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Incentives for Nondiscriminatory Wellness Programs in Group Health Plans; Final Rule

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DEPARTMENT OF LABOR

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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[CMS–9979–F]

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Incentives for Nondiscriminatory Wellness Programs in Group Health Plans

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

ACTION: Final rule.

SUMMARY: This document contains final regulations, consistent with the Affordable Care Act, regarding nondiscriminatory wellness programs in group health coverage. Specifically, these final regulations increase the maximum permissible reward under a health-contingent wellness program offered in connection with a group health plan (and any related health insurance coverage) from 20 percent to 30 percent of the cost of coverage. The final regulations further increase the maximum permissible reward to 50 percent for wellness programs designed to prevent or reduce tobacco use. These regulations also include other clarifications regarding the reasonable design of health-contingent wellness programs and the reasonable alternatives they must offer in order to avoid prohibited discrimination.

DATES: *Effective Date:* August 2, 2013.

Applicability Date: These final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after January 1, 2014. These final regulations generally apply to individual health insurance issuers for policy years beginning on or after January 1, 2014.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

The Patient Protection and Affordable Care Act, Pub. L. 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act, Pub. L. 111–152, was enacted on March 30, 2010 (these are collectively known as the ''Affordable Care Act''). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.[1] The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by these references are sections 2701 through 2728.

B. Wellness Exception to HIPAA Nondiscrimination Provisions

Prior to the enactment of the Affordable Care Act, titles I and IV of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191, added section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act (HIPAA nondiscrimination and wellness provisions). These provisions generally prohibit group health plans and group health insurance issuers from discriminating against individual participants and beneficiaries in eligibility, benefits, or premiums based on a health factor.[2] An exception to the general rule allows premium discounts or rebates or modification to otherwise applicable cost sharing (including copayments, deductibles, or coinsurance) in return for adherence to certain programs of health promotion and disease prevention.

The Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments[3]) published joint final regulations implementing the HIPAA nondiscrimination and wellness provisions on December 13, 2006 at 71 FR 75014 (the 2006 regulations).[4] The 2006 regulations divided wellness programs into two general categories: Participatory wellness programs and health-contingent wellness programs. Under the 2006 regulations, participatory wellness programs[5] are considered to comply with the HIPAA nondiscrimination requirements

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

[2] The HIPAA nondiscrimination provisions set forth eight health status-related factors, which the December 13, 2006 final regulations refer to as ''health factors.'' Under HIPAA and the 2006 regulations, as well as under PHS Act section 2705 (as added by the Affordable Care Act), the eight health factors are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), and disability. *See* 66 FR 1379, January 8, 2001.

[3] Note, however, that in the Economic Analysis and Paperwork Burden section of this preamble, 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.

[4] *See* 26 CFR 54.9802–1; 29 CFR 2590.702; 45 CFR 146.121. Prior to issuance of the final 2006 regulations, the Departments published interim final regulations with request for comment implementing the HIPAA nondiscrimination provisions on April 8, 1997 at 62 FR 16894, followed by proposed regulations regarding wellness programs on January 8, 2001 at 66 FR 1421.

[5] Under the 2006 regulations, a participatory wellness program is generally a program under which none of the conditions for obtaining a reward is based on an individual satisfying a standard related to a health factor or under which no reward is offered.

without having to satisfy any additional standards if participation in the program is made available to all similarly situated individuals, regardless of health status. Paragraph (d) of the 2006 regulations provided that, generally, distinctions among groups of similarly situated participants in a health plan must be based on bona fide employment-based classifications consistent with the employer's usual business practice. A plan may also distinguish between beneficiaries based on, for example, their relationship to the plan participant (such as spouse or dependent child) or based on the age of dependent children. Distinctions are not permitted to be based on any of the health factors listed in the 2006 regulations.

Under the 2006 regulations, plans and issuers with health-contingent wellness programs [6] were permitted to vary benefits (including cost-sharing mechanisms), premiums, or contributions based on whether an individual has met the standards of a wellness program that meets the requirements of paragraph (f)(2), which outlined five specific criteria.

C. Amendments Made by the Affordable Care Act

The Affordable Care Act (section 1201) amended the HIPAA nondiscrimination and wellness provisions of the PHS Act (but not of ERISA section 702 or Code section 9802). (Affordable Care Act section 1201 also moved those provisions from PHS Act section 2702 to PHS Act section 2705.) As amended by the Affordable Care Act, the nondiscrimination and wellness provisions of PHS Act section 2705 largely reflect the 2006 regulations (except as discussed later in this preamble), and extend the HIPAA nondiscrimination protections to the individual market.[7] The wellness program exception to the prohibition on discrimination under PHS Act section 2705 applies with respect to group health plans (and any health insurance coverage offered in connection with such plans), but does not apply to coverage in the individual market.

D. Proposed Regulations Implementing PHS Act Section 2705 and Amending the 2006 Regulations

On November 26, 2012, the Departments published proposed regulations at 77 FR 70620, to implement PHS Act section 2705 and amend the 2006 regulations regarding nondiscriminatory wellness programs in group health coverage. Like the 2006 regulations, the proposed regulations continued to divide wellness programs into participatory wellness programs and health-contingent wellness programs. Examples of participatory wellness programs provided in the proposed regulations included a program that reimburses for all or part of the cost of membership in a fitness center; a diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes; and a program that provides a reward to employees for attending a monthly, no-cost health education seminar. Examples of health-contingent wellness programs in the proposed regulations included a program that imposes a premium surcharge based on tobacco use; and a program that uses a biometric screening or a health risk assessment to identify employees with specified medical conditions or risk factors (such as high cholesterol, high blood pressure, abnormal body mass index, or high glucose level) and provides a reward to employees identified as within a normal or healthy range (or at low risk for certain medical conditions), while requiring employees who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, or complying with a health care provider's plan of care) to obtain the same reward.

The proposed regulations re-stated that participatory wellness programs are not required to meet the five requirements applicable to health-contingent wellness programs. The proposed regulations also outlined the conditions for health-contingent wellness programs, as follows:

1. The program must give eligible individuals an opportunity to qualify for the reward at least once per year.

2. The reward for a health-contingent wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed 30 percent of the total cost of employee-only coverage under the plan, or 50 percent to the extent the program is designed to prevent or reduce tobacco use.

3. The reward must be available to all similarly situated individuals. For this purpose, a reasonable alternative standard (or waiver of the otherwise applicable standard) must be made available to any individual for whom, during that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard (or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard).

4. The program must be reasonably designed to promote health or prevent disease. For this purpose, it must have a reasonable chance of improving the health of, or preventing disease in, participating individuals, and not be overly burdensome, not be a subterfuge for discriminating based on a health factor, and not be highly suspect in the method chosen to promote health or prevent disease. The proposed regulations also stated that, to the extent a plan's initial standard for obtaining a reward (or a portion of a reward) is based on results of a measurement, test, or screening that is related to a health factor (such as a biometric examination or a health risk assessment), the plan is not reasonably designed unless it makes available to all individuals who do not meet the standard based on the measurement, test, or screening, a different, reasonable means of qualifying for the reward.

5. The plan must disclose in all plan materials describing the terms of the program the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard.

II. Overview of the Final Regulations

A. General Overview

The Departments believe that appropriately designed wellness programs have the potential to contribute importantly to promoting health and preventing disease. After consideration of all the comments, the Departments are issuing these final regulations to provide comprehensive guidance with respect to the general requirements for wellness programs. At the same time, the Departments recognize that each wellness program is unique and questions may remain regarding the application of these requirements. The Departments anticipate issuing future subregulatory guidance to provide additional clarity and potentially proposing modifications to this final rule as necessary. These final regulations generally implement standards for group health plans and health insurance issuers offering group health insurance coverage with respect

[6] Under the 2006 regulations, a health-contingent wellness program is generally a program under which any of the conditions for obtaining a reward is based on an individual satisfying a standard related to a health factor (such as not smoking, attaining certain results on biometric screenings, or meeting targets for exercise).

[7] Section 1201 of the Affordable Care Act also moved the guaranteed availability provisions that were previously codified in PHS Act section 2711 to PHS Act section 2702, and extended those requirements to the individual market.

to the wellness program exception from the HIPAA nondiscrimination provisions in PHS Act section 2705, ERISA section 702, and Code section 9802, as amended by the Affordable Care Act. These final regulations replace the wellness program provisions of paragraph (f) of the 2006 regulations and are applicable to both grandfathered and non-grandfathered group health plans and group health insurance coverage for plan years beginning on or after January 1, 2014.[8] These regulations also implement the nondiscrimination provisions of PHS Act section 2705 applicable to non-grandfathered individual health insurance coverage for policy years beginning on or after January 1, 2014. This rulemaking does not modify provisions of the 2006 regulations other than paragraph (f).

Stakeholder feedback suggested that there is some degree of confusion regarding the scope of the HIPAA and Affordable Care Act rules governing wellness programs, which is clarified in these final regulations. Specifically, these final regulations do not establish requirements for all types of programs or information technology platforms offered by an employer, health plan, or health insurance issuer that could be labeled a wellness program, disease management program, case management program, or similar term. Instead, these final regulations set forth criteria for a program of health promotion or disease prevention offered or provided by a group health plan or group health insurance issuer that must be satisfied in order for the plan or issuer to qualify for an exception to the prohibition on discrimination based on health status under paragraphs (b)(2)(ii) and (c)(3) of the 2006 regulations (which provide exceptions to the general prohibition against discrimination based on a health factor in benefits and premiums or contributions, respectively).[9] That is, these rules set forth criteria for an affirmative defense that can be used by plans and issuers in response to a claim that the plan or issuer discriminated under the HIPAA nondiscrimination provisions.

These final regulations are restructured, as compared to the proposed regulations, to help clarify this relationship and how the five statutory requirements apply to different types of programs, including different types of health-contingent wellness programs (described below as activity-only wellness programs and outcome-based wellness programs). The final regulations also reorganize the presentation of the steps a plan or issuer must take to ensure a wellness program: is reasonably designed to promote health or prevent disease; has a reasonable chance of improving the health of, or preventing disease in, participating individuals; is not overly burdensome; is not a subterfuge for discriminating based on a health factor; and is not highly suspect in the method chosen to promote health or prevent disease. To meet these standards, health-contingent wellness programs that are outcome-based wellness programs must offer a ''reasonable alternative standard'' (or waiver of the otherwise applicable standard) to a broader group of individuals than is required for activity-only wellness programs. Specifically, for activity-only wellness programs, a reasonable alternative standard for obtaining the reward must be provided for any individual for whom, for that period, it is either unreasonably difficult due to a medical condition to meet the otherwise applicable standard, or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard. For outcome-based wellness programs, which generally provide rewards based on whether an individual has attained a certain health outcome (such as a particular body mass index (BMI), cholesterol level, or non-smoking status, determined through a biometric screening or health risk assessment), a reasonable alternative standard must be provided to all individuals who do not meet the initial standard, to ensure that the program is reasonably designed to improve health and is not a subterfuge for underwriting or reducing benefits based on health status.[10] These requirements are generally intended to be the same as those included in the proposed rules, but the terminology has changed (for example, the term ''different, reasonable means,'' which was used side by side with the term ''reasonable alternative standard,'' has been dropped to reduce confusion). These changes help to clarify that the group of individuals that must be offered a reasonable alternative standard differs when comparing the requirements for an activity-only wellness program to the requirements for an outcome-based wellness program. The requirements that the alternative be reasonable taking into account an individual's medical condition, and the option of waiving the initial standard, remain the same. The term ''reasonable alternative standard'' is used in these final rules as it is in the statute.[11]

The intention of the Departments in these final regulations is that, regardless of the type of wellness program, every individual participating in the program should be able to receive the full amount of any reward or incentive, regardless of any health factor. The reorganized requirements of the final regulations explain how a plan or issuer is required to provide such an opportunity for each category of wellness program.

B. Definitions

Paragraph (f)(1) provides several definitions that govern for purposes of these final regulations.

Reward. References in these final regulations to an individual obtaining a reward include both obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as a deductible, copayment, or coinsurance), an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a surcharge or other financial or nonfinancial disincentives). References in the final regulations to a plan providing a reward include both providing a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive).

Participatory wellness programs. Consistent with the 2006 regulations and PHS Act section 2705(j), these final regulations continue to divide wellness programs into two categories: ''participatory wellness programs,'' which are a majority of wellness programs (as noted below), and ''health-contingent wellness programs.'' Participatory wellness programs are defined under the final regulations as programs that either do not provide a reward or do not include any conditions for obtaining a reward that are based on an individual satisfying a standard that is related to a health factor. Several examples of participatory wellness programs are provided in these final

[8] *See* section 1251 of the Affordable Care Act and interim final regulations at 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 for the definition of a grandfathered health plan.

[9] 26 CFR 54.9802–1(b)(2)(ii) and (c)(3); 29 CFR 2590.702(b)(2)(ii) and (c)(3); and 45 CFR 146.121(b)(2)(ii) and (c)(3).

[10] *See* 77 FR 70625.

[11] The ''reasonable alternative standard'' is separate and distinct from the standard for ''reasonable accommodations'' under the Americans with Disabilities Act of 1990 (ADA) and related laws, regulations and guidance. *See* section II.H later in this preamble for a discussion of how compliance with the nondiscrimination rules (including the wellness program provisions) is not determinative of compliance with any other law.

regulations, including: (1) A program that reimburses employees for all or part of the cost of membership in a fitness center; (2) a diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes; and (3) a program that provides a reward to employees for attending a monthly, no-cost health education seminar.

Health-contingent wellness programs. In contrast, health-contingent wellness programs require an individual to satisfy a standard related to a health factor to obtain a reward (or require an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward). This standard may be performing or completing an activity relating to a health factor, or it may be attaining or maintaining a specific health outcome. In these final regulations, the category of health-contingent wellness programs is subdivided into: (1) Activity-only wellness programs, and (2) outcome-based wellness programs. Under paragraphs (b)(2)(ii) and (c)(3) of the 2006 regulations (which remain unchanged),[12] both of these types of health-contingent wellness programs are permissible only if they comply with the criteria of these final regulations.[13]

Activity-only wellness programs. Activity-only wellness programs are a subcategory of health-contingent wellness programs. Under an activity-only wellness program, an individual is required to perform or complete an activity related to a health factor in order to obtain a reward. Activity-only wellness programs do not require an individual to attain or maintain a specific health outcome. Examples of activity-only wellness programs include walking, diet, or exercise programs. Some individuals participating in an activity-only wellness program may be unable to participate in or complete (or have difficulty participating in or completing) the program's prescribed activity due to a health factor. For example, an individual may be unable to participate in a walking program due to a recent surgery or pregnancy, or may have difficulty participating due to severe asthma. The final regulations, therefore, provide safeguards to ensure these individuals are given a reasonable opportunity to qualify for the reward.

Outcome-based wellness programs. Outcome-based wellness programs are a subcategory of health-contingent wellness programs. Under an outcome-based wellness program, an individual must attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward. Generally, these programs have two tiers: (a) A measurement, test, or screening as part of an initial standard; and (b) a larger program that then targets individuals who do not meet the initial standard with wellness activities. For individuals who do not attain or maintain the specific health outcome, compliance with an educational program or an activity may be offered as an alternative to achieve the same reward. However, this alternative pathway does not mean that the overall program, which has an outcome-based initial standard, is not an outcome-based wellness program. That is, if a measurement, test, or screening is used as part of an initial standard and individuals who meet the standard are granted the reward, the program is considered an outcome-based wellness program. Examples of outcome-based wellness programs include a program that tests individuals for specified medical conditions or risk factors (such as high cholesterol, high blood pressure, abnormal BMI, or high glucose level) and provides a reward to employees identified as within a normal or healthy range (or at low risk for certain medical conditions), while requiring employees who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, or complying with a health care provider's plan of care) to obtain the same reward.

C. Requirement for Participatory Wellness Programs

Paragraph (f)(2) of these final regulations requires a participatory wellness program to be made available to all similarly situated individuals, regardless of health status. Participatory wellness programs are not required to meet the requirements applicable to health-contingent wellness programs under these final regulations. Some comments requested that the Departments impose additional requirements with respect to participatory wellness programs. Other commenters proposed that the Departments require that plans and issuers take into account an individual's income or other personal circumstances in determining whether a participatory wellness program is available or accessible to all similarly situated individuals.

As discussed earlier, the HIPAA nondiscrimination provisions generally prohibit group health plans and health insurance issuers from discriminating against individual participants and beneficiaries in eligibility, benefits, or premiums based on a health factor. To the extent a plan or issuer establishes a wellness program that does not adjust benefits or premiums based on a health factor, these wellness program provisions are generally not implicated. These final rules make clear that such ''participatory'' wellness programs (in contrast to ''health-contingent wellness programs'') are permissible under the HIPAA nondiscrimination rules, as amended by the Affordable Care Act, provided they are available to all similarly situated individuals regardless of health status.

Availability regardless of health status ensures that the general prohibition against discrimination based on a health factor is not implicated. If factors other than health status (such as scheduling limitations) limit an individual's ability to take part in a program, that does not mean that the plan has violated the general rule prohibiting discrimination based on a health factor because the program was not discriminatory under the HIPAA nondiscrimination rules to begin with. For example, if a plan made available a premium discount in return for attendance at an educational seminar, but only healthy individuals were provided the opportunity to attend, the program would discriminate based on a health factor because only healthy individuals were provided the opportunity to reduce their premiums. However, if all similarly situated individuals were permitted to attend, but a particular individual could not attend because the seminar was held on a weekend day and the individual was unavailable to attend at that time, that does not mean the program discriminated against that individual based on a health factor. Because there is no discrimination based on a health factor under HIPAA, the wellness exception is not relevant. At the same time, as discussed in section II.H of this preamble, compliance with the HIPAA nondiscrimination and wellness provisions is not determinative of compliance with any other applicable Federal or State law, which may impose additional accessibility standards for wellness programs.

[12] 26 CFR 54.9802–1(b)(2)(ii) and (c)(3); 29 CFR 2590.702(b)(2)(ii) and (c)(3); and 45 CFR 146.121(b)(2)(ii) and (c)(3).

[13] Until these final regulations are effective and applicable, the provisions of the 2006 regulations, at 26 CFR 54.9802–1(f), 29 CFR 2590.702(f), and 45 CFR 146.121(f), generally remain applicable to group health plans and group health insurance issuers.

D. Requirements for Health-Contingent Wellness Programs

These final regulations generally retain the proposed five requirements for health-contingent wellness programs, but the regulations have been reorganized, subdividing health-contingent wellness programs into activity-only wellness programs and outcome-based wellness programs, to make it clearer to whom a plan or issuer is required to provide a reasonable alternative standard. The final regulations retain the proposed modification relating to the size of the reward, as well as clarifications that were proposed to address questions and issues raised by stakeholders since the 2006 regulations were issued and to be consistent with the amendments made by the Affordable Care Act.

(1) Frequency of Opportunity to Qualify

These final regulations retain the requirement, for both activity-only and outcome-based wellness programs, that individuals eligible for the program be given the opportunity to qualify for the reward at least once per year. As stated in the preamble to the 2006 regulations and the proposed regulations, the once-per-year requirement was included as a bright-line standard for determining the minimum frequency that is consistent with a reasonable design for promoting good health or preventing disease.[14]

(2) Size of Reward

Like the proposed regulations, these final regulations continue to limit the total amount of the reward for health-contingent wellness programs (both activity-only and outcome-based) with respect to a plan, whether offered alone or coupled with the reward for other health-contingent wellness programs. Specifically, as in the proposed regulations, the total reward offered to an individual under all health-contingent wellness programs with respect to a plan cannot exceed the applicable percentage (as defined in paragraph (f)(5) of the final regulations) of the total cost of employee-only coverage under the plan, taking into account both employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. If, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the health-contingent wellness program, the reward cannot exceed the applicable percentage of the total cost of the coverage in which the employee and any dependents are enrolled (such as family coverage or employee-plus-one coverage).

Several comments addressed health-contingent wellness programs that allow dependents to participate, and what portion of the reward should be attributable to each participating dependent. For health-contingent wellness programs that allow a class of dependents to participate, some commenters suggested that the maximum allowed reward or incentive be prorated based on the portion of the premium or contribution attributable to that family member. These commenters argued that if, for example, one family member fails to meet the standard related to a health factor, the entire family should not be faced with the maximum penalty. Other commenters requested that the Departments not set forth rules for the apportionment of the reward where dependent coverage exists. These commenters argued that it would be an administrative challenge to apportion the reward to each covered family member. While final regulations issued by HHS under PHS Act section 2701 require health insurance issuers in the small group market [15] to apply rating variations to family coverage based on the portion of the premium attributable to each family member covered under the coverage,[16] these final regulations do not set forth detailed rules governing apportionment of the reward under a health-contingent wellness program. Instead, plans and issuers have flexibility to determine apportionment of the reward among family members, as long as the method is reasonable. Additional subregulatory guidance may be provided by the Departments if questions persist or if the Departments become aware of apportionment designs that seem unreasonable.

(3) Reasonable Design

Consistent with the 2006 regulations and PHS Act section 2705(j), these final regulations continue to require that health-contingent wellness programs be reasonably designed to promote health or prevent disease, whether activity-only or outcome-based. Some commenters urged that the Departments not impose a rigid set of pre-approved wellness program structures or guidelines, which may inhibit innovation in designing wellness programs. On the other hand, other commenters requested that the Departments require that all wellness programs be based on evidence-based clinical guidelines and national standards established by bodies such as the Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services, or the National Institutes of Health. These final regulations state that a wellness program is reasonably designed if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and is not overly burdensome, is not a subterfuge for discrimination based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. The determination of whether a health-contingent wellness program is reasonably designed is based on all the relevant facts and circumstances. While programs are not required to be accredited or based on particular evidence-based clinical standards, these practices, such as those found in CDC's Guide to Community Preventive Services,[17] may increase the likelihood of wellness program success and are encouraged as a best practice.

These final regulations continue to provide plans and issuers flexibility and encourage innovation.[18] Some commenters requested confirmation that plans and issuers could design wellness programs that are limited to targeted groups of individuals with adverse health factors. Consistent with paragraph (g) of the 2006 regulations, nothing in these final regulations

[14] *See* 71 FR at 75018. *See also* 77 FR at 70623.

[15] Small group market means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer. *See* PHS Act section 2791(e)(5); 45 CFR 144.103. For this purpose, for plan years beginning on or after January 1, 2014, amendments made by the Affordable Care Act provide that the term ''small employer'' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. *See* PHS Act section 2791(e)(4). In the case of plan years beginning before January 1, 2016, a State may elect to substitute ''50 employees'' for ''100 employees'' in its definition of a small employer. *See* section 1304(b)(3) of the Affordable Care Act.

[16] 45 CFR 147.102(c).

[17] *See www.thecommunityguide.org/index.html.*

[18] The preamble to the 2006 regulations stated that the ''reasonably designed'' standard was designed to prevent abuse, but otherwise was ''intended to be an easy standard to satisfy . . . There does not need to be a scientific record that the method promotes wellness to satisfy this standard. The standard is intended to allow experimentation in diverse ways of promoting wellness.'' *See* 71 FR at 75018. The preamble also stated that the Departments did not ''want plans and issuers to be constrained by a narrow range of programs . . . but want plans and issuers to feel free to consider innovative programs for motivating individuals to make efforts to improve their health.'' *See* 71 FR at 75019.

prevents a plan or issuer from establishing more favorable rules for eligibility or premium rates (including rewards for adherence to certain wellness programs) for individuals with an adverse health factor than for individuals without the adverse health factor.

Several comments requested that the reasonable design requirement include strong consumer protections to ensure that the opportunity for a discount is available in practice and accessible to all individuals regardless of health status. Some commenters argued that wellness programs which set clear markers of medical illness, disability, or largely non-preventable conditions as standards are not reasonably designed and should therefore be prohibited under the final regulations. Other commenters suggested that a ''reasonably designed'' wellness program must include a set of programs, resources, and worksite policies designed to promote health and prevent disease and must include more than a biometric test.

After consideration of all the comments, as in the proposed rules, the final regulations direct that an outcome-based wellness program must provide a reasonable alternative standard to qualify for the reward, for all individuals who do not meet the initial standard that is related to a health factor, in order to be reasonably designed. This approach is intended to ensure that outcome-based programs are more than mere rewards in return for results in biometric screenings or responses to a health risk assessment, and are instead part of a larger wellness program designed to promote health and prevent disease, ensuring the program is not a subterfuge for discrimination or underwriting based on a health factor.

(4) Uniform Availability and Reasonable Alternative Standards

An important element of these final regulations is the requirement that the full reward under a health-contingent wellness program, whether activity-only or outcome-based, be available to all similarly situated individuals. As stated earlier, the proposed regulations included requirements that, in certain circumstances, a health-contingent wellness program provide a reasonable alternative standard (or waiver of the otherwise applicable standard) and, to the extent that a plan's initial standard for obtaining a reward (or a portion of a reward) is based on the results of a measurement, test, or screening that is related to a health factor (such as a biometric examination or a health risk assessment), provide a different, reasonable means of qualifying for the reward. Several commenters pointed out that the interaction between these two requirements was confusing and unclear. As discussed earlier in this preamble, these final regulations retain the same requirements contained in the proposed regulations, but the terminology has been changed to reduce confusion and provide clarity for the regulated community.

Many clarifications regarding the reasonable alternative standards are equally applicable to activity-only wellness programs and outcome-based wellness programs. First, in order to satisfy the requirement to provide a reasonable alternative standard, the same, full reward must be available under a health-contingent wellness program (whether an activity-only or outcome-based wellness program) to individuals who qualify by satisfying a reasonable alternative standard as is provided to individuals who qualify by satisfying the program's otherwise applicable standard. Accordingly, while an individual may take some time to request, establish, and satisfy a reasonable alternative standard, the same, full reward must be provided to that individual as is provided to individuals who meet the initial standard for that plan year. (For example, if a calendar year plan offers a health-contingent wellness program with a premium discount and an individual who qualifies for a reasonable alternative standard satisfies that alternative on April 1, the plan or issuer must provide the premium discounts for January, February, and March to that individual.) Plans and issuers have flexibility to determine how to provide the portion of the reward corresponding to the period before an alternative was satisfied (*e.g.,* payment for the retroactive period or pro rata over the remainder of the year) as long as the method is reasonable and the individual receives the full amount of the reward. In some circumstances, an individual may not satisfy the reasonable alternative standard until the end of the year. In such circumstances, the plan or issuer may provide a retroactive payment of the reward for that year within a reasonable time after the end of the year, but may not provide pro rata payments over the following year (a year after the year to which the reward corresponds). The Departments may provide additional subregulatory guidance if questions persist or if the Departments become aware of payment designs that seem unreasonable with respect to individuals who satisfy the reasonable alternative standard.

Other clarifications were retained from the proposed regulations. The final regulations reiterate that, in lieu of providing a reasonable alternative standard, a plan or issuer may always waive the otherwise applicable standard and provide the reward. These final regulations also do not require plans and issuers to establish a particular reasonable alternative standard in advance of an individual's specific request for one, as long as a reasonable alternative standard is provided by the plan or issuer (or the condition for obtaining the reward is waived) upon an individual's request. Plans and issuers have flexibility to determine whether to provide the same reasonable alternative standard for an entire class of individuals (provided that it is reasonable for that class) or provide the reasonable alternative standard on an individual-by-individual basis, based on the facts and circumstances presented.

The Departments received several comments requesting that the final regulations permit employers to retain flexibility to make reasonable alternative standards health-focused and stringent enough so that these alternatives do not become a loophole for individuals who can meet the initial standard. These final regulations continue to permit plans and issuers flexibility in designing reasonable alternative standards (including using reasonable alternative standards that are health-contingent), while also providing some clarification of what constitutes being ''reasonable'' in the context of an alternative standard.

All the facts and circumstances are taken into account in determining whether a plan or issuer has provided a reasonable alternative standard, including but not limited to the following factors listed in these final regulations:

- If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted) and may not require an individual to pay for the cost of the program.
- The time commitment required must be reasonable.
- If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.
- If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical

professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness.

The final regulations generally retain the factors that were included in the proposed regulations with a few added clarifications. Specifically, in response to comments, the final rules clarify that in order for an alternative standard to be reasonable, the time commitment must be reasonable. For example, requiring attendance nightly at a one-hour class would be unreasonable.

In addition, the proposed regulations stated that if a reasonable alternative standard is compliance with the recommendations of a medical professional who is an agent of the plan, and an individual's personal physician states that the recommendations are not medically appropriate for that individual, the plan must provide a second reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness, and that normal cost sharing could be imposed for medical items and services furnished pursuant to the physician's recommendations. The final rules retain the clarification of the proposed regulations, and add an additional clarification that an individual's personal physician can make recommendations regarding medical appropriateness that must be accommodated with respect to any plan standard (and is not limited to a situation in which a personal physician disagrees with the specific recommendations of an agent of the plan with respect to an individual). This additional clarification is consistent with the final regulations' overall requirement that wellness programs be designed to promote health and prevent disease, and not be a subterfuge for discrimination or underwriting based on a health factor. As stated in the preamble to the Departments' regulations implementing the internal claims and appeals and external review processes under PHS Act section 2719, adverse benefit determinations based on whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program are considered to involve medical judgment and therefore are eligible for Federal external review.[19] Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished in accordance with the physician's recommendations.

The Departments continue to maintain that, with respect to tobacco cessation, ''overcoming an addiction sometimes requires a cycle of failure and renewed effort,'' as stated in the preamble to the proposed regulations.[20] For plans with an initial outcome-based standard that an individual not use tobacco, a reasonable alternative standard in Year 1 may be to try an educational seminar. As clarified in an example in the final regulations, an individual who attends the seminar is then entitled to the reward, regardless of whether the individual quits smoking. At the same time, in Year 2, the plan may require completion of a different reasonable alternative standard, such as a complying with a new recommendation from the individual's personal physician or a new nicotine replacement therapy (and completion of that standard would qualify the individual to receive the reward).

It is the view of the Departments that the same can be true with respect to meeting any outcome-based standard. That is, with respect to weight loss and weight management, for example, clinical evidence suggests that a number of environmental factors can influence an individual's ability to achieve a desired health outcome.[21] Under these final regulations, plans and issuers cannot cease to provide a reasonable alternative standard under any health-contingent wellness program merely because an individual was not successful in satisfying the initial standard before; plans and issuers must continue to offer a reasonable alternative standard whether it is the same or different and, to the extent the reasonable alternative standard is, itself, a health-contingent wellness program, it must meet the relevant requirements of these final regulations. Language in the final regulations clarifies that, for example, if a plan or issuer provides a walking program as a reasonable alternative standard to a running program, individuals for whom it is unreasonably difficult due to a medical condition to complete the walking program (or for whom it is medically inadvisable to attempt to complete the walking program) must be provided a reasonable alternative standard to the walking program. Similarly, to the extent a reasonable alternative standard is, itself, an outcome-based wellness program, the reasonable alternative standard must comply with the requirements for outcome-based wellness programs, subject to certain special rules, described below.

While, as discussed earlier, many clarifications regarding the reasonable alternative standards are equally applicable to activity-only wellness programs and outcome-based wellness programs, some of the requirements apply in different ways depending on whether the program is an activity-only or an outcome-based wellness program.

(a) Activity-Only Wellness Programs

An activity-only wellness program must make the full reward under the program available to all similarly-situated individuals. Under paragraph (f)(3)(iv) of these final regulations, a reward under a wellness program is not available to all similarly situated individuals for a period unless the program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is either unreasonably difficult due to a medical condition to meet the otherwise applicable standard, or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

Under an activity-only wellness program, it is permissible for a plan or issuer to seek verification, such as a statement from the individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard in an activity-only wellness program, if reasonable under the circumstances.[22] Some commenters stated that it is common practice to require verification

[19] *See* 76 FR at 37216.

[20] *See* 71 FR 75019 (December 13, 2006) and 77 FR 70624 (November 26, 2012).

[21] *See* Katz DL, O'Connell M, Yeh MC, Nawaz H, Njike V, Anderson LM, Cory S, Dietz W: Task Force on Community Preventive Services. Public health strategies for preventing and controlling overweight and obesity in school and worksite settings: a report on recommendations of the Task Force on Community Preventive Services. MMWR Recomm Rep 2005, 7; 54 (RR–10):1–12. *See also* Fiore, M., Jaen, C., Baker, T., Bailey, W., Benowitz, N., Curry, S., Healton, C. (2008). Treating tobacco use and dependence; 2008 clinical practice guideline. Rockville, MD: U.S. Department of Health and Human Services.

[22] The 2006 regulations provided that it is permissible for a plan or issuer to seek verification, such as a statement from the individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard. The Affordable Care Act amendments codified this provision with one modification: PHS Act section 2705(j)(3)(D)(ii) makes clear that verification, such as a statement from an individual's personal physician, may be required by a plan or issuer ''if reasonable under the circumstances.''

when an individual requests a reasonable alternative standard and urged the Departments to permit plans and issuers to require physician verification in all circumstances involving a request for a reasonable alternative standard. Other commenters supported the approach set forth in the proposed rules that limits plans' and issuers' ability to impose verification requirements to verification of claims that require the use of medical judgment to evaluate. Some of these commenters also asked the Departments to clarify that verification, when allowed, could be performed by any type of medical professional. The Departments also received comments on the example in the proposed regulations that stated it would not be reasonable for a plan or issuer to seek verification of a claim that is obviously valid based on the nature of the individual's medical condition that is known to the plan or issuer. Many commenters had questions about what the Departments would consider a plan or issuer to know or not know, cited the fact that different information technology systems exist for wellness program information and claims data, and raised concerns regarding what types of situations would be ''obviously valid'' under this standard.

The Departments originally included the example in the proposed regulations in the context of what these final regulations now refer to as outcome-based wellness programs, so that if an individual requested a reasonable alternative standard after failing to meet an initial standard based on a measurement, test, or screening, the plan or issuer could not then require physician verification of the need for a reasonable alternative standard. As described in more detail below, the reorganized final regulations clarify that, with respect to outcome-based wellness programs, plans and issuers cannot require verification by the individual's physician that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard as a condition of providing a reasonable alternative to the initial standard. While plans and issuers may still require such verification as a condition of providing a reasonable alternative standard in the context of an activity-only wellness program, the reorganization of the final regulations makes the language stating that it would not be reasonable for an issuer to seek verification of a claim which is obviously valid, as it was included in the proposed regulations, now moot. Therefore, after reviewing the comments received in response to the proposed regulations, the Departments have deleted this example from the regulatory text. Plans and issuers are still permitted under these final regulations to seek verification in the case of an activity-only wellness program with respect to requests for a reasonable alternative standard for which it is reasonable to determine that medical judgment is required to evaluate the validity of the request.

In addition, with respect to which type of medical professional can be required by the plan or issuer to provide verification, the final regulations repeat the statutory language. Wellness programs and reasonable alternative standards can vary greatly, and the nature of the program or alternative standard may require different levels of clinical expertise to evaluate reasonableness with respect to any particular individual. These final regulations do not expressly prohibit plan provisions that require verification to be provided by a physician in clinically appropriate circumstances. Nor do these final regulations expressly require that medical professionals other than a physician be permitted to provide verification in specific circumstances if a physician's expertise would be required to evaluate the validity of a request. Instead, the Departments generally view any plan requirement for verification to be subject to the broader standards for reasonable design and intend to examine verification requirements in light of all the relevant facts and circumstances. The Departments may provide future guidance on this issue.

A number of commenters raised concerns about the privacy and confidentiality of health information provided to wellness programs, particularly with respect to employer access to such information and the potentially discriminatory results of such access. As noted in section II.H later in this preamble, these final regulations are implementing only the provisions regarding wellness programs in the Affordable Care Act. Other State and Federal laws may apply with respect to the privacy, disclosure, and confidentiality of information provided to these programs. For example, HIPAA-covered entities, including certain health plans and providers, must comply with the HIPAA Privacy and Security Rules [23] with respect to the confidentiality of individually identifiable health information, and employers subject to the Americans with Disabilities Act of 1990 (ADA) must comply with any applicable ADA requirements for disclosure and confidentiality of medical information and non-discrimination on the basis of disability.

(b) Outcome-Based Wellness Programs

Outcome-based wellness programs allow plans and issuers to conduct screenings and employ measurement techniques in order to target wellness programs effectively, as discussed earlier. For example, plans and issuers are able to target only individuals with high cholesterol for participation in cholesterol reduction programs, or individuals who use tobacco for participation in tobacco cessation programs, rather than the entire population of participants and beneficiaries, with the reward based on health outcomes or participation in reasonable alternatives. For outcome-based wellness programs to meet the requirement that the reward be available to all similarly situated individuals, the proposed regulations generally required that the program allow a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual who does not meet the initial standard based on a measurement, test, or screening. Several commenters asserted that a reasonable alternative standard should be required to be made available only to individuals who have a medical condition that prevents them from meeting the initial standard. As discussed earlier, programs consisting solely of a measurement, test, or screening are not reasonably designed to promote health and prevent disease. Therefore, if an individual does not meet a plan's target biometrics (or other, similar initial standards), that individual must be provided with a reasonable alternative standard regardless of any medical condition or other health status, to ensure that outcome-based initial standards are not a subterfuge for discrimination or underwriting based on a health factor.

The requirement to provide a reasonable alternative standard to all individuals who do not meet or achieve a particular health outcome is not intended to transform all outcome-based wellness programs to participatory wellness programs, although plans may choose to utilize participatory programs, such as educational programs, when designing reasonable alternative standards. Plans and issuers may provide reasonable alternative standards that are themselves health-contingent wellness programs. To the extent a reasonable alternative standard under

[23] *See* 45 CFR Parts 160 and 164.

an outcome-based wellness program is, itself, an activity-only wellness program, the reasonable alternative standard must comply with the requirements for activity-only programs as if it were an initial program standard. Therefore, for example, as discussed in more detail earlier in this preamble, if a plan or issuer provides a walking program as an alternative to a running program, the plan must provide reasonable alternatives to individuals who cannot complete the walking program because of a medical condition.

Moreover, to the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, another outcome-based wellness program, it must generally comply with the requirements for outcome-based wellness programs, subject to certain special rules. Among other things, these special rules prevent a never-ending cycle of reasonable alternative standards being required to be provided by plans and issuers, while also ensuring that a reasonable alternative standard prescribed for an individual is, in fact, reasonable in light of the individual's actual circumstances, as determined to be medically appropriate in the judgment of the individual's personal physician. Under the first special rule, the final regulations provide that the reasonable alternative standard cannot be a requirement to meet a different level of the same standard without additional time to comply that takes into account the individual's circumstances. For example, if the initial standard is to achieve a BMI less than 30, the reasonable alternative standard cannot be to achieve a BMI less than 31 on that same date. However, if the initial standard is to achieve a BMI less than 30, a reasonable alternative standard for the individual could be to reduce the individual's BMI by a small amount or a small percentage over a realistic period of time, such as within a year. Second, an individual must be given the opportunity to comply with the recommendations of the individual's personal physician as a second reasonable alternative standard to meeting the reasonable alternative standard defined by the plan or issuer, but only if the physician joins in the request. The individual can make a request to involve a personal physician's recommendations at any time and the personal physician can adjust the physician's recommendations at any time, consistent with medical appropriateness, as determined by the personal physician.

With respect to outcome-based wellness programs, it is not reasonable to require verification, such as a statement from the individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard as a condition of providing a reasonable alternative to the initial standard. (As discussed in the preceding paragraph, however, an individual must be given the opportunity to comply with the recommendations of the individual's personal physician as a second reasonable alternative standard to meeting the reasonable alternative standard defined by the plan or issuer, but only if the physician joins in the request.) However, if a plan or issuer provides an activity-only wellness program as an alternative to the otherwise applicable measurement, test, or screening of the outcome-based wellness program, then the plan or issuer may, if reasonable under the circumstances, seek verification with respect to the activity-only component of the program that it is unreasonably difficult due to a medical condition for an individual to perform or complete the activity (or it is medically inadvisable to attempt to perform or complete the activity). For example, if an outcome-based wellness program requires participants to maintain a certain healthy weight and provides a diet and exercise program for individuals who do not meet the targeted weight (which is an activity-only standard), a plan or issuer may seek verification that a second reasonable alternative standard is needed for individuals for whom it would be unreasonably difficult due to a medical condition to comply, or medically inadvisable to attempt to comply, with the diet and exercise program, due to a medical condition.

(5) Notice of Availability of Reasonable Alternative Standard

These final regulations, like the proposed regulations, require plans and issuers to disclose the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard) in all plan materials describing the terms of a health-contingent wellness program (both activity-only and outcome-based wellness programs). These final regulations clarify that a disclosure of the availability of a reasonable alternative standard includes contact information for obtaining the alternative and a statement that recommendations of an individual's personal physician will be accommodated. For outcome based-wellness programs, this notice must also be included in any disclosure that an individual did not satisfy an initial outcome-based standard.

For all health contingent wellness programs (both activity-only and outcome-based wellness programs), if plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. For example, a summary of benefits and coverage required under section 2715 of the PHS Act that notes that cost sharing may vary based on participation in a diabetes wellness program, without describing the standards of the program, would not trigger this disclosure. In contrast, a plan disclosure that references a premium differential based on tobacco use, or based on the results of a biometric exam, is a disclosure describing the terms of a health-contingent wellness program and, therefore, must include this disclosure.

The proposed regulations provided new sample language in the regulatory text and in examples that was intended to be simpler for individuals to understand and to increase the likelihood that those who qualify for a reasonable alternative standard will contact the plan or issuer to request one. Some commenters supported the new sample language, while others suggested additions and modifications. Several commenters proposed adding additional information to the notice, in most cases related to requests for a reasonable alternative standard. The model notice is intended to be brief and many of the details regarding a wellness program are available in other plan documents.[24] Accordingly, these final regulations do not adopt all of the suggestions made by commenters (for example, the sample language does not provide examples of reasons why an employee may request a reasonable alternative or government contact information for complaints). However, the sample language now includes a statement that recommendations of an individual's personal physician will be accommodated.

E. Applicable Percentage

Paragraph (f)(5) of the final regulations sets the applicable percentage for the size of the reward under a health-contingent wellness

[24] For ERISA plans, wellness program terms (including the availability of any reasonable alternative standard) are generally required to be disclosed in the summary plan description (SPD), as well as in the applicable governing plan documents (which must be provided upon request), if compliance with the wellness program affects premiums, cost sharing, or other benefits under the terms of the plan.

program. The 2006 regulations specified 20 percent as the maximum permissible reward for participation in a health-contingent wellness program. PHS Act section 2705(j)(3)(A), effective for plan years beginning on or after January 1, 2014, increases the maximum reward to 30 percent and authorizes the Departments to increase the maximum reward to as much as 50 percent, if the Departments determine that such an increase is appropriate. These final regulations increase the applicable percentage from 20 percent to 30 percent, effective for plan years beginning on or after January 1, 2014, with an increase of an additional 20 percentage points (to 50 percent) for health-contingent wellness programs designed to prevent or reduce tobacco use. Examples illustrate how to calculate the applicable percentage.

As described in the proposed regulations, the additional increase for programs designed to prevent or reduce tobacco use is warranted to conform to the new PHS Act section 2701, to avoid inconsistency across group health coverage, whether insured or self-insured, or offered in the small group or large group market, and to provide grandfathered plans the same flexibility to promote health and prevent disease as non-grandfathered plans. Specifically, PHS Act section 2701, the ''fair health insurance premium'' provision, sets forth the factors that issuers may use to vary premium rates in the individual or small group market. PHS Act section 2701(a)(1)(A)(iv) provides that issuers in the individual and small group markets cannot vary rates for tobacco use by more than a ratio of 1.5 to 1 (that is, allowing up to a 50 percent premium surcharge for tobacco use). HHS published a final regulation implementing PHS Act section 2701 [25] stating that health insurance issuers in the small group market are permitted to implement the tobacco use surcharge under PHS Act section 2701 to employees only in connection with a wellness program meeting the standards of PHS Act section 2705(j) and its implementing regulations.

As discussed in the proposed rule, to coordinate these regulations with the tobacco use rating provisions of PHS Act section 2701, these final regulations use the authority in PHS Act section 2705(j)(3)(A) (and, with respect to grandfathered health plans, the preexisting authority in the HIPAA nondiscrimination and wellness provisions) to increase the applicable percentage for determining the size of the reward for participating in a health-contingent wellness program by an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is attributed to tobacco use prevention or reduction.

Several commenters requested clarification that an individual's statement regarding tobacco use is not grounds for a permissible rescission under PHS Act section 2712 and its implementing regulations. Under the HHS final regulation implementing PHS Act section 2701, an issuer that must comply with the requirements under PHS Act section 2701 may not rescind coverage on the basis that an enrollee is found to have reported false or incorrect information about their tobacco use.[26] While the HHS final regulation implementing PHS Act section 2701 addresses rescission, that provision is only applicable to health insurance issuers providing coverage in the individual and small group markets, and does not apply to self-insured group health plans and large insured group health plans.[27] Whether self-insured group health plans and large insured group health plans can recoup the otherwise applicable premiums or benefits is generally determined under the plan terms and other applicable law, such as ERISA. Rescission in connection with an individual's statement regarding tobacco use under self-insured and large, insured group health plans may be addressed by the Departments in future regulations or subregulatory guidance under PHS Act section 2712.

F. Application to Grandfathered Plans

Under these final regulations, the same wellness program standards apply to grandfathered health plans (under authority in the HIPAA nondiscrimination and wellness provisions) and non-grandfathered plans (under the rules of PHS Act section 2705 governing rewards for adherence to certain wellness programs, which largely adopt the wellness program provisions of the 2006 regulations with some modification and clarification). While section 1251 of the Affordable Care Act provides that certain amendments made by the Affordable Care Act (including the amendments to PHS Act section 2705(j)) do not apply to grandfathered health plans,[28] the Departments believe that the provisions of these final regulations are authorized under both HIPAA and the Affordable Care Act. This approach is intended to avoid inconsistency across group health coverage and to provide grandfathered plans the same flexibility to promote health and prevent disease as non-grandfathered plans.

G. Application of Nondiscrimination Provisions to the Individual Health Insurance Market

The HHS proposed regulations included a new 45 CFR 147.110 to apply the nondiscrimination protections of the 2006 regulations to non-grandfathered individual health insurance coverage effective for policy years beginning on or after January 1, 2014. The proposed regulation, however, did not extend the wellness provisions to the individual health insurance market because the wellness exception of PHS Act section 2705(j) does not apply to the individual health insurance market.

Commenters requested that the wellness provisions be extended to the individual market or that states be allowed to authorize participatory programs in the individual market. Although the proposed rule addressing the individual market is being finalized without change, it is HHS's belief that participatory wellness programs in the individual market do not violate the nondiscrimination provisions provided that such programs are consistent with State law and available to all similarly situated individuals enrolled in the individual health insurance coverage. This is because participatory wellness programs do not base rewards on achieving a standard related to a health factor, and thus do not discriminate based upon health status.

[25] *See* 45 CFR 147.102(a)(1)(iv), published on February 27, 2013 at 78 FR 13406.

[26] The remedy of recouping the tobacco premium surcharge that should have been paid since the beginning of the plan or policy year is provided under PHS Act section 2701 and its implementing regulations. As stated in the preamble to those regulations, it is the view of the Departments (which share interpretive jurisdiction over section 2712 of the PHS Act) that this remedy of recoupment renders any misrepresentation with regard to tobacco use no longer a ''material'' fact for purposes of rescission under PHS Act section 2712 and its implementing regulations. *See* 78 FR 13414.

[27] Starting in 2017, States will have the option of allowing health insurance issuers in the large group market to participate in the Exchange. In States that elect this option, issuers in the large group market will be subject to the rating requirements of PHS section 2701 including the prohibition against rescinding based on failure to report tobacco use.

[28] In these final regulations, the Departments have deleted language from the applicability date section of the proposed regulations that references the regulations regarding grandfathered health plans. This deletion was made to avoid confusion regarding the applicability of these final regulations, which apply the same wellness program standards to both grandfathered and non-grandfathered health plans. The HHS regulations continue to provide, however, that with respect to individual health insurance coverage, the nondiscrimination provisions do not apply to grandfathered health plans.

H. No Effect on Other Laws

Many commenters requested that the Departments address the interaction of these wellness program requirements with other laws. Paragraph (h) of the 2006 regulations clarifies that compliance with the HIPAA nondiscrimination rules (which were later amended by the Affordable Care Act), including the wellness program requirements in paragraph (f), is not determinative of compliance with any other provision of ERISA, or any other State or Federal law, including the ADA.[29] This paragraph is unchanged by these final regulations and remains in effect. As stated in the preamble to the 2006 regulations,[30] the Departments recognize that many other laws may regulate plans and issuers in their provision of benefits to participants and beneficiaries. These laws include, but are not limited to, the ADA, Title VII of the Civil Rights Act of 1964, Code section 105(h) and PHS Act section 2716 (prohibiting discrimination in favor of highly compensated individuals), the Genetic Information Nondiscrimination Act of 2008, the Family and Medical Leave Act, ERISA's fiduciary provisions, and State law. The Departments did not attempt to summarize the requirements of those laws in the 2006 regulations and do not attempt to do so in these final regulations. Employers, plans, issuers, and other service providers should consider the applicability of these laws to their coverage and contact legal counsel or other government agencies such as the Equal Employment Opportunity Commission and State Departments of Insurance if they have questions about those laws. As stated earlier in this preamble, this rulemaking does not modify paragraph (h) or any provisions of the 2006 regulations, other than paragraph (f). The Departments reiterate that compliance with these final regulations is not determinative of compliance with any other applicable requirements.

I. Applicability Date

These final regulations are applicable to group health plans and health insurance issuers in the group and individual markets for plan years (in the individual market, policy years) beginning on or after January 1, 2014, consistent with the statutory effective date of PHS Act section 2705, as well as PHS Act section 2701.

III. Economic Impact and Paperwork Burden

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Management and Budget (OMB) has determined that this final rule is a ''significant regulatory action'' under section 3(f)(4) of Executive Order 12866, because it raises novel legal or policy issues arising from the President's priorities. Accordingly, the rule has been reviewed by the OMB.

TABLE 1—ACCOUNTING TABLE

Benefits	Quantified: Minimal due to low expected use of higher reward limits. Qualitative: Benefits include the ability to increase the reward based on a health factor to incentivize individuals to meet a health standard associated with improved health, which could improve the health of the individual and reduce health care costs. Improved standards could reduce the use of wellness programs as a subterfuge for discrimination based on a health factor.
Costs	Quantified: Minimal since employers are expected to create or expand wellness programs only if the expected benefit exceeds the cost as well as due to low expected use of higher reward limits. Qualitative: Costs of the rule include clarifications regarding what costs individuals may pay as part of an alternative means of complying with the health standard. To the extent an individual faces an increased cost for not meeting a health standard, the individual would have reduced resources to use for other purposes.
Transfers	Quantified: Minimal due to low expected use of higher reward limits. Qualitative: Transfers resulting from the rule include transfers from those who do not meet a health standard to those who do meet the standard or the associated alternative standard.

Based on the Departments'[31] review of the most recent literature and studies regarding wellness programs, as summarized in Table 1, the Departments have reached the conclusion that the impact of the benefits, costs, and transfers associated with the final rules will be minimal. As discussed in this analysis, few health-contingent wellness programs today come close to meeting the 20 percent limit (based on the data, the usual reward percentage ranges from three to 11 percent).[32] Therefore, the Departments do not believe that expanding the limit to 30 percent (or 50 percent for programs designed to prevent or reduce tobacco use) will result in significantly higher participation of employers in such programs. The Departments provide a qualitative discussion below and cite the survey data used to substantiate this conclusion. Moreover, most wellness programs appear to be participatory wellness programs that do not require an individual to meet a standard related to a health factor in order to obtain a reward. As stated earlier in this preamble, these participatory wellness programs are not required to meet the five requirements that apply to health-contingent wellness programs, but they are required to be made available to all similarly situated individuals regardless of health status.

Although the Departments believe few plans will expand the reward percentage, the Departments provide a qualitative discussion regarding the sources of benefits, costs, and transfers that could occur if plans were to expand the reward beyond the current

[29] Moreover, in paragraph (b) of the 2006 regulations, the general rule governing the application of the nondiscrimination rules to benefits clarifies that whether any plan provision or practice with respect to benefits complies with paragraph (b)(2)(i) does not affect whether the provision or practice is permitted under any other provision of the Code, ERISA, or the PHS Act, the Americans with Disabilities Act, or any other law, whether State or Federal.

[30] *See* 71 FR 75014, 75015 (December 13, 2006).

[31] In section III of this preamble, some subsections have a heading listing one or two of the three Departments. In those subsections, the term ''Departments'' generally refers only to the Departments listed in the heading.

[32] The 2012 RAND Employer Survey found that the maximum premium differential offered in a survey respondent was 16 percent.

maximum of 20 percent. Currently, insufficient broad-based evidence makes it difficult to definitively assess the impact of workplace wellness programs on health outcomes and cost, although, overall, employers largely report that workplace wellness programs in general (participatory wellness programs and health-contingent wellness programs) are delivering on their intended objectives of improving health and reducing costs.

The one source of potential additional cost discussed in the impact analysis is the clarification that plans must provide a reasonable alternative standard. The Departments present evidence that currently employers not only allow a reasonable alternative standard, but that most employers already pay for these alternatives. The Departments do not have an estimate of how many plans are not currently paying for alternatives consistent with the clarifications set forth in the final regulations, but the number appears to be small. The Departments also employ economic logic to conclude that employers will create or expand their wellness program and provide reasonable alternatives only if the expected benefits exceed the expected costs. Therefore, the Departments believe that the benefits of the final rule will justify the costs.

B. Background and Need for Regulatory Action—Department of Labor and Department of Health and Human Services

As discussed earlier in this preamble, on December 13, 2006, the Departments published joint final regulations implementing the HIPAA nondiscrimination and wellness provisions, which, among other things, allowed plans and issuers with health-contingent wellness programs to vary benefits (including cost-sharing mechanisms), premiums, or contributions based on whether an individual has met the standards of a wellness program that met five specific requirements. *See* section I.B. of this preamble for a detailed discussion of the HIPAA nondiscrimination and wellness provisions and the 2006 regulations.

C. Regulatory Alternatives—Department of Labor and Department of Health and Human Services

The 2006 regulations outlined five specific criteria that must be met for health-contingent wellness programs to comply with the nondiscrimination requirements, including that the total reward for wellness programs offered by a plan sponsor not exceed 20 percent of the total cost of coverage under the plan.[33] As amended by the Affordable Care Act, the nondiscrimination and wellness provisions of PHS Act section 2705 largely reflect the 2006 regulations with some modification and clarification. Most notably, it increased the maximum reward that can be provided under a health-contingent wellness program from 20 percent to 30 percent and authorized the Departments to increase the maximum reward to as much as 50 percent if the Departments determine that such an increase is appropriate.

PHS Act section 2701(a)(1)(A)(iv) provides that issuers in the individual and small group markets cannot vary rates for tobacco use by more than a ratio of 1.5 to 1 (that is, allowing up to a 50 percent premium surcharge for tobacco use). PHS Act section 2701 applies to non-grandfathered health insurance coverage in the individual and small group markets, but does not apply in the large group market or to self-insured plans. On February 27, 2013, HHS published a final regulation stating that issuers in the small group market are permitted to implement the tobacco use surcharge under PHS Act section 2701 to employees only in connection with a wellness program meeting the standards of PHS Act section 2705(j) and its implementing regulations.[34]

An important policy goal of the Departments is to provide the large group market and self-insured plans and grandfathered health plans with the same flexibility as non-grandfathered plans in the small group market to promote tobacco-free workforces. The Departments considered several regulatory alternatives to meet this objective, including the following:

(1) *Stacking premium differentials.* One alternative considered was to permit a 50 percent premium differential for tobacco use in the small group market under PHS Act section 2701 without requiring a reasonable alternative standard. Under PHS Act section 2705, an additional 30 percent premium differential would also be permitted if the five criteria for a health-contingent wellness program were met (including the offering of a reasonable alternative standard). Under this option, an 80 percent premium differential would have been allowable in the small group market based on factors related to health status. Large and self-insured plans would have been limited to the 30 percent maximum reward. Allowing such a substantial difference between what was permissible in the small group market and the large group market was not in line with the Departments' policy goal of providing consistency in flexibility for plans.

(2) *Concurrent premium differentials with no reasonable alternative required to be offered for tobacco use.* Another alternative would be to read sections 2701 and 2705 together such that, for non-grandfathered health plans in the small group market, up to a 50 percent premium differential would be permitted based on tobacco use, as authorized under PHS Act section 2701(a)(1)(A)(iv), with no reasonable alternative standard required for the tobacco use program. With respect to non-tobacco-related wellness programs, a reward could be offered only to the extent that a tobacco use wellness program were less than 30 percent of the cost of coverage because the two provisions apply concurrently, and a reward would not be permitted under PHS Act section 2705 if the maximum reward already were exceeded by virtue of PHS Act section 2701. Thus, the 50 percent tobacco surcharge under PHS Act section 2701 would be available only to non-grandfathered, insured, small group plans. The chosen approach is intended to avoid inconsistency and to provide grandfathered plans the same flexibility to promote health and prevent disease as non-grandfathered plans.

D. Current Use of Wellness Programs and Economic Impacts—Department of Labor and Department of Health and Human Services

The current use of wellness programs and economic impacts of these final regulations are discussed in this analysis.

Wellness programs[35] have become common among employers in the United States. The 2012 Kaiser/HRET survey indicates that 63 percent of all employers who offered health benefits also offered at least one wellness program.[36] A RAND Employer Survey found that 51 percent of employers offer wellness programs.[37] The uptake of

[33] *See* 26 CFR 54.9802–1(f)(2)(i), 29 CFR 2590.702(f)(2)(i), and 45 CFR 146.121(f)(2)(i).

[34] *See* 45 CFR 147.102(a)(1)(iv), published on February 27, 2013 at 78 FR 13406.

[35] On behalf of the Departments, RAND researchers did a review of the current literature on this topic. ''A Review of the U.S. Workplace Wellness Market'' February 2012. The report can be found at *http://www.dol.gov/ebsa/pdf/workplacewellnessmarketreview2012.pdf.*

[36] Kaiser Family Foundation, *Employer Health Benefits: 2012 Annual Survey.* 2012, The Kaiser Family Foundation, Menlo Park, CA; Health Research & Educational Trust, Chicago, IL.

[37] On behalf of the Departments, RAND produced the ''Workplace Wellness Programs Study Final Report,'' to submit to Congress contemporaneous

Continued

wellness programs continues to be more common among large employers. For example, the Kaiser/HRET survey found that health risk assessments are offered by 38 percent of large employers offering health benefits, but only 18 percent of employers with fewer than 200 workers.

The Kaiser/HRET survey indicates that 27 percent of all firms and 65 percent of large firms offered weight loss programs, while 29 percent and 65 percent, respectively, offered gym memberships or on-site exercise facilities. Meanwhile, 30 percent of all employers and 70 percent of large employers offered smoking cessation resources. Despite widespread availability, actual participation of employees in wellness programs remains limited. While no nationally representative data exist, a 2010 non-representative survey suggests that typically less than 20 percent of eligible employees participate in wellness interventions such as smoking cessation.[38]

Currently, insufficient broad-based evidence makes it difficult to definitively assess the impact of workplace wellness on health outcomes and cost; however, available evidence suggests that wellness programs may have some effect on improving health outcomes. The RAND Corporation's analysis of the Care Continuum Alliance (CCA) database [39] found statistically significant and clinically meaningful improvements in exercise frequency, smoking behavior, and weight control between wellness program participants and non-participants.

Overall, employers largely report that workplace wellness programs are delivering on their intended benefit of improving health and reducing costs. According to the 2012 Kaiser/HRET survey, 73 percent of respondents that offered wellness programs stated that these programs improved employee health, and 52 percent believed that they reduced costs. Larger firms (defined as those with more than 200 workers in the Kaiser/HRET survey) were more positive in believing that wellness programs reduced costs, as 68 percent said that it reduced cost, as opposed to 51 percent among smaller firms.[40] Forty percent of respondents to a survey by Buck Consultants indicated that they had measured the impact of their wellness program on the growth trend of their health care costs, and of these, 45 percent reported a reduction in that growth trend. The majority of these employers, 61 percent, reported that the reduction in growth trend of their health care costs was between two and five percentage points per year.[41] There are numerous accounts of the positive impact of workplace wellness programs in many industries, regions, and types of employers. For example, RAND determined in their analysis that available data are suggestive that incentives above $50 are effective to encourage participation in wellness programs, and that incentives above $200 have a small, but statistically significant, effect on weight loss, exercise, and smoking outcomes. Additionally, a recent article published by the *Harvard Business Review* cited positive outcomes reported by private-sector employers along several different dimensions, including health care savings, reduced absenteeism, and employee satisfaction.[42]

Several studies that looked at the impact of smoking cessation programs found significantly higher quit rates or less tobacco use.[43] Smoking cessation programs typically offered education and counseling to increase social support.[44] RAND found notable evidence of the effectiveness of smoking cessation programs in its analysis of the CCA database and case studies. The CCA database analysis found that participation in a program targeting smoking cessation decreases the smoking rate among participating smokers by 30 percent in the first year. Employer D in RAND's case studies reported that a smoking cessation program helped 33 employees quit smoking, which resulted in a one-percentage point decrease in the total number of smokers. Two other studies reported that individuals in the intervention group quit smoking at a rate approximately 10 percentage points higher than those in the control group, and another reported that participants were almost four times as likely as nonparticipants to reduce tobacco use.[45]

Overall, evidence on the effectiveness of wellness programs is promising, but it is not yet conclusive. An in-depth evaluation of an extensive wellness program involving a St. Louis hospital system found that the wellness program brought down inpatient hospitalization costs, but these cost savings were cancelled out by increased outpatient costs.[46] Additionally, a recent article published by *Health Affairs* found that employer savings from wellness programs may result more from cost shifting, rather than from healthier outcomes and reduced health care usage.[47] Finally, a study investigating the effectiveness of a smoking cessation program showed significant differences in smoking rates at a one-month follow-up, but showed no significant

with the issuance of these final regulations. This report includes a literature review, case studies, analysis of an employer survey conducted by RAND for the Departments, and a review of Care Continuum Alliance data.

[38] Nyce, S. *Boosting Wellness Participation Without Breaking the Bank.* TowersWatson Insider. July, 2010:1–9.

[39] The Care Continuum Alliance (CCA) is the trade organization of the health and wellness management industry. The CCA database includes data on health plan enrollment, medical and prescription claims, health risk assessment (HRA) responses, biometric screening information, and employee participation in health and wellness programs.

[40] Kaiser Family Foundation, Employer Health Benefits: 2012 Annual Survey. 2012, The Kaiser Family Foundation, Menlo Park, CA; Health Research & Educational Trust, Chicago, IL.

[41] Buck Consultants, Working Well: A Global Survey of Health Promotion and Workplace Wellness Strategies. 2010, Buck Consultants: San Francisco, CA.

[42] Berry, L., A. Mirabito, and W. Baun, What's the Hard Return on Employee Wellness Programs? Harvard Business Review, 2010. 88(12): p. 104.

[43] Heirich, M. and C.J. Sieck, Worksite cardiovascular wellness programs as a route to substance abuse prevention. J Occup Environ Med, 2000. 42(1): p. 47–56; 40; McMahon, S.D. and L.A. Jason, Social support in a worksite smoking intervention. A test of theoretical models. Behav Modif, 2000. 24(2): p. 184–201; Okechukwu, C.A., *et al.,* MassBuilt: effectiveness of an apprenticeship site-based smoking cessation intervention for unionized building trades workers. Cancer Causes Control, 2009. 20(6): p. 887–94; Sorensen, G., *et al.,* A comprehensive worksite cancer prevention intervention: behavior change results from a randomized controlled trial (United States). J Public Health Policy, 2003. 24(1): p. 5–25. Gold, D.B., D.R. Anderson, and S.A. Serxner, *Impact of a telephone-based intervention on the reduction of health risks.* Am J Health Promot, 2000. 15(2): p. 97–106; Herman, C.W., *et al., Effectiveness of an incentive-based online physical activity intervention on employee health status.* Journal of Occupational and Environmental Medicine, 2006. 48(9): p. 889–895; Ozminkowski, R.J., *et al., The impact of the Citibank, NA, health management program on changes in employee health risks over time.* J Occup Environ Med, 2000. 42(5): p. 502–11.

[44] Heirich, M. and C.J. Sieck, Worksite cardiovascular wellness programs as a route to substance abuse prevention. J Occup Environ Med, 2000. 42(1): p. 47–56; McMahon, S.D. and L.A. Jason, Social support in a worksite smoking intervention. A test of theoretical models. Behav Modif, 2000. 24(2): p. 184–201.

[45] Heirich, M. and C.J. Sieck, Worksite cardiovascular wellness programs as a route to substance abuse prevention. J Occup Environ Med, 2000. 42(1): p. 47–56; Okechukwu, C.A., *et al.,* MassBuilt: effectiveness of an apprenticeship site-based smoking cessation intervention for unionized building trades workers. Cancer Causes Control, 2009. 20(6): p. 887–94. In the study, 42% of participants reduced their risk for tobacco use. See Gold, D.B., D.R. Anderson, and S.A. Serxner, Impact of a telephone-based intervention on the reduction of health risks. Am J Health Promot, 2000. 15(2): p. 97–106.

[46] Gautam Gowrisankaran, Karen Norberg, Steven Kymes, Michael E. Chernew, Dustin Stwalley, Leah Kemper and William Peck ''A Hospital System's Wellness Program Linked To Health Plan Enrollment Cut Hospitalizations But Not Overall Costs'' Health Affairs, 32, no.3 (2013):477–485.

[47] Jill R. Horwitz, Brenna D. Kelly, and John E. DiNardo ''Wellness Incentives In The Workplace: Cost Savings Through Cost Shifting To Unhealthy Workers'' Health Affairs, 32, no.3 (2013):468–476.

differences in quit rates at six months, highlighting the need to investigate the sustainability of results.[48]

While employer plan sponsors generally are satisfied with the results, more than half stated in a recent survey that they do not know their programs' return on investment.[49] In the RAND Employer Survey, only about half of employers with wellness programs stated that they had formally evaluated program impact, and only two percent reported actual cost savings. When RAND conducted their case studies, they found that none of their employers had formally evaluated their programs, although three of the five case studies did examine some data metrics to conduct some level of assessment.

The Departments are mindful that the peer-reviewed literature, while predominantly positive, covers only a small proportion of the universe of programs, limiting the generalizability of the reported findings. Evaluating such complex interventions is difficult and poses substantial methodological challenges that can invalidate findings. Further, although correlations often can be easily demonstrated, it can be difficult to show causal relationships. For example, it can be difficult to separate individuals' varying levels of motivation to become healthier, and their self-selection to participate in wellness programs, from measures of the effectiveness of wellness programs themselves.

In the Departments' impact analysis for the proposed rules, available data indicated that employers' use of incentives in wellness programs was relatively low. The Departments' review of more recent literature indicates the use of incentives has become more common in wellness programs that are not health-contingent programs. Over two-thirds of RAND Employee Survey respondents reported using incentives to promote employee participation in wellness programs. The Kaiser/HRET Survey also reported that 41 percent offered any kind of incentive, which was nearly double the percent reporting some kind of incentive offering in 2010. Mercer Consulting's 2011 National Survey of Employer-Sponsored Health Plans found similar patterns, estimating 33 percent of those with 500 or more employees provided financial incentives for participating in at least one program, which was a 12 percentage point increase from the 2009 Survey.[50]

Employers, especially large ones, are also looking to continue to add incentives to their wellness programs. For example, the 2012 Mercer Survey found that as much as 87 percent of employers with more than 200 employees plan to add or strengthen incentive programs.[51] TowersWatson found that 17 percent of all employers intend to add a reward or penalty based on tobacco-use status.[52] The use of incentives to promote employee engagement remains poorly understood, so it is not clear how type (for example, cash or non-cash), direction (reward versus penalty), and strength of incentive are related to employee engagement and outcomes. The Health Enhancement Research Organization and associated organizations also recognized this deficiency and provided seven questions for future research.[53] There are also no data on potential unintended effects, such as discrimination against employees based on their health or health behaviors.

Currently, the most commonly incentivized program appears to be associated with completion of a health risk assessment. According to the RAND Employer Survey, 30 percent of employers with a wellness program offered incentives for completing a health risk assessment. The 2009 Mercer survey found similar results, reporting that 10 percent of all firms and 23 percent of large employers that offered a health risk assessment provided an incentive for completing the assessment. For other types of health management programs that the survey assessed, only two to four percent of all employers and 13 to 19 percent of large employers offered incentives.[54] The Kaiser/HRET survey found that 63 percent of large firms that offered a health risk assessment provided a financial incentive to employees who completed it.

Cash and cash-equivalent incentives are the most popular incentive for completion of a health risk assessment. The 2009 Mercer survey reports that five percent of all employers and ten percent of those with 500 or more workers provided cash incentives for completion of a health risk assessment; one percent and two percent, respectively, offering lower cost sharing; and two percent and seven percent, respectively, offering lower premium contributions.[55] Note that in the Mercer survey, the results cited reflect the incentives provided by all firms that offer a health risk assessment.

Incentives may be triggered by a range of different levels of employee engagement. The simplest incentives are triggered by program enrollment—that is, by merely signing up for a wellness program. At the next level, incentives are triggered by program participation—for instance, attending a class or initiating a program, such as a smoking cessation intervention. Other incentive programs may require completion of a program, whether or not any particular health-related goals are achieved, to earn an incentive. The health-contingent incentive programs require successfully meeting a specific health outcome (or an alternative standard) to trigger an incentive, such as verifiably quitting smoking. Health-contingent incentive programs appear to be among the least common incentive schemes. According to the RAND Employer Survey, only 10 percent of employers with more than 50 employees that offer a wellness program use any incentives tied to health standards, only seven percent link the incentives to health insurance premiums, and only seven percent administer results-based incentives through their health plans.

The most common form of outcome-based incentives is reported to be awarded for smoking cessation. The 2010 survey by NBGH and TowersWatson indicated that while 25 percent of responding employers offered a financial incentive for employees to become tobacco-free, only four percent offered financial incentives for maintaining a BMI within target levels, three percent did so for maintaining blood pressure within targets, and three percent for maintaining targeted cholesterol levels.[56] The RAND

[48] Kechukwu, C.A., *et al.,* MassBuilt: effectiveness of an apprenticeship site-based smoking cessation intervention for unionized building trades workers. Cancer Causes Control, 2009. 20(6): p. 887–94.

[49] Buck Consultants, Working Well: A Global Survey of Health Promotion and Workplace Wellness Strategies. 2010, Buck Consultants: San Francisco, CA.

[50] Mercer, National Survey of Employer-Sponsored Health Plans: 2011 Survey Report. 2012, Mercer.

[51] ''Employers accelerate efforts to bring health benefit costs under control,'' Mercer: November 16, 2011; Available from: *http://www.mercer.com/press-releases/national-survey-employer-sponsored-health-plans.*

[52] ''Employer Survey on Purchasing Value in Health Care,'' 17th Annual Towers Watson/National Business Group on Health Employer Survey on Purchasing Value in Health Care.

[53] ''Guidance for a Reasonably Designed, Employer-Sponsored Wellness Program Using Outcomes-Based Incentives,'' joint consensus statement of the Health Enhancement Research Organization, American College of Occupational and Environmental Medicine, American Cancer Society and American Cancer Society Cancer Action Network, American Diabetes Association, and American Heart Association.

[54] Mercer, National Survey of Employer-Sponsored Health Plans: 2009 Survey Report. 2010, Mercer.

[55] Mercer, National Survey of Employer-Sponsored Health Plans: 2009 Survey Report. 2010, Mercer.

[56] TowersWatson, Raising the Bar on Health Care: Moving Beyond Incremental Change.

Employer Survey found that almost the same percentage of employers rewarded actual smoking cessation (19%) as rewarded mere participation in a smoking cessation program (21%), whereas employers were three to four times as likely to reward participation as outcomes for other health factors. When RAND conducted its case studies for the Departments, they found that four of five employers targeted smoking cessation outcomes with incentives, whereas only two of five employers had incentives for other outcomes.

The value of incentives can vary widely. Estimates from representative surveys of the average value of incentives per year range between $152 [57] and $557,[58] or between three and 11 percent of the $5,049 average cost of individual coverage in 2010,[59] among employees who receive them. According to the RAND Employer Survey, the maximum incentives average less than 10 percent. This suggests that companies typically are not close to reaching the 20 percent of the total cost of coverage threshold set forth in the 2006 regulations.

The Departments lack sufficient information to assess how firms that currently are at the 20 percent limit will respond to the increased limits. The Departments received comments indicating that some firms may increase their limits, as permitted by the final rules; however, the number of these firms currently at the 20 percent limit is low. Furthermore, if a large number of firms already viewed the current 20 percent reward limit as sufficient, then the Departments would not expect that increasing the limit would provide an incentive for program design changes. These findings indicate that, based on currently available data, increasing the maximum reward for particpating in a health-contingent wellness program to 30 percent (and the Departments' decision to allow an additional 20 percentage points for programs designed to prevent or reduce tobacco use) is unlikely to have a significant impact.

It is possible that the increased wellness program reward limits will incentivize firms without health-contingent wellness programs to establish them. The Departments, however, do not expect a significant number of new programs to be created as a result of this change because firms without health-contingent wellness programs could already have provided rewards up to the 20 percent limit before the enactment of the Affordable Care Act, but did not.

Two important elements of these final regulations are (1) the standard that the reward under a health-contingent wellness program be available to all similarly situated individuals and (2) the standard that a program be reasonably designed to promote health or prevent disease.[60]

As discussed earlier in this preamble, the final regulations do not prescribe a particular type of alternative standard that must be provided. Instead, they permit plan sponsors flexibility to provide any reasonable alternative. The Departments expect that plan sponsors will select alternatives that entail the minimum net costs (or, stated differently, the maximum net benefits) that are possible to achieve offsetting benefits, such as a higher smoking cessation success rate.

It seems reasonable to presume that the net cost plan sponsors will incur in the provision of alternatives, including transfers as well as new economic costs and benefits, will not exceed the transfer cost of waiving surcharges for all individuals who qualify for alternatives. The Departments expect that many plan sponsors will find more cost effective ways to satisfy this requirement, should they exercise the option to provide incentives through a health-contingent wellness program, and that the true net cost to them will therefore be much smaller than the transfer cost of waiving surcharges for all plan participants who qualify for alternatives. The Departments have no basis for estimating the magnitude of the cost of providing alternative standards or of potential offsetting benefits at this time.

The Departments note that plan sponsors will have strong motivation to identify and provide reasonable alternative standards that have positive net economic effects. Plan sponsors will be disinclined to provide alternatives that undermine their overall wellness program and worsen behavioral and health outcomes, or that make financial rewards available absent meaningful efforts by participants to improve their health habits and overall health. Instead, plan sponsors will be inclined to provide alternatives that sustain or reinforce plan participants' incentive to improve their health habits and overall health, and/or that help participants make such improvements. It therefore seems likely that gains in economic welfare from this requirement will equal or outweigh losses. The Departments intend that the requirement to provide a reasonable alternative standard will eliminate instances where wellness programs serve only to shift costs to higher risk individuals and increase instances where programs succeed at helping high risk individuals improve their health.

In considering the transfers that might derive from the availability of (and participants' satisfaction with) reasonable alternative standards, the transfers arising from this requirement may take the form of transfers to individuals who satisfy a reasonable alternative standard, to such individuals from other individuals, or some combination of these. The existence of a health-contigent wellness program creates a transfer from those who do not meet the standard to those who do meet the standard. Allowing individuals to satisfy a reasonable alternative standard in order to qualify for a reward is a transfer to those who satisfy the reasonable alternative standard from everyone else in the risk pool.

The reward associated with the wellness program is an incentive to encourage individuals to meet health standards associated with better or improved health, which in turn is associated with lower health care costs. If the rewards are effective, health care costs will be reduced as an individual's health improves. Some of these lower health care costs could translate into lower premiums paid by employers and employees, which could offset some of the transfers. To the extent larger rewards are more effective at improving health and lowering costs, these final regulations will produce more benefits than the current requirements.

Rewards also could create costs to individuals and to the extent the new larger rewards create more costs than smaller rewards, these final regulations may increase the costs relative to the 2006 regulations. To the extent an individual does not meet a standard or satisfy a reasonable alternative standard, they could face higher costs. (For example, in the case of an individual participating in a wellness program with a tobacco cessation program, a plan or issuer is permitted to apply premium surcharge of up to 50 percent for tobacco use if certain conditions are met.)

Based on the foregoing discussion, the Departments expect the benefits, costs, and transfers associated with these final regulations to be minimal. However, the Departments are not able to provide aggregate estimates, because they do not

[57] Mercer, *National Survey of Employer-Sponsored Health Plans: 2009 Survey Report.* 2010, Mercer.

[58] Linnan, L., *et al., Results of the 2004 national worksite health promotion survey.* American Journal of Public Health, 2008. 98(8): p. 1503–1509.

[59] Kaiser Family Foundation, *Employer Health Benefits: 2010 Annual Survey.*

[60] *See* section II.C, earlier in this preamble for a more detailed discussion of these requirements.

have sufficient data to estimate the number of plans that will take advantage of the new limits.

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

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) applies to most Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). Unless an agency certifies that such a rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis at the time of the publication of the rulemaking describing the impact of the rule on small entities. Small entities include small businesses, organizations and governmental jurisdictions.

For purposes of analysis under the RFA, the Departments consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(3) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for welfare benefit plans that cover fewer than 100 participants.[61] While some large employers may have small plans, in general, small employers maintain most small plans. Thus, the Departments believe that assessing the impact of these final regulations on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR § 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*). The Departments requested comments on the appropriateness of this size standard at the proposed rule stage and received several supportive responses and no negative responses.

The Departments expect that these final regulations will affect few small plans. While a large number of small plans offer a wellness program, the 2012 Kaiser/HRET survey reported that only seven percent of employers with fewer than 200 employees had a wellness program that offered cash or cash equivalent incentives (including gift cards, merchandise, or travel incentives.)[62] In addition, only two percent of these firms offered lower employee health plan premiums to wellness participants, less than one percent offered lower deductibles, and less than one percent offered higher health reimbursement account or health savings account contributions. Therefore, the Departments expect that few small plans will be affected by increasing the rewards threshold from 20 percent to 30 percent (50 percent for programs targeting tobacco use prevention or reduction), because only a small percentage of plans have health-contingent wellness programs. Moreover, as discussed in the Economic Impacts section earlier in this preamble, few plans that offer health-contingent wellness programs come close to reaching the 20 percent limit, and most participatory wellness programs are associated with completing the health risk assessment irrespective of the results, which are not subject to the limitation.

The Kaiser/HRET survey also reports that about 80 percent of small plans had their wellness programs provided by the health plan provider. Industry experts indicated to the Departments that when wellness programs are offered by the health plan provider, they typically supply alternative education programs and offer them free of charge. This finding indicates that the requirement in the final rule for health-contingent wellness programs to provide and pay for a reasonable alternative standard for individuals for whom it is either unreasonably difficult or medically inadvisable to meet the original activity-only standard or for all individuals who fail to meet the initial outcome-based standard will impose little new costs or transfers to the affected plans.

The Departments received a comment suggesting that the rule would have a significant economic impact on small entities no matter how they are defined, because a final regulation issued by HHS on February 27, 2013 provided that that issuers in the small group market can vary rates for tobacco use by up to a ratio of 1.5 to 1 (that is, allowing up to a 50 percent premium surcharge for tobacco use), pursuant to PHS Act section 2701(a)(1)(A)(iv) only in connection with a wellness program meeting the standards of PHS Act section 2705(j) and these final regulations.[63] Since there are no data available to support this prediction, and the Departments only received one comment suggesting a substantial increase in the number of wellness programs, the Departments do not believe that a substantial increase in the number of wellness programs will occur.

In the event that the number of wellness programs associated with small plans does increase, the Departments believe that this final rule contains considerable regulatory flexibility for plans to design wellness programs that suit their needs. With this flexibility in mind, the Departments expect that plans will only choose to offer a wellness program if the benefits outweigh the costs. If plans choose to offer a wellness program, they will design one that minimizes costs and is not overly burdensome. With this design flexibility, this rule should not disproportionately impact small entities. Thus, the commenter has highlighted the possibility that this final rule may affect a substantial number of small entities, but the Departments do not see any evidence to indicate that this final rule will have a significant impact on small entities.

Based on the foregoing, the Departments hereby certify that these final regulations will not have a significant economic impact on a substantial number of small entities.

F. Paperwork Reduction Act—Department of Labor and Department of the Treasury

The 2006 regulations and the proposed regulations regarding wellness programs did not include an information collection request (ICR). As described earlier in this preamble, these final regulations, like the 2006 final regulations, require plans and issuers to disclose the availability of a reasonable alternative standard to qualify for the reward (and if applicable, the possibility of waiver of the otherwise applicable standard) in all plan materials describing the terms of a health-contingent wellness program (both activity-only and outcome-based wellness programs). These final regulations clarify that a disclosure of the availability of a reasonable alternative standard includes contact information for obtaining the alternative and a statement that recommendations of an individual's personal physician will be accommodated. For outcome-

[61] Under ERISA section 104(a)(2), the Secretary may also provide exemptions or simplified reporting and disclosure requirements for pension plans. Pursuant to the authority of ERISA section 104(a)(3), the Department of Labor has previously issued at 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46, and 2520.104b–10 certain simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, that cover fewer than 100 participants and satisfy certain other requirements.

[62] Kaiser Family Foundation, *Employer Health Benefits: 2012 Annual Survey.* 2012, The Kaiser Family Foundation, Menlo Park, CA; Health Research & Educational Trust, Chicago, IL.

[63] 78 FR 13405.

based wellness programs, this notice must also be included in any disclosure that an individual did not satisfy an initial outcome-based standard. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. These final regulations include sample language that can be used to satisfy this requirement.

In concluding that these final regulations did not include an ICR, the Departments reasoned that much of the information required was likely already provided as a result of state and local requirements or the usual business practices of group health plans and group health insurance issuers in connection with the offer and promotion of health care coverage. In addition, the sample disclosures would enable group health plans to make any necessary modifications with minimal effort.

Finally, although the final regulations do not include an ICR, the regulations could be interpreted to require a revision to an existing collection of information. Administrators of group health plans covered under Title I of ERISA are generally required to make certain disclosures about the terms of a plan and material changes in terms through a Summary Plan Description (SPD) or Summary of Material Modifications (SMM) pursuant to sections 101(a) and 102(a) of ERISA and related regulations. The ICR related to the SPD and SMM is currently approved by OMB under OMB control number 1210–0039. While these materials may in some cases require revisions to comply with the final regulations, the associated burden is expected to be negligible, and is already accounted for in the SPD, SMM, and the ICR by a burden estimation methodology, which anticipates ongoing revisions. Based on the foregoing, the Departments do not expect that any change to the existing ICR arising from these final regulations will be substantive or material. Accordingly, the Departments have not filed an application for approval of a revision to the existing ICR with OMB in connection with these final regulations.

G. Paperwork Reduction Act—Department of Health and Human Services

As described in earlier in this preamble, The 2006 regulations and the proposed regulations regarding wellness programs did not include an information collection request (ICR). As described earlier in this preamble, these final regulations, like the 2006 final regulations, require plans and issuers to disclose the availability of a reasonable alternative standard to qualify for the reward (and if applicable, the possibility of waiver of the otherwise applicable standard) in all plan materials describing the terms of a health-contingent wellness program (both activity-only and outcome-based wellness programs). These final regulations clarify that a disclosure of the availability of a reasonable alternative standard includes contact information for obtaining the alternative and a statement that recommendations of an individual's personal physician will be accommodated. For outcome-based wellness programs, this notice must also be included in any disclosure that an individual did not satisfy an initial outcome-based standard. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. These final regulations include sample language that can be used to satisfy this requirement.

The burden associated with this requirement was previously approved under OMB control number 0938–0819. We are not seeking reinstatement of the information collection request under the aforementioned OMB control number, since we believe that much of the information required is likely already provided as a result of state and local requirements or the usual business practices of group health plans and group health insurance issuers in connection with the offer and promotion of health care coverage. In addition, the sample disclosures would enable group health plans to make any necessary modifications with minimal effort.

H. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury it has been determined that this final rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these final regulations, and, because these final regulations do not impose a collection of information on small entities, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this final rule was submitted to the Small Business Administration for comment on its impact on small business.

I. Congressional Review Act

These final regulations 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.*) and will be transmitted to Congress and the Comptroller General for review. These regulations, do not constitute a ''major rule,'' as that term is defined in 5 U.S.C. 804 because they are unlikely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

J. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, these final regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector, of $100 million or more, adjusted for inflation.[64]

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

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

In the Departments' view, these final regulations have federalism implications, however, in the Departments' view, the federalism implications of these final regulations are substantially mitigated because, with respect to health insurance issuers, the vast majority of states have enacted

[64] In 2013, that threshold level is approximately $141 million.

laws, which meet or exceed the federal HIPAA standards prohibiting discrimination based on health factors. Therefore, the regulations are not likely to require substantial additional oversight of states by the Department of HHS.

In general, through section 514, ERISA supersedes state laws to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. While ERISA prohibits states from regulating a plan as an insurance or investment company or bank, HIPAA added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements for group health insurance coverage. With respect to the HIPAA nondiscrimination provisions, states may continue to apply state law requirements except to the extent that the requirements prevent the application of the portability, access, and renewability requirements of HIPAA, which include HIPAA's nondiscrimination requirements provisions. 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. 736, 104th Cong. 2d Session 205, 1996). State insurance laws that are more stringent than the federal requirements are unlikely to ''prevent the application of'' the HIPAA nondiscrimination provisions, and therefore are not preempted. Accordingly, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 (62 FR 16904) and on December 30, 2004 (69 FR 78720), and these final regulations clarify and implement the statute's minimum standards and do not significantly reduce the discretion given the states by the statute.

HIPAA provides that the states may enforce the provisions of HIPAA as they pertain to issuers, but that the Secretary of HHS must enforce any provisions that a state chooses not to or fails to substantially enforce. When exercising its responsibility to enforce provisions of HIPAA, HHS works cooperatively with the State for the purpose of addressing the state's concerns and avoiding conflicts with the exercise of state authority.[65] HHS has developed procedures to implement its enforcement responsibilities, and to afford the states the maximum opportunity to enforce HIPAA'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 policy making discretion of the States, DOL and HHS have engaged in numerous efforts to consult with and work cooperatively with affected state and local officials.

The Departments received a comment letter suggesting that they failed to take into account the reduction in states' tobacco tax revenue that would occur if the proposed regulations result in fewer people smoking. The Departments note that reduced tobacco tax revenue is one of many indirect effects of reduced smoking. However, the Departments believe that any lost tax revenue will be more than offset by the benefits to the public welfare that will result from reduced smoking. As the commenter stated in its letter, ''[t]hrough employees' active participation in nondiscriminatory wellness programs, sick leave, absenteeism, health plan costs, and worker's compensation will be reduced. Needless to mention, a healthier workforce is a more sustainable workforce. Therefore, from the point of view of public health, the rule greatly contributes to the promotion of healthy lifestyle of the states' population. If every small and large entity improves the health of their employees, the overall health of the states will be improved as well.''

In conclusion, throughout the process of developing these regulations, to the extent feasible within the specific preemption provisions of HIPAA, the Departments have attempted to balance the states' interests in regulating health plans and health insurance issuers, and the rights of those individuals that Congress intended to protect through the enactment of HIPAA.

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. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (January 9, 2012).

The Department of Health and Human Services regulations are adopted, with respect to 45 CFR part 146, pursuant to the authority contained in sections 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92) prior to the amendments made by the Affordable Care Act and sections 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended by the Affordable Care Act; with respect to 45 CFR part 147, 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 by the Affordable Care Act.

List of Subjects

26 CFR Part 54

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

29 CFR Part 2590

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

45 CFR Parts 146 and 147

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

[65] This authority applies to insurance issued with respect to group health plans generally, including plans covering employees of church organizations. Thus, this discussion of federalism applies to all group health insurance coverage that is subject to the PHS Act, including those church plans that provide coverage through a health insurance issuer (but not to church plans that do not provide coverage through a health insurance issuer).

Approved: May 23, 2013.

Beth Tucker,

Deputy Commissioner for Operations Support, Internal Revenue Service.

Signed this May 15, 2013.

Mark Mazur,

Assistant Secretary of the Treasury (Tax Policy).

Dated: April 25, 2013.

Phyllis C. Borzi,

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

Dated: April 29, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Kathleen Sebelius,

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 is amended by adding an entry for § 54.9815–2705 in numerical order to read in part as follows:

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

Section 54.9815–2705 also issued under 26 U.S.C. 9833.

■ **Par. 2.** In § 54.9802–1, paragraph (f) is revised to read as follows:

§ 54.9802–1 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) *Nondiscriminatory wellness programs—in general.* A wellness program is a program of health promotion or disease prevention. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that satisfies the requirements of this paragraph (f).

(1) *Definitions.* The definitions in this paragraph (f)(1) govern in applying the provisions of this paragraph (f).

(i) *Reward.* Except where expressly provided otherwise, references in this section to an individual obtaining a reward include both obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge or other financial or nonfinancial disincentive). References in this section to a plan providing a reward include both providing a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive).

(ii) *Participatory wellness programs.* If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program. Examples of participatory wellness programs are:

(A) A program that reimburses employees for all or part of the cost for membership in a fitness center.

(B) A diagnostic testing program that provides a reward for participation in that program and does not base any part of the reward on outcomes.

(C) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits. (Note that, with respect to non-grandfathered plans, § 54.9815–2713T requires benefits for certain preventive health services without the imposition of cost sharing.)

(D) A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.

(E) A program that provides a reward to employees for attending a monthly, no-cost health education seminar.

(F) A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment. (*See also* § 54.9802–3T for rules prohibiting collection of genetic information.)

(iii) *Health-contingent wellness programs.* A health-contingent wellness program is a program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward). A health-contingent wellness program may be an activity-only wellness program or an outcome-based wellness program.

(iv) *Activity-only wellness programs.* An activity-only wellness program is a type of health-contingent wellness program that requires an individual to perform or complete an activity related to a health factor in order to obtain a reward but does not require the individual to attain or maintain a specific health outcome. Examples include walking, diet, or exercise programs, which some individuals may be unable to participate in or complete (or have difficulty participating in or completing) due to a health factor, such as severe asthma, pregnancy, or a recent surgery. *See* paragraph (f)(3) of this section for requirements applicable to activity-only wellness programs.

(v) *Outcome-based wellness programs.* An outcome-based wellness program is a type of health-contingent wellness program that requires an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward. To comply with the rules of this paragraph (f), an outcome-based wellness program typically has two tiers. That is, for individuals who do not attain or maintain the specific health outcome, compliance with an educational program or an activity may be offered as an alternative to achieve the same reward. This alternative pathway, however, does not mean that the overall program, which has an outcome-based component, is not an outcome-based wellness program. That is, if a measurement, test, or screening is used as part of an initial standard and individuals who meet the standard are granted the reward, the program is considered an outcome-based wellness program. For example, if a wellness program tests individuals for specified medical conditions or risk factors (including biometric screening such as testing for high cholesterol, high blood pressure, abnormal body mass index, or high glucose level) and provides a reward to individuals identified as within a normal or healthy range for these medical conditions or risk factors, while requiring individuals who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, complying with a walking or exercise program, or complying with a health care provider's plan of care) to obtain the same reward,

the program is an outcome-based wellness program. *See* paragraph (f)(4) of this section for requirements applicable to outcome-based wellness programs.

(2) *Requirement for participatory wellness programs.* A participatory wellness program, as described in paragraph (f)(1)(ii) of this section, does not violate the provisions of this section only if participation in the program is made available to all similarly situated individuals, regardless of health status.

(3) *Requirements for activity-only wellness programs.* A health-contingent wellness program that is an activity-only wellness program, as described in paragraph (f)(1)(iv) of this section, does not violate the provisions of this section only if all of the following requirements are satisfied:

(i) *Frequency of opportunity to qualify.* The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) *Size of reward.* The reward for the activity-only wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances.

(iv) *Uniform availability and reasonable alternative standards.* The full reward under the activity-only wellness program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(3)(iv), a reward under an activity-only wellness program is not available to all similarly situated individuals for a period unless the program meets both of the following requirements:

(*1*) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(*2*) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) While plans and issuers are not required to determine a particular reasonable alternative standard in advance of an individual's request for one, if an individual is described in either paragraph (f)(3)(iv)(A)(*1*) or (*2*) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived.

(C) All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(*1*) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted), and may not require an individual to pay for the cost of the program.

(*2*) The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

(*3*) If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.

(*4*) If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(D) To the extent that a reasonable alternative standard under an activity-only wellness program is, itself, an activity-only wellness program, it must comply with the requirements of this paragraph (f)(3) in the same manner as if it were an initial program standard. (Thus, for example, if a plan or issuer provides a walking program as a reasonable alternative standard to a running program, individuals for whom it is unreasonably difficult due to a medical condition to complete the walking program (or for whom it is medically inadvisable to attempt to complete the walking program) must be provided a reasonable alternative standard to the walking program.) To the extent that a reasonable alternative standard under an activity-only wellness program is, itself, an outcome-based wellness program, it must comply with the requirements of paragraph (f)(4) of this section, including paragraph (f)(4)(iv)(D).

(E) If reasonable under the circumstances, a plan or issuer may seek verification, such as a statement from an individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard of an activity-only wellness program. Plans and issuers may seek verification with respect to requests for a reasonable alternative standard for which it is reasonable to determine that medical judgment is required to evaluate the validity of the request.

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an activity-only wellness program the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

(vi) *Example.* The provisions of this paragraph (f)(3) are illustrated by the following example:

Example. (i) *Facts.* A group health plan provides a reward to individuals who participate in a reasonable specified walking program. If it is unreasonably difficult due to a medical condition for an individual to participate (or if it is medically inadvisable for an individual to attempt to participate), the plan will waive the walking program requirement and provide the reward. All materials describing the terms of the walking program disclose the availability of the waiver.

(ii) *Conclusion.* In this *Example,* the program satisfies the requirements of paragraph (f)(3)(iii) of this section because the walking program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(3)(iv) of this section because the reward under the program is available to all similarly situated individuals. It accommodates individuals for whom it is unreasonably difficult to participate in the walking program due to a medical condition (or for whom it would be medically inadvisable to attempt to participate) by providing them with the reward even if they do not participate in the walking program (that is, by waiving the condition). The plan also complies with the disclosure requirement of paragraph (f)(3)(v) of this section. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

(4) *Requirements for outcome-based wellness programs.* A health-contingent wellness program that is an outcome-based wellness program, as described in paragraph (f)(1)(v) of this section, does not violate the provisions of this section only if all of the following requirements are satisfied:

(i) *Frequency of opportunity to qualify.* The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) *Size of reward.* The reward for the outcome-based wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(4)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances. To ensure that an outcome-based wellness program is reasonably designed to improve health and does not act as a subterfuge for underwriting or reducing benefits based on a health factor, a reasonable alternative standard to qualify for the reward must be provided to any individual who does not meet the initial standard based on a measurement, test, or screening that is related to a health factor, as explained in paragraph (f)(4)(iv) of this section.

(iv) *Uniform availability and reasonable alternative standards.* The full reward under the outcome-based wellness program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(4)(iv), a reward under an outcome-based wellness program is not available to all similarly situated individuals for a period unless the program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual who does not meet the initial standard based on the measurement, test, or screening, as described in this paragraph (f)(4)(iv).

(B) While plans and issuers are not required to determine a particular reasonable alternative standard in advance of an individual's request for one, if an individual is described in paragraph (f)(4)(iv)(A) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived.

(C) All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(*1*) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted), and may not require an individual to pay for the cost of the program.

(*2*) The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

(*3*) If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.

(*4*) If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(D) To the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, an activity-only wellness program, it must comply with the requirements of paragraph (f)(3) of this section in the same manner as if it were an initial program standard. To the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, another outcome-based wellness program, it must comply with the requirements of this paragraph (f)(4), subject to the following special rules:

(*1*) The reasonable alternative standard cannot be a requirement to meet a different level of the same standard without additional time to comply that takes into account the individual's circumstances. For example, if the initial standard is to achieve a BMI less than 30, the reasonable alternative standard cannot be to achieve a BMI less than 31 on that same date. However, if the initial standard is to achieve a BMI less than 30, a reasonable alternative standard for the individual could be to reduce the individual's BMI by a small amount or small percentage, over a realistic period of time, such as within a year.

(*2*) An individual must be given the opportunity to comply with the recommendations of the individual's personal physician as a second reasonable alternative standard to meeting the reasonable alternative standard defined by the plan or issuer, but only if the physician joins in the request. The individual can make a

request to involve a personal physician's recommendations at any time and the personal physician can adjust the physician's recommendations at any time, consistent with medical appropriateness.

(E) It is not reasonable to seek verification, such as a statement from an individual's personal physician, under an outcome-based wellness program that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard as a condition of providing a reasonable alternative to the initial standard. However, if a plan or issuer provides an alternative standard to the otherwise applicable measurement, test, or screening that involves an activity that is related to a health factor, then the rules of paragraph (f)(3) of this section for activity-only wellness programs apply to that component of the wellness program and the plan or issuer may, if reasonable under the circumstances, seek verification that it is unreasonably difficult due to a medical condition for an individual to perform or complete the activity (or it is medically inadvisable to attempt to perform or complete the activity). (For example, if an outcome-based wellness program requires participants to maintain a certain healthy weight and provides a diet and exercise program for individuals who do not meet the targeted weight, a plan or issuer may seek verification, as described in paragraph (f)(3)(iv)(D) of this section, if reasonable under the circumstances, that a second reasonable alternative standard is needed for certain individuals because, for those individuals, it would be unreasonably difficult due to a medical condition to comply, or medically inadvisable to attempt to comply, with the diet and exercise program, due to a medical condition.)

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an outcome-based wellness program, and in any disclosure that an individual did not satisfy an initial outcome-based standard, the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

(vi) *Examples.* The rules of this paragraph (f)(4) are illustrated by the following examples:

Example 1—Cholesterol screening with reasonable alternative standard to work with personal physician. (i) *Facts.* A group health plan offers a reward to participants who achieve a count under 200 on a total cholesterol test. If a participant does not achieve the targeted cholesterol count, the plan allows the participant to develop an alternative cholesterol action plan in conjunction with the participant's personal physician that may include recommendations for medication and additional screening. The plan allows the physician to modify the standards, as medically necessary, over the year. (For example, if a participant develops asthma or depression, requires surgery and convalescence, or some other medical condition or consideration makes completion of the original action plan inadvisable or unreasonably difficult, the physician may modify the original action plan.) All plan materials describing the terms of the program include the following statement: ''Your health plan wants to help you take charge of your health. Rewards are available to all employees who participate in our Cholesterol Awareness Wellness Program. If your total cholesterol count is under 200, you will receive the reward. If not, you will still have an opportunity to qualify for the reward. We will work with you and your doctor to find a Health Smart program that is right for you.'' In addition, when any individual participant receives notification that his or her cholesterol count is 200 or higher, the notification includes the following statement: ''Your plan offers a Health Smart program under which we will work with you and your doctor to try to lower your cholesterol. If you complete this program, you will qualify for a reward. Please contact us at [contact information] to get started.''

(ii) *Conclusion.* In this *Example 1,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health outcome (a certain cholesterol level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because the cholesterol program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes available to all participants who do not meet the cholesterol standard a reasonable alternative standard to qualify for the reward. Lastly, the plan also discloses in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard the availability of a reasonable alternative standard (including contact information and the individual's ability to involve his or her personal physician), as required by paragraph (f)(4)(v) of this section. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 2—Cholesterol screening with plan alternative and no opportunity for personal physician involvement. (i) *Facts.* Same facts as *Example 1,* except that the wellness program's physician or nurse practitioner (rather than the individual's personal physician) determines the alternative cholesterol action plan. The plan does not provide an opportunity for a participant's personal physician to modify the action plan if it is not medically appropriate for that individual.

(ii) *Conclusion.* In this *Example 2,* the wellness program does not satisfy the requirements of paragraph (f)(4)(iii) of this section because the program does not accommodate the recommendations of the participant's personal physician with regard to medical appropriateness, as required under paragraph (f)(4)(iv)(C)(*3*) of this section. Thus, the program is not reasonably designed under paragraph (f)(4)(iii) of this section and is not available to all similarly situated individuals under paragraph (f)(4)(iv) of this section. The notice also does not provide all the content required under paragraph (f)(4)(v) of this section.

Example 3—Cholesterol screening with plan alternative that can be modified by personal physician. (i) *Facts.* Same facts as *Example 2,* except that if a participant's personal physician disagrees with any part of the action plan, the personal physician may modify the action plan at any time, and the plan discloses this to participants.

(ii) *Conclusion.* In this *Example 3,* the wellness program satisfies the requirements of paragraph (f)(4)(iii) of this section because the participant's personal physician may modify the action plan determined by the wellness program's physician or nurse practitioner at any time if the physician states that the recommendations are not medically appropriate, as required under paragraph (f)(4)(iv)(C)(*3*) of this section. Thus, the program is reasonably designed under paragraph (f)(4)(iii) of this section and is available to all similarly situated individuals under paragraph (f)(4)(iv) of this section. The notice, which includes a statement that recommendations of an individual's personal physician will be accommodated, also complies with paragraph (f)(4)(v) of this section.

Example 4—BMI screening with walking program alternative. (i) *Facts.* A group health plan will provide a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is unreasonably difficult due to a medical condition to comply with this walking program (and any participant for whom it is medically inadvisable to attempt to comply with the walking program) during the year is given the same discount if the participant satisfies an alternative standard that is reasonable taking into consideration the participant's medical situation, is not unreasonably burdensome or

impractical to comply with, and is otherwise reasonably designed based on all the relevant facts and circumstances. All plan materials describing the terms of the wellness program include the following statement: ''Fitness is Easy! Start Walking! Your health plan cares about your health. If you are considered overweight because you have a BMI of over 26, our Start Walking program will help you lose weight and feel better. We will help you enroll. (* *If your doctor says that walking isn't right for you, that's okay too. We will work with you (and, if you wish, your own doctor) to develop a wellness program that is.)'' Participant *E* is unable to achieve a BMI that is 26 or lower within the plan's timeframe and receives notification that complies with paragraph (f)(4)(v) of this section. Nevertheless, it is unreasonably difficult due to a medical condition for *E* to comply with the walking program. *E* proposes a program based on the recommendations of *E*'s physician. The plan agrees to make the same discount available to *E* that is available to other participants in the BMI program or the alternative walking program, but only if *E* actually follows the physician's recommendations.

(ii) *Conclusion.* In this *Example 4,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health outcome (a certain BMI level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because it is reasonably designed to promote health and prevent disease. The program also satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes available to all individuals who do not satisfy the BMI standard a reasonable alternative standard to qualify for the reward (in this case, a walking program that is not unreasonably burdensome or impractical for individuals to comply with and that is otherwise reasonably designed based on all the relevant facts and circumstances). In addition, the walking program is, itself, an activity-only standard and the plan complies with the requirements of paragraph (f)(3) of this section (including the requirement of paragraph (f)(3)(iv) that, if there are individuals for whom it is unreasonably difficult due to a medical condition to comply, or for whom it is medically inadvisable to attempt to comply, with the walking program, the plan provide a reasonable alternative to those individuals). Moreover, the plan satisfies the requirements of paragraph (f)(4)(v) of this section because it discloses, in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard, the availability of a reasonable alternative standard (including contact information and the individual's option to involve his or her personal physician) to qualify for the reward or the possibility of waiver of the otherwise applicable standard. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 5—BMI screening with alternatives available to either lower BMI or meet personal physician's recommendations. (i) *Facts.* Same facts as *Example 4* except that, with respect to any participant who does not meet the target BMI, instead of a walking program, the participant is expected to reduce BMI by one point. At any point during the year upon request, any individual can obtain a second reasonable alternative standard, which is compliance with the recommendations of the participant's personal physician regarding weight, diet, and exercise as set forth in a treatment plan that the physician recommends or to which the physician agrees. The participant's personal physician is permitted to change or adjust the treatment plan at any time and the option of following the participant's personal physician's recommendations is clearly disclosed.

(ii) *Conclusion.* In this *Example 5,* the reasonable alternative standard to qualify for the reward (the alternative BMI standard requiring a one-point reduction) does not make the program unreasonable under paragraph (f)(4)(iii) or (iv) of this section because the program complies with paragraph (f)(4)(iv)(C)(*4*) of this section by allowing a second reasonable alternative standard to qualify for the reward (compliance with the recommendations of the participant's personal physician, which can be changed or adjusted at any time). Accordingly, the program continues to satisfy the applicable requirements of paragraph (f) of this section.

Example 6—Tobacco use surcharge with smoking cessation program alternative. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a premium differential based on tobacco use, determined using a health risk assessment. The following statement is included in all plan materials describing the tobacco premium differential: ''Stop smoking today! We can help! If you are a smoker, we offer a smoking cessation program. If you complete the program, you can avoid this surcharge.'' The plan accommodates participants who smoke by facilitating their enrollment in a smoking cessation program that requires participation at a time and place that are not unreasonably burdensome or impractical for participants, and that is otherwise reasonably designed based on all the relevant facts and circumstances, and discloses contact information and the individual's option to involve his or her personal physician. The plan pays for the cost of participation in the smoking cessation program. Any participant can avoid the surcharge for the plan year by participating in the program, regardless of whether the participant stops smoking, but the plan can require a participant who wants to avoid the surcharge in a subsequent year to complete the smoking cessation program again.

(ii) *Conclusion.* In this *Example 6,* the premium differential satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v). The program is an outcome-based wellness program because the initial standard for obtaining a reward is dependent on the results of a health risk assessment (a measurement, test, or screening). The program is reasonably designed under paragraph (f)(4)(iii) because the plan provides a reasonable alternative standard (as required under paragraph (f)(4)(iv) of this section) to qualify for the reward to all tobacco users (a smoking cessation program). The plan discloses, in all materials describing the terms of the program, the availability of the reasonable alternative standard (including contact information and the individual's option to involve his or her personal physician). Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 7—Tobacco use surcharge with alternative program requiring actual cessation. (i) *Facts.* Same facts as *Example 6,* except the plan does not provide participant *F* with the reward in subsequent years unless *F* actually stops smoking after participating in the tobacco cessation program.

(ii) *Conclusion.* In this *Example 7,* the program is not reasonably designed under paragraph (f)(4)(iii) of this section and does not provide a reasonable alternative standard as required under paragraph (f)(4)(iv) of this section. The plan cannot cease to provide a reasonable alternative standard merely because the participant did not stop smoking after participating in a smoking cessation program. The plan must continue to offer a reasonable alternative standard whether it is the same or different (such as a new recommendation from *F*'s personal physician or a new nicotine replacement therapy).

Example 8—Tobacco use surcharge with smoking cessation program alternative that is not reasonable. (i) *Facts.* Same facts as *Example 6,* except the plan does not facilitate participant *F*'s enrollment in a smoking cessation program. Instead the plan advises *F* to find a program, pay for it, and provide a certificate of completion to the plan.

(ii) *Conclusion.* In this *Example 8,* the requirement for *F* to find and pay for *F*'s own smoking cessation program means that the alternative program is not reasonable. Accordingly, the plan has not offered a reasonable alternative standard that complies with paragraphs (f)(4)(iii) and (iv) of this section and the program fails to satisfy the requirements of paragraph (f) of this section.

(5) *Applicable percentage*—(i) For purposes of this paragraph (f), the applicable percentage is 30 percent, except that the applicable percentage is increased by an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use.

(ii) The provisions of this paragraph (f)(5) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan. The annual premium for employee-only coverage is $6,000 (of which the employer pays $4,500 per year and the employee pays $1,500 per year). The plan offers employees a health-contingent wellness program with several components, focused on exercise, blood sugar, weight, cholesterol, and blood pressure. The reward for compliance is an annual premium rebate of $600.

(ii) *Conclusion.* In this *Example 1,* the reward for the wellness program, $600, does not exceed the applicable percentage of 30

percent of the total annual cost of employee-only coverage, $1,800. ($6,000 × 30% = $1,800.)

Example 2. (i) *Facts.* Same facts as *Example 1,* except the wellness program is exclusively a tobacco prevention program. Employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program are charged a $1,000 premium surcharge (in addition to their employee contribution towards the coverage). (Those who participate in the plan's tobacco cessation program are not assessed the $1,000 surcharge.)

(ii) *Conclusion.* In this *Example 2,* the reward for the wellness program (absence of a $1,000 surcharge), does not exceed the applicable percentage of 50 percent of the total annual cost of employee-only coverage, $3,000. ($6,000 × 50% = $3,000.)

Example 3. (i) *Facts.* Same facts as *Example 1,* except that, in addition to the $600 reward for compliance with the health-contingent wellness program, the plan also imposes an additional $2,000 tobacco premium surcharge on employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program. (Those who participate in the plan's tobacco cessation program are not assessed the $2,000 surcharge.)

(ii) *Conclusion.* In this *Example 3,* the total of all rewards (including absence of a surcharge for participating in the tobacco program) is $2,600 ($600 + $2,000 = $2,600), which does not exceed the applicable percentage of 50 percent of the total annual cost of employee-only coverage ($3,000); and, tested separately, the $600 reward for the wellness program unrelated to tobacco use does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage ($1,800).

Example 4. (i) *Facts.* An employer sponsors a group health plan. The total annual premium for employee-only coverage (including both employer and employee contributions towards the coverage) is $5,000. The plan provides a $250 reward to employees who complete a health risk assessment, without regard to the health issues identified as part of the assessment. The plan also offers a Healthy Heart program, which is a health-contingent wellness program, with an opportunity to earn a $1,500 reward.

(ii) *Conclusion.* In this *Example 4,* even though the total reward for all wellness programs under the plan is $1,750 ($250 + $1,500 = $1,750, which exceeds the applicable percentage of 30 percent of the cost of the annual premium for employee-only coverage ($5,000 × 30% = $1,500)), only the reward offered for compliance with the health-contingent wellness program ($1,500) is taken into account in determining whether the rules of this paragraph (f)(5) are met. (The $250 reward is offered in connection with a participatory wellness program and therefore is not taken into account.) Accordingly, the health-contingent wellness program offers a reward that does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage.

(6) *Sample language.* The following language, or substantially similar language, can be used to satisfy the notice requirement of paragraphs (f)(3)(v) or (f)(4)(v) of this section: ''Your health plan is committed to helping you achieve your best health. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you (and, if you wish, with your doctor) to find a wellness program with the same reward that is right for you in light of your health status.''

* * * * *

■ 3. Section 54.9815–2705 is added to read as follows:

§ 54.9815–2705 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) *In general.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with the requirements of § 54.9802–1.

(b) *Applicability date.* This section is applicable to group health plans and health insurance issuers offering group health insurance coverage for plan years beginning on or after January 1, 2014.

Department of Labor

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, 29 CFR part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 4. 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).

Subpart B—Health Coverage Portability, Nondiscrimination, and Renewability

■ 5. Section 2590.702 is amended by revising paragraph (f) to read as follows:

§ 2590.702 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) *Nondiscriminatory wellness programs—in general.* A wellness program is a program of health promotion or disease prevention. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that satisfies the requirements of this paragraph (f).

(1) *Definitions.* The definitions in this paragraph (f)(1) govern in applying the provisions of this paragraph (f).

(i) *Reward.* Except where expressly provided otherwise, references in this section to an individual obtaining a reward include both obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge or other financial or nonfinancial disincentive). References in this section to a plan providing a reward include both providing a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive).

(ii) *Participatory wellness programs.* If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program. Examples of participatory wellness programs are:

(A) A program that reimburses employees for all or part of the cost for membership in a fitness center.

(B) A diagnostic testing program that provides a reward for participation in that program and does not base any part of the reward on outcomes.

(C) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits. (Note that, with respect to non-grandfathered plans, § 2590.715–2713 of this part requires benefits for certain preventive health

services without the imposition of cost sharing.)

(D) A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.

(E) A program that provides a reward to employees for attending a monthly, no-cost health education seminar.

(F) A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment. (*See also* § 2590.702–1 for rules prohibiting collection of genetic information.)

(iii) *Health-contingent wellness programs.* A health-contingent wellness program is a program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward). A health-contingent wellness program may be an activity-only wellness program or an outcome-based wellness program.

(iv) *Activity-only wellness programs.* An activity-only wellness program is a type of health-contingent wellness program that requires an individual to perform or complete an activity related to a health factor in order to obtain a reward but does not require the individual to attain or maintain a specific health outcome. Examples include walking, diet, or exercise programs, which some individuals may be unable to participate in or complete (or have difficulty participating in or completing) due to a health factor, such as severe asthma, pregnancy, or a recent surgery. *See* paragraph (f)(3) of this section for requirements applicable to activity-only wellness programs.

(v) *Outcome-based wellness programs.* An outcome-based wellness program is a type of health-contingent wellness program that requires an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward. To comply with the rules of this paragraph (f), an outcome-based wellness program typically has two tiers. That is, for individuals who do not attain or maintain the specific health outcome, compliance with an educational program or an activity may be offered as an alternative to achieve the same reward. This alternative pathway, however, does not mean that the overall program, which has an outcome-based component, is not an outcome-based wellness program. That is, if a measurement, test, or screening is used as part of an initial standard and individuals who meet the standard are granted the reward, the program is considered an outcome-based wellness program. For example, if a wellness program tests individuals for specified medical conditions or risk factors (including biometric screening such as testing for high cholesterol, high blood pressure, abnormal body mass index, or high glucose level) and provides a reward to individuals identified as within a normal or healthy range for these medical conditions or risk factors, while requiring individuals who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, complying with a walking or exercise program, or complying with a health care provider's plan of care) to obtain the same reward, the program is an outcome-based wellness program. *See* paragraph (f)(4) of this section for requirements applicable to outcome-based wellness programs.

(2) *Requirement for participatory wellness programs.* A participatory wellness program, as described in paragraph (f)(1)(ii) of this section, does not violate the provisions of this section only if participation in the program is made available to all similarly situated individuals, regardless of health status.

(3) *Requirements for activity-only wellness programs.* A health-contingent wellness program that is an activity-only wellness program, as described in paragraph (f)(1)(iv) of this section, does not violate the provisions of this section only if all of the following requirements are satisfied:

(i) *Frequency of opportunity to qualify.* The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) *Size of reward.* The reward for the activity-only wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances.

(iv) *Uniform availability and reasonable alternative standards.* The full reward under the activity-only wellness program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(3)(iv), a reward under an activity-only wellness program is not available to all similarly situated individuals for a period unless the program meets both of the following requirements:

(*1*) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(*2*) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) While plans and issuers are not required to determine a particular reasonable alternative standard in advance of an individual's request for one, if an individual is described in either paragraph (f)(3)(iv)(A)(*1*) or (*2*) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived.

(C) All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(*1*) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted), and may not require an individual to pay for the cost of the program.

(*2*) The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

(*3*) If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.

(*4*) If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(D) To the extent that a reasonable alternative standard under an activity-only wellness program is, itself, an activity-only wellness program, it must comply with the requirements of this paragraph (f)(3) in the same manner as if it were an initial program standard. (Thus, for example, if a plan or issuer provides a walking program as a reasonable alternative standard to a running program, individuals for whom it is unreasonably difficult due to a medical condition to complete the walking program (or for whom it is medically inadvisable to attempt to complete the walking program) must be provided a reasonable alternative standard to the walking program.) To the extent that a reasonable alternative standard under an activity-only wellness program is, itself, an outcome-based wellness program, it must comply with the requirements of paragraph (f)(4) of this section, including paragraph (f)(4)(iv)(D).

(E) If reasonable under the circumstances, a plan or issuer may seek verification, such as a statement from an individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard of an activity-only wellness program. Plans and issuers may seek verification with respect to requests for a reasonable alternative standard for which it is reasonable to determine that medical judgment is required to evaluate the validity of the request.

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an activity-only wellness program the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

(vi) *Example.* The provisions of this paragraph (f)(3) are illustrated by the following example:

Example. (i) *Facts.* A group health plan provides a reward to individuals who participate in a reasonable specified walking program. If it is unreasonably difficult due to a medical condition for an individual to participate (or if it is medically inadvisable for an individual to attempt to participate), the plan will waive the walking program requirement and provide the reward. All materials describing the terms of the walking program disclose the availability of the waiver.

(ii) *Conclusion.* In this *Example,* the program satisfies the requirements of paragraph (f)(3)(iii) of this section because the walking program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(3)(iv) of this section because the reward under the program is available to all similarly situated individuals. It accommodates individuals for whom it is unreasonably difficult to participate in the walking program due to a medical condition (or for whom it would be medically inadvisable to attempt to participate) by providing them with the reward even if they do not participate in the walking program (that is, by waiving the condition). The plan also complies with the disclosure requirement of paragraph (f)(3)(v) of this section. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

(4) *Requirements for outcome-based wellness programs.* A health-contingent wellness program that is an outcome-based wellness program, as described in paragraph (f)(1)(v) of this section, does not violate the provisions of this section only if all of the following requirements are satisfied:

(i) *Frequency of opportunity to qualify.* The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) *Size of reward.* The reward for the outcome-based wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(4)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances. To ensure that an outcome-based wellness program is reasonably designed to improve health and does not act as a subterfuge for underwriting or reducing benefits based on a health factor, a reasonable alternative standard to qualify for the reward must be provided to any individual who does not meet the initial standard based on a measurement, test, or screening that is related to a health factor, as explained in paragraph (f)(4)(iv) of this section.

(iv) *Uniform availability and reasonable alternative standards.* The full reward under the outcome-based wellness program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(4)(iv), a reward under an outcome-based wellness program is not available to all similarly situated individuals for a period unless the program allows a

reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual who does not meet the initial standard based on the measurement, test, or screening, as described in this paragraph (f)(4)(iv).

(B) While plans and issuers are not required to determine a particular reasonable alternative standard in advance of an individual's request for one, if an individual is described in paragraph (f)(4)(iv)(A) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived.

(C) All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(*1*) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted), and may not require an individual to pay for the cost of the program.

(*2*) The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

(*3*) If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.

(*4*) If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(D) To the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, an activity-only wellness program, it must comply with the requirements of paragraph (f)(3) of this section in the same manner as if it were an initial program standard. To the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, another outcome-based wellness program, it must comply with the requirements of this paragraph (f)(4), subject to the following special provisions:

(*1*) The reasonable alternative standard cannot be a requirement to meet a different level of the same standard without additional time to comply that takes into account the individual's circumstances. For example, if the initial standard is to achieve a BMI less than 30, the reasonable alternative standard cannot be to achieve a BMI less than 31 on that same date. However, if the initial standard is to achieve a BMI less than 30, a reasonable alternative standard for the individual could be to reduce the individual's BMI by a small amount or small percentage, over a realistic period of time, such as within a year.

(*2*) An individual must be given the opportunity to comply with the recommendations of the individual's personal physician as a second reasonable alternative standard to meeting the reasonable alternative standard defined by the plan or issuer, but only if the physician joins in the request. The individual can make a request to involve a personal physician's recommendations at any time and the personal physician can adjust the physician's recommendations at any time, consistent with medical appropriateness.

(E) It is not reasonable to seek verification, such as a statement from an individual's personal physician, under an outcome-based wellness program that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard as a condition of providing a reasonable alternative to the initial standard. However, if a plan or issuer provides an alternative standard to the otherwise applicable measurement, test, or screening that involves an activity that is related to a health factor, then the rules of paragraph (f)(3) of this section for activity-only wellness programs apply to that component of the wellness program and the plan or issuer may, if reasonable under the circumstances, seek verification that it is unreasonably difficult due to a medical condition for an individual to perform or complete the activity (or it is medically inadvisable to attempt to perform or complete the activity). (For example, if an outcome-based wellness program requires participants to maintain a certain healthy weight and provides a diet and exercise program for individuals who do not meet the targeted weight, a plan or issuer may seek verification, as described in paragraph (f)(3)(iv)(D) of this section, if reasonable under the circumstances, that a second reasonable alternative standard is needed for certain individuals because, for those individuals, it would be unreasonably difficult due to a medical condition to comply, or medically inadvisable to attempt to comply, with the diet and exercise program, due to a medical condition.)

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an outcome-based wellness program, and in any disclosure that an individual did not satisfy an initial outcome-based standard, the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

(vi) *Examples.* The provisions of this paragraph (f)(4) are illustrated by the following examples:

Example 1—Cholesterol screening with reasonable alternative standard to work with personal physician. (i) *Facts.* A group health plan offers a reward to participants who achieve a count under 200 on a total cholesterol test. If a participant does not achieve the targeted cholesterol count, the plan allows the participant to develop an alternative cholesterol action plan in conjunction with the participant's personal physician that may include recommendations for medication and additional screening. The plan allows the physician to modify the standards, as medically necessary, over the year. (For example, if a participant develops asthma or depression, requires surgery and convalescence, or some other medical condition or consideration makes completion of the original action plan inadvisable or unreasonably difficult, the physician may modify the original action plan.) All plan materials describing the terms of the program include the following statement: ''Your health plan wants to help you take charge of your health. Rewards are available to all employees who participate in our Cholesterol Awareness Wellness Program. If your total cholesterol count is under 200, you will receive the reward. If not, you will still have an opportunity to qualify for the reward. We will work with you and your doctor to find a Health Smart program that is right for you.'' In addition, when any individual participant

receives notification that his or her cholesterol count is 200 or higher, the notification includes the following statement: ''Your plan offers a Health Smart program under which we will work with you and your doctor to try to lower your cholesterol. If you complete this program, you will qualify for a reward. Please contact us at [contact information] to get started.''

(ii) *Conclusion.* In this *Example 1,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health outcome (a certain cholesterol level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because the cholesterol program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes available to all participants who do not meet the cholesterol standard a reasonable alternative standard to qualify for the reward. Lastly, the plan also discloses in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard the availability of a reasonable alternative standard (including contact information and the individual's ability to involve his or her personal physician), as required by paragraph (f)(4)(v) of this section. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 2—Cholesterol screening with plan alternative and no opportunity for personal physician involvement. (i) *Facts.* Same facts as *Example 1,* except that the wellness program's physician or nurse practitioner (rather than the individual's personal physician) determines the alternative cholesterol action plan. The plan does not provide an opportunity for a participant's personal physician to modify the action plan if it is not medically appropriate for that individual.

(ii) *Conclusion.* In this *Example 2,* the wellness program does not satisfy the requirements of paragraph (f)(4)(iii) of this section because the program does not accommodate the recommendations of the participant's personal physician with regard to medical appropriateness, as required under paragraph (f)(4)(iv)(C)(*3*) of this section. Thus, the program is not reasonably designed under paragraph (f)(4)(iii) of this section and is not available to all similarly situated individuals under paragraph (f)(4)(iv) of this section. The notice also does not provide all the content required under paragraph (f)(4)(v) of this section.

Example 3—Cholesterol screening with plan alternative that can be modified by personal physician. (i) *Facts.* Same facts as *Example 2,* except that if a participant's personal physician disagrees with any part of the action plan, the personal physician may modify the action plan at any time, and the plan discloses this to participants.

(ii) *Conclusion.* In this *Example 3,* the wellness program satisfies the requirements of paragraph (f)(4)(iii) of this section because the participant's personal physician may modify the action plan determined by the wellness program's physician or nurse practitioner at any time if the physician states that the recommendations are not medically appropriate, as required under paragraph (f)(4)(iv)(C)(*3*) of this section. Thus, the program is reasonably designed under paragraph (f)(4)(iii) of this section and is available to all similarly situated individuals under paragraph (f)(4)(iv) of this section. The notice, which includes a statement that recommendations of an individual's personal physician will be accommodated, also complies with paragraph (f)(4)(v) of this section.

Example 4—BMI screening with walking program alternative. (i) Facts. A group health plan will provide a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is unreasonably difficult due to a medical condition to comply with this walking program (and any participant for whom it is medically inadvisable to attempt to comply with the walking program) during the year is given the same discount if the participant satisfies an alternative standard that is reasonable taking into consideration the participant's medical situation, is not unreasonably burdensome or impractical to comply with, and is otherwise reasonably designed based on all the relevant facts and circumstances. All plan materials describing the terms of the wellness program include the following statement: ''Fitness is Easy! Start Walking! Your health plan cares about your health. If you are considered overweight because you have a BMI of over 26, our Start Walking program will help you lose weight and feel better. We will help you enroll. (**If your doctor says that walking isn't right for you, that's okay too. We will work with you (and, if you wish, your own doctor) to develop a wellness program that is.)'' Participant *E* is unable to achieve a BMI that is 26 or lower within the plan's timeframe and receives notification that complies with paragraph (f)(4)(v) of this section. Nevertheless, it is unreasonably difficult due to a medical condition for *E* to comply with the walking program. *E* proposes a program based on the recommendations of *E*'s physician. The plan agrees to make the same discount available to *E* that is available to other participants in the BMI program or the alternative walking program, but only if *E* actually follows the physician's recommendations.

(ii) *Conclusion.* In this *Example 4,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health outcome (a certain BMI level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because it is reasonably designed to promote health and prevent disease. The program also satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes available to all individuals who do not satisfy the BMI standard a reasonable alternative standard to qualify for the reward (in this case, a walking program that is not unreasonably burdensome or impractical for individuals to comply with and that is otherwise reasonably designed based on all the relevant facts and circumstances). In addition, the walking program is, itself, an activity-only standard and the plan complies with the requirements of paragraph (f)(3) of this section (including the requirement of paragraph (f)(3)(iv) that, if there are individuals for whom it is unreasonably difficult due to a medical condition to comply, or for whom it is medically inadvisable to attempt to comply, with the walking program, the plan provide a reasonable alternative to those individuals). Moreover, the plan satisfies the requirements of paragraph (f)(4)(v) of this section because it discloses, in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard, the availability of a reasonable alternative standard (including contact information and the individual's option to involve his or her personal physician) to qualify for the reward or the possibility of waiver of the otherwise applicable standard. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 5—BMI screening with alternatives available to either lower BMI or meet personal physician's recommendations. (i) *Facts.* Same facts as *Example 4* except that, with respect to any participant who does not meet the target BMI, instead of a walking program, the participant is expected to reduce BMI by one point. At any point during the year upon request, any individual can obtain a second reasonable alternative standard, which is compliance with the recommendations of the participant's personal physician regarding weight, diet, and exercise as set forth in a treatment plan that the physician recommends or to which the physician agrees. The participant's personal physician is permitted to change or adjust the treatment plan at any time and the option of following the participant's personal physician's recommendations is clearly disclosed.

(ii) *Conclusion.* In this *Example 5,* the reasonable alternative standard to qualify for the reward (the alternative BMI standard requiring a one-point reduction) does not make the program unreasonable under paragraph (f)(4)(iii) or (iv) of this section because the program complies with paragraph (f)(4)(iv)(C)(*4*) of this section by allowing a second reasonable alternative standard to qualify for the reward (compliance with the recommendations of the participant's personal physician, which can be changed or adjusted at any time). Accordingly, the program continues to satisfy the applicable requirements of paragraph (f) of this section.

Example 6—Tobacco use surcharge with smoking cessation program alternative. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a premium differential based on tobacco use, determined using a health risk assessment. The following statement is included in all plan materials describing the tobacco premium differential: ''Stop smoking today! We can help! If you are a smoker, we

offer a smoking cessation program. If you complete the program, you can avoid this surcharge.'' The plan accommodates participants who smoke by facilitating their enrollment in a smoking cessation program that requires participation at a time and place that are not unreasonably burdensome or impractical for participants, and that is otherwise reasonably designed based on all the relevant facts and circumstances, and discloses contact information and the individual's option to involve his or her personal physician. The plan pays for the cost of participation in the smoking cessation program. Any participant can avoid the surcharge for the plan year by participating in the program, regardless of whether the participant stops smoking, but the plan can require a participant who wants to avoid the surcharge in a subsequent year to complete the smoking cessation program again.

(ii) *Conclusion.* In this *Example 6,* the premium differential satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v). The program is an outcome-based wellness program because the initial standard for obtaining a reward is dependent on the results of a health risk assessment (a measurement, test, or screening). The program is reasonably designed under paragraph (f)(4)(iii) because the plan provides a reasonable alternative standard (as required under paragraph (f)(4)(iv) of this section) to qualify for the reward to all tobacco users (a smoking cessation program). The plan discloses, in all materials describing the terms of the program, the availability of the reasonable alternative standard (including contact information and the individual's option to involve his or her personal physician). Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 7—Tobacco use surcharge with alternative program requiring actual cessation. (i) *Facts.* Same facts as *Example 6,* except the plan does not provide participant *F* with the reward in subsequent years unless *F* actually stops smoking after participating in the tobacco cessation program.

(ii) *Conclusion.* In this *Example 7,* the program is not reasonably designed under paragraph (f)(4)(iii) of this section and does not provide a reasonable alternative standard as required under paragraph (f)(4)(iv) of this section. The plan cannot cease to provide a reasonable alternative standard merely because the participant did not stop smoking after participating in a smoking cessation program. The plan must continue to offer a reasonable alternative standard whether it is the same or different (such as a new recommendation from *F*'s personal physician or a new nicotine replacement therapy).

Example 8—Tobacco use surcharge with smoking cessation program alternative that is not reasonable. (i) *Facts.* Same facts as *Example 6,* except the plan does not facilitate participant *F*'s enrollment in a smoking cessation program. Instead the plan advises *F* to find a program, pay for it, and provide a certificate of completion to the plan.

(ii) *Conclusion.* In this *Example 8,* the requirement for *F* to find and pay for *F*'s own smoking cessation program means that the alternative program is not reasonable. Accordingly, the plan has not offered a reasonable alternative standard that complies with paragraphs (f)(4)(iii) and (iv) of this section and the program fails to satisfy the requirements of paragraph (f) of this section.

(5) *Applicable percentage*—(i) For purposes of this paragraph (f), the applicable percentage is 30 percent, except that the applicable percentage is increased by an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use.

(ii) The rules of this paragraph (f)(5) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan. The annual premium for employee-only coverage is $6,000 (of which the employer pays $4,500 per year and the employee pays $1,500 per year). The plan offers employees a health-contingent wellness program with several components, focused on exercise, blood sugar, weight, cholesterol, and blood pressure. The reward for compliance is an annual premium rebate of $600.

(ii) *Conclusion.* In this *Example 1,* the reward for the wellness program, $600, does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage, $1,800. ($6,000 × 30% = $1,800.)

Example 2. (i) *Facts.* Same facts as *Example 1,* except the wellness program is exclusively a tobacco prevention program. Employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program are charged a $1,000 premium surcharge (in addition to their employee contribution towards the coverage). (Those who participate in the plan's tobacco cessation program are not assessed the $1,000 surcharge.)

(ii) *Conclusion.* In this *Example 2,* the reward for the wellness program (absence of a $1,000 surcharge), does not exceed the applicable percentage of 50 percent of the total annual cost of employee-only coverage, $3,000. ($6,000 × 50% = $3,000.)

Example 3. (i) *Facts.* Same facts as *Example 1,* except that, in addition to the $600 reward for compliance with the health-contingent wellness program, the plan also imposes an additional $2,000 tobacco premium surcharge on employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program. (Those who participate in the plan's tobacco cessation program are not assessed the $2,000 surcharge.)

(ii) *Conclusion.* In this *Example 3,* the total of all rewards (including absence of a surcharge for participating in the tobacco program) is $2,600 ($600 + $2,000 = $2,600), which does not exceed the applicable percentage of 50 percent of the total annual cost of employee-only coverage ($3,000); and, tested separately, the $600 reward for the wellness program unrelated to tobacco use does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage ($1,800).

Example 4. (i) *Facts.* An employer sponsors a group health plan. The total annual premium for employee-only coverage (including both employer and employee contributions towards the coverage) is $5,000. The plan provides a $250 reward to employees who complete a health risk assessment, without regard to the health issues identified as part of the assessment. The plan also offers a Healthy Heart program, which is a health-contingent wellness program, with an opportunity to earn a $1,500 reward.

(ii) *Conclusion.* In this *Example 4,* even though the total reward for all wellness programs under the plan is $1,750 ($250 + $1,500 = $1,750, which exceeds the applicable percentage of 30 percent of the cost of the annual premium for employee-only coverage ($5,000 × 30% = $1,500)), only the reward offered for compliance with the health-contingent wellness program ($1,500) is taken into account in determining whether the rules of this paragraph (f)(5) are met. (The $250 reward is offered in connection with a participatory wellness program and therefore is not taken into account.) Accordingly, the health-contingent wellness program offers a reward that does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage.

(6) *Sample language.* The following language, or substantially similar language, can be used to satisfy the notice requirement of paragraphs (f)(3)(v) or (f)(4)(v) of this section: ''Your health plan is committed to helping you achieve your best health. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you (and, if you wish, with your doctor) to find a wellness program with the same reward that is right for you in light of your health status.''

* * * * *

Subpart C—Other Requirements

■ 6. Section 2590.715–2705 is added to read as follows:

§ 2590.715–2705 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) *In general.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with the requirements of § 2590.702 of this part.

(b) *Applicability date.* This section is applicable to group health plans and health insurance issuers offering group health insurance coverage for plan years beginning on or after January 1, 2014.

Department of Health and Human Services

45 CFR Subtitle A

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR Parts 146 and 147 as follows:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 7. The authority citation for part 146 continues to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92) (1996).

Section 146.121 is also issued under 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 (2010).

■ 8. In § 146.121, paragraph (f) is revised to read as follows:

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) *Nondiscriminatory wellness programs—in general.* A wellness program is a program of health promotion or disease prevention. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that satisfies the requirements of this paragraph (f).

(1) *Definitions.* The definitions in this paragraph (f)(1) govern in applying the provisions of this paragraph (f).

(i) *Reward.* Except where expressly provided otherwise, references in this section to an individual obtaining a reward include both obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge or other financial or nonfinancial disincentive). References in this section to a plan providing a reward include both providing a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive).

(ii) *Participatory wellness programs.* If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program. Examples of participatory wellness programs are:

(A) A program that reimburses employees for all or part of the cost for membership in a fitness center.

(B) A diagnostic testing program that provides a reward for participation in that program and does not base any part of the reward on outcomes.

(C) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits. (Note that, with respect to non-grandfathered plans, § 147.130 of this subchapter requires benefits for certain preventive health services without the imposition of cost sharing.)

(D) A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.

(E) A program that provides a reward to employees for attending a monthly, no-cost health education seminar.

(F) A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment. (*See also* § 146.122 for rules prohibiting collection of genetic information.)

(iii) *Health-contingent wellness programs.* A health-contingent wellness program is a program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward). A health-contingent wellness program may be an activity-only wellness program or an outcome-based wellness program.

(iv) *Activity-only wellness programs.* An activity-only wellness program is a type of health-contingent wellness program that requires an individual to perform or complete an activity related to a health factor in order to obtain a reward but does not require the individual to attain or maintain a specific health outcome. Examples include walking, diet, or exercise programs, which some individuals may be unable to participate in or complete (or have difficulty participating in or completing) due to a health factor, such as severe asthma, pregnancy, or a recent surgery. *See* paragraph (f)(3) of this section for requirements applicable to activity-only wellness programs.

(v) *Outcome-based wellness programs.* An outcome-based wellness program is a type of health-contingent wellness program that requires an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward. To comply with the rules of this paragraph (f), an outcome-based wellness program typically has two tiers. That is, for individuals who do not attain or maintain the specific health outcome, compliance with an educational program or an activity may be offered as an alternative to achieve the same reward. This alternative pathway, however, does not mean that the overall program, which has an outcome-based component, is not an outcome-based wellness program. That is, if a measurement, test, or screening is used as part of an initial standard and individuals who meet the standard are granted the reward, the program is considered an outcome-based wellness program. For example, if a wellness program tests individuals for specified medical conditions or risk factors (including biometric screening such as testing for high cholesterol, high blood pressure, abnormal body mass index, or high glucose level) and provides a reward to individuals identified as within a normal or healthy range for these medical conditions or risk factors, while requiring individuals who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, complying with a walking or exercise program, or complying with a health care provider's plan of care) to obtain the same reward, the program is an outcome-based wellness program. *See* paragraph (f)(4) of this section for requirements applicable to outcome-based wellness programs.

(2) *Requirement for participatory wellness programs.* A participatory wellness program, as described in paragraph (f)(1)(ii) of this section, does not violate the provisions of this section only if participation in the program is

made available to all similarly situated individuals, regardless of health status.

(3) *Requirements for activity-only wellness programs.* A health-contingent wellness program that is an activity-only wellness program, as described in paragraph (f)(1)(iv) of this section, does not violate the provisions of this section only if all of the following requirements are satisfied:

(i) *Frequency of opportunity to qualify.* The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) *Size of reward.* The reward for the activity-only wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances.

(iv) *Uniform availability and reasonable alternative standards.* The full reward under the activity-only wellness program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(3)(iv), a reward under an activity-only wellness program is not available to all similarly situated individuals for a period unless the program meets both of the following requirements:

(*1*) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(*2*) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) While plans and issuers are not required to determine a particular reasonable alternative standard in advance of an individual's request for one, if an individual is described in either paragraph (f)(3)(iv)(A)(*1*) or (*2*) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived.

(C) All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(*1*) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted), and may not require an individual to pay for the cost of the program.

(*2*) The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

(*3*) If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.

(*4*) If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(D) To the extent that a reasonable alternative standard under an activity-only wellness program is, itself, an activity-only wellness program, it must comply with the requirements of this paragraph (f)(3) in the same manner as if it were an initial program standard. (Thus, for example, if a plan or issuer provides a walking program as a reasonable alternative standard to a running program, individuals for whom it is unreasonably difficult due to a medical condition to complete the walking program (or for whom it is medically inadvisable to attempt to complete the walking program) must be provided a reasonable alternative standard to the walking program.) To the extent that a reasonable alternative standard under an activity-only wellness program is, itself, an outcome-based wellness program, it must comply with the requirements of paragraph (f)(4) of this section, including paragraph (f)(4)(iv)(D).

(E) If reasonable under the circumstances, a plan or issuer may seek verification, such as a statement from an individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard of an activity-only wellness program. Plans and issuers may seek verification with respect to requests for a reasonable alternative standard for which it is reasonable to determine that medical judgment is required to evaluate the validity of the request.

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an activity-only wellness program the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

(vi) *Example.* The provisions of this paragraph (f)(3) are illustrated by the following example:

Example. (i) *Facts.* A group health plan provides a reward to individuals who participate in a reasonable specified walking program. If it is unreasonably difficult due to a medical condition for an individual to participate (or if it is medically inadvisable for an individual to attempt to participate), the plan will waive the walking program requirement and provide the reward. All

materials describing the terms of the walking program disclose the availability of the waiver.

(ii) *Conclusion.* In this *Example,* the program satisfies the requirements of paragraph (f)(3)(iii) of this section because the walking program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(3)(iv) of this section because the reward under the program is available to all similarly situated individuals. It accommodates individuals for whom it is unreasonably difficult to participate in the walking program due to a medical condition (or for whom it would be medically inadvisable to attempt to participate) by providing them with the reward even if they do not participate in the walking program (that is, by waiving the condition). The plan also complies with the disclosure requirement of paragraph (f)(3)(v) of this section. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

(4) *Requirements for outcome-based wellness programs.* A health-contingent wellness program that is an outcome-based wellness program, as described in paragraph (f)(1)(v) of this section, does not violate the provisions of this section only if all of the following requirements are satisfied:

(i) *Frequency of opportunity to qualify.* The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) *Size of reward.* The reward for the outcome-based wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(4)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances. To ensure that an outcome-based wellness program is reasonably designed to improve health and does not act as a subterfuge for underwriting or reducing benefits based on a health factor, a reasonable alternative standard to qualify for the reward must be provided to any individual who does not meet the initial standard based on a measurement, test, or screening that is related to a health factor, as explained in paragraph (f)(4)(iv) of this section.

(iv) *Uniform availability and reasonable alternative standards.* The full reward under the outcome-based wellness program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(4)(iv), a reward under an outcome-based wellness program is not available to all similarly situated individuals for a period unless the program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual who does not meet the initial standard based on the measurement, test, or screening, as described in this paragraph (f)(4)(iv).

(B) While plans and issuers are not required to determine a particular reasonable alternative standard in advance of an individual's request for one, if an individual is described in paragraph (f)(4)(iv)(A) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived.

(C) All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(*1*) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted), and may not require an individual to pay for the cost of the program.

(*2*) The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

(*3*) If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.

(*4*) If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(D) To the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, an activity-only wellness program, it must comply with the requirements of paragraph (f)(3) of this section in the same manner as if it were an initial program standard. To the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, another outcome-based wellness program, it must comply with the requirements of this paragraph (f)(4), subject to the following special rules:

(*1*) The reasonable alternative standard cannot be a requirement to meet a different level of the same standard without additional time to comply that takes into account the individual's circumstances. For example, if the initial standard is to achieve a BMI less than 30, the reasonable alternative standard cannot be to achieve a BMI less than 31 on that same date. However, if the initial standard is to achieve a BMI less than 30, a reasonable alternative standard for the individual could be to reduce the individual's BMI by a small amount or small percentage, over a realistic period of time, such as within a year.

(*2*) An individual must be given the opportunity to comply with the recommendations of the individual's personal physician as a second reasonable alternative standard to meeting the reasonable alternative standard defined by the plan or issuer, but only if the physician joins in the request. The individual can make a request to involve a personal physician's recommendations at any time and the personal physician can adjust the physician's recommendations at any time, consistent with medical appropriateness.

(E) It is not reasonable to seek verification, such as a statement from an individual's personal physician, under an outcome-based wellness program that a health factor makes it

unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard as a condition of providing a reasonable alternative to the initial standard. However, if a plan or issuer provides an alternative standard to the otherwise applicable measurement, test, or screening that involves an activity that is related to a health factor, then the rules of paragraph (f)(3) of this section for activity-only wellness programs apply to that component of the wellness program and the plan or issuer may, if reasonable under the circumstances, seek verification that it is unreasonably difficult due to a medical condition for an individual to perform or complete the activity (or it is medically inadvisable to attempt to perform or complete the activity). (For example, if an outcome-based wellness program requires participants to maintain a certain healthy weight and provides a diet and exercise program for individuals who do not meet the targeted weight, a plan or issuer may seek verification, as described in paragraph (f)(3)(iv)(D) of this section, if reasonable under the circumstances, that a second reasonable alternative standard is needed for certain individuals because, for those individuals, it would be unreasonably difficult due to a medical condition to comply, or medically inadvisable to attempt to comply, with the diet and exercise program, due to a medical condition.)

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an outcome-based wellness program, and in any disclosure that an individual did not satisfy an initial outcome-based standard, the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

(vi) *Examples.* The provisions of this paragraph (f)(4) are illustrated by the following examples:

Example 1—Cholesterol screening with reasonable alternative standard to work with personal physician. (i) *Facts.* A group health plan offers a reward to participants who achieve a count under 200 on a total cholesterol test. If a participant does not achieve the targeted cholesterol count, the plan allows the participant to develop an alternative cholesterol action plan in conjunction with the participant's personal physician that may include recommendations for medication and additional screening. The plan allows the physician to modify the standards, as medically necessary, over the year. (For example, if a participant develops asthma or depression, requires surgery and convalescence, or some other medical condition or consideration makes completion of the original action plan inadvisable or unreasonably difficult, the physician may modify the original action plan.) All plan materials describing the terms of the program include the following statement: ''Your health plan wants to help you take charge of your health. Rewards are available to all employees who participate in our Cholesterol Awareness Wellness Program. If your total cholesterol count is under 200, you will receive the reward. If not, you will still have an opportunity to qualify for the reward. We will work with you and your doctor to find a Health Smart program that is right for you.'' In addition, when any individual participant receives notification that his or her cholesterol count is 200 or higher, the notification includes the following statement: ''Your plan offers a Health Smart program under which we will work with you and your doctor to try to lower your cholesterol. If you complete this program, you will qualify for a reward. Please contact us at [contact information] to get started.''

(ii) *Conclusion.* In this *Example 1,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health outcome (a certain cholesterol level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because the cholesterol program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes available to all participants who do not meet the cholesterol standard a reasonable alternative standard to qualify for the reward. Lastly, the plan also discloses in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard the availability of a reasonable alternative standard (including contact information and the individual's ability to involve his or her personal physician), as required by paragraph (f)(4)(v) of this section. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 2—Cholesterol screening with plan alternative and no opportunity for personal physician involvement. (i) *Facts.* Same facts as *Example 1,* except that the wellness program's physician or nurse practitioner (rather than the individual's personal physician) determines the alternative cholesterol action plan. The plan does not provide an opportunity for a participant's personal physician to modify the action plan if it is not medically appropriate for that individual.

(ii) *Conclusion.* In this *Example 2,* the wellness program does not satisfy the requirements of paragraph (f)(4)(iii) of this section because the program does not accommodate the recommendations of the participant's personal physician with regard to medical appropriateness, as required under paragraph (f)(4)(iv)(C)(*3*) of this section. Thus, the program is not reasonably designed under paragraph (f)(4)(iii) of this section and is not available to all similarly situated individuals under paragraph (f)(4)(iv) of this section. The notice also does not provide all the content required under paragraph (f)(4)(v) of this section.

Example 3—Cholesterol screening with plan alternative that can be modified by personal physician. (i) *Facts.* Same facts as *Example 2,* except that if a participant's personal physician disagrees with any part of the action plan, the personal physician may modify the action plan at any time, and the plan discloses this to participants.

(ii) *Conclusion.* In this *Example 3,* the wellness program satisfies the requirements of paragraph (f)(4)(iii) of this section because the participant's personal physician may modify the action plan determined by the wellness program's physician or nurse practitioner at any time if the physician states that the recommendations are not medically appropriate, as required under paragraph (f)(4)(iv)(C)(*3*) of this section. Thus, the program is reasonably designed under paragraph (f)(4)(iii) of this section and is available to all similarly situated individuals under paragraph (f)(4)(iv) of this section. The notice, which includes a statement that recommendations of an individual's personal physician will be accommodated, also complies with paragraph (f)(4)(v) of this section.

Example 4—BMI screening with walking program alternative. (i) *Facts.* A group health plan will provide a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is unreasonably difficult due to a medical condition to comply with this walking program (and any participant for whom it is medically inadvisable to attempt to comply with the walking program) during the year is given the same discount if the participant satisfies an alternative standard that is reasonable taking into consideration the participant's medical situation, is not unreasonably burdensome or impractical to comply with, and is otherwise reasonably designed based on all the relevant facts and circumstances. All plan materials describing the terms of the wellness program include the following statement: ''Fitness is Easy! Start Walking! Your health plan cares about your health. If you are considered overweight because you have a BMI of over 26, our Start Walking program will help you lose weight and feel better. We will help you enroll. (**If your doctor says that walking

isn't right for you, that's okay too. We will work with you (and, if you wish, your own doctor) to develop a wellness program that is.)'' Participant *E* is unable to achieve a BMI that is 26 or lower within the plan's timeframe and receives notification that complies with paragraph (f)(4)(v) of this section. Nevertheless, it is unreasonably difficult due to a medical condition for *E* to comply with the walking program. *E* proposes a program based on the recommendations of *E*'s physician. The plan agrees to make the same discount available to *E* that is available to other participants in the BMI program or the alternative walking program, but only if *E* actually follows the physician's recommendations.

(ii) *Conclusion.* In this *Example 4,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health outcome (a certain BMI level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because it is reasonably designed to promote health and prevent disease. The program also satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes available to all individuals who do not satisfy the BMI standard a reasonable alternative standard to qualify for the reward (in this case, a walking program that is not unreasonably burdensome or impractical for individuals to comply with and that is otherwise reasonably designed based on all the relevant facts and circumstances). In addition, the walking program is, itself, an activity-only standard and the plan complies with the requirements of paragraph (f)(3) of this section (including the requirement of paragraph (f)(3)(iv) that, if there are individuals for whom it is unreasonably difficult due to a medical condition to comply, or for whom it is medically inadvisable to attempt to comply, with the walking program, the plan provide a reasonable alternative to those individuals). Moreover, the plan satisfies the requirements of paragraph (f)(4)(v) of this section because it discloses, in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard, the availability of a reasonable alternative standard (including contact information and the individual's option to involve his or her personal physician) to qualify for the reward or the possibility of waiver of the otherwise applicable standard. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 5—BMI screening with alternatives available to either lower BMI or meet personal physician's recommendations. (i) *Facts.* Same facts as *Example 4* except that, with respect to any participant who does not meet the target BMI, instead of a walking program, the participant is expected to reduce BMI by one point. At any point during the year upon request, any individual can obtain a second reasonable alternative standard, which is compliance with the recommendations of the participant's personal physician regarding weight, diet, and exercise as set forth in a treatment plan that the physician recommends or to which the physician agrees. The participant's personal physician is permitted to change or adjust the treatment plan at any time and the option of following the participant's personal physician's recommendations is clearly disclosed.

(ii) *Conclusion.* In this *Example 5,* the reasonable alternative standard to qualify for the reward (the alternative BMI standard requiring a one-point reduction) does not make the program unreasonable under paragraph (f)(4)(iii) or (iv) of this section because the program complies with paragraph (f)(4)(iv)(C)(*4*) of this section by allowing a second reasonable alternative standard to qualify for the reward (compliance with the recommendations of the participant's personal physician, which can be changed or adjusted at any time). Accordingly, the program continues to satisfy the applicable requirements of paragraph (f) of this section.

Example 6—Tobacco use surcharge with smoking cessation program alternative. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a premium differential based on tobacco use, determined using a health risk assessment. The following statement is included in all plan materials describing the tobacco premium differential: ''Stop smoking today! We can help! If you are a smoker, we offer a smoking cessation program. If you complete the program, you can avoid this surcharge.'' The plan accommodates participants who smoke by facilitating their enrollment in a smoking cessation program that requires participation at a time and place that are not unreasonably burdensome or impractical for participants, and that is otherwise reasonably designed based on all the relevant facts and circumstances, and discloses contact information and the individual's option to involve his or her personal physician. The plan pays for the cost of participation in the smoking cessation program. Any participant can avoid the surcharge for the plan year by participating in the program, regardless of whether the participant stops smoking, but the plan can require a participant who wants to avoid the surcharge in a subsequent year to complete the smoking cessation program again.

(ii) *Conclusion.* In this *Example 6,* the premium differential satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v). The program is an outcome-based wellness program because the initial standard for obtaining a reward is dependent on the results of a health risk assessment (a measurement, test, or screening). The program is reasonably designed under paragraph (f)(4)(iii) because the plan provides a reasonable alternative standard (as required under paragraph (f)(4)(iv) of this section) to qualify for the reward to all tobacco users (a smoking cessation program). The plan discloses, in all materials describing the terms of the program, the availability of the reasonable alternative standard (including contact information and the individual's option to involve his or her personal physician). Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 7—Tobacco use surcharge with alternative program requiring actual cessation. (i) *Facts.* Same facts as *Example 6,* except the plan does not provide participant *F* with the reward in subsequent years unless *F* actually stops smoking after participating in the tobacco cessation program.

(ii) *Conclusion.* In this *Example 7,* the program is not reasonably designed under paragraph (f)(4)(iii) of this section and does not provide a reasonable alternative standard as required under paragraph (f)(4)(iv) of this section. The plan cannot cease to provide a reasonable alternative standard merely because the participant did not stop smoking after participating in a smoking cessation program. The plan must continue to offer a reasonable alternative standard whether it is the same or different (such as a new recommendation from *F*'s personal physician or a new nicotine replacement therapy).

Example 8—Tobacco use surcharge with smoking cessation program alternative that is not reasonable. (i) *Facts.* Same facts as *Example 6,* except the plan does not facilitate participant *F*'s enrollment in a smoking cessation program. Instead the plan advises *F* to find a program, pay for it, and provide a certificate of completion to the plan.

(ii) *Conclusion.* In this *Example 8,* the requirement for *F* to find and pay for *F*'s own smoking cessation program means that the alternative program is not reasonable. Accordingly, the plan has not offered a reasonable alternative standard that complies with paragraphs (f)(4)(iii) and (iv) of this section and the program fails to satisfy the requirements of paragraph (f) of this section.

(5) *Applicable percentage*—(i) For purposes of this paragraph (f), the applicable percentage is 30 percent, except that the applicable percentage is increased by an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use.

(ii) The rules of this paragraph (f)(5) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan. The annual premium for employee-only coverage is $6,000 (of which the employer pays $4,500 per year and the employee pays $1,500 per year). The plan offers employees a health-contingent wellness program with several components, focused on exercise, blood sugar, weight, cholesterol, and blood pressure. The reward for compliance is an annual premium rebate of $600.

(ii) *Conclusion.* In this *Example 1,* the reward for the wellness program, $600, does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage, $1,800. ($6,000 × 30% = $1,800.)

Example 2. (i) *Facts.* Same facts as *Example 1,* except the wellness program is exclusively a tobacco prevention program. Employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program are charged a $1,000 premium surcharge (in addition to their employee contribution towards the

coverage). (Those who participate in the plan's tobacco cessation program are not assessed the $1,000 surcharge.)

(ii) *Conclusion.* In this *Example 2,* the reward for the wellness program (absence of a $1,000 surcharge), does not exceed the applicable percentage of 50 percent of the total annual cost of employee-only coverage, $3,000. ($6,000 × 50% = $3,000.)

Example 3. (i) *Facts.* Same facts as *Example 1,* except that, in addition to the $600 reward for compliance with the health-contingent wellness program, the plan also imposes an additional $2,000 tobacco premium surcharge on employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program. (Those who participate in the plan's tobacco cessation program are not assessed the $2,000 surcharge.)

(ii) *Conclusion.* In this *Example 3,* the total of all rewards (including absence of a surcharge for participating in the tobacco program) is $2,600 ($600 + $2,000 = $2,600), which does not exceed the applicable percentage of 50 percent of the total annual cost of employee-only coverage ($3,000); and, tested separately, the $600 reward for the wellness program unrelated to tobacco use does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage ($1,800).

Example 4. (i) *Facts.* An employer sponsors a group health plan. The total annual premium for employee-only coverage (including both employer and employee contributions towards the coverage) is $5,000. The plan provides a $250 reward to employees who complete a health risk assessment, without regard to the health issues identified as part of the assessment. The plan also offers a Healthy Heart program, which is a health-contingent wellness program, with an opportunity to earn a $1,500 reward.

(ii) *Conclusion.* In this *Example 4,* even though the total reward for all wellness programs under the plan is $1,750 ($250 + $1,500 = $1,750, which exceeds the applicable percentage of 30 percent of the cost of the annual premium for employee-only coverage ($5,000 × 30% = $1,500)), only the reward offered for compliance with the health-contingent wellness program ($1,500) is taken into account in determining whether the rules of this paragraph (f)(5) are met. (The $250 reward is offered in connection with a participatory wellness program and therefore is not taken into account.) Accordingly, the health-contingent wellness program offers a reward that does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage.

(6) *Sample language.* The following language, or substantially similar language, can be used to satisfy the notice requirement of paragraphs (f)(3)(v) or (f)(4)(v) of this section: ''Your health plan is committed to helping you achieve your best health. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you (and, if you wish, with your doctor) to find a wellness program with the same reward that is right for you in light of your health status.''

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PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL 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 (2010).

■ 10. Section 147.110 is added to read as follows:

§ 147.110 Prohibiting discrimination against participants, beneficiaries, and individuals based on a health factor.

(a) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must comply with all the requirements under 45 CFR 146.121 applicable to a group health plan and a health insurance issuer offering group health insurance coverage. Accordingly, with respect to an issuer offering health insurance coverage in the individual market, the issuer is subject to the requirements of § 146.121 to the same extent as an issuer offering group health insurance coverage, except the exception contained in § 146.121(f) (concerning nondiscriminatory wellness programs) does not apply.

(b) *Applicability date.* This section is applicable to group health plans and health insurance issuers offering group or individual health insurance coverage for plan years (in the individual market, policy years) beginning on or after January 1, 2014. See § 147.140, which provides that the rules of this section do not apply to grandfathered health plans that are individual health insurance coverage.

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