- (2) Additional information that may be required. The notice of special enrollment must also include, if applicable, the notice described in paragraph (a)(3)(iv) of this section (the notice required to be furnished to an individual declining coverage if the plan requires the reason for declining coverage to be in writing).
- (d) Treatment of special enrollees—(1) If an individual requests enrollment while the individual is entitled to special enrollment under either paragraph (a) or (b) of this section, the individual is a special enrollee, even if the request for enrollment coincides with a late enrollment opportunity under the plan. Therefore, the individual cannot be treated as a late enrollee.
- (2) Special enrollees must be offered all the benefit packages available to similarly situated individuals who enroll when first eligible. For this purpose, any difference in benefits or costsharing requirements for different individuals constitutes a different benefit package. In addition, a special enrollee cannot be required to pay more for coverage than a similarly situated individual who enrolls in the same coverage when first eligible.
- (3) The rules of this section are illustrated by the following example:

Example. (i) Facts. Employer Y maintains a group health plan that has an enrollment period for late enrollees every November 1 through November 30 with coverage effective the following January 1. On October 18, Individual B loses coverage under another group health plan and satisfies the requirements of paragraphs (a)(2), (3), and (4) of this section. B submits a completed application for coverage on November 2.

(ii) Conclusion. In this Example, B is a special enrollee. Therefore, even though B's request for enrollment coincides with an open enrollment period, B's coverage is required to be made effective no later than December 1 (rather than the plan's January 1 effective date for late enrollees).

[69 FR 78794, Dec. 30, 2004, as amended at 79 FR 10314, Feb. 24, 2014]

# § 146.119 HMO affiliation period as an alternative to a preexisting condition exclusion.

The rules for HMO affiliation periods have been superseded by the prohibition on preexisting condition exclusions. See § 147.108 of this subchapter for

rules prohibiting the imposition of a preexisting condition exclusion.

[79 FR 10314, Feb. 24, 2014]

## § 146.120 Interaction with the Family and Medical Leave Act. [Reserved]

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

- (a) Health factors. (1) The term health factor means, in relation to an individual, any of the following health status-related factors:
  - (i) Health status:
- (ii) Medical condition (including both physical and mental illnesses), as defined in §144.103 of this chapter;
  - (iii) Claims experience;
  - (iv) Receipt of health care;
  - (v) Medical history;
- (vi) Genetic information, as defined in §146.122(a) of this subchapter;
  - (vii) Evidence of insurability; or
  - (viii) Disability.
- $\begin{array}{ccc} \hbox{(2)} & \hbox{Evidence} & \hbox{of} & \hbox{insurability} & \hbox{includes} \\ \hline \end{array}$
- (i) Conditions arising out of acts of domestic violence; and
- (ii) Participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities.
- (3) The decision whether health coverage is elected for an individual (including the time chosen to enroll, such as under special enrollment or late enrollment) is not, itself, within the scope of any health factor. (However, under §146.117, a plan or issuer must treat special enrollees the same as similarly situated individuals who are enrolled when first eligible.)
- (b) Prohibited discrimination in rules for eligibility—(1) In general—42V3(4839):

As used in this part, unless the context indicates otherwise—(i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not establish any rule for eligibility (including continued eligibility) of any individual to enroll for benefits under the terms of the plan or group health insurance coverage that discriminates based on any health factor that relates to that individual or a dependent of that individual. This rule

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is subject to the provisions of paragraph (b)(2) of this section (explaining how this rule applies to benefits), paragraph (d) of this section (containing rules for establishing groups of similarly situated individuals), paragraph (e) of this section (relating to nonconfinement, actively-at-work, and other service requirements), paragraph (f) of this section (relating to wellness programs), and paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors).

- (ii) For purposes of this section, rules for eligibility include, but are not limited to, rules relating to—
  - (A) Enrollment;
  - (B) The effective date of coverage;
  - (C) Waiting (or affiliation) periods;
  - (D) Late and special enrollment;
- (E) Eligibility for benefit packages (including rules for individuals to change their selection among benefit packages);
- (F) Benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles), as described in paragraphs (b)(2) and (b)(3) of this section;
  - (G) Continued eligibility; and
- (H) Terminating coverage (including disenrollment) of any individual under the plan.
- (iii) The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan that is available to all employees who enroll within the first 30 days of their employment. However, employees who do not enroll within the first 30 days cannot enroll later unless they pass a physical examination.

(ii) Conclusion. In this Example 1, the requirement to pass a physical examination in order to enroll in the plan is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 2. (i) Facts. Under an employer's group health plan, employees who enroll during the first 30 days of employment (and during special enrollment periods) may choose between two benefit packages: an indemnity option and an HMO option. However, employees who enroll during late enrollment are permitted to enroll only in the HMO option and only if they provide evidence of good health.

(ii) Conclusion. In this Example 2, the requirement to provide evidence of good health in order to be eligible for late enrollment in the HMO option is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1). However, if the plan did not require evidence of good health but limited late enrollees to the HMO option, the plan's rules for eligibility would not discriminate based on any health factor, and thus would not violate this paragraph (b)(1), because the time an individual chooses to enroll is not, itself, within the scope of any health factor.

Example 3. (i) Facts. Under an employer's group health plan, all employees generally may enroll within the first 30 days of employment. However, individuals who participate in certain recreational activities, including motorcycling, are excluded from coverage.

(ii) Conclusion. In this Example 3, excluding from the plan individuals who participate in recreational activities, such as motorcycling, is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 4. (i) Facts. A group health plan applies for a group health policy offered by an issuer. As part of the application, the issuer receives health information about individuals to be covered under the plan. Individual A is an employee of the employer maintaining the plan. A and A's dependents have a history of high health claims. Based on the information about A and A's dependents, the issuer excludes A and A's dependents from the group policy it offers to the employer.

- (ii) Conclusion. In this Example 4, the issuer's exclusion of A and A's dependents from coverage is a rule for eligibility that discriminates based on one or more health factors, and thus violates this paragraph (b)(1). (If the employer is a small employer under 45 CFR 144.103 (generally, an employer with 50 or fewer employees), the issuer also may violate 45 CFR 146.150, which requires issuers to offer all the policies they sell in the small group market on a guaranteed available basis to all small employers and to accept every eligible individual in every small employer group.) If the plan provides coverage through this policy and does not provide equivalent coverage for A and A's dependents through other means, the plan will also violate this paragraph (b)(1).
- (2) Application to benefits—(i) General rule—(A) Under this section, a group health plan or group health insurance issuer is not required to provide coverage for any particular benefit to any group of similarly situated individuals.

(B) However, benefits provided under a plan must be uniformly available to all similarly situated individuals (as described in paragraph (d) of this section). Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances). Thus, for example, a plan may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan or issuer may require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In the case of a cost-sharing requirement, see also paragraph (b)(2)(ii) of this section, which permits variances in the application of a cost-sharing mechanism made available under a wellness program. (Whether any plan provision or practice with respect to benefits complies with this paragraph (b)(2)(i) does not affect whether the provision or practice is permitted under ERISA, the Affordable Care Act (including the requirements related to essential health benefits), the Americans with Disabilities Act, or any other law, whether State or Federal.)

(C) For purposes of this paragraph (b)(2)(i), a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not

considered to be directed at any individual participants or beneficiaries.

(D) The rules of this paragraph (b)(2)(i) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan applies a \$10,000 annual limit on a specific covered benefit that is not an essential health benefit to each participant or beneficiary covered under the plan. The limit is not directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 1, the limit does not violate this paragraph (b)(2)(1) because coverage of the specific, non-essential health benefit up to \$10,000 is available uniformly to each participant and beneficiary under the plan and because the limit is applied uniformly to all participants and beneficiaries and is not directed at individual participants or beneficiaries.

Example 2. (i) Facts. A group health plan has a \$500 deductible on all benefits for participants covered under the plan. Participants a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a \$2,000 deductible on benefits for the treatment of AIDS, effective before the beginning of the next plan year.

(ii) Conclusion. The facts of this Example 2 strongly suggest that the plan modification is directed at B based on B's claim. Absent outweighing evidence to the contrary, the plan violates this paragraph (b)(2)(i).

Example 3. (i) A group health plan applies for a group health policy offered by an issuer. Individual C is covered under the plan and has an adverse health condition. As part of the application, the issuer receives health information about the individuals to be covered, including information about C's adverse health condition. The policy form offered by the issuer generally provides benefits for the adverse health condition that C has, but in this case the issuer offers the plan a policy modified by a rider that excludes benefits for C for that condition. The exclusionary rider is made effective the first day of the next plan year.

(ii) Conclusion. In this Example 3, the issuer violates this paragraph (b)(2)(i) because benefits for C's condition are available to other individuals in the group of similarly situated individuals that includes C but are not available to C. Thus, the benefits are not uniformly available to all similarly situated individuals. Even though the exclusionary rider is made effective the first day of the next plan year, because the rider does not apply to all similarly situated individuals, the issuer violates this paragraph (b)(2)(i).

Example 4. (i) Facts. A group health plan has a \$2,000 lifetime limit for the treatment of temporomandibular joint syndrome

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(TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 4, the limit does not violate this paragraph (b)(2)(i) because \$2,000 of benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries. (However, applying a lifetime limit on TMJ may violate §147.126 of this subchapter, if TMJ coverage is an essential health benefit, depending on the essential health benefits benchmark plan as defined in §156.20 of this subchapter. This example does not address whether the plan provision is permissible under any other applicable law, including PHS Act section 2711 or the Americans with Disabilities Act.)

Example 5. (i) Facts. A group health plan applies a \$2 million lifetime limit on all benefits. However, the \$2 million lifetime limit is reduced to \$10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.

(ii) Conclusion. In this Example 5, the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals. Additionally, this plan provision is prohibited under §147.126 of this subchapter because it imposes a lifetime limit on essential health benefits.

Example 6. (i) Facts. A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 6, the exclusion from coverage of drugs not listed on the drug formulary does not violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 7. (i) Facts. Under a group health plan, doctor visits are generally subject to a \$250 annual deductible and 20 percent coinsurance requirement. However, prenatal doctor visits are not subject to any deductible or coinsurance requirement. These rules are applied uniformly to all similarly situated individuals and are not directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 7, imposing different deductible and coinsurance requirements for prenatal doctor visits and other visits does not violate this paragraph (b)(2)(i) because a plan may establish different deductibles or coinsurance requirements for different services if the deductible or coinsurance requirement is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries

(ii) Exception for wellness programs. A group health plan or group health insurance issuer may vary benefits, including cost-sharing mechanisms (such as a deductible, copayment, or coinsurance), based on whether an individual has met the standards of a wellness program that satisfies the requirements of paragraph (f) of this section.

(iii) Specific rule relating to source-ofinjury exclusions—(A) If a group health plan or group health insurance coverage generally provides benefits for a type of injury, the plan or issuer may not deny benefits otherwise provided for treatment of the injury if the injury results from an act of domestic violence or a medical condition (including both physical and mental health conditions). This rule applies in the case of an injury resulting from a medical condition even if the condition is not diagnosed before the injury.

(B) The rules of this paragraph (b)(2)(iii) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan generally provides medical/surgical benefits, including benefits for hospital stays, that are medically necessary. However, the plan excludes benefits for self-inflicted injuries or injuries sustained in connection with attempted suicide. Because of depression, Individual D attempts suicide. As a result, D sustains injuries and is hospitalized for treatment of the injuries. Under the exclusion, the plan denies D benefits for treatment of the injuries.

(ii) Conclusion. In this Example 1, the suicide attempt is the result of a medical condition (depression). Accordingly, the denial of benefits for the treatments of D's injuries violates the requirements of this paragraph (b)(2)(iii) because the plan provision excludes benefits for treatment of an injury resulting from a medical condition.

Example 2. (i) Facts. A group health plan provides benefits for head injuries generally. The plan also has a general exclusion for any injury sustained while participating in any

of a number of recreational activities, including bungee jumping. However, this exclusion does not apply to any injury that results from a medical condition (nor from domestic violence). Participant E sustains a head injury while bungee jumping. The injury did not result from a medical condition (nor from domestic violence). Accordingly, the plan denies benefits for E's head injury.

- (ii) Conclusion. In this Example 2, the plan provision that denies benefits based on the source of an injury does not restrict benefits based on an act of domestic violence or any medical condition. Therefore, the provision is permissible under this paragraph (b)(2)(iii) and does not violate this section. (However, if the plan did not allow E to enroll in the plan (or applied different rules for eligibility to E) because E frequently participates in bungee jumping, the plan would violate paragraph (b)(1) of this section.)
- (c) Prohibited discrimination in premiums or contributions—(1) In general. (i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require an individual, as a condition of enrollment or continued enrollment under the plan or group health insurance coverage, to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual (described in paragraph (d) of this section) enrolled in the plan or group health insurance coverage based on any health factor that relates to the individual or a dependent of the individual.
- (ii) Discounts, rebates, payments in kind, and any other premium differential mechanisms are taken into account in determining an individual's premium or contribution rate. (For rules relating to cost-sharing mechanisms, see paragraph (b)(2) of this section (addressing benefits).)
- (2) Rules relating to premium rates—(i) Group rating based on health factors not restricted under this section. Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan. But see §146.122(b) of this part, which prohibits adjustments in group premium or contribution rates based on genetic information.
- (ii) List billing based on a health factor prohibited. However, a group health insurance issuer, or a group health plan, may not quote or charge an employer

(or an individual) a different premium for an individual in a group of similarly situated individuals based on a health factor. (But see paragraph (g) of this section permitting favorable treatment of individuals with adverse health factors.)

(iii) *Examples*. The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual F had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of F's claims experience.

- (ii) Conclusion. In this Example 1, the issuer does not violate the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for F than for a similarly situated individual based on F's claims experience. (However, if the issuer used genetic information in computing the group rate, it would violate §146.122(b) of this part.)
- Example 2. (i) Facts. Same facts as Example I, except that the issuer quotes the employer a higher premium rate for F, because of F's claims experience, than for a similarly situated individual.
- (ii) Conclusion. In this Example 2, the issuer violates this paragraph (c)(2). Moreover, even if the plan purchased the policy based on the quote but did not require a higher participant contribution for F than for a similarly situated individual, the issuer would still violate this paragraph (c)(2) (but in such a case the plan would not violate this paragraph (c)(2)).
- (3) Exception for wellness programs. Notwithstanding paragraphs (c)(1) and (c)(2) of this section, a plan or issuer may vary the amount of premium or contribution it requires similarly situated individuals to pay based on whether an individual has met the standards of a wellness program that satisfies the requirements of paragraph (f) of this section.
- (d) Similarly situated individuals. The requirements of this section apply only within a group of individuals who are

treated as similarly situated individuals. A plan or issuer may treat participants as a group of similarly situated individuals separate from beneficiaries. In addition, participants may be treated as two or more distinct groups of similarly situated individuals and beneficiaries may be treated as two or more distinct groups of similarly situated individuals in accordance with the rules of this paragraph (d). Moreover, if individuals have a choice of two or more benefit packages, individuals choosing one benefit package may be treated as one or more groups of similarly situated individuals distinct from individuals choosing another benefit

(1) Participants. Subject to paragraph (d)(3) of this section, a plan or issuer may treat participants as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of participants is based on a bona fide employment-based classification consistent with the emplover's usual business practice. Whether an employment-based classification is bona fide is determined on the basis of all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Subject to paragraph (d)(3) of this section, examples of classifications that, based on all the relevant facts and circumstances, may be bona fide include full-time versus parttime status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee former employee status, and different occupations. However, a classification based on any health factor is not a bona fide employment-based classification, unless the requirements of paragraph (g) of this section are satisfied (permitting favorable treatment of individuals with adverse health factors).

(2) Beneficiaries. (i) Subject to paragraph (d)(3) of this section, a plan or issuer may treat beneficiaries as two or more distinct groups of similarly situated individuals if the distinction be-

tween or among the groups of beneficiaries is based on any of the following factors:

- (A) A bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage:
- (B) Relationship to the participant (for example, as a spouse or as a dependent child);
  - (C) Marital status;
- (D) With respect to children of a participant, age or student status; or
- (E) Any other factor if the factor is not a health factor.
- (ii) Paragraph (d)(2)(i) of this section does not prevent more favorable treatment of individuals with adverse health factors in accordance with paragraph (g) of this section.
- (3) Discrimination directed at individuals. Notwithstanding paragraphs (d)(1) and (d)(2) of this section, if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. the classification is not permitted under this paragraph (d), unless it is permitted under paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors). Thus, if an employer modified an employment-based classification to single out, based on a health factor, individual participants and beneficiaries and deny them health coverage, the new classification would not be permitted under this section.
- (4) Examples. The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan for full-time employees only. Under the plan (consistent with the employer's usual business practice), employees who normally work at least 30 hours per week are considered to be working full-time. Other employees are considered to be working part-time. There is no evidence to suggest that the classification is directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 1, treating the full-time and part-time employees as two separate groups of similarly situated individuals is permitted under this paragraph (d) because the classification is bona fide and is not directed at individual participants or beneficiaries.

Example 2. (i) Facts. Under a group health plan, coverage is made available to employees, their spouses, and their children. However, coverage is made available to a child only if the child is under age 26 (or under age 29 if the child is continuously enrolled fulltime in an institution of higher learning (full-time students)). There is no evidence to suggest that these classifications are directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 2, treating spouses and children differently by imposing an age limitation on children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and children is permitted under paragraph (d)(2) of this section and is not prohibited under paragraph (d)(3) of this section because it is not directed at individual participants or beneficiaries. It is also permissible to treat children who are under age 26 (or full-time students under age 29) as a group of similarly situated individuals separate from those who are age 26 or older (or age 29 or older if they are not full-time students) because the classification is permitted under paragraph (d)(2) of this section and is not directed at individual participants or beneficiaries.

Example 3. (i) Facts. A university sponsors a group health plan that provides one health benefit package to faculty and another health benefit package to other staff. Faculty and staff are treated differently with respect to other employee benefits such as retirement benefits and leaves of absence. There is no evidence to suggest that the distinction is directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 3, the classification is permitted under this paragraph (d) because there is a distinction based on a bona fide employment-based classification consistent with the employer's usual business practice and the distinction is not directed at individual participants and beneficiaries.

Example 4. (i) Facts. An employer sponsors a group health plan that is available to all current employees. Former employees may also be eligible, but only if they complete a specified number of years of service, are enrolled under the plan at the time of termination of employment, and are continuously enrolled from that date. There is no evidence to suggest that these distinctions are directed at individual participants or beneficiaries.

(ii) Conclusion. In this Example 4, imposing additional eligibility requirements on former employees is permitted because a classification that distinguishes between current and former employees is a bona fide employment-based classification that is permitted under this paragraph (d), provided that it is not directed at individual participants or

beneficiaries. In addition, it is permissible to distinguish between former employees who satisfy the service requirement and those who do not, provided that the distinction is not directed at individual participants or beneficiaries. (However, former employees who do not satisfy the eligibility criteria may, nonetheless, be eligible for continued coverage pursuant to a COBRA continuation provision or similar State law.)

Example 5. (i) Facts. An employer sponsors a group health plan that provides the same benefit package to all seven employees of the employer. Six of the seven employees have the same job title and responsibilities, but Employee G has a different job title and different responsibilities. After G files an expensive claim for benefits under the plan, coverage under the plan is modified so that employees with G's job title receive a different benefit package that includes a higher deductible than in the benefit package made available to the other six employees.

- (ii) Conclusion. Under the facts of this Ex-ample 5, changing the coverage classification for G based on the existing employment classification for G is not permitted under this paragraph (d) because the creation of the new coverage classification for G is directed at G based on one or more health factors.
- (e) Nonconfinement and actively-atwork provisions—(1) Nonconfinement provisions—(i) General rule. Under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is confined to a hospital or other health care institution. In addition, under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility or set any individual's premium or contribution rate based on an individual's ability to engage in normal life activities, except to the extent permitted under paragraphs (e)(2)(ii) and (e)(3) of this section (permitting plans and issuers, under certain circumstances, to distinguish among employees based on the performance of services).
- (ii) *Examples*. The rules of this paragraph (e)(1) are illustrated by the following examples:

Example 1. (i) Facts. Under a group health plan, coverage for employees and their dependents generally becomes effective on the first day of employment. However, coverage for a dependent who is confined to a hospital

or other health care institution does not become effective until the confinement ends.

(ii) Conclusion. In this Example 1, the plan violates this paragraph (e)(1) because the plan delays the effective date of coverage for dependents based on confinement to a hospital or other health care institution.

Example 2. (i) Facts. In previous years, a group health plan has provided coverage through a group health insurance policy offered by Issuer M. However, for the current year, the plan provides coverage through a group health insurance policy offered by Issuer N. Under Issuer N's policy, items and services provided in connection with the confinement of a dependent to a hospital or other health care institution are not covered if the confinement is covered under an extension of benefits clause from a previous health insurance issuer.

(ii) Conclusion. In this Example 2, Issuer N violates this paragraph (e)(1) because the group health insurance coverage restricts benefits (a rule for eligibility under paragraph (b)(1)) based on whether a dependent is confined to a hospital or other health care institution that is covered under an extension of benefits clause from a previous issuer. State law cannot change the obligation of Issuer N under this section. However, under State law Issuer M may also be responsible for providing benefits to such a dependent. In a case in which Issuer N has an obligation under this section to provide benefits and Issuer M has an obligation under State law to provide benefits, any State laws designed to prevent more than 100% reimbursement, such as State coordination-ofbenefits laws, continue to apply.

(2) Actively-at-work and continuous service provisions—(i) General rule. (A) Under the rules of paragraphs (b) and (c) of this section and subject to the exception for the first day of work described in paragraph (e)(2)(ii) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is actively at work (including whether an individual is continuously employed), unless absence from work due to any health factor (such as being absent from work on sick leave) is treated, for purposes of the plan or health insurance coverage, as being actively at work.

(B) The rules of this paragraph (e)(2)(i) are illustrated by the following examples:

Example 1. (i) Facts. Under a group health plan, an employee generally becomes eligible

to enroll 30 days after the first day of employment. However, if the employee is not actively at work on the first day after the end of the 30-day period, then eligibility for enrollment is delayed until the first day the employee is actively at work.

(ii) Conclusion. In this Example 1, the plan violates this paragraph (e)(2) (and thus also violates paragraph (b) of this section). However, the plan would not violate paragraph (e)(2) or (b) of this section if, under the plan, an absence due to any health factor is considered being actively at work.

Example 2. (i) Facts. Under a group health plan, coverage for an employee becomes effective after 90 days of continuous service; that is, if an employee is absent from work (for any reason) before completing 90 days of service, the beginning of the 90-day period is measured from the day the employee returns to work (without any credit for service before the absence).

(ii) Conclusion. In this Example 2, the plan violates this paragraph (e)(2) (and thus also paragraph (b) of this section) because the 90-day continuous service requirement is a rule for eligibility based on whether an individual is actively at work. However, the plan would not violate this paragraph (e)(2) or paragraph (b) of this section if, under the plan, an absence due to any health factor is not considered an absence for purposes of measuring 90 days of continuous service. (In addition, any eligibility provision that is time-based must comply with the requirements of PHS Act section 2708 and its implementing regulations.)

(ii) Exception for the first day of work.

(A) Notwithstanding the general rule in paragraph (e)(2)(i) of this section, a plan or issuer may establish a rule for eligibility that requires an individual to begin work for the employer sponsoring the plan (or, in the case of a multiemployer plan, to begin a job in covered employment) before coverage becomes effective, provided that such a rule for eligibility applies regardless of the reason for the absence.

(B) The rules of this paragraph (e)(2)(ii) are illustrated by the following examples:

Example 1. (i) Facts. Under the eligibility provision of a group health plan, coverage for new employees becomes effective on the first day that the employee reports to work. Individual H is scheduled to begin work on August 3. However, H is unable to begin work on that day because of illness. H begins working on August 4, and H's coverage is effective on August 4.

(ii) Conclusion. In this Example 1, the plan provision does not violate this section. However, if coverage for individuals who do not

report to work on the first day they were scheduled to work for a reason unrelated to a health factor (such as vacation or bereavement) becomes effective on the first day they were scheduled to work, then the plan would violate this section.

Example 2. (i) Facts. Under a group health plan, coverage for new employees becomes effective on the first day of the month following the employee's first day of work, regardless of whether the employee is actively at work on the first day of the month. Individual J is scheduled to begin work on March 24. However, J is unable to begin work on March 24 because of illness. J begins working on April 7 and J's coverage is effective May 1.

- (ii) Conclusion. In this Example 2, the plan provision does not violate this section. However, as in Example 1, if coverage for individuals absent from work for reasons unrelated to a health factor became effective despite their absence, then the plan would violate this section
- (3) Relationship to plan provisions defining similarly situated individuals. (i) Notwithstanding the rules of paragraphs (e)(1) and (e)(2) of this section, a plan or issuer may establish rules for eligibility or set any individual's premium or contribution rate in accordance with the rules relating to similarly situated individuals in paragraph (d) of this section. Accordingly, a plan or issuer may distinguish in rules for eligibility under the plan between fulltime and part-time employees, between permanent and temporary or seasonal employees, between current and former employees, and between employees currently performing services and employees no longer performing services for the employer, subject to paragraph (d) of this section. However, other Federal or State laws (including the COBRA continuation provisions and the Family and Medical Leave Act of 1993) may require an employee or the employee's dependents to be offered coverage and set limits on the premium or contribution rate even though the employee is not performing services.
- (ii) The rules of this paragraph (e)(3) are illustrated by the following examples:

Example 1. (i) Facts. Under a group health plan, employees are eligible for coverage if they perform services for the employer for 30 or more hours per week or if they are on paid leave (such as vacation, sick, or bereavement leave). Employees on unpaid leave are treated as a separate group of similarly situated

individuals in accordance with the rules of paragraph (d) of this section.

(ii) Conclusion. In this Example 1, the plan provisions do not violate this section. However, if the plan treated individuals performing services for the employer for 30 or more hours per week, individuals on vacation leave, and individuals on bereavement leave as a group of similarly situated individuals separate from individuals on sick leave, the plan would violate this paragraph (e) (and thus also would violate paragraph (b) of this section) because groups of similarly situated individuals cannot be established based on a health factor (including the taking of sick leave) under paragraph (d) of this section.

Example 2. (i) Facts. To be eligible for coverage under a bona fide collectively bargained group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the three-month period that ends one month before the beginning of the current calendar quarter. The distinction between employees working at least 250 hours and those working less than 250 hours in the earlier three-month period is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.

(ii) Conclusion. In this Example 2, the plan provision does not violate this section because, under the rules for similarly situated individuals allowing full-time employees to be treated differently than part-time employees, employees who work at least 250 hours in a three-month period can be treated differently than employees who fail to work 250 hours in that period. The result would be the same if the plan permitted individuals to apply excess hours from previous periods to satisfy the requirement for the current quarter.

Example 3. (i) Facts. Under a group health plan, coverage of an employee is terminated when the individual's employment is terminated, in accordance with the rules of paragraph (d) of this section. Employee B has been covered under the plan. B experiences a disabling illness that prevents B from working. B takes a leave of absence under the Family and Medical Leave Act of 1993. At the end of such leave, B terminates employment and consequently loses coverage under the plan. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) Conclusion. In this Example 3, the plan provision terminating B's coverage upon B's termination of employment does not violate this section

Example 4. (i) Facts. Under a group health plan, coverage of an employee is terminated when the employee ceases to perform services for the employer sponsoring the plan, in

accordance with the rules of paragraph (d) of this section. Employee C is laid off for three months. When the layoff begins, C's coverage under the plan is terminated. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

- (ii) Conclusion. In this Example 4, the plan provision terminating C's coverage upon the cessation of C's performance of services does not violate this section.
- (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:
- (I) 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)(I) 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 activityonly 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 outcomebased 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 recommenda-

- tions 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 vear.
- (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 appropriate-

(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 physi-

cian 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)(ii) 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 rec-ommendations 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 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)(ii) 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,

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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  $\vartheta$ , 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  $\times$  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  $\times$  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."

(g) More favorable treatment of individuals with adverse health factors permitted—(1) In rules for eligibility. (i) Nothing in this section prevents a group health plan or group health insurance issuer from establishing more favorable rules for eligibility (described in paragraph (b)(1) of this section) for individuals with an adverse health factor, such as disability, than for individuals without the adverse health factor. Moreover, nothing in this section prevents a plan or issuer from charging a higher premium or contribution with respect to individuals with an adverse health factor if they would not be eligible for the coverage were it not for the adverse health factor. (However, other laws, including State insurance laws, may set or limit premium rates; these laws are not affected by this section.)

(ii) The rules of this paragraph (g)(1) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan that generally is available to employees, spouses of employees, and dependent children until age 26. However, dependent children who are disabled are eligible for coverage beyond age 26.

(ii) Conclusion. In this Example 1, the plan provision allowing coverage for disabled dependent children beyond age 26 satisfies this paragraph (g)(1) (and thus does not violate this section).

Example 2. (i) Facts. An employer sponsors a group health plan, which is generally available to employees (and members of the employee's family) until the last day of the month in which the employee ceases to perform services for the employer. The plan generally charges employees \$50 per month for employee-only coverage and \$125 per month for family coverage. However, an employee who ceases to perform services for the employer by reason of disability may remain covered under the plan until the last day of the month that is 12 months after the month in which the employee ceased to perform services for the employer. During this extended period of coverage, the plan charges the employee \$100 per month for employeeonly coverage and \$250 per month for family coverage. (This extended period of coverage is without regard to whatever rights the emplovee (or members of the employee's family) may have for COBRA continuation cov-

(ii) Conclusion. In this Example 2, the plan provision allowing extended coverage for dis-

abled employees and their families satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled employees a higher premium during the extended period of coverage.

Example 3. (i) Facts. To comply with the requirements of a COBRA continuation provision, a group health plan generally makes COBRA continuation coverage available for a maximum period of 18 months in connection with a termination of employment but makes the coverage available for a maximum period of 29 months to certain disabled individuals and certain members of the disabled individual's family. Although the plan generally requires payment of 102 percent of the applicable premium for the first 18 months of COBRA continuation coverage, the plan requires payment of 150 percent of the applicable premium for the disabled individual's COBRA continuation coverage during the disability extension if the disabled individual would not be entitled to COBRA continuation coverage but for the disability.

- (ii) Conclusion. In this Example 3, the plan provision allowing extended COBRA continuation coverage for disabled individuals satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled individuals a higher premium for the extended coverage if the individuals would not be eligible for COBRA continuation coverage were it not for the disability. (Similarly, if the plan provided an extended period of coverage for disabled individuals pursuant to State law or plan provision rather than pursuant to a COBRA continuation coverage provision, the plan could likewise charge the disabled individuals a higher premium for the extended coverage.)
- (2) In premiums or contributions. (i) Nothing in this section prevents a group health plan or group health insurance issuer from charging individuals a premium or contribution that is less than the premium (or contribution) for similarly situated individuals if the lower charge is based on an adverse health factor, such as disability.
- (ii) The rules of this paragraph (g)(2) are illustrated by the following example:

Example. (i) Facts. Under a group health plan, employees are generally required to pay \$50 per month for employee-only coverage and \$125 per month for family coverage under the plan. However, employees who are disabled receive coverage (whether employee-only or family coverage) under the plan free of charge.

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- (ii) Conclusion. In this Example, the plan provision waiving premium payment for disabled employees is permitted under this paragraph (g)(2) (and thus does not violate this section).
- (h) No effect on other laws. Compliance with this section is not determinative of compliance with any other provision of the PHS Act (including the COBRA continuation provisions) or any other State or Federal law, such as the Disabilities Americans with Therefore, although the rules of this section would not prohibit a plan or issuer from treating one group of similarly situated individuals differently from another (such as providing different benefit packages to current and former employees), other Federal or State laws may require that two separate groups of similarly situated individuals be treated the same for certain purposes (such as making the same benefit package available to COBRA qualified beneficiaries as is made available to active employees). In addition, although this section generally does not impose new disclosure obligations on plans and issuers, this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation.
- (i) Applicability dates—(1) Generally. This section applies for plan years beginning on or after July 1, 2007.
- (2) Special rule for self-funded non-federal governmental plans exempted under 45 CFR 146.180. (i) If coverage has been denied to any individual because the sponsor of a self-funded nonfederal governmental plan has elected under §146.180 to exempt the plan from the requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance with the requirements of this section, the plan—
- (A) Must notify the individual that the plan will be coming into compliance with the requirements of this section, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance with this section (as a matter of administrative convenience, the notice may be disseminated to all employees);

- (B) Must give the individual an opportunity to enroll that continues for at least 30 days;
- (C) Must permit coverage to be effective as of the first day of plan coverage for which an exemption election under §146.180 of this part (with regard to this section) is no longer in effect; and
- (D) May not treat the individual as a late enrollee or a special enrollee.
- (ii) For purposes of this paragraph (i)(2), an individual is considered to have been denied coverage if the individual failed to apply for coverage because, given an exemption election under §146.180 of this part, it was reasonable to believe that an application for coverage would have been denied based on a health factor.
- (iii) The rules of this paragraph (i)(2) are illustrated by the following examples:

Example 1. (i) Facts. Individual D was hired by a nonfederal governmental employer in June 1999. The employer maintains a selffunded group health plan with a plan year beginning on October 1. The plan sponsor elected under §146.180 of this part to exempt the plan from the requirements of this section for the plan year beginning October 1, 2005, and renewed the exemption election for the plan year beginning October 1, 2006. Under the terms of the plan while the exemption was in effect, employees and their dependents were allowed to enroll when the employee was first hired without regard to any health factor. If an individual declines to enroll when first eligible, the individual could enroll effective October 1 of any plan year if the individual could pass a physical examination. The evidence-of-good-health requirement for late enrollees, absent an exemption election under §146.180 of this part, would have been in violation of this section. D chose not to enroll for coverage when first hired. In February of 2006, D was treated for skin cancer but did not apply for coverage under the plan for the plan year beginning October 1, 2006, because D assumed D could not meet the evidence-of-good-health requirement. With the plan year beginning October 1, 2007 the plan sponsor chose not to renew its exemption election and brought the plan into compliance with this section. The plan notifies individual D (and all other employees) that it will be coming into compliance with the requirements of this section. The notice specifies that the effective date of compliance will be October 1, 2007, explains the applicable enrollment restrictions that will apply under the plan, states that individuals will have at least 30 days to enroll, and explains that coverage for those

who choose to enroll will be effective as of October 1, 2007. Individual *D* timely requests enrollment in the plan, and coverage commences under the plan on October 1, 2007.

(ii) Conclusion. In this  $Example\ 1$ , the plan complies with this paragraph (i)(2).

Example 2. (i) Facts. Individual E was hired by a nonfederal governmental employer in February 1999. The employer maintains a self-funded group health plan with a plan year beginning on September 1. The plan sponsor elected under §146.180 of this part to exempt the plan from the requirements of this section and "§146.111 (limitations on preexisting condition exclusion periods) for the plan year beginning September 1, 2002, and renews the exemption election for the plan years beginning September 1, 2003, September 1, 2004, September 1, 2005, and September 1, 2006. Under the terms of the plan while the exemption was in effect, employees and their dependents were allowed to enroll when the employee was first hired without regard to any health factor. If an individual declined to enroll when first eligible, the individual could enroll effective September 1 of any plan year if the individual could pass a physical examination. Also under the terms of the plan, all enrollees were subject to a 12month preexisting condition exclusion period, regardless of whether they had creditable coverage. E chose not to enroll for coverage when first hired. In June of 2006, E is diagnosed as having multiple sclerosis (MS). With the plan year beginning September 1, 2007, the plan sponsor chooses to bring the plan into compliance with this section, but renews its exemption election with regard to limitations on preexisting condition exclusion periods. The plan notifies E of her opportunity to enroll, without a physical examination, effective September 1, 2007. The plan gives E 30 days to enroll. E is subject to a 12-month preexisting condition exclusion period with respect to any treatment E receives that is related to E's MS, without regard to any prior creditable coverage Emay have. Beginning September 1, 2008, the plan will cover treatment of E's MS.

(ii) Conclusion. In this Example 2, the plan complies with the requirements of this section. (The plan is not required to comply with the requirements of §146.111 because the plan continues to be exempted from those requirements in accordance with the plan sponsor's election under §146.180.)

[71 FR 75046, Dec. 13, 2006, as amended at 74 FR 51688, Oct. 7, 2009; 78 FR 33187, June 3, 2013; 79 FR 10314, Feb. 24, 2014]

#### §146.122 Additional requirements prohibiting discrimination based on genetic information.

(a) Definitions. Unless otherwise provided, the definitions in this paragraph

- (a) govern in applying the provisions of this section.
- (1) Collect means, with respect to information, to request, require, or purchase such information.
- (2) Family member means, with respect to an individual—
- (i) A dependent (as defined in §144.103 of this part) of the individual; or
- (ii) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).
- (A) First-degree relatives include parents, spouses, siblings, and children.
- (B) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.
- (C) Third-degree relatives include great-grandparents, great-grand-children, great aunts, great uncles, and first cousins.
- (D) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.
  - (3) Genetic information means—
- (i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, with respect to an individual, information about—
- (A) The individual's genetic tests (as defined in paragraph (a)(5) of this section);
- (B) The genetic tests of family members of the individual:
- (C) The manifestation (as defined in paragraph (a)(6) of this section) of a disease or disorder in family members of the individual; or
- (D) Any request for, or receipt of, genetic services (as defined in paragraph (a)(4) of this section), or participation in clinical research which includes genetic services, by the individual or any family member of the individual.
- (ii) The term *genetic information* does not include information about the sex or age of any individual.