventive service may be subject to cost sharing. The Departments anticipate that the determination of the primary purpose of the visit will be resolved through normal billing and coding activities, as they are for other services. If questions arise regarding the application of this rule to common medical scenarios, the Departments may issue additional subregulatory guidance.

(iii) Out-of-network providers.

With respect to a plan or health insurance coverage that maintains a network of providers, the July 2010 interim final regulations provided that the plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. The plan or issuer may also impose cost sharing for recommended preventive services delivered by an out-of-network provider.

Several commenters requested the rule be amended to require that preventive services be provided without cost sharing when services are provided out-of-network in all instances. Other commenters suggested that the rule be amended to require out-of-network coverage if an in-network provider is not available to the individual, or if the services are not available to a material segment of the plan's population. One commenter asked that, in a situation where preventive services are obtained from a network provider with the assistance of medical professionals who are out-of-network, all of the services be treated as in-network services, and thus not subject to cost sharing. Several commenters stated that cost sharing for recommended preventive services received from out-of-network providers should not be higher than cost sharing for other ambulatory health services provided on an out-of-network basis.

In response to comments, the Departments issued an FAQ clarifying that, if a plan or issuer does not have in its network a provider who can provide a particular recommended

preventive service, then, consistent with the statute and July 2010 interim final regulations, the plan or issuer must cover, without cost sharing, the item or service when performed by an out-of-network provider.¹² These final regulations adopt the rule of the July 2010 interim final regulations with respect to out-of-network providers, with one clarification. These final regulations incorporate the clarification that a plan or issuer that does not have in its network a provider who can provide a particular recommended preventive service is required to cover the preventive service when performed by an out-of-network provider, and may not impose cost sharing with respect to the preventive service.

(iv) Reasonable medical management.

The July 2010 interim final regulations included a provision on reasonable medical management. Specifically, if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer may use reasonable medical management techniques to determine any coverage limitations.

The Departments received a number of comments related to the use of reasonable medical management techniques. Some commenters were concerned that the July 2010 interim final regulations did not clearly outline what constitutes reasonable medical management techniques, and requested that the Departments provide greater clarity, particularly with respect to a situation where a patient's attending provider determines that the frequency, method, treatment, or setting of a particular item or service is medically appropriate for a particular patient. The Departments issued an FAQ clarifying that, under the July 2010 interim final regulations, to the extent not specified in a recommendation or guideline, a plan or issuer may

¹² See FAQ about Affordable Care Act Implementation Part XII, Q3 at <http://www.dol.gov/ebsa/faqs/faq-aca12.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

rely on the relevant evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for the provision of a recommended preventive service.¹³ These final regulations incorporate the clarification of the July 2010 interim final regulations set forth in the FAQ.

On May 11, 2015, the Departments issued FAQs to provide further guidance on the extent to which plans and issuers may utilize reasonable medical management when providing coverage for recommended women's contraception services in the HRSA guidelines.¹⁴ If further questions arise regarding the permissible application of reasonable medical management techniques, the Departments may issue additional subregulatory guidance.

Other commenters cited the importance of flexibility to permit plans and issuers to maintain programs that are cost-effective, negotiate treatments with high-quality providers at reduced costs, and reduce fraud and abuse. Commenters requested guidance on how plans and issuers may employ value-based insurance designs (VBID) in a manner that complies with the preventive services coverage requirements.¹⁵ Some commenters requested that the final regulations permit plans and issuers to impose cost sharing on non-preferred network tiers for VBIDs. Another commenter requested the Departments permit cost sharing for preventive care delivered at centers of excellence. On December 22, 2010, the Departments issued an FAQ to

¹³ See FAQs about Affordable Care Act Implementation Part II, Q8 available at <http://www.dol.gov/ebsa/faqs/faq-aca2.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.

¹⁴ See FAQs about Affordable Care Act Implementation Part XXVI, available at www.dol.gov/ebsa/faqs/faq-aca26.html and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

¹⁵ The Departments first solicited comments on value-based insurance designs in the July 2010 interim final regulations. 75 FR 41726, 41729. Subsequently, the Departments published a request for information (RFI) related to value-based insurance design on December 28, 2010. 75 FR 81544.

provide guidance regarding VBID related to the coverage of preventive services.¹⁶ If questions arise regarding VBID and the preventive services coverage requirements, the Departments may issue additional subregulatory guidance. Several commenters stated that plans and issuers should be required to use and identify credible references or sources supporting their medical management techniques. The Departments recognize the importance of having access to information relating to medical management techniques that a plan or issuer may apply. Several provisions applicable to plans and issuers address these concerns. ERISA section 104 and the Department of Labor's implementing regulations¹⁷ provide that, for plans subject to ERISA, the plan documents and other instruments under which the plan is established or operated must generally be furnished by the plan administrator to plan participants¹⁸ upon request. In addition, the Department of Labor's claims procedure regulations¹⁹ (applicable to ERISA plans), as well as the Departments' internal claims and appeals and external review regulations under the Affordable Care Act (applicable to all non-grandfathered group health plans and health insurance issuers in the group and individual markets),²⁰ set forth rules regarding claims and appeals, including the right of claimants (or their authorized representatives), upon appeal of an adverse benefit determination (or a final internal adverse benefit determination), to be provided by the plan or issuer, upon request and free of charge, reasonable access to and copies of all documents,

¹⁶ See FAQs about Affordable Care Act Implementation Part V, Q1, available at <http://www.dol.gov/ebsa/faqs/faq-aca5.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.

¹⁷ 29 CFR 2520.104b-1.

¹⁸ ERISA section 3(7) defines a “participant” to include any employee or former employee who is or may become eligible to receive a benefit of any type from an employee benefit plan or whose beneficiaries may be eligible to receive any such benefit. Accordingly, employees who are not enrolled but are, for example, in a waiting period for coverage, or who are otherwise shopping among benefit package options during open season, generally are considered plan participants for this purpose.

¹⁹ 29 CFR 2560.503-1(h)(2)(iii).

²⁰ 29 CFR 2590.715-2719(b)(2)(i) and 45 CFR 147.136(b)(2)(i).

records, and other information relevant to the claimant's claim for benefits. Other Federal and State law requirements may also apply, as applicable.

(v) Services not described.

The July 2010 interim final regulations clarified that a plan or issuer may cover preventive services in addition to those required to be covered by PHS Act section 2713. These final regulations continue to provide that for the additional preventive services, a plan or issuer may impose cost sharing at its discretion, consistent with applicable law. Moreover, a plan or issuer may impose cost sharing for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

(vi) Timing.

The July 2010 interim final regulations provided that plans and issuers must provide coverage for new recommended preventive services for plan years (in the individual market, policy years) beginning on or after the date that is one year after the date the relevant recommendation or guideline under PHS Act section 2713 is issued. Some commenters encouraged the Departments to adopt a shorter implementation timeframe. With respect to the Advisory Committee recommendations, one commenter requested that the effective date for any new recommendation be either the publication of the committee's provisional recommendations or the publication of the official CDC immunization schedules, whichever occurs first. Other commenters expressed support for the implementation timeframe set forth in the July 2010 interim final regulations. The statute requires the Departments to establish an interval of not less than one year between when recommendations or guidelines under PHS Act section 2713(a)²¹

²¹ Section 2713(b)(1) refers to an interval between "the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or

are issued, and the plan year (in the individual market, policy year) for which coverage of the services addressed in the recommendations or guidelines must be in effect.

To provide plans and issuers adequate time to incorporate changes or updates to recommendations and guidelines, as provided in the July 2010 interim final regulations, these final regulations continue to provide that a recommendation or guideline of the Task Force is considered to be issued on the last day of the month on which the Task Force publishes or otherwise releases the recommendation; a recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the CDC; and a recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued on the date on which it is accepted by the Administrator of HRSA or, if applicable, adopted by the Secretary of HHS.

Several commenters supported the policy that plans and issuers should not need to check the recommendations or guidelines for changes during the plan or policy year in order to determine coverage requirements and should not be required to implement changes during the plan or policy year. The Departments adopted this approach in the July 2010 interim final regulations with respect to new recommendations or guidelines that impose additional preventive services coverage requirements, but adopted a different standard for changes in recommendations or guidelines, allowing plans and issuers to eliminate coverage for preventive

guideline.” While the first part of this statement does not mention guidelines under subsection (a)(4), it is the Departments’ view that it would not be reasonable to treat the services covered under subsection (a)(4) any differently than those in subsections (a)(1), (a)(2), and (a)(3). First, the statement refers to “the requirement described in subsection (a),” which would include a requirement under subsection (a)(4). Secondly, the guidelines under (a)(4) are from the same source as those under (a)(3), except with respect to women, rather than infants, children and adolescents; and other preventive services involving women are addressed in subsection (a)(1), so it is reasonable to treat the guidelines under subsection (a)(4) similarly. Third, without this clarification, it would be unclear when such services would have to be covered. The July 2010 interim final regulations and these final regulations accordingly apply the intervals established therein to services under section 2713(a)(4).

services that are no longer recommended during the plan or policy year, consistent with other applicable federal and state law. We agree with those commenters who stated that changes in coverage should not occur during the plan or policy year, and are implementing an approach with respect to changes in recommendations or guidelines that narrow or eliminate coverage requirements for previously recommended services that is similar to the one adopted in the July 2010 interim final regulations for new recommendations or guidelines. Furthermore, participants and beneficiaries of group health plans (and enrollees and dependents in individual market coverage) may make coverage choices based on the benefits offered at the beginning of the plan or policy year. Plan years (and individual market policy years) vary and recommendations and guidelines may be issued at any time during a plan or policy year. These final regulations protect against disruption and provide certainty in coverage (including cost-sharing requirements) for the duration of the plan or policy year. Accordingly, these final regulations state that a plan or issuer that is required to provide coverage for any recommended preventive service on the first day of a plan or policy year under a particular recommendation or guideline must generally provide that coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is eliminated during the plan or policy year.

However, there are limited circumstances under which it may be inadvisable for a plan or issuer to continue to cover preventive items or services associated with a recommendation or guideline that was in effect on the first day of a plan year or policy year (for example, due to safety concerns). Therefore, these final regulations establish that if, during a plan or policy year, (1) an “A” or “B” recommendation or guideline of the Task Force that was in effect on the first day of a plan or policy year is downgraded to a “D” rating (meaning that the Task Force has determined that there is strong evidence that there is no net benefit, or that the harms outweigh

the benefits, and therefore discourages the use of this service), or (2) any item or service associated with any preventive service recommendation or guideline specified in 26 CFR 54.9815-2713(a)(1) or 29 CFR. 2590.715-2713(a)(1) or 45 CFR 147.130(a)(1) that was in effect on the first day of a plan or policy year is the subject of a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate that item or service, there is no requirement under this section to cover these items and services through the last day of the plan or policy year. Should such circumstances arise, the Departments expect to issue subregulatory guidance to this effect with respect to such preventive item or service.

Other requirements of federal or state law may apply in connection with ceasing to provide coverage or changing cost-sharing requirements for any item or service. For example, PHS Act section 2715(d)(4) and its implementing regulations state that if a group health plan or health insurance issuer makes any material modification in any of the terms of the plan or coverage involved that would affect the content of the Summary of Benefits and Coverage (SBC), that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees not later than 60 days prior to the date on which the notification will become effective.

A list of the recommended preventive services is available at <https://www.healthcare.gov/preventive-care-benefits>. We intend to update this list to include the date on which the recommendation or guideline was accepted or adopted. New recommendations and guidelines will also be reflected on this site. Plans and issuers need not make changes to coverage and cost-sharing requirements based on a new recommendation or guideline until the first plan year (in the individual market, policy year) beginning on or after the

date that is one year after the new recommendation or guideline goes into effect. Therefore, by visiting this site once per year, plans or issuers should have access to all the information necessary to identify any additional items or services that must be covered without cost sharing, or to identify any items or services that are no longer required to be covered.

B. Accommodations in Connection with Coverage of Preventive Health Services – 26 CFR 54.9815-2713A, 29 CFR 2510.3-16 and 2590.715-2713A, and 45 CFR 147.131.

(i) The process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services.

After issuing the July 2013 final regulations, the Departments issued August 2014 interim final regulations in light of the Supreme Court's Wheaton interim order concerning notice to the federal government that an eligible organization has a religious objection to providing contraceptive coverage, as an alternative to the EBSA Form 700 method of self-certification, and to preserve participants' and beneficiaries' (and, in the case of student health insurance coverage, enrollees' and dependents') access to coverage for the full range of FDA-approved contraceptives, as prescribed by a health care provider, without cost sharing.

These final regulations continue to allow eligible organizations to choose between using EBSA Form 700 or the alternative process consistent with the Wheaton interim order. The alternative process provides that an eligible organization may notify HHS in writing of its religious objection to covering all or a subset of contraceptive services. The notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to covering some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is,

whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers.²² A model notice to HHS that eligible organizations may, but are not required to, use is available at:

<http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Prevention>. If there is a change in any of the information required to be included, the organization must provide updated information to HHS.

The content required for the notice represents the minimum information necessary for the Departments to determine which entities are covered by the accommodation, to administer the accommodation, and to implement the policies in the July 2013 final regulations.²³ Comments on the August 2014 interim final regulations did not identify any way to administer the accommodation without this information, or any alternative means the Departments can use to obtain the required information. Nothing in this alternative notice process (or in the EBSA Form 700 notice process) provides for a government assessment of the sincerity of the religious belief underlying the eligible organization's objection. The notice to HHS, and any subsequent updates, should be sent electronically to: marketreform@cms.hhs.gov, or by regular mail to: Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 200 Independence Avenue SW, Washington, D.C., 20201, Room 739H.

²² Church plans are exempt from ERISA pursuant to ERISA section 4(b)(2). As such, a third party administrator of a self-insured church plan established or maintained by an eligible organization does not become the plan administrator by operation of 29 CFR 2510.3-16, although such third party administrators may voluntarily provide or arrange separate payments for contraceptive services and seek reimbursement for associated expenses under the process set forth in 45 CFR 156.50.

²³ An accommodation cannot be effectuated until all of the necessary information is submitted. If HHS receives a notice that does not include all of the required information, HHS will attempt to notify the organization of the incompleteness, so the organization can submit additional information to make its notice complete.

When an eligible organization that establishes or maintains a self-insured plan subject to ERISA provides a notice to HHS, the Department of Labor (DOL) (working with HHS) will send a separate notification to each third party administrator of the ERISA plan. The DOL notification will inform each third party administrator of the eligible organization's religious objection to funding or administering some or all contraceptive coverage, will list the contraceptive services to which the employer objects, will describe the obligations of the third party administrator(s) under 29 CFR 2590.715-2713A and 26 CFR 54.9815-2713A, and will designate the relevant third party administrator(s) as plan administrator under section 3(16) of ERISA for those contraceptive benefits that the third party administrator would otherwise manage on behalf of the eligible organization. The DOL notification will be an instrument under which the plan is operated, and will supersede any earlier designation. In establishing and implementing this alternative process, DOL is exercising its broad rulemaking authority under title I of ERISA, which includes the ability to interpret and apply the definition of a plan administrator under ERISA section 3(16)(A).

If an eligible organization that establishes or maintains an insured group health plan or insured student health plan provides a notice to HHS under this alternative process, HHS will send a separate notification to each health insurance issuer of the plan. HHS's notification will inform each health insurance issuer of the eligible organization's religious objection to funding or administering some or all contraceptive coverage, will list the contraceptive services to which the organization objects, and will describe the obligations of the issuer(s) under 26 CFR 54.9815-2713A , 29 CFR 2590.715-2713A, and 45 CFR 147.131. Issuers remain responsible for compliance with the statutory and regulatory requirement to provide coverage for contraceptive services without cost sharing to participants and beneficiaries of insured group health plans, and

to enrollees and dependents of insured student health plans, notwithstanding that the policyholder is an eligible organization with a religious objection to contraceptive coverage that will not have to contract, arrange, pay, or refer for the coverage.

Several comments addressed oversight and enforcement to monitor the accommodation. The Departments will use their established oversight processes, applicable to all the Affordable Care Act market reforms of PHS Act title XXVII, part A to monitor compliance with the requirement to arrange for or provide separate payments for contraceptive services without cost sharing.²⁴

(ii) Definition of a closely held for-profit entity.

(a) General structure of a closely held for-profit entity.

After issuing the July 2013 final regulations, the Departments issued August 2014 proposed regulations in light of the Supreme Court's ruling in Hobby Lobby, that, under the Religious Freedom Restoration Act of 1993 (RFRA),²⁵ the requirement to provide contraceptive coverage could not be applied to certain closely held for-profit entities that had a religious objection to providing coverage for some or all the FDA-approved contraceptive methods. The proposed regulations solicited comments on a number of different approaches for defining a closely held for-profit entity for purposes of qualifying as an eligible organization that can avail itself of an accommodation, and solicited comments on a number of other related issues.

The Departments received more than 75,000 comments in response to the August 2014 proposed regulations. Numerous comments addressed matters outside the scope of the proposed

²⁴ The Departments' oversight and enforcement role with respect to the market reforms under the Affordable Care Act builds upon their respective roles with respect to the market reforms under title I of HIPAA. For a description of the latter, see Notice of Signing of a Memorandum of Understanding among the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services at 64 FR 70165 (Dec. 15, 1999).

²⁵ 42 U.S.C. 2000bb *et. seq.*

regulations (for example, many comments expressed support for or disagreement with the Supreme Court's Hobby Lobby decision, contraception in general, or different methods of contraception), and are not addressed in this preamble. To the extent comments addressed matters that were within the scope of the proposed regulations, those portions of the comments were considered, and all significant comments related to matters within the scope of the proposed regulations are discussed in this preamble. Many commenters expressed support for or disagreement with the general requirement to provide coverage for contraceptive services without cost sharing. Some commenters expressed support for the notion that any employer that has religious objections to covering contraceptive services should either be exempt from doing so, or should be able to avail itself of the accommodation. Other commenters stated that women should have access to contraceptive services without cost sharing, regardless of where they work, and that employers should not be permitted to deny them coverage, whether the employer's decision is for religious or other reasons. Many commenters suggested that the set of closely held for-profit entities eligible for the accommodation be defined as narrowly as possible.

The August 2014 proposed regulations would extend the availability of the accommodation to closely held for-profit entities. The preamble proposed two possible approaches to defining a closely held for-profit entity. Under the first proposed approach, a qualifying closely held for-profit entity would be a for-profit entity where none of the ownership interests in the entity are publicly traded, and where the entity has fewer than a specified number of shareholders or owners (the Departments did not propose a specific number, but solicited comment on what the number should be). As explained in the preamble to the August 2014 proposed regulations, there is precedent in other areas of federal law for limiting the definition of

closely held entities to those with a relatively small number of owners.²⁶ Under the second proposed approach, a qualifying closely held entity would be a for-profit entity in which the ownership interests are not publicly traded, and in which a specified fraction of the ownership interest is concentrated in a limited and specified number of owners (the Departments did not propose a specific level of ownership concentration but solicited comment on what that level should be). As explained in the preamble to the August 2014 proposed regulations, this approach also has precedent in federal law, which limits certain tax treatment to entities that are more than 50 percent owned by or for not more than five individuals.²⁷ The Departments invited comments on the appropriate scope of the definition of a qualifying closely held for-profit entity.

As explained in more detail below, these final regulations extend the accommodation to a for-profit entity that is not publicly traded, is majority-owned by a relatively small number of individuals, and objects to providing contraceptive coverage based on its owners' religious beliefs. This definition includes for-profit entities that are controlled and operated by individual owners who are likely to have associational ties, are personally identified with the entity, and can be regarded as conducting personal business affairs through the entity. Those entities appear to be the types of closely held for-profit entities contemplated by Hobby Lobby, which involved two family-owned corporations that were operated in accordance with their owners' shared religious beliefs.²⁸ The Departments also believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. That assessment is supported by the comments received on the proposed

²⁶ See discussion of definition of S corporations under section 1361 of the Tax Code, at 79 FR 51122.

²⁷ See discussion of several Tax code provisions, including 26 U.S.C. 856(h), 542(a)(2), and 469(j)(1), at 79 FR 51122.

²⁸ See 134 S. Ct. at 2764-2768.

regulation. As explained below, the Departments sought comment on a definition similar to the one adopted here, and we believe that no commenter identified an entity that would want to avail itself of the accommodation but that would be excluded by the definition. In addition, based on the available information, it appears that the definition adopted in these final regulations includes all of the for-profit entities that have as of the date of issuance of these regulations challenged the contraceptive coverage requirement in court.

The Departments believe that the definition adopted in these regulations complies with and goes beyond what is required by RFRA and Hobby Lobby. The Departments have extended the accommodations to the specified class of for-profit entities in order to provide additional protection to entities that may have religious objections to providing contraceptive coverage, and because the Departments believe that eligibility for the accommodations should be based on a rule that has origins in existing law.

Under the August 2014 proposed regulations and these final regulations, the first prong that an eligible organization (whether it be a nonprofit entity or a closely held for-profit entity) must meet in order to avail itself of the accommodation is that the entity must oppose providing coverage for some or all of any contraceptive item or service required to be covered, on account of religious objections. This requirement remains unchanged in these final regulations. (In the case of a for-profit entity, the entity must be opposed to providing these services on account of its owners' religious objections).

Many commenters supported excluding publicly traded entities from the definition of a closely held for-profit entity. However, a few commenters stated that a publicly traded entity should not be disqualified from the accommodation. Although the entities in Hobby Lobby were not publicly traded, one commenter noted that the Court did not expressly preclude publicly

traded corporations from the protections of RFRA. Another commenter stated that if a publicly traded corporation could provide evidence of a sincere religious objection to providing contraceptive coverage, it should not be precluded from the accommodation.

These final regulations exclude publicly traded entities from the definition of an eligible organization. Hobby Lobby did not involve RFRA's application to publicly traded companies, and the Supreme Court emphasized that "the idea that unrelated shareholders – including institutional investors with their own sets of stakeholders – would agree to run a corporation under the same religious beliefs seems improbable."²⁹

Many commenters favored limiting the number of owners to "a handful," without specifying a maximum number. One commenter urged the Departments to establish a limit on the maximum number of shareholders for closely held entities of 999.

One commenter favored limiting the number of owners, but stated that any particular limit could lead to anomalous results for entities with more than the permitted number of owners that seek the accommodation. The commenter noted, for example, that if the maximum number of shareholders or owners is ten, non-publicly traded companies with eleven shareholders would have to provide contraceptive coverage, no matter how sincerely held the religious objections of the owners. Another commenter who favored the approach stated that the definition should be limited to entities that have ten or fewer shareholders, and that shareholders should be counted based upon the definitions under subchapter S – that is, individuals should be counted along with certain trusts and estates. This would account for Qualified Subchapter S Trusts, but would not allow for other partnerships or corporations to be shareholders. This commenter also urged that members of the same family be counted as separate shareholders. Another commenter explained

²⁹ 134 S. Ct. at 2744.

that a closely held company is commonly understood to be one that chooses S-corporation status or has fewer than 100 shareholders, and that many are privately held and owned by family members. Beyond these characteristics, the commenter urged, the size of the company should not matter. One commenter suggested following the close corporation definition from the applicable state or, in the absence of a corporate form, following the definition of a close corporation under Delaware law.

A few commenters supported a test that would be aligned with one of the federal tax law's definitions of a "closely held corporation." For example, commenters supported a definition that provides that the corporation may not have ownership interests that are publicly traded, that more than 50 percent of the outstanding ownership interests in the corporation must be owned (directly or indirectly) by five or fewer individuals at any time during the last half of the tax year, and that the corporation may not be a personal service corporation. The commenters favored identifying closely held entities through an approach based on this definition because such an approach would be easy to apply and already familiar to corporations that apply similar concepts under the Code.

Other commenters were generally opposed to a limited ownership-concentration test. One commenter observed that under this approach, a corporation would be able to concentrate a fraction of ownership, for example 50 percent, in a specified number of owners, such as ten people. The commenter observed that those ten individuals, who might comprise fewer than half of the total number of owners, would be able to direct the corporation to seek the accommodation, potentially against the wishes of the minority shareholders.

Several commenters suggested that basing the definition either on the number of owners, or upon a concentration of ownership, would be inappropriate. One commenter stated that there

is no basis in the Hobby Lobby decision to restrict the definition based on measures such as shareholder numbers, fractions of ownership, or tax rules. Another commenter stated that each of the proposed definitions of a "closely held corporation" is based on an arbitrary metric unrelated to the religious beliefs of the owners of the corporation. Another commenter stated that any rule that defines "closely held" in a narrow manner, such as by limiting the number, kind, or percentage control of a share of its owners, or by adopting definitions used in the Code, will violate RFRA and the Hobby Lobby decision. One commenter stated that a numerical test of shareholders will be both under- and over-inclusive, capturing corporations that meet the numerical test but whose shareholders are not expressing a religious belief through the corporation, and failing to capture corporations with a relatively large number of shareholders united in their religious interests. Another commenter believed that basing the definition of "closely held entity" solely on the number of owners would not limit eligibility to those types of entities addressed in the Hobby Lobby case.

One commenter believed that, for purposes of qualifying for the accommodation, an entity should only employ individuals who adhere to the owners' religious beliefs. The Departments do not believe this is a necessary characteristic for an entity to qualify as an eligible organization that can avail itself of the accommodation, and in Hobby Lobby the court granted relief to companies that did not possess this feature. Additionally, while the Departments have noted that exempting churches and their integrated auxiliaries (which the regulations refer to as "religious employers") from the requirement to provide contraceptive coverage does not impermissibly undermine the government's compelling interests in promoting public health and ensuring that women have equal access to health care because churches are more likely to hire

co-religionists,³⁰ the exemption to the contraceptive coverage requirement was provided against the backdrop of the longstanding governmental recognition of a particular sphere of autonomy for houses of worship, such as the special treatment given to those organizations in the Code.³¹ This exemption for churches and houses of worship is consistent with their special status under longstanding tradition in our society and under federal law, and is not a mere product of the likelihood that these institutions hire coreligionists. Hiring coreligionists is not itself a determinative factor as to whether an organization should be accommodated or exempted from the contraceptive requirements.

Another commenter stated that ownership of the entity should be limited to family members. The Departments do not believe that ownership of a closely held for-profit entity eligible for the accommodation should be limited to members of one family. Although many closely held corporations are family-owned, existing state and federal definitions of closely held or close corporations do not typically include this requirement. As stated below, however, for purposes of these final regulations, an individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family, meaning brothers and sisters (including half-brothers and half-sisters), spouses, ancestors, and lineal descendants. The Departments agree with the commenters who urged us to define a closely held entity, for purposes of these regulations, based on an existing federal definition. The Departments believe that this approach will minimize confusion for entities seeking the accommodation.

At the same time, the Departments also recognize the need for flexibility in the definition for purposes of the accommodation. Therefore, the Departments are adopting in these

³⁰ 78 FR 39887.

³¹ 26 U.S.C. 6033(a)(3)(A).

regulations a definition that is generally based on – but is more flexible than – the definition of a closely held corporation found in the Code³² (which we refer to as the tax-law definition). Under the tax-law definition, a closely held corporation is a corporation that has more than 50 percent of the value of its outstanding stock owned (directly or indirectly) by five or fewer individuals at any time during the last half of the tax year, and is not a personal service corporation.³³ The definitions for closely held corporation in various Code provisions reference the ownership test for personal holding companies contained in Code section 542(a)(2), which generally has the effect of identifying those corporations that are controlled by a small group of individuals and closely affiliated with their owners.

Drawing on the tax-law definition, with appropriate modifications to reflect the context here, these regulations establish that to be eligible for the accommodation, a closely held, for-profit entity must, among other criteria, be an entity that is not a nonprofit entity, and have more than 50 percent of the value of its ownership interests owned directly or indirectly by five or fewer individuals, or must have an ownership structure that is substantially similar.

As previously stated, for purposes of defining a closely held for-profit entity in these regulations, the Departments are using a definition that is more flexible than the tax-law definition of closely held corporation. Because the Departments believe that the tax-law definition might exclude some entities that should be considered to be closely held for purposes

³² Code section 469(j)(1) states the “term ‘closely held C corporation’ means any C corporation described in section 465(a)(1)(B).” Section 465(a)(1)(B) provides “a C corporation with respect to which the stock ownership requirement of paragraph (2) of section 542(a) is met.” Section 542(a)(2) provides that the applicable stock ownership requirement is met if “[a]t any time during the last half of the taxable year more than 50 percent in value of its outstanding stock is owned, directly or indirectly, by or for not more than 5 individuals.” Similarly, section 856(h)(1)(A) provides “a corporation, trust, or association is closely held if the stock ownership requirement of section 542(a)(2) is met.”

³³ See <http://www.irs.gov/Help-&-Resources/Tools-&-FAQs/FAQs-for-Individuals/Frequently-Asked-Tax-Questions-&-Answers/Small-Business,-Self-Employed,-Other-Business/Entities/Entities-5>.

of the accommodation, and because some for-profit entities may have unusual or non-traditional ownership structures not readily analyzed under the 5/50 test, the definition under these final regulations also includes, as stated above, entities with ownership structures that are “substantially similar” to structures that satisfy the 5-owner/50-percent requirement.

For example, an entity where 49 percent of the value of the outstanding ownership interests are owned directly by six individuals could also qualify as a closely held for-profit entity because it has an ownership structure that is substantially similar to one in which five or fewer individuals hold at least 50 percent of the value of the outstanding ownership interests.

As another example, an entity owned by a series of corporate parents, where among the ultimate stockholders are a nonprofit entity and a for-profit corporation with three individual owners, who collectively own 45 percent of the outstanding ownership interests, also has a substantially similar ownership structure.

We note, however, that a publicly traded entity would not qualify as having a substantially similar ownership structure.

For purposes of the accommodation, the value of the ownership interests in the entity, whether the total ownership interests or those owned by five or fewer individuals, should be calculated based on all ownership interests, regardless of whether they have associated voting rights or any other privileges. This is consistent with how the tax-law definition of a closely held corporation is applied.

Because the accommodation will be sought on a prospective basis, the Departments do not believe it appropriate to incorporate, from the tax-law definition, the time interval over which the test is measured – that the given ownership structure be in place during the last half of the tax

year –and instead adopt a test that is measured as of the date of the entity’s self-certification or notice of its objection to provide contraceptive services on account of religious objections.

The tax-law definition of “closely held corporation” excludes certain “personal services corporations,” such as accounting firms, actuarial science firms, architecture firms, and law firms. Although there are legitimate reasons for excluding personal service firms from the definition of “closely held corporation” for purposes of taxation, the Departments do not believe the distinction is necessary in this context. Therefore, a personal services corporation may qualify as a closely held for-profit entity under these final regulations, provided it satisfies the other criteria.

Following the tax-law definition, to determine if more than 50 percent of the value of the ownership interests is owned by five or fewer individuals, the following rules apply:

- Ownership interests owned by or for a corporation, partnership, estate, or trust are considered owned proportionately by the entity’s shareholders, partners, or beneficiaries. For example, if a for-profit entity is 100 percent owned by a partnership, and the partnership is owned 100 percent by four individuals, the for-profit entity, for purposes of these regulations, is considered to be owned 100 percent by those four individuals.
- An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. The “family” includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants. Accordingly, the family members count as a single owner for purposes of these final regulations.
- If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. If the entity does not receive a response from HHS to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure, it will be considered to meet the requirement set forth in 26 CFR 54.9815-2713A(a)(4)(iii), 29 USC 2590.715-2713A(a)(4)(iii), and 45 CFR 147.131(b)(4)(iii). However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

Based on the information available, it appears that the definition of closely held for-profit entity set forth in these final regulations includes all the for-profit corporations that have filed lawsuits alleging that the contraceptive coverage requirement, absent an accommodation, violates RFRA.

One commenter stated that the definition should include any for-profit entity that is controlled directly or indirectly by a nonprofit eligible organization. The Departments agree, because in this case the nonprofit entity will represent one shareholder that owns more than 50 percent of the ownership interests in the for-profit entity.³⁴ The same facts and circumstances that are considered in determining whether a given for-profit entity qualifies as an eligible for-profit organization under these final regulations will also apply when one or more of its owners is a nonprofit organization. For purposes of the ownership concentration test set forth in these final regulations that applies to for-profit entities, a nonprofit organization that has an ownership interest in a for-profit entity will be considered one individual owner of the for-profit entity, and

³⁴ See EBSA Form 700.

the non-profit organization's percentage ownership in the for-profit entity will be attributed to that nonprofit organization.

(b) The process for making the decision to object to covering contraceptive services.

The August 2014 proposed regulations proposed that a closely held for-profit entity's objection to covering some or all of the contraceptive services otherwise required to be covered on account of its owners' sincerely held religious beliefs must be made in accordance with the organization's applicable rules of governance, consistent with state law. Some comments proposed alternative or additional criteria for how the decision must be made. One criterion suggested by many commenters was unanimity among all owners regarding opposition to contraception. However, one commenter objected to this requirement, stating that the regulations should not require unanimous shareholder consent because neither the Hobby Lobby decision nor state corporate law imposes such a requirement.

Some commenters favored requiring each equity holder to certify, under penalty of perjury, that he or she has a religious objection to the entity providing contraceptive coverage. These final regulations do not adopt a requirement that the owners unanimously decide that the entity will not offer contraceptive coverage based on a religious objection, or that any equity holder certify under penalty of perjury that he or she has a religious objection to the entity providing the coverage. The Departments believe that either requirement would be unduly restrictive, and would unnecessarily interfere with for-profit entities' decision-making processes. Instead, these final regulations provide that the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by the owners) must adopt a resolution (or take other similar action consistent with the organization's applicable rules

of governance and with state law) establishing that the organization objects to covering some or all of the contraceptive services on account of its owners' sincerely held religious beliefs.

(c) Documentation of the decision to assert a religious objection to contraceptive coverage.

In the August 2014 proposed regulations, the Departments sought comments on whether a for-profit entity seeking the accommodation should be required to document its decision-making process for objecting to coverage for some or all contraceptive services on account of religious objections (as opposed to merely disclosing the fact that it made such a decision). Many comments supported a requirement that the decision-making process be documented, and that the entity submit, to its third party administrator or health insurance issuer, as applicable, and to the federal government, documentation of the entity's decision. These final regulations require that a for-profit entity seeking the accommodation must make the decision pursuant to a resolution (or other similar action), as described above. However, the Departments are not requiring that this resolution be provided as a matter of course to the federal government or any other party. Generally, the Departments believe it is sufficient that the fact of the decision itself, as opposed to documentation of the decision, be communicated as set forth in August 2014 interim final regulations and these final regulations. However, with respect to documentation of the decision, record retention requirements under section 107 of ERISA apply directly to ERISA-covered plans and, with respect to other plans or coverage subject to these final regulations, by operation of these final regulations, which incorporate the record retention requirements under ERISA section 107 by reference. This approach is consistent with document standards for nonprofit entities seeking the accommodation.

(d) Disclosure of the decision to assert a religious objection to contraceptive services.

In the August 2014 proposed regulations, the Departments sought comments on whether a for-profit entity seeking the accommodation should be required to disclose publicly or to its employees its decision not to cover some or all contraceptive services on account of religious objections. This requirement would be in addition to the requirement that an eligible organization that is a for-profit entity that seeks the accommodation make its self-certification or notice of objection to providing contraceptive coverage on account of religious objections available for examination upon request by the first day of the plan year to which the accommodation applies, and be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

Many commenters suggested that the entity should be required to notify HHS of its decision to object (even if it chooses to self-certify and send the self-certification to its issuer or third party administrator). A few commenters stated that all employees and prospective employees (or student enrollees and their covered dependents) must be made aware of their employer's (or educational institution's) refusal to offer contraceptive coverage. One commenter stated that a closely held for-profit entity should disclose the following to its shareholders and employees: (A) the reasons the decision was made, (B) the changes that will take place as a result of the decision, and (C) the number of people that will be affected by the decision. Another commenter stated that entities availing themselves of the accommodation should be required to publicize their justifications for denying women access to coverage of medications that serve purposes other than contraception. One commenter noted the need of employees to know by the employer's annual open enrollment period whether the employer is availing itself of the accommodation.

These final regulations do not establish any additional requirements to disclose the decision. The Departments believe that the current notice and disclosure standards afford individuals eligible for or enrolled in group health plans (and students eligible for or enrolled in student health insurance) with an accommodation adequate opportunity to know that the employer (or educational institution) has elected the accommodation for its group health plan (or insurance coverage), and that they are entitled to separate payment for contraceptive services from another source without cost sharing. Those standards require that, for each plan year to which the accommodation applies, a third party administrator that is required to provide or arrange payments for contraceptive services, and a health insurance issuer required to provide payment for these services, provide to plan participants and beneficiaries (or student enrollees and their covered dependents) written notice of the availability of separate payments for these services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment or re-enrollment in health coverage. Model language for this notice is provided in the regulations.

(e) Sincerity of the owners' religious beliefs.

Many commenters suggested that, for a closely held for-profit entity to be eligible for an accommodation, it should not be sufficient that the entity's owners object to providing contraceptive coverage. Rather, the commenters proposed that owners should also be required to agree to operate the entity in a manner consistent with religious principles, and in fact to so operate the entity. Some commenters pointed out that the July 2013 final regulations require non-profit religious organizations that avail themselves of the accommodation to "hold themselves out" as religious organizations.

The Departments have not adopted such a criterion for for-profit entities. The Supreme Court's decision in Hobby Lobby discussed the application of RFRA in connection with the religious beliefs of the owners of a closely held corporation.³⁵ These final regulations similarly focus on the religious exercise of the owners of the closely held entity and provide that the entity, in advancing the religious objection, represent that it does so on the basis of the religious beliefs of the owners. The Departments do not believe it is also necessary that the entity itself demonstrate by its bylaws, mission statement, or other documents or practices that it has a religious character. Non-profit entities ordinarily do not have owners in the same way as do for-profit entities, and thus the religious character of a non-profit entity would be reflected in how it holds itself out.

(f) Other steps the Departments should take to ensure contraceptive coverage with no cost sharing.

The August 2014 proposed regulations solicited comments on other steps the Departments should take to help ensure that participants and beneficiaries (in the case of student health insurance coverage, enrollees and dependents) in plans subject to an accommodation are able to obtain, without cost, the full range of FDA-approved contraceptives without cost sharing. Many commenters stated that a government enforcement body should be established to monitor compliance by plan sponsors, third party administrators, and health insurance issuers, of their respective obligations associated with the accommodation. At this time, the Departments do not believe that an independent body need be established, although as stated above, the Departments will use their established oversight processes, applicable to all the Affordable Care Act market reforms of title XXVII of the PHS Act to monitor compliance with the requirement to provide

³⁵ See 134 S. Ct. at 2768.

contraceptive services without cost sharing. As part of those processes, the Departments will work with non-compliant parties to bring them into compliance, and will take enforcement action as appropriate.

Other commenters stated that the federal government should ensure that no barriers to contraceptive coverage exist due to an enrollee's cultural background, English proficiency, disability, or sexual orientation. The Departments agree that no barriers should exist. The same federal and applicable state laws that would prohibit discrimination by employers, group health plans, third party administrators, and health insurance issuers generally would also apply with respect to the entities arranging for or providing separate payments for contraceptive services for women in group health plans and student health insurance subject to an accommodation.

Other commenters urged that the separate payments for contraceptive services be provided in the same manner in which the group health plan or student health insurance would have otherwise covered these services had they not had an accommodation, or in the same manner in which the plan or coverage subject to an accommodation covers other, non-contraceptive benefits. The Departments, however, maintain the view that reasonable differences in the way services are paid for or provided would not necessarily be inappropriate, provided those differences do not create barriers to accessing payments for contraceptive services. Another commenter stated that health insurance issuers of plans subject to an accommodation should not be permitted to require enrollees to have two insurance cards, one for contraceptive benefits, and one for other benefits. The Departments do not believe that this practice, in of itself, would constitute a barrier to accessing separate payments for contraceptive services.

(g) Other comments that relate to the July 2013 final regulations.

In the August 2014 proposed regulations and interim final regulations, the Departments sought comment on other potential changes to the July 2013 final regulations in light of the proposed change to the definition of eligible organization. In particular, the Departments sought comment on applying the approach set forth in the July 2013 final regulations in the context of the expanded definition of eligible organization. The July 2013 final regulations provide for separate payments for contraceptive services for participants and beneficiaries in self-insured group health plans of eligible organizations in a manner that enables these organizations to completely separate themselves from administration and payment for contraceptive coverage. Specifically, the third party administrator must provide or arrange the payments, and the third party administrator can seek reimbursement for the costs (including an allowance for administrative costs and margin) by making an arrangement with a participating issuer – that is, an issuer offering coverage through a Federally-facilitated Exchange (FFE). The participating issuer can receive an adjustment to its FFE user fees to finance these costs.

One commenter suggested that the federal government set up a program to dispense these services using contractors. Another commenter suggested that pharmaceutical companies could provide certain contraceptives directly by mail to persons who are told at a dispensing pharmacy that their plan has denied coverage. Additionally, the pharmaceutical companies could directly supply doctors who prescribe birth control, who in turn could dispense directly to patients who are not covered under their employer-sponsored group health plan or student health insurance coverage. One commenter suggested making contraception available for any woman free of charge through a doctor. One commenter suggested providing contraceptive care through Medicaid.

The Departments have not adopted the proposals advanced by these commenters for two reasons. First, the Departments do not have the legal authority to require pharmaceutical companies or doctors to provide contraceptives directly, nor do they have the authority to implement the other alternative arrangements proposed by these commenters. Second, these alternatives raise obstacles to access to seamless coverage. Consistent with the statutory objective of promoting access to contraceptive coverage and other preventive services without cost sharing, plan beneficiaries and enrollees should not be required to incur additional costs – financial or otherwise – to receive access and thus should not be required to enroll in new programs or to surmount other hurdles to receive access to coverage. The Departments believe that the third party administrators and health insurance issuers already paying for other medical and pharmacy services on behalf of the women seeking the contraceptive services are better placed to provide seamless coverage of the contraceptive services, than are other providers that may not be in the insurance coverage network, and that lack the coverage administration infrastructure to verify the identity of women in accommodated health plans and provide formatted claims data for government reimbursement.

Some commenters suggested other changes to the July 2013 regulations, with respect to how separate payments for contraceptive services provided under the accommodation are funded. One commenter expressed concern that the August 2014 proposed regulations are silent as to possible funds for reimbursement of costs incurred for contraception services where there is no FFE operating in the state. This commenter also noted that the regulations do not consider the possibility that the cost for contraceptive services may exceed the issuer's FFE user fee, nor do they address how a third party administrator would be reimbursed if the issuer is no longer a participating issuer in the FFE. The commenter suggested the Departments consider several

different financing options: the user fee for the risk adjustment program; the CMS program management fund; the user fee for the Medicare Part D program; the Prevention and Public Health Fund; medical loss ratio rebates; CMS innovation funding; and the health insurance provider fee.

Another commenter recommended that HHS provide for an expedited process of adjusting FFE user fees in case the volume of contraceptive claims is greater than expected. This commenter also suggested that the Departments also consider alternative means of generating funding for this purpose, such as allowing an issuer to charge a premium of at least an amount equal to the pro rata share of the rate the eligible organization would have paid had it not elected the accommodation, or directly subsidize the cost of contraception using funding provided by the Prevention and Public Health Fund.

One commenter stated that the Departments should evaluate the limitations of current funding arrangements with respect to the current accommodation for eligible non-profit entities, given the additional demands of the proposal to expand the accommodation to certain for-profit entities. The commenter suggested allowing a separate government funded reimbursement mechanism for enrollees in both insured and self-funded plans as an alternative approach to funding the program. If the current funding approach is continued, the commenter recommended a reassessment of the limitations of the approach for third party administrators. If third party administrators remain responsible for providing or arranging separate payments for contraceptive services, the commenter recommended a broadening of the pool available for reimbursement beyond individually negotiated arrangements with issuers participating in the FFE, including potentially establishing a single pool for reimbursement or finding an alternative, simpler

financing mechanism for third party administrators, including offsets from federal income taxes, and offsets to amounts due from other lines of business operated by the third party administrator.

At this time, the Departments are not adopting an alternative approach to funding separate payments for contraceptive services with respect to costs incurred for women in plans subject to an accommodation, although the Departments will continue to explore the feasibility of different ideas, including those proposed in the comments.

One commenter suggested that issuers should be permitted to treat the cost of providing separate payments for contraceptive services for women in plans subject to an accommodation as an adjustment to claims costs for purposes of calculating their medical loss ratios, while still being allowed to treat such payments as an administrative cost spread across the issuer's entire risk pool.³⁶ With respect to calculating medical loss ratios, HHS has previously stated in rulemaking that an insurer of an accommodated insured group health or student plan may include the cost of the actual payments it makes for contraceptive services in the numerator of its medical loss ratio.³⁷

Several commenters asked whether, in light of the fact that the accommodation was proposed to be expanded to a new set of entities, if the Department's discussion in the preamble to the July 2013 final regulations about the extent to which the accommodation has an effect on other laws, continues to apply.³⁸ The Departments explained in that discussion that state insurance laws that provide greater access to contraceptive coverage than federal standards are

³⁶ See Discussion of how an issuer may achieve cost neutrality in the preamble to the July 2013 final regulations, at 78 FR 39878.

³⁷ See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015 (Mar. 11, 2014), at 79 FR 13809.

³⁸ 78 FR 39888.

unlikely to be preempted, and that, in states with broader religious exemptions and accommodations with respect to health insurance issuers than those in the regulations, plans are still required to comply with the federal standard. These principles continue to apply.

One commenter stated that the Hobby Lobby decision applies to every form of medical care, not just contraception, and that the regulations should reflect that. However, in Hobby Lobby, the Court stated:

In any event, our decision in these cases is concerned solely with the contraceptive mandate. Our decision should not be understood to hold that an insurance-coverage mandate must necessarily fail if it conflicts with an employer's religious beliefs. Other coverage requirements, such as immunizations, may be supported by different interests (for example, the need to combat the spread of infectious diseases) and may involve different arguments about the least restrictive means of providing them.³⁹

Regarding fully insured plans, one commenter noted that the July 2013 final regulations permit issuers that are providing separate payments for contraceptive services under the accommodation, to pay for all FDA-approved contraceptive services, or only for those services to which the eligible organization objects to covering on religious grounds. The commenter noted that this approach simplifies the operational issues associated with implementing the accommodation across multiple employers, and sought clarification that this approach is available to third party administrators as well. The Departments clarify that this option is available to third party administrators with respect to self-insured plans.

One commenter requested that notices of objection to covering contraceptive services on religious grounds be provided with at least 60 days' advance notice, and that any change in objection status based on change of ownership of the employer not be implemented until the next plan year or policy year. The Departments do not adopt this suggestion. Instead, the

³⁹ 134 S. Ct. at 2783.

Departments are extending, to closely held for-profit entities, the same timeframes that have been in effect for non-profit eligible organizations, that is, a plan sponsor can provide such notice, and implement plan benefit changes associated with the accommodation, at any time. For group health plans subject to ERISA, existing notice and timeframe requirements under ERISA apply.

Another commenter stated that health insurance issuers and third party administrators should only be required to provide or arrange for separate payments for contraceptive services for eligible organizations that have invoked an accommodation no earlier than the first day of the first plan year that follows publication of these final regulations. To provide employers, institutions of higher education, third party administrators, and health insurance issuers adequate time to comply, these final regulations apply beginning on the first day of the first plan year (or, in the individual market, the first policy year) after these regulations are effective. Accordingly these final regulations are effective beginning on the first day of the first plan year (or, in the individual market, the first policy year) that begins on or after **[insert day 60 days after date of publication in the FEDERAL REGISTER].**

Several commenters stated that the decision to not cover some or all contraceptives on religious grounds should be made annually. The Departments do not believe such a requirement is appropriate or necessary.

One commenter asked for clarification as to how a notice of objection would be provided by employers purchasing coverage through the Small Business Health Options Program (SHOP) and whether there will be a mechanism in place that permits an eligible organization to select a small group plan and provide a notice of objection. With respect to employers purchasing coverage through the SHOP, health insurance issuers selling policies through it, and participants

and beneficiaries in such plans, all of the rights and obligations that are associated with these regulations apply no differently than if the employer were to purchase coverage outside of the SHOP.

One commenter stated that providing separate payments for contraceptive services is not cost-neutral for an issuer, and that it is not appropriate for an issuer of a student health insurance plan to be required to make separate payments for contraceptive services for enrollees in student health plans subject to an accommodation, and suggested that the Marketplaces should instead offer free individual market policies covering contraception to those who desire such coverage, or that such individuals get such services through existing clinics. In the alternative, the commenter proposed an “above the line” deduction on their federal income taxes for all costs incurred for separate payments made for contraceptive services for enrollees in a student health plan subject to an accommodation. The Departments do not adopt the comment. For the reasons stated in the July 2013 final regulations, the Departments believe that covering contraceptive services is cost-neutral for an issuer at risk for the enrollees in a plan subject to an accommodation. With respect to student health insurance plans, these regulations finalize a clarification proposed in the August 2014 proposed regulations under which a reference to the definition of “institution of higher education” found in 20 U.S.C. 1002 is added to 45 CFR 147.131(f), to clarify that both nonprofit and closely held for-profit institutions of higher education, with respect to their insured student health plans, may qualify as eligible organizations.

III. Economic Impact and Paperwork Burden

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

Executive Order 12866 (58 FR 51735) directs 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 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a proposed rule--(1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below, the Departments anticipate that these regulations – most notably the policies first established in the 2010 interim final rule – are likely to have economic impacts of \$100 million or more in any one year, and therefore meet the definition of “significant rule” under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and

transfers associated with these final regulations. In accordance with the provisions of Executive Order 12866, these final regulations were reviewed by the OMB.

1. Need for Regulatory Action

These final regulations finalize the July 2010 interim final regulations related to coverage of recommended preventive services, the August 2014 interim final regulations related to the process an eligible organization uses to provide notice of its religious objections to the coverage of contraceptive services, and the August 2014 proposed regulations related to the definition of eligible organization.

As discussed later in the RIA, historically there has been an underutilization of preventive services, as health insurance issuers have had little incentive to cover these services. Currently, there is still an underutilization of some preventive services due to a number of barriers, including costs, ethnic/gender disparities⁴⁰, and a general lack of knowledge by those with medical coverage.⁴¹ While many of these factors are being addressed through the Affordable Care Act and these final regulations, the current underutilization of preventive services stems from three main factors. First, due to turnover in the health insurance market, health insurance issuers have historically lacked incentives to cover preventive services, whose benefits may only be realized in the future when an individual may no longer be enrolled with that issuer. Second, many preventive services generate benefits that do not accrue immediately to the individual that receives the services, making the individual less likely to avail themselves of the services, especially in the face of direct, immediate costs. Third, some of the benefits of preventive

⁴⁰ Call, K. T., McAlpine, D. D., Garcia, C. M., Shippee, N., Beebe, T., Adeniyi, T. C., & Shippee, T. (2014). Barriers to Care in an Ethnically Diverse Publicly Insured Population. *Medical Care*.

⁴¹ Reed, M. E., Graetz, I., Fung, V., Newhouse, J. P., & Hsu, J. (2012). In consumer-driven health plans, a majority of patients were unaware of free or low-cost preventive care. *Health Affairs*, 31(12), 2641-2648.

services accrue to society as a whole, and thus do not get factored into an individual's decision making over whether to obtain such services.

The July 2010 interim final regulations and these final regulations address these market failures through two avenues. First, the regulations require coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers in the group and individual markets, thereby overcoming plans' lack of incentive to invest in these services. Second, the regulations eliminate cost-sharing requirements, thereby removing a barrier that could otherwise lead an individual to not obtain such services, given the long-term and partially external nature of these benefits.

The August 2014 interim final regulations provided an alternate process that eligible organizations can use to provide notice of their religious objections to providing coverage for some or all of the contraceptive services to HHS, instead of providing the EBSA Form 700 to the issuers or third party administrators of their group health plan. The provisions of those interim final regulations are being finalized without any changes.

These final regulations also amend the definition of an eligible organization to include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered by the group health plan or student health insurance plan established, maintained, or arranged by the organization.

These final regulations are necessary in order to provide rules that plan sponsors and issuers can continue to use to determine how to provide coverage for certain recommended preventive services without the imposition of cost sharing, to ensure women's ability to receive those services, and to respect the religious beliefs of qualifying eligible organizations with respect to their objection to covering contraceptive services.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table III.1 below depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. It is expected that all non-grandfathered plans are already complying with the provisions of the July 2010 and August 2014 interim final regulations. Therefore, benefits related to those regulations have been experienced and costs have already been incurred. The Departments are providing an assessment of the impacts of existing provisions already experienced and expected in the future, in addition to the anticipated impacts of new provisions in these final regulations.

Table III.1: Accounting Table

Benefits:
Qualitative: * Increased access to and utilization of recommended preventive services, leading to the following benefits: (1) prevention and reduction in transmission of illnesses as a result of immunization and screening of transmissible diseases; (2) delayed onset, earlier treatment, and reduction in morbidity and mortality as a result of early detection, screening, and counseling; (3) increased productivity and reduced absenteeism; and (4) savings from lower health care costs. * Benefits to eligible for-profit entities from not being required to facilitate access to or pay for services that contradict their owners' religious beliefs.
Costs:
Qualitative: * New costs to the health care system when individuals increase their use of preventive services in response to the changes in coverage and cost-sharing requirements of preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand and the percentage change in prices facing those with reduced cost sharing or newly gaining coverage. * Administrative cost to eligible for-profit entities to provide self-certification to issuers or third party administrators or notice to HHS. * Administrative cost to issuers and third party administrators for plans sponsored by eligible closely held for-profit entities to provide notice to enrollees.

Transfers:

- * Costs previously paid out-of-pocket for certain preventive services are now covered by group health plans and issuers.
- * Risk pooling in the group market will result in sharing expected cost increases across an entire plan or employee group as higher average premiums for all enrollee. However, not all of those covered will utilize preventive services to an equivalent extent. As a result, these final regulations create a small transfer from those paying premiums in the group market utilizing less than the average volume of preventive services in their risk pool to those whose utilization is greater than average. To the extent there is risk pooling in the individual market, a similar transfer will occur.
- * Transfer of costs related to certain preventive services from eligible self-funded closely held for-profit entities to third party administrators and issuers that provide (or arrange) separate payments for contraceptive services. Third party administrators can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs, and the issuer offering coverage through the FFE can receive an adjustment to the FFE user fee.

3. Estimated number of Affected Entities

For purposes of this analysis, the Departments have defined a large group health plan as an employer plan with 100 or more workers and a small group plan as an employer plan with less than 100 workers. The Departments estimate that there are approximately 140,000 large and 2.2 million small ERISA-covered group health plans with an estimated 93.2 million participants in large group plans and 36 million participants in small group plans. The Departments estimate that there are approximately 128,000 governmental plans with 39 million participants in large plans and 2.8 million participants in small plans.⁴² In 2013, approximately 12.26 million participants were covered by individual health insurance policies.⁴³

Group health plans and health insurance issuers offering group and individual health insurance coverage that are not grandfathered health plans will be affected by these regulations.

⁴² All participant counts and the estimates of individual policies are from the U.S. Department of Labor, EBSA calculations using the March 2013 Current Population Survey Annual Social and Economic Supplement and the 2012 Medical Expenditure Panel Survey and the 2012 Census of Government.

⁴³ This estimate includes enrollment in student health insurance plans. Source: Data from Medical Loss Ratio submissions for 2013 reporting year, available at <http://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

There are an estimated 500 issuers offering group and individual health insurance coverage.⁴⁴

The number of employer-sponsored grandfathered plans has been decreasing steadily since 2010.

Thirty-seven percent of employers offering health benefits offered at least one grandfathered health plan in 2014, compared to 54 percent in 2013 and 72 percent in 2011. Therefore, more and more enrollees in employer-sponsored plans have gained access to preventive services without cost sharing. Twenty-six percent of covered workers were enrolled in a grandfathered health plan in 2014, as compared to 36 percent in 2013 and 56 percent in 2011.⁴⁵ In the individual market, it is expected that a large proportion of individual policies are not grandfathered. In addition, enrollees in qualified health plans purchased through the Marketplaces have non-grandfathered policies. At the end of the second enrollment period, nearly 11.7 million individuals selected or were automatically reenrolled into a 2015 health insurance plan through the Marketplaces.⁴⁶

It is uncertain how many closely held for-profit entities have religious objections to providing coverage for some or all of the contraceptive services otherwise required to be covered. Based on litigation and communication received by HHS, the Departments estimate that at least 87 closely held for-profit eligible organizations will seek the religious accommodation provided in these final regulations. Health insurance issuers (or third party administrators for self-insured plans) for the group health plans established or maintained by

⁴⁴ Source: Data from Medical Loss Ratio submissions for 2013 reporting year.

⁴⁵ See Kaiser Family Foundation and Health Research and Education Trust, Employer Health Benefits 2014 Annual Survey (2014), available at <http://kff.org/private-insurance/report/2014-employer-health-benefits-survey/>; and Employer Health Benefits 2011 Annual Survey (2011) available at <http://kff.org/health-costs/report/employer-health-benefits-annual-survey-archives/>.

⁴⁶ This estimate represents the number of individuals who have selected, or been automatically reenrolled into a 2015 plan through the Marketplaces, with or without payment of premium. See ASPE, Health Insurance Marketplaces 2015 Open Enrollment Period: March Enrollment Report, available at http://aspe.hhs.gov/health/reports/2015/MarketPlaceEnrollment/Mar2015/ib_2015mar_enrollment.pdf.

these eligible organizations (and health insurance issuers of closely held for-profit institutions of higher education) will assume sole responsibility for providing (or arranging) separate payments for contraceptive services directly for plan participants and beneficiaries (and for student enrollees and dependents), without cost sharing, premium, fee, or other charge to plan participants or beneficiaries (or student enrollees and dependents) or to the eligible organization or its plan. In addition, based on litigation, the Departments estimate that at least 122 non-profit eligible organizations will have the option to provide notice of their religious objections to HHS, instead of providing the EBSA Form 700 to the issuer or third party administrator of their group health plan. These numbers are likely to underestimate the number of eligible organizations that will seek the accommodation. However, these are the best estimates available to the Departments at this time.

4. Benefits

In the July 2010 interim final regulations, the Departments anticipated several types of benefits that will result from expanding coverage and eliminating cost sharing for recommended preventive services. First, individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. Second, healthier workers and children will be more productive with fewer missed days of work or school. Third, some of the recommended preventive services will result in savings due to lower health care costs.

As stated in the July 2010 interim final regulations, preventive service coverage is limited to those recommended by the Task Force (grade of A or B), an applicable Advisory Committee,

and HRSA.⁴⁷ These final regulations can be expected to continue to increase access to and utilization of these services, which have been historically underutilized. For example, 27.7 percent of adults aged 50 to 75 have never been screened for colorectal cancer (such as sigmoidoscopy and/or colonoscopy).⁴⁸ In 2012, the median percentage of women over the age of 18 that have not had a pap test in the past 3 years was 22 percent.⁴⁹ The CDC recently found that in adults over 50, fewer than 30 percent are up-to-date with core preventive services.⁵⁰

As explained in the July 2010 interim final regulations, numerous studies have shown that improved coverage, or reduced costs, of preventive services results in higher utilization of these services⁵¹ leading to potentially substantial benefits. Research suggests there are significant health benefits associated with a number of newly covered preventive services required under the statute and these final regulations. The National Council on Preventive Priorities (NCPP) has estimated that achieving a utilization rate of 90 percent for eight clinical preventive services would save more than 150,000 lives each year in the U.S., including 42,000 if smokers were offered medication or other cessation assistance (Table III.2).⁵² From an

⁴⁷ See <http://www.ahrq.gov/research/findings/final-reports/uspstf/uspstfeval.pdf> for details of the Task Force grading and <http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/> for current recommendations.

⁴⁸ CDC. Vital Signs: colorectal cancer screening test use – United States, 2012. MMWR 2013;62:881-888.

⁴⁹ Behavioral Risk Factor Surveillance System Numbers (2012), <http://apps.nccd.cdc.gov/BRFSS/page.asp?cat=CC&yr=2012&state>All#CC>.

⁵⁰ CDC Focuses on Need for Older Adults To Receive Clinical Preventive Services, brief released by CDC (2012), <http://www.cdc.gov/aging/pdf/cps-clinical-preventive-services.pdf>.

⁵¹ See e.g., Meeker D, Joyce GF, Malkin J, et al. Coverage and preventive screening. Health Serv Res. 2011; 46:173–184. Study found that patients responded to the exclusion of preventive services from deductibles and reducing cost sharing resulted in increased utilization of lipid screening, pap smears, and other services. See e.g., Jill Bernstein, Deborah Chollet, and G. Gregory Peterson, Encouraging Appropriate Use of Preventive Health Services, Issue Brief *Mathematica Policy Research Inc.*, Princeton, NJ (May 2010) Number 2.

⁵² National Commission on Prevention Priorities. *Preventive Care: A National Profile on Use, Disparities, and Health Benefits*. Partnership for Prevention, August 2007.

economic viewpoint, many preventive services offer high economic value⁵³ resulting in an estimated savings of \$3.7 billion.⁵⁴ Even if a rate of 90 percent utilization is not achieved due to a variety of barriers, including financial, service accessibility, and socioeconomic disparities, the Departments expect that utilization will increase among those individuals in plans subject to the regulations because the provisions eliminate cost sharing and require coverage for these services. It is expected that the increased utilization of these services will lead providers to increase their use of these services knowing that they will be covered without cost sharing.

Table III.2 – Lives Saved From Increasing Utilization of Selected Preventive Services

Preventive Service	Population Group	Percent utilization (2005)	Lives saved annually if 90 percent utilization
Regular aspirin use	Men 40+ / Women 50+	40	45,000
Smoking cessation (medication and advice)	All adult smokers	28	42,000
Colorectal cancer screening	Adults 50+	48	14,000
Influenza vaccination	Adults 50+	37	12,000
Cervical cancer screening (in past 3 years)	Women 18-64	83	620
Cholesterol screening	Men 35+ / Women 45+	79	2,450
Breast cancer screening (in past 2 years)	Women 40+	67	3,700
Chlamydia screening	Women 16-25	40	30,000

Source: National Commission on Prevention Priorities, 2007

Studies comparing the utilization of preventive services among adults show utilization rates range from as high as 89 percent for blood pressure checks to only 40 percent for annual flu

<http://www.prevent.org/data/files/initiatives/ncpppreventivecarereport.pdf> .

⁵³ Woolf, Steven. A Closer Look at the Economic Argument for Disease Prevention. *JAMA* 2009; 301(5):536–538.

⁵⁴ Maciosek, Michael V., Coffield, Ashley B., Flottemesch, *et al.*, Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost. *Health Affairs* 2010, 29(9) 1656-1660.

vaccinations.⁵⁵ Under the Affordable Care Act, there have been significantly higher usage rates of several preventive services in young adults and women, including blood pressure tests, cholesterol screening, and contraceptive services.⁵⁶ Numerous studies have shown that improved coverage, or reduced costs, of preventive services results in higher utilization of these services⁵⁷ leading to potentially substantial benefits. The Departments expect that utilization of preventive services will continue to increase over time among those individuals in plans affected by these regulations because the provisions eliminate cost sharing and require coverage for these services.

Some recommended preventive services have both individual and public health value. Vaccines have reduced or eliminated serious diseases that, prior to vaccination, routinely caused serious illnesses or deaths. Maintaining high levels of immunization in the general population protects the un-immunized from exposure so that individuals who cannot receive, or who do not have a sufficient immune response to the vaccine, are indirectly protected.⁵⁸

A second type of benefit of these final regulations is improved workplace productivity and decreased absenteeism for school children. A study by *Gallup* has found that among workers working at least 30 hours a week, those considered overweight or obese with one or

⁵⁵ The Commonwealth Fund. “Current Trends in Health Coverage and the Effects of Implementing the Affordable Care Act” (2013). http://www.commonwealthfund.org/~media/files/publications/fund-report/2013/apr/1681_collins_insuring_future_bienial_survey_2012_final.pdf.

⁵⁶ See. e.g., Lau JS, Adams SH, Park MJ, Boscardin WJ, Irwin CE. Improvement in preventive care of young adults after the affordable care act: the affordable care act is helping. *JAMA Pediatr.* 2014; 168(12):1101-1106. See e.g., Sonfield, A., Tapales, A., Jones RK., Finer, LB. Impact of the federal contraceptive coverage guarantee on out-of-pocket payments for contraceptives: 2014 update. *Contraception*, 2015; 91(1): 44-48.

⁵⁷ See e.g., Meeker D, Joyce GF, Malkin J, et al. Coverage and preventive screening. *Health Serv Res.* 2011; 46:173–184. Study found exclusion of deductibles from, and reduced cost sharing of preventive services resulted in increased utilization of lipid screening, pap smears, and other services. See e.g., Jill Bernstein, Deborah Chollet, and G. Gregory Peterson, Issue Brief Mathematica Research Policy Inc., Princeton, NJ (May 2010) Number 2.

⁵⁸ See Modern Infectious Disease Epidemiology by Johan Giesecke 1994, Chapter 18, The Epidemiology of Vaccination.

more chronic condition will miss one to 3.5 days of work a month.⁵⁹ With an estimated 450 million days lost to absenteeism, the cost of lost productivity due to personal health or the inability to concentrate due to their own or a family member's illness is estimated to be between \$153 and \$260 billion annually.⁶⁰

Illness and poorly controlled chronic disease also contribute to increased absenteeism among school children. Recent data indicates that in the 2011-2012 academic year, 6.2 percent of children aged 6 through 17 missed 11 or more days of school.⁶¹ Studies have shown that student health and well-being have been positively linked to students' academic outcomes, including attendance, grades, test scores, and high school graduation.⁶² As discussed in the July 2010 interim final rules, studies show that reduced cost sharing and increased access to care can improve productivity in both schools and the labor market. Thus, it is expected that these final regulations can have a substantial benefit to the children in the nation's education system and the labor market, both current and future.

A third type of benefit from some preventive services is cost savings. Increasing the provision of preventive services is expected to reduce the incidence or severity of illness, and, as

⁵⁹ Unhealthy U.S. Workers' Absenteeism Costs \$153 Billion. Well-Being, Gallop October 17, 2011 at <http://www.gallup.com/poll/150026/Unhealthy-Workers-Absenteeism-Costs-153-Billion.aspx>.

⁶⁰ Ibid, see e.g., Health and Productivity Among U.S. Workers, Karen Davis, Ph.D., Sara R. Collins, Ph.D., Michelle M. Doty, Ph.D., Alice Ho, and Alyssa L. Holmgren, The Commonwealth Fund, August 2005. <http://www.commonwealthfund.org/publications/issue-briefs/2005/aug/health-and-productivity-among-u-s-workers>

⁶¹ Children Who Missed 11 or More Days of School per Year Due to Illness or Injury, Kids Count Data Center at <http://datacenter.kidscount.org/data/tables/5202-children-who-missed-11-or-more-days-of-school-per-year-due-to-illness-or-injury?loc=1&loct=2#detailed/1/any/false/1021,18,14/691,30,18/11683>

⁶² Vaughn, B., Princiotta, D., Barry, M., Fish, H., & Schmitz, H. (2013). Safe Supportive Living Brief: Schools and The Affordable Care Act. https://safesupportivelearning.ed.gov/sites/default/files/1953_Schools%20Affordable%20Care%20Brief_d3%20lvr.pdf

a result, reduce expenditures on treatment of illness. As discussed in the July 2010 interim final regulations and elsewhere,⁶³ childhood vaccinations have been found to generate considerable benefit and savings to both individuals and society. Employing a decision analysis cohort model of U.S. children born during 1994-2013, researchers at CDC analyzed the economic impact of DTaP (diphtheria and tetanus toxoids and acellular Pertussis), Hib (*Haemophilus influenza* type b), Polio (OPV then IPV), MMR (measles, mumps and rubella), Hepatitis B, varicella, pneumococcal disease (PCV, 7-valent and 13-valent), and rotavirus vaccines in children aged ≤6 years. The study estimates that among the 78.6 million children born during this period, these routine immunizations will prevent 322 million illnesses and 21 million hospitalizations, averting 732,000 premature deaths over their lifetime. Furthermore, it was estimated that these routine vaccinations will potentially avert \$402 billion in direct costs and \$1.5 trillion in societal costs and a net savings of \$295 billion and \$1.38 trillion for payers and society, respectively (in 2013 dollars).⁶⁴

As with immunizations, other preventive services have been estimated to have cost-savings benefits. As discussed in the July 2010 interim final regulations, aspirin use with high risk adults and tobacco cessation and screening can both yield net savings. For example, in Massachusetts, the availability of tobacco cessation treatments combined with promotional campaigns resulted in a ten percent decline in Medicaid enrolled smokers, a \$3.12 savings for

⁶³ See e.g. Maciosek, Michael V., Coffield, Ashley B., Flottemesch, et al., Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost. *Health Affairs* 2010 29(9) 1656-1660. See eg. Zhou F, Santoli J, Messonnier ML, et al. Economic Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States, 2001. *Arch Pediatr Adolesc Med.* 2005; 159(12):1136-1144.

⁶⁴ Whitney, CG., Zhou, F., Singleton, J., Schuchat, A.. Benefits from Immunization During the Vaccines of Children Program Era – United States, 1994-2013. *MMWR* 2014;63(16):352-355.

every dollar spent on the benefit.⁶⁵ As discussed in more detail in the July 2010 interim final regulations, another area where prevention can achieve savings is obesity prevention and reduction. Based on recent guidelines, up to 116.1 million American adults are candidates for both pharmaceutical and behavioral treatments for weight loss, and up to 32 million are eligible for bariatric surgery.⁶⁶ According to the CDC, from 2011-2012, 16.9 percent of children 2 through 19 years of age and 34.9 percent of adults aged 20 and over were obese (defined as having a body mass index (BMI) greater than or equal to the age and sex-specific 95th percentiles of the 200 CDC growth charts).⁶⁷ One study used the number of obese and overweight twelve-year olds in 2005 to simulate a cohort over their lifetimes, indicating that a sustained one-percentage-point decrease in the prevalence of obesity over the lifetime of this cohort would result in an estimated savings of \$260.4 million in total medical expenditures.⁶⁸ These final regulations are expected to increase the take-up rate of preventative services counseling for obesity and other conditions among patients, and lead physicians to increase appropriate referrals for such services. The effect of these final regulations is expected to be magnified due to the numerous public and private sector initiatives dedicated to combating the obesity epidemic and smoking cessation.

Eligible closely held for-profit entities that seek the accommodation to exclude coverage for contraceptive services from health coverage offered to their employees and students, and

⁶⁵ McAfee, T., Babb, S., McNabb, S., Fiore, MC. *N Engl J Med* 2015; 372:5-7.

⁶⁶ Stevens, J., Oakkar, EE., Cui, Z., Cai, J., Truesdale, KP. US adults recommended for weight reduction by 1998 and 2013 obesity guidelines, NHANES 2007-2012, 2015 *Obesity* 23(3) 527-531.

⁶⁷ Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of Childhood and Adult Obesity in the United States, 2011–2012. *JAMA*. 2014; 311(8):806-814.

⁶⁸ Trasande, L., 2010, How Much Should We Invest in Preventing Childhood Obesity? *Health Affairs*, 29, no. 3 :372-378

eligible organizations that opt to provide notice to HHS, will benefit from not being required to facilitate access to or pay for coverage that are contrary to their owners' religious beliefs.

Women enrolled in plans under this accommodation will have continued access to contraceptive services without cost sharing.

5. Costs and Transfers

The changes in how plans and issuers continue to cover the recommended preventive services resulting from these final regulations will result in changes in covered benefits and premiums for individuals in plans and health insurance coverage subject to these final regulations. New costs to the health system result when individuals increase their use of preventive services in response to the changes in coverage of those services. Cost sharing, including coinsurance, deductibles, and copayments, divides the costs of health services between the plan or issuer and the enrollees. The removal of cost sharing increases the quantity of services demanded by lowering the direct cost of the service to consumers. Therefore, the Departments expect that the statute and these final regulations will continue to increase utilization of the covered preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand.

Several studies have found that individuals are sensitive to prices for health services.⁶⁹ CDC researchers who studied out-of-pocket costs of immunizations for privately insured children up to age 5 (in families in Georgia in 2003) found that a one percent increase in out-of-pocket

⁶⁹ Liu, S., and Chollet, D., Price and Income Elasticity of the Demand for Health Insurance and Health Care Services: A Critical Review of the Literature, *Mathematica Policy Research Inc.*, (March 2006) <http://www.mathematica-mpr.com/~media/publications/PDFs/priceincome.pdf>. See e.g., Ringel, JS., Hosek, SD., Vollaard, BA., and S. Mahnovski (2002), The elasticity of demand for health care; A review of the literature and its application to the military health system, National Defense Research Institute, RAND Health. http://www.rand.org/content/dam/rand/pubs/monograph_reports/2005/MR1355.pdf.

costs for routine immunizations (DTaP, IPV, MMR, Hib, and Hep B) was associated with a 0.07 percent decrease in utilization.⁷⁰

Eligible closely held for-profit entities that seek the accommodation for contraceptive services will incur administrative costs to provide self-certifications to issuers or third party administrators or notices to HHS. Issuers and third party administrators for health plans sponsored by these eligible organizations will also incur administrative costs to provide notifications to enrollees. The costs related to these information collection requirements are estimated in section D below.

Along with new costs of induced utilization, there are transfers associated with these final regulations. A transfer is a change in who pays for the services, where there is not an actual change in the level of resources used. For example, costs that were previously paid out-of-pocket for certain preventive services will now be covered by plans and issuers under these final regulations. Such a transfer of costs could be expected to lead to an increase in premiums.

In the July 2010 interim final regulations, the Departments analyzed the impact of eliminating cost sharing, increases in services covered, and induced utilization on the average insurance premium using a model to evaluate private health insurance plans against a nationally representative population. In the July 2010 interim final regulations, the Departments analyzed Medical Expenditure Panel Survey (MEPS) data and determined the average person with employer-sponsored insurance (ESI) would have \$264 in covered preventive service expenses, of which \$240 would be paid by insurance and \$24 paid out-of-pocket.⁷¹ When preventive services

⁷⁰ See e.g., Noelle-Angelique Molinari et al., “Out-of-Pocket Costs of Childhood Immunizations: A Comparison by Type of Insurance Plan,” Pediatrics, 120(5) pp. e1148–e1156 (2007).

are covered with zero copayment, the Departments estimated the average preventive benefit (holding utilization constant) would increase by \$24, or a 0.6 percent increase in insurance benefits and premiums for plans that have relinquished their grandfather status. Furthermore, in the July 2010 interim final regulations, the Departments estimated that additional coverage for genetic screening, depression screening, lead testing, autism testing, and oral health screening would result in a total average increase in insurance benefits on these services to be 0.12 percent, or just over \$4 per insured person. This increase represented a mixture of new costs and transfers, dependent on whether beneficiaries previously purchased these services on their own. Impacts were expected to vary depending on baseline benefit levels, and grandfathered health plans were not expected to experience any impact from those interim final regulations.

As discussed in the July 2010 interim final regulations, the Departments used the standard actuarial “induction formula” $1/(1+\alpha * P)$, where α is the “induction parameter” and P is the average fraction of the cost of services paid by consumers to estimate behavioral changes to estimate the induced demand for preventive services.⁷² Removing cost sharing for preventive services lowers the direct cost to consumers of using preventive services, which induces additional utilization, estimated with the model above to increase covered expenses and benefits by approximately \$17, or 0.44 percent in insurance benefits in group health plans. A similar, but larger, effect was anticipated in the individual market because individual health insurance policies generally had less generous benefits for preventive services than group health plans.

⁷¹ The model does not distinguish between recommended and non-recommended preventive services, and so this likely represents an overestimate of the insurance benefits for preventive services.

⁷² Standard formula best described in “Quantity- Price Relationships in Health Insurance”, Charles L Trowbridge, Chief Actuary, Social Security Administration (DHEW Publication No. (SSA) 73- 11507, November 1972).

When eligible closely held for-profit entities seek the accommodation, health insurance issuers (or third party administrators for self-insured plans) for the group health plans established or maintained by the eligible organizations (and health insurance issuers of student health plans arranged by eligible organizations that are institutions of higher education) will assume sole responsibility for providing (or arranging) separate payments for contraceptive services directly for plan participants and beneficiaries (or student enrollees and dependents), without cost sharing, premium, fee, or other charge to plan participants or beneficiaries (or student enrollees and dependents) or to the eligible organization or its plan. The Departments continue to believe that issuers will find that providing contraceptive coverage is at least cost neutral because they will be insuring the same set of individuals under both the group or student health insurance policies for whom they will also be making the separate payments for contraceptive services and, as a result, will experience lower costs from improvements in women's health, healthier timing and spacing of pregnancies, and fewer unplanned pregnancies. Several studies have estimated that the costs of providing contraceptive coverage are balanced by cost savings from lower pregnancy-related costs and from improvements in women's health.⁷³ A third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs (including an allowance for administrative costs and margin). The issuer offering coverage through the FFE can receive an adjustment to the FFE user fee, and the

⁷³ Bertko, J., Glied, S., et al. The Cost of Covering Contraceptives Through Health Insurance (February 9, 2012), <http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml>; Washington Business Group on Health, Promoting Healthy Pregnancies: Counseling and Contraception as the First Step, Report of a Consultation with Business and Health Leader (September 20, 2000), Campbell, K.P., Investing in Maternal and Child Health: An Employer's Toolkit, National Business Group on Health (2007) http://www.businessgrouphealth.org/healthtopics/maternalchild/investing/docs/mch_toolkit.pdf; Trussell, J., et al. The Economic Value of Contraception: A Comparison of 15 Methods, American Journal Public Health, 1995; 85(4):494-503, Revenues of H.R. 3162, the Children's Health and Medicare Protection Act, for the Rules Committee (August 1, 2007)

issuer is expected to pass on a portion of that adjustment to the third party administrator to account for the costs of providing or arranging payments for contraceptive services.

B. Regulatory Alternatives

Several provisions in these final regulations involved policy choices. One was whether to allow a plan or issuer to impose cost sharing for an office visit when a recommended preventive service is provided in that visit. Sometimes a recommended preventive service is billed separately from the office visit; sometimes it is not. The Departments decided that the cost - sharing prohibition of these final regulations applies to the specific preventive service as recommended by the guidelines. Therefore, if the preventive service is billed separately (or is tracked as individual encounter data separately) from the office visit, it is the preventive service that has cost sharing waived, not the entire office visit.

A second policy choice was, if the preventive service is not billed separately (or is not tracked as individual encounter data separately) from the office visit, whether these final regulations should prohibit cost sharing for any office visit in which any recommended preventive service was administered, or whether cost sharing should be prohibited only when the preventive service is the primary purpose of the office visit. Prohibiting cost sharing for office visits when any recommended preventive service is provided, regardless of the primary purpose of the visit, could lead to an overly broad application of these final regulations; for example, a person who sees a specialist for a particular condition could end up with a zero copayment simply because his or her blood pressure was taken as part of the office visit. This could create financial incentives for consumers to request preventive services at office visits that are intended for other purposes in order to avoid copayments and deductibles. The increased prevalence of

the application of zero cost sharing would lead to increased premiums compared with the chosen option, without a meaningful additional gain in access to preventive services.

A third issue involves health plans that have differential cost sharing for services provided by in-network vs. out-of-network providers. These final regulations provide that a plan or issuer generally is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. The plan or issuer generally may also impose cost sharing for recommended preventive services delivered by an out-of-network provider. However, if the plan or issuer does not have in its network a provider who can provide the recommended preventive service, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service. The Departments considered that requiring coverage by out-of-network providers with no cost sharing would result in higher premiums. Plans and issuers negotiate allowed charges with in-network providers as a way to promote effective, efficient health care, and allowing differences in cost sharing in- and out-of- network enables plans to encourage use of in-network providers. Allowing zero cost sharing for out-of-network providers could reduce providers' incentives to participate in insurer networks. The Departments decided that permitting cost sharing for recommended preventive services provided by out-of-network providers (except in cases where the recommended service is only available from an out-of-network provider) is the appropriate option to preserve a choice of providers for individuals, while avoiding potentially larger increases in costs and transfers as well as potentially lower quality care.

As discussed previously in the preamble, the Departments also considered different ways to define a closely held for-profit entity. Under one approach, a qualifying closely held for-profit

entity would have been defined as a for-profit entity where none of the ownership interests in the entity is publicly traded and where the entity has fewer than a specified number of shareholders or owners.

Under the second approach, a qualifying closely held for-profit entity would have been defined as a for-profit entity in which the ownership interests are not publicly traded, and in which a specified fraction of the ownership interest is concentrated in a limited and specified number of owners. Within the second approach, the Departments considered adopting the IRS test to define a closely held corporation. The definition adopted in these final rules, although based on the IRS test, is more flexible and ensures that it does not exclude some entities that should be considered to be closely held for the purposes of these final regulations.

Under a third approach, the Departments considered a test under which none of the ownership interests in the entity is publicly traded, without any other restrictions on the number of owners or on ownership concentration. The Departments believe, however, that such a test would be excessively broad.

C. Special Analyses – Department of Treasury

For purposes of the Department of the Treasury, it has been determined that this rule is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this rule. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the regulations merely modify the definition of eligible organization to include certain closely held for-profit entities. This

modification, as adopted, will not increase costs to or burdens on the affected organizations.

Pursuant to section 7805(f) of the Code, the proposed rule preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business and no comments were received.

D. Paperwork Reduction Act - Department of Health and Human Services

These final regulations contain information collection requirements that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

1. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm).

2. Information Collection Requirements (ICRs)

a. ICRs Regarding Self-Certification (§147.131(b)(3))

All eligible organizations will have the option of either providing a self-certification (EBSA Form 700) to the issuers or third party administrators of the plans that would otherwise arrange for or provide coverage for the contraceptive services, or providing a notice to HHS. For the purpose of estimating burdens, HHS is assigning the burden of the self-certification to eligible for-profit entities and the burden of notice to HHS to eligible non-profit organizations.

The July 2013 final regulations require an eligible organization that seeks an accommodation to self-certify that it meets the definition of an eligible organization using the EBSA Form 700 and provide it directly to each third party administrator or issuer of the plan that would otherwise arrange for or provide coverage for the contraceptive services. These final regulations continue to allow eligible organizations to use EBSA Form 700 to notify their third party administrators and issuers, as set forth in the July 2013 final regulations and guidance.

The Departments received comments that HHS underestimated the number of closely held for-profit eligible organizations that may seek the accommodation. Some commenters noted that it would be difficult to estimate this number. One commenter estimated that about 1.3 million S-corporations offer health insurance to their employees and, based on this data, objection rates of 1 percent of S-corporations would result in 13,000 objecting firms, an objection rate of 2 percent would result in 26,000 objecting firms and an objection rate of 5 percent would result in 65,000 objecting firms. However, the Departments have no indication that such large numbers of closely held for-profit entities would seek the accommodation. The Departments also note that the definition of a qualifying closely held for-profit entity adopted in these final regulations differs from the definition of an S-corporation. In the proposed rules, based on the number of plaintiffs that are for-profit employers in recent litigation objecting on religious grounds to the provision of contraceptive services, HHS estimated that 71 closely held

for-profit entities would seek the accommodation. In the final regulations, based on updated information, HHS is revising the estimate to 87. Even though this may underestimate the number of eligible closely held for-profit entities that will seek the accommodation, this is the best estimate available to the Departments at this time.

For each eligible organization, it is assumed that clerical staff will gather and enter the necessary information, send the self-certification to its issuer(s) or third party administrator(s) or the notice to HHS, and retain a copy for recordkeeping. A manager and legal counsel will subsequently review the information, and a senior executive will execute it. It is estimated that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per hour, 10 minutes for a manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127 per hour, and 5 minutes for a senior executive at a cost of \$121 per hour) to execute the self-certification. Therefore, the total one-time burden for preparing and providing the information in the self-certification is estimated to be approximately \$53 for each eligible organization. The certification may be electronically transmitted to the issuer or third party administrator at minimal cost or mailed. For purposes of this analysis, HHS assumes that all notices will be mailed. It is estimated that mailing each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.54.

Based on this estimate of 87 affected entities and the individual burden estimates of 50 minutes and a cost of \$53, we estimate the total hour burden to be 72.5 hours with an equivalent cost of \$4,611. The total paper filing cost burden for the notices is approximately \$47. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 36.25

burden hours at an equivalent cost of approximately \$2,306 and a paper filing cost burden of approximately \$23, with approximately 44 respondents.

b. ICRs Regarding Notice to HHS (§147.131(b)(3))

These final regulations provide an organization seeking to be treated as an eligible organization under the August 2014 interim final regulations an alternative process, consistent with the Supreme Court's interim order in Wheaton College, under which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. The eligible organization must maintain the notice to HHS in its records. The burden related to this alternate notice is currently approved under OMB Control Number 0938-1248.

Based on litigation, HHS believes that at least 122 eligible non-profit organizations will have the option to provide the alternative notice to HHS rather than their third party administrators or issuers. Even though this likely underestimates the number of eligible non-profit organizations that will seek the accommodation, this is the best estimate available to the Departments at this time. In order to complete this task, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the notice. HHS assumes that a compensation and benefits manager and inside legal counsel will review the notice and a senior executive will execute it. HHS estimates that an eligible organization will spend approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per hour, 10 minutes for a compensation and benefits manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127 per hour, and 5 minutes by a senior executive at a cost of \$121 per hour) preparing and sending the notice and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the notice to HHS will require

approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$53 for a total hour burden of 102 hours with an equivalent cost of \$6,425. As HHS and DOL share jurisdiction, they are splitting the hour burden so each will account for 51 burden hours with an equivalent cost of \$3,213, with a total of 61 respondents.

Notices to HHS may be sent electronically at minimal cost or by mail. For purposes of this analysis, HHS assumes that all notices will be mailed. It is estimated that mailing each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) with a total postage and materials cost for each notice sent via mail of \$0.54. The total cost burden for the notices is approximately \$66. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for \$33 of the cost burden.

c. Notice of Availability of Separate Payments for Contraceptive Services (§147.131(d))

As required by the July 2013 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers may, but are not required to, use the model language set forth in the July 2013 final regulations or substantially similar language.

As mentioned, HHS is anticipating that at least 122 non-profit and 87 closely held for-profit entities will seek an accommodation. It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 209. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$30 per hour) and 15 minutes of management review (at \$102 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately \$56. The total burden for all issuers or third party administrators will be 261.25 hours, with an equivalent cost of \$11,600. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 130.63 burden hours with an equivalent cost of \$5,800, with approximately 105 respondents.

d. Letter to HHS Regarding Ownership Structure (§147.131(b)(4)(v))

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

As stated earlier in the preamble, the Departments believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. In addition, it appears based on available information that the definition adopted in these final regulations includes all of the for-profit entities that have, as of the date of issuance of these regulations, challenged the contraceptive coverage requirement in court. Therefore, the Departments anticipate that fewer than 10 entities will submit a letter to

HHS. Under 5 CFR 1320.3(c)(4), this provision is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

3. Summary of Proposed Annual Burden Estimates

Table III.3 Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB Control No.	Respondents	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Burden Cost per respondent (\$)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
Self-Certification (\$147.131(b)(3))	New	44	44	0.83	36.25	\$53	\$2,306	\$23	\$2,329
Notice to HHS (\$147.131(b)(3))	0938-1248	61	61	0.83	51	\$53	\$3,213	\$33	\$3,246
Notice of Availability of Separate Payments for Contraceptive Services (\$147.131(d))	New	105	105	1.25	130.63	\$56	\$5,800	\$0	\$5,800
Total		210	210		217.88		\$11,319	\$56	\$11,375

4. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

E. Paperwork Reduction Act - Department of Labor

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)), the Department submitted an information collection request (ICR) to OMB in accordance with 44 U.S.C. 3507(d), contemporaneously with the publication of the interim final regulation, for OMB's review under the emergency PRA procedures.⁷⁴ OMB approved the ICR on August 27, 2014 under OMB Control Number 1210-0150 through February 28, 2015.

⁷⁴ 5 CFR 1320.13.

Contemporaneously with the publication of the emergency ICR, the Department published a separate **Federal Register** notice informing the public that it intends to request OMB to extend the approval for 3 years and soliciting comments on the ICR.⁷⁵ The Department submitted the extension request to OMB on February 27, 2015. OMB approved the ICR extension on April 14, 2015, which currently is scheduled to expire on April 30, 2018.

The Department also submitted an ICR to OMB in accordance with 44 U.S.C. 3507(d), for the ICR contained in the August 2014 proposed regulations contemporaneously with the publication of the proposal that solicited public comments on the ICR. OMB filed a comment regarding the proposed ICR on October 16, 2014, stating that it was not approving the ICR associated with the proposed rule at the proposed rule stage and requesting the Department to resubmit the ICR at the final rule stage after taking into account public comments. OMB assigned OMB Control Number 1210-0152 to the proposed ICR.

Although no public comments were received in response to the ICRs contained in the August 2014 interim final and proposed regulations that specifically addressed the paperwork burden analysis of the information collections, the comments that were submitted, and which are described earlier in this preamble, contained information relevant to the costs and administrative burdens attendant to the proposals. The Department took into account the public comments in connection with making changes to the proposal, analyzing the economic impact of the proposals, and developing the revised paperwork burden analysis summarized below.

In connection with publication of this final rule, the Department submitted ICRs to OMB as a revision to OMB Control Number 1210-0150 for eligible non-profit organizations and under

⁷⁵ 79 FR 51197 (Aug. 27, 2014).

new OMB Control Number 1210-0152 for eligible for-profit organizations and received OMB approval for both ICRs.

A copy of the ICRs may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>. 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.

1. ICRs Regarding Self-Certification (29 CFR 2590.2713A(b) or (c))

Under these final regulations, all eligible organizations will have the option of either providing (1) a self-certification (EBSA Form 700) to the issuers or third party administrators of the plans that would otherwise arrange for or provide coverage for the contraceptive services or (2) a notice to HHS. For the purpose of estimating burdens, the Department is assigning the burden of the self-certification to eligible for-profit entities and the burden of notice to HHS to eligible non-profit organizations.

The July 2013 final regulations require an eligible organization that seeks an accommodation to self-certify that it meets the definition of an eligible organization using the EBSA Form 700 and provide it directly to each third party administrator or issuer of the plan that would otherwise arrange for or provide coverage for the contraceptive services. These final regulations continue to allow eligible organizations to use EBSA Form 700 to notify their third party administrators and issuers, as set forth in the July 2013 final regulations and guidance.

In response to the public comment solicitation for the ICRs in the August 2014 proposed regulations, the Departments received comments that they underestimated the number of closely held for-profit eligible organizations that may seek the accommodation. Some commenters

noted that it would be difficult to estimate this number. One commenter estimated that about 1.3 million S-corporations offer health insurance to their employees and, based on this data, objection rates of 1 percent of S-corporations would result in 13,000 objecting firms, an objection rate of 2 percent would result in 26,000 objecting firms and an objection rate of 5 percent would result in 65,000 objecting firms. However, the Departments have no indication that such large numbers of closely held for-profit entities would seek the accommodation. The Departments also note that the definition of a qualifying closely held for-profit entity adopted in these final regulations differs from the definition of an S-corporation. In the proposed rules, based on the number of plaintiffs that are for-profit employers in recent litigation objecting on religious grounds to the provision of contraceptive services, the Departments estimated that 71 closely held for-profit entities would seek the accommodation. In these final regulations, based on updated information, the Departments are revising the estimate to 87. Even though this may underestimate of the number of eligible closely held for-profit entities that will seek the accommodation, this is the best estimate available to the Departments at this time.

For each eligible organization, the Departments assume that clerical staff will gather and enter the necessary information, send the self-certification to its issuer(s) or third party administrator(s) or the notice to HHS, and retain a copy for recordkeeping. A manager and legal counsel will subsequently review the information, and a senior executive will execute it. It is estimated that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per hour,⁷⁶ 10 minutes for a manager at a cost of \$102 per hour,⁷⁷ 5 minutes for

⁷⁶ Secretaries, Except Legal, Medical, and Executive (43-6014): \$16.13(2012 BLS Wage rate)/0.679(ECEC ratio)
*1.2(Overhead Load Factor) *1.019(Inflation rate) ^2(Inflated 2 years from base year) = \$29.60

⁷⁷ Compensation and Benefits Manager (11-3041): \$50.92(2012 BLS Wage rate) /0.697(ECEC ratio)
*1.35(Overhead Load Factor) *1.019(Inflation rate) ^2(Inflated 2 years from base year) = \$102.41

legal counsel at a cost of \$127 per hour,⁷⁸ and 5 minutes for a senior executive at a cost of \$121 per hour⁷⁹) to execute the self-certification. Therefore, the Departments estimate that the total one-time burden for preparing and providing the information in the self-certification is estimated to be approximately \$53 for each eligible organization. The certification may be electronically transmitted to the issuer or third party administrator at minimal cost or mailed. For purposes of this analysis, the Departments assume that all notices will be mailed. The Departments estimate that mailing each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.54.

Based on this estimate of 87 affected entities and the individual burden estimates of 50 minutes and a cost of \$53, the Departments estimate the total hour burden associated with the ICR to be 72.5 hours with an equivalent cost of \$4,611. The total paper filing cost burden for the notices is approximately \$47. The hour burden associated with the ICR is allocated equally between DOL and HHS, because the agencies share jurisdiction of preventive health services resulting in an hour burden for each agency of 36.25 burden hours at an equivalent cost of approximately \$2,306 and a paper filing cost burden of approximately \$23, with approximately 44 respondents.

2. ICRs Regarding Notice to HHS (29 CFR 2590.2713A (b) or (c))

These final regulations provide an organization seeking to be treated as an eligible organization under the August 2014 interim final regulations with an alternative process, consistent with the Supreme Court's interim order in Wheaton College, under which an eligible

⁷⁸ Legal Professional (23-1011): \$62.93(2012 BLS Wage rate) /0.697(ECEC ratio) *1.35(Overhead Load Factor) *1.019(Inflation rate) ^2(Inflated 2 years from base year) = \$126.56

⁷⁹ Financial Managers (11-3031): \$59.26(2012 BLS Wage rate) /0.689(ECEC ratio) *1.35(Overhead Load Factor) *1.019(Inflation rate) ^2(Inflated 2 years from base year) = \$120.57

organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. The eligible organization must maintain the notice to HHS in its records. The burden related to this alternate notice is currently approved under OMB Control Number 1210-0150.

Based on litigation, the Departments estimate that at least 122 eligible non-profit organizations will have the option to provide the alternative notice to HHS rather than their third party administrators or issuers. Even though this may underestimate the number of eligible non-profit organizations that will seek the accommodation, it is the best estimate available to the Departments at this time. In order to complete this task, the Departments assume that clerical staff for each eligible organization will gather and enter the necessary information and send the notice. The Departments assume that a compensation and benefits manager and inside legal counsel will review the notice and a senior executive will execute it. The Departments estimate that an eligible organization will spend approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per hour, 10 minutes for a compensation and benefits manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127 per hour, and 5 minutes by a senior executive at a cost of \$121 per hour) preparing and sending the notice and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$53 for a total hour burden of 102 hours with an equivalent cost of \$6,425. As HHS and DOL share jurisdiction, they are splitting the hour burden so each will account for 51 burden hours with an equivalent cost of \$3,213, with a total of 61 respondents.

Notices to HHS may be sent electronically at minimal cost or by mail. For purposes of this analysis, the Departments assume that all notices will be mailed. It is estimated that mailing each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) with a total postage and materials cost for each notice sent via mail of \$0.54. The total cost burden for the notices is approximately \$66. As DOL and HHS share jurisdiction, they are sharing the cost burden equally and each is attributed \$33 of the cost burden.

3. Notice of Availability of Separate Payments for Contraceptive Services (29 CFR 2590.2713A(d))

As required by the July 2013 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries (or student enrollees and covered dependents) in insured plans of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers may, but are not required to, use the model language set forth in the July 2013 final regulations or substantially similar language.

As mentioned, the Departments anticipate that at least 122 non-profit and 87 closely held for-profit entities will seek an accommodation. It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but that for the purposes of the analysis, the Departments assume at least

209 do. The Departments assume that each issuer or third party administrator will need approximately one hour of clerical labor (at \$30 per hour) and 15 minutes of management review (at \$102 per hour) to prepare the notices. Therefore, the Departments estimate that the total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately \$56. The total burden for all issuers or third party administrators will be 261.25 hours, with an equivalent cost of \$11,600. The cost burden associated with this ICR is allocated equally between DOL and HHS, because the agencies share jurisdiction under the provision. Therefore, the hour burden for each is 130.63 burden hours with an equivalent cost of \$5,800 for approximately 105 respondents.

4. Letter to HHS Regarding Ownership Structure (29 CFR 2590.2713A(a)(4)(v))

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

As stated earlier in the preamble, the Departments believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. In addition, it appears based on available information that the definition adopted in these final regulations includes all of the for-profit entities that have, as of the date of issuance of these regulations, challenged the contraceptive coverage requirement in court. Therefore, the Departments anticipate that fewer than 10 entities will submit a letter to HHS. Under 5 CFR 1320.3(c)(4), this provision is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

F. Regulatory Flexibility Act - Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a 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 non-profit 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 percent to 5 percent.

As discussed in the Web Portal interim final rule with comment period published on May 5, 2010 (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 it was 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 \$38.5 million in annual receipts for health insurance issuers).⁸⁰ In addition, analysis of data from Medical Loss Ratio annual report submissions for the 2013 reporting year was used to develop an estimate of the number of small entities that offer comprehensive major medical coverage. It is estimated that 141 out of 500 issuers of health insurance coverage nationwide had total premium revenue of \$38.5 million or less. This estimate may overstate the actual number of small health insurance

⁸⁰ “Table of Small Business Size Standards Matched To North American Industry Classification System Codes,” effective July 14, 2014, U.S. Small Business Administration, available at <http://www.sba.gov>.

companies that would be affected, since 77 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding \$38.5 million. For these reasons, the Departments expect that these final regulations will not affect a significant number of small issuers.

The provisions of these final regulations affect small employers with self-insured group health plans by requiring them to include coverage under their group health plans for recommended preventive services without cost sharing. However, small employers also benefit from having healthier employees and reduced absenteeism. Small employers are less likely to be self-insured compared to large employers; only about 13.3 percent of employers with less than 100 employees that offer a group health plan have a self-funded plan.⁸¹

With respect to contraceptive coverage, some eligible organizations that seek the accommodation may be small entities and will incur costs to provide the self-certification to issuers or third party administrators or notice to HHS. However, the related administrative costs are expected to be minimal.

Third party administrators for self-insured group health plans established or maintained by eligible organizations will incur administrative costs to send notices to enrollees and arrange for separate payments for contraceptive services. It is unknown how many third party administrators impacted by this requirement have revenues below the size thresholds for “small” business established by the SBA (currently \$32.5 million for third party administrators). However, a third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for the third party administrator’s costs.

⁸¹ Source: Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2013 Medical Expenditure Panel Survey-Insurance Component.

G. 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. In the Departments’ view, these final regulations have federalism implications, but the federalism implications are substantially mitigated because, with respect to health insurance issuers, 45 states are either enforcing the requirements related to coverage of specified preventive services (including contraception) without cost sharing pursuant to state law or otherwise are working collaboratively with HHS to ensure that issuers meet these standards. In five states, HHS ensures that issuers comply with these requirements. Therefore, the final regulations are not likely to require substantial additional oversight of states by HHS.

In general, section 514 of ERISA provides that state laws are superseded to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. ERISA also prohibits states from regulating a covered plan as an insurance or investment company or bank. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements on group health insurance coverage. States may continue to apply state law requirements but not to the extent that such requirements prevent the application of the federal requirement that group health insurance coverage provided in connection with certain group health plans (or student health insurance issuers) provide coverage for specified preventive services without cost sharing. HIPAA’s Conference Report states that the conferees intended the narrowest preemption of state laws with regard to health

insurance issuers (H.R. Conf. Rep. No. 104-736, 104th Cong. 2d Session 205, 1996). State insurance laws that are more stringent than the federal requirement are unlikely to “prevent the application of” the preventive services coverage provision, and therefore are unlikely to be preempted. Accordingly, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than those in federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 (62 FR 16904) and December 30, 2004 (69 FR 78720), and these final regulations implement the preventive services coverage provision’s minimum standards and do not significantly reduce the discretion given to states under the statutory scheme.

The PHS Act provides that states may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but that the Secretary of HHS will enforce any provisions that a state does not have authority to enforce or that a state has failed to substantially enforce. When exercising its responsibility to enforce provisions of the PHS Act, HHS works cooperatively with the state to address the state’s concerns and avoid conflicts with the state’s exercise of its authority. HHS has developed procedures to implement its enforcement responsibilities, and to afford states the maximum opportunity to enforce the PHS Act’s requirements in the first instance. In compliance with Executive Order 13132’s requirement that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of states, the Departments have engaged in numerous efforts to consult and work cooperatively with affected state and local officials.

In conclusion, throughout the process of developing these final regulations, to the extent feasible within the specific preemption provisions of ERISA and the PHS Act, the Departments have attempted to balance states’ interests in regulating health insurance coverage and health

insurance issuers, and the rights of individuals intended to be protected in the PHS Act, ERISA, and the Code.

H. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by state, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold level is approximately \$144 million.

UMRA does not address the total cost of a regulatory action. Rather, it focuses on certain categories of cost, mainly those “Federal mandate” costs resulting from--(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs. These final regulations include no mandates on state, local, or tribal governments. Health insurance issuers, third party administrators and eligible organizations would incur costs to comply with the provisions of these final regulations. However, consistent with policy embodied in UMRA, these final regulations have been designed to be the least burdensome alternative while achieving the objectives of the Affordable Care Act.

I. Congressional Review Act

These final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule

along with other specified information, and have been transmitted to Congress and the Comptroller General for review.

IV. Statutory Authority

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

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 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 1-2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111-148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects**26 CFR Part 54**

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

29 CFR Part 2510

Employee benefit plans, Pensions.

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, State regulation of health insurance.

Approved: July 8, 2015.

John Dalrymple,
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved: July 8, 2015.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).

Signed this 7th day of May 2015.

Phyllis C. Borzi,

Assistant Secretary,

Employee Benefits Security Administration,

Department of Labor.

Dated: May 7, 2015.

Andrew M. Slavitt,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Approved: May 20, 2015.

Sylvia M. Burwell,
Secretary,
Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54--PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

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

Section 54.9815-2713 also issued under 26 U.S.C. 9833;

* * * * *

Par.2. Section 54.9815-2713 is amended by adding paragraphs (a)(1)(i), (ii), and (iii), and revising paragraphs (a)(2), (3), (4), and (5), (b), and (c) to read as follows:

§54.9815-2713 Coverage of preventive health services.

(a) * * *

(1) * * *

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director

of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

* * * *

(2) Office visits – (i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the

United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) Conclusion. In this Example 1, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) Facts. Same facts as Example 1 of this section. As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) Conclusion. In this Example 2, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) Facts. An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) Conclusion. In this Example 3, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) Facts. A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive

guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) Conclusion. In this Example 4, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) Out-of-network providers. (i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost-sharing with respect to the item or service.

(4) Reasonable medical management. Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a

recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(5) Services not described. Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) Timing--(1) In general. A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) Changes in recommendations or guidelines. (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year must provide coverage through the last day of the plan year, even if the recommendation or guideline changes is or is no longer described in paragraph (a)(1) of this section, during the plan year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a

plan year is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan year, there is no requirement under this section to cover these items and services through the last day of the plan year.

(c) Recommendations not current. For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

Par.3 Section 54.9815-2713A is amended by revising paragraphs (a), (b), (c)(1), and (c)(2)(i) introductory text to read as follows:

§ 54.9815-2713A Accommodations in connection with coverage of preventive health services.

(a) Eligible organizations. An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under § 54.9815-2713(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (a)(4) of this section, and the organization’s highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has

adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owner's sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary of Labor or provide notice to the Secretary of Health and Human Services as described in paragraph (b) or (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that --

(i) Is not a nonprofit entity;

(ii) Has no publicly traded ownership interests, (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and

(iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (a)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (a)(4)(iii) of this section.

(b) Contraceptive coverage—self-insured group health plans. (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis complies for one or more plan years with any requirement under §54.9815-2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) are satisfied:

(i) The eligible organization or its plan contracts with one or more third party administrators.

(ii) The eligible organization provides either a copy of the self-certification to each third party administrator or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3-16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3-16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and agrees to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, the third party administrator shall provide or arrange payments for contraceptive services using one of the following methods—

- (i) Provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or
- (ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(c) * * *

(1) General rule. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under §54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

(i) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with §54.9815-2713. An issuer may not require any further documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the

plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section .

(2) * * *

(i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (c)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under §54.9815-2713(a)(1)(iv) must—

* * * *

§54.9815-2713AT [REMOVED]

Par. 4. Section 54.9815-2713AT is removed.

§54.9815-2713T [REMOVED]

Par. 5. Section 54.9815-2713T is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, under the authority contained in 29 U.S.C. 1002(16), 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 1-2011, 77 FR 1088 (Jan. 9, 2012) the Department of Labor adopts as final the interim rules amending 29 CFR part 2590 published on

July 19, 2010 (75 FR 41726) and amending 29 CFR parts 2510 and 2590 published August 27, 2014 (79 FR 51092) and further amends 29 CFR part 2590 as follows:

PART 2590--RULES AND REGULATIONS FOR GROUP HEALTH PLANS

6. 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. 12(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 1-2011, 77 FR 1088 (January 9, 2012).

7. Section 2590.715-2713 is amended by revising paragraphs (a)(3) and (4) and (b)(2) to read as follows:

§ 2590.715-2713 Coverage of preventive health services

(a) * * *

(3) Out-of-network providers-(i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or

service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(4) Reasonable medical management. Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

* * * *

(b) * *

(2) Changes in recommendations or guidelines. (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year must provide coverage through the last day of the plan year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the plan year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan year, there is no requirement under this section to cover these items and services through the last day of the plan year.

* * * *

8. Section 2590.715-2713A is amended by revising paragraph (a) to read as follows:

§ 2590.715-2713A Accommodations in connection with coverage of preventive health services.

(a) Eligible organizations. An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under §2590.715-2713(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (a)(4) of this section, and the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owners' sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary or provide notice to the Secretary of Health and Human Services as described in paragraph (b) or (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be

maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that --

(i) Is not a nonprofit entity;

(ii) Has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and

(iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (a)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for-profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to

the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (a)(4)(iii) of this section.

* * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, under the authority contained in Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92, as amended), the Department of Health and Human Services adopts as final the interim rules amending 45 CFR part 147 published on July 19, 2010 (75 FR 41726) and amending 45 CFR part 147 published August 27, 2014 (79 FR 51092) and further amends 45 CFR part 147 as follows:

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

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

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

10. Section 147.130 is amended by revising paragraphs (a)(3) and (4) and (b)(2) to read as follows:

§ 147.130 Coverage of preventive health services

(a) *

(3) Out-of-network providers--(i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(4) Reasonable medical management. Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

* * * *

(b) * *

(2) Changes in recommendations or guidelines. (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year (in the individual market, policy year) must provide coverage through the last day of the plan or policy year, even

if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year (in the individual market, policy year) is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the plan or policy year.

* * * *

11. Section 147.131 is amended by revising paragraphs (b) and (f) to read as follows:

§147.131 Exemption and accommodations in connection with coverage of preventive health services.

* * * *

(b) Eligible organizations. An eligible organization is an organization that meets the criteria of paragraphs (b)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under §147.130(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (b)(4) of this section, and the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owners' sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary of Labor or provide notice to the Secretary of Health and Human Services as described in paragraph (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that --

- (i) Is not a nonprofit entity;
- (ii) Has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and
- (iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (b)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders, partners, or beneficiaries.

Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for-profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (b)(4)(iii) of this section.

* * * *

(f) Application to student health insurance coverage. The provisions of this section apply to student health insurance coverage arranged by an eligible organization that is an institution of higher education as defined in 20 U.S.C. 1002 in a manner comparable to that in which they apply to group health insurance coverage provided in connection with a group health

plan established or maintained by an eligible organization that is an employer. In applying this section in the case of student health insurance coverage, a reference to "plan participants and beneficiaries" is a reference to student enrollees and their covered dependents.

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