no more than 120 days after the effective date of the final regulations.

(b) All reports on the registry of qualified long-term care insurance policies issued to individuals or individuals under group coverage specified in §144.206(b)(1)(ii) must be submitted within 30 days of the end of the 6-month reporting period.

(c) All reports on the claims paid under qualified long-term care insurance policies issued to individual and individuals under group coverage specified in §144.206(b)(2)(i) must be submitted within 30 days of the end of the 3-month quarterly reporting period.

§ 144.210 Form and manner of reports.

All reports specified in §144.206 must be submitted in the form and manner specified by the Secretary.

§ 144.212 Confidentiality of information.

Data collected and reported under the requirements of this subpart are subject to the confidentiality of information requirements specified in regulations under 42 CFR Part 401, Subpart B, and 45 CFR Part 5, Subpart F.

§ 144.214 Notifications of noncompliance with reporting requirements.

If an insurer of a qualified long-term care insurance policy does not submit the required reports by the due dates specified in this subpart, the Secretary notifies the appropriate State insurance commissioner within 45 days after the deadline for submission of the information and data specified in §144.208.

PART 145 [RESERVED]

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

Subpart A—General Provisions

Subpart B—Requirements Relating to Access and Renewability of Coverage, and Limitations on Preexisting Condition Exclusion Periods

Subpart C—Requirements Related to Benefits

Subpart D—Preemption and Special Rules

Subpart E—Provisions Applicable to Only Health Insurance Issuers

Subpart F—Exclusion of Plans and Enforcement

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

SOURCE: 62 FR 16958, Apr. 8, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 146.101 Basis and scope.

(a) *Statutory basis.* This part implements the Group Market requirements of the PHS Act. Its purpose is to improve access to group health insurance coverage, to guarantee the renewability of all coverage in the group market, and to provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth. Sections 2791 and 2792 of the PHS Act define terms used in the regulations in this subchapter and provide the basis for issuing these regulations, respectively.

(b) *Scope.* A group health plan or health insurance issuer offering group health insurance coverage may provide greater rights to participants and beneficiaries than those set forth in this part.

(1) *Subpart B.* Subpart B of this part sets forth minimum requirements for group health plans and health insurance issuers offering group health insurance coverage concerning:

(i) Limitations on a preexisting condition exclusion period.

(ii) Certificates and disclosure of previous coverage.

(iii) Methods of counting creditable coverage.

(iv) Special enrollment periods.

(v) Use of an affiliation period by an HMO as an alternative to a preexisting condition exclusion.

(vi) Prohibiting discrimination against participants and beneficiaries based on a health factor.

(vii) Additional requirements prohibiting discrimination against participants and beneficiaries based on genetic information.

(2) *Subpart C.* Subpart C of this part sets forth the requirements that apply to plans and issuers with respect to coverage for hospital stays in connection with childbirth. It also sets forth the regulations governing parity between medical/surgical benefits and mental health benefits in group health plans and health insurance coverage offered by issuers in connection with a group health plan.

(3) *Subpart D.* Subpart D of this part sets forth exceptions to the requirements of Subpart B for certain plans and certain types of benefits.

(4) *Subpart E.* Subpart E of this part implements requirements relating to group health plans and issuers in the Group Health Insurance Market.

(5) *Subpart F.* Subpart F of this part addresses the treatment of non-Federal governmental plans, and sets forth enforcement procedures.

[62 FR 16958, Apr. 8, 1997, as amended at 63 FR 57559, Oct. 27, 1998; 71 FR 75046, Dec. 13, 2006; 74 FR 51688, Oct. 7, 2009, as amended at 75 FR 27138, May 13, 2010]

Subpart B—Requirements Relating to Access and Renewability of Coverage, and Limitations on Preexisting Condition Exclusion Periods

§ 146.111 Limitations on preexisting condition exclusion period.

(a) *Preexisting condition exclusion*—(1) *Defined* (i) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning set forth in § 144.103 of this part.

(ii) *Examples.* The rules of this paragraph (a)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *S*. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *T*. Issuer *T*'s policy excludes benefits for any prosthesis if the body part was lost before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1*, the exclusion of benefits for any prosthesis if the body part was lost before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. (Therefore, the exclusion of benefits is required to comply with the limitations on preexisting condition exclusions in this section. For an example illustrating the application of these limitations to a succeeding insurance policy, see *Example 3* of paragraph (a)(3)(iv) of this section.)

Example 2. (i) *Facts.* A group health plan provides coverage for cosmetic surgery in cases of accidental injury, but only if the injury occurred while the individual was covered under the plan.

(ii) *Conclusion.* In this *Example 2*, the plan provision excluding cosmetic surgery benefits for individuals injured before enrolling in the plan is a preexisting condition exclusion because it operates to exclude benefits relating to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

Example 3. (i) *Facts.* A group health plan provides coverage for the treatment of diabetes, generally not subject to any lifetime dollar limit. However, if an individual was diagnosed with diabetes before the effective date of coverage under the plan, diabetes coverage is subject to a lifetime limit of $10,000.

(ii) *Conclusion.* In this *Example 3*, the $10,000 lifetime limit is a preexisting condition exclusion because it limits benefits for a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

Example 4. (i) *Facts.* A group health plan provides coverage for the treatment of acne, subject to a lifetime limit of $2,000. The plan counts against this $2,000 lifetime limit acne treatment benefits provided under prior health coverage.

(ii) *Conclusion.* In this *Example 4*, counting benefits for a specific condition provided under prior health coverage against a lifetime limit for that condition is a preexisting condition exclusion because it operates to limit benefits for a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

Example 5. (i) *Facts.* When an individual's coverage begins under a group health plan, the individual generally becomes eligible for all benefits. However, benefits for pregnancy are not available until the individual has been covered under the plan for 12 months.

(ii) *Conclusion.* In this *Example 5*, the requirement to be covered under the plan for 12 months to be eligible for pregnancy benefits is a subterfuge for a preexisting condition exclusion because it is designed to exclude benefits for a condition (pregnancy) that arose before the effective date of coverage. Because a plan is prohibited under paragraph (b)(5) of this section from imposing any preexisting condition exclusion on pregnancy, the plan provision is prohibited. However, if the plan provision included an exception for women who were pregnant before the effective date of coverage under the plan (so that the provision applied only to women who became pregnant on or after the effective date of coverage) the plan provision would not be a preexisting condition exclusion (and would not be prohibited by paragraph (b)(5) of this section).

Example 6. (i) *Facts.* A group health plan provides coverage for medically necessary items and services, generally including treatment of heart conditions. However, the plan does not cover those same items and services when used for treatment of congenital heart conditions.

(ii) *Conclusion.* In this *Example 6*, the exclusion of coverage for treatment of congenital heart conditions is a preexisting condition exclusion because it operates to exclude benefits relating to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

Example 7. (i) *Facts.* A group health plan generally provides coverage for medically necessary items and services. However, the plan excludes coverage for the treatment of cleft palate.

(ii) *Conclusion.* In this *Example 7*, the exclusion of coverage for treatment of cleft palate is not a preexisting condition exclusion because the exclusion applies regardless of when the condition arose relative to the effective date of coverage. The plan provision, therefore, is not subject to the limitations on preexisting condition exclusions in this section.

Example 8. (i) *Facts.* A group health plan provides coverage for treatment of cleft palate, but only if the individual being treated has been continuously covered under the plan from the date of birth.

(ii) *Conclusion.* In this *Example 8*, the exclusion of coverage for treatment of cleft palate for individuals who have not been covered under the plan from the date of birth operates to exclude benefits in relation to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

(2) *General rules.* Subject to paragraph (b) of this section (prohibiting the imposition of a preexisting condition exclusion with respect to certain individuals and conditions), a group health plan, and a health insurance issuer offering group health insurance coverage, may impose, with respect to a participant or beneficiary, a preexisting condition exclusion only if the

requirements of this paragraph (a)(2) are satisfied.

(i) *6-month look-back rule.* A preexisting condition exclusion must relate to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period (or such shorter period as applies under the plan) ending on the enrollment date.

(A) For purposes of this paragraph (a)(2)(i), medical advice, diagnosis, care, or treatment is taken into account only if it is recommended by, or received from, an individual licensed or similarly authorized to provide such services under State law and operating within the scope of practice authorized by State law.

(B) For purposes of this paragraph (a)(2)(i), the 6-month period ending on the enrollment date begins on the 6-month anniversary date preceding the enrollment date. For example, for an enrollment date of August 1, 1998, the 6-month period preceding the enrollment date is the period commencing on February 1, 1998 and continuing through July 31, 1998. As another example, for an enrollment date of August 30, 1998, the 6-month period preceding the enrollment date is the period commencing on February 28, 1998 and continuing through August 29, 1998.

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

Example 1. (i) *Facts.* Individual *A* is diagnosed with a medical condition 8 months before *A*'s enrollment date in Employer *R*'s group health plan. *A*'s doctor recommends that *A* take a prescription drug for 3 months, and *A* follows the recommendation.

(ii) *Conclusion.* In this *Example 1,* Employer *R*'s plan may impose a preexisting condition exclusion with respect to *A*'s condition because A received treatment during the 6-month period ending on *A*'s enrollment date in Employer *R*'s plan by taking the prescription medication during that period. However, if *A* did not take the prescription drug during the 6-month period, Employer *R*'s plan would not be able to impose a preexisting condition exclusion with respect to that condition.

Example 2. (i) *Facts.* Individual *B* is treated for a medical condition 7 months before the enrollment date in Employer *S*'s group health plan. As part of such treatment, *B*'s physician recommends that a follow-up examination be given 2 months later. Despite this recommendation, *B* does not receive a follow-up examination, and no other medical advice, diagnosis, care, or treatment for that condition is recommended to *B* or received by *B* during the 6-month period ending on *B*'s enrollment date in Employer *S*'s plan.

(ii) *Conclusion.* In this *Example 2,* Employer *S*'s plan may not impose a preexisting condition exclusion with respect to the condition for which *B* received treatment 7 months prior to the enrollment date.

Example 3. (i) *Facts.* Same facts as *Example 2,* except that Employer *S*'s plan learns of the condition and attaches a rider to *B*'s certificate of coverage excluding coverage for the condition. Three months after enrollment, *B*'s condition recurs, and Employer *S*'s plan denies payment under the rider.

(ii) *Conclusion.* In this *Example 3,* the rider is a preexisting condition exclusion and Employer *S*'s plan may not impose a preexisting condition exclusion with respect to the condition for which *B* received treatment 7 months prior to the enrollment date. (In addition, such a rider would violate the provisions of §146.121, even if *B* had received treatment for the condition within the 6-month period ending on the enrollment date.)

Example 4. (i) *Facts.* Individual *C* has asthma and is treated for that condition several times during the 6-month period before *C*'s enrollment date in Employer *T*'s plan. Three months after the enrollment date, *C* begins coverage under Employer *T*'s plan. Two months later, *C* is hospitalized for asthma.

(ii) *Conclusion.* In this *Example 4,* Employer *T*'s plan may impose a preexisting condition exclusion with respect to *C*'s asthma because care relating to *C*'s asthma was received during the 6-month period ending on *C*'s enrollment date (which, under the rules of paragraph (a)(3)(i) of this section, is the first day of the waiting period).

Example 5. (i) *Facts.* Individual *D,* who is subject to a preexisting condition exclusion imposed by Employer *U*'s plan, has diabetes, as well as retinal degeneration, a foot condition, and poor circulation (all of which are conditions that may be directly attributed to diabetes). *D* receives treatment for these conditions during the 6-month period ending on *D*'s enrollment date in Employer *U*'s plan. After enrolling in the plan, *D* stumbles and breaks a leg.

(ii) *Conclusion.* In this *Example 5,* the leg fracture is not a condition related to D's diabetes, retinal degeneration, foot condition, or poor circulation, even though they may have contributed to the accident. Therefore, benefits to treat the leg fracture cannot be subject to a preexisting condition exclusion. However, any additional medical services that may be needed because of *D*'s preexisting diabetes, poor circulation, or retinal degeneration that would not be needed by

another patient with a broken leg who does not have these conditions may be subject to the preexisting condition exclusion imposed under Employer *U*'s plan.

(ii) *Maximum length of preexisting condition exclusion.* A preexisting condition exclusion is not permitted to extend for more than 12 months (18 months in the case of a late enrollee) after the enrollment date. For example, for an enrollment date of August 1, 1998, the 12-month period after the enrollment date is the period commencing on August 1, 1998 and continuing through July 31, 1999; the 18-month period after the enrollment date is the period commencing on August 1, 1998 and continuing through January 31, 2000.

(iii) *Reducing a preexisting condition exclusion period by creditable coverage*—(A) The period of any preexisting condition exclusion that would otherwise apply to an individual under a group health plan is reduced by the number of days of creditable coverage the individual has as of the enrollment date, as counted under §146.113. Creditable coverage may be evidenced through a certificate of creditable coverage (required under §146.115(a)), or through other means in accordance with the rules of §146.115(c).

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

Example. (i) *Facts.* Individual *D* works for Employer *X* and has been covered continuously under *X*'s group health plan. *D*'s spouse works for Employer *Y*. *Y* maintains a group health plan that imposes a 12-month preexisting condition exclusion (reduced by creditable coverage) on all new enrollees. *D* enrolls in *Y*'s plan, but also stays covered under *X*'s plan. *D* presents *Y*'s plan with evidence of creditable coverage under *X*'s plan.

(ii) *Conclusion.* In this *Example*, *Y*'s plan must reduce the preexisting condition exclusion period that applies to *D* by the number of days of coverage that *D* had under *X*'s plan as of *D*'s enrollment date in *Y*'s plan (even though *D*'s coverage under *X*'s plan was continuing as of that date).

(iv) *Other standards.* See §146.121 for other standards in this Subpart A that may apply with respect to certain benefit limitations or restrictions under a group health plan. Other laws may also apply, such as the Uniformed Services Employment and Reemployment Rights Act (USERRA), which can affect the application of a preexisting condition exclusion to certain individuals who are reinstated in a group health plan following active military service.

(3) *Enrollment definitions*—(i) *Enrollment date* means the first day of coverage (as described in paragraph (a)(3)(ii) of this section) or, if there is a waiting period, the first day of the waiting period. If an individual receiving benefits under a group health plan changes benefit packages, or if the plan changes group health insurance issuers, the individual's enrollment date does not change.

(ii) *First day of coverage* means, in the case of an individual covered for benefits under a group health plan, the first day of coverage under the plan and, in the case of an individual covered by health insurance coverage in the individual market, the first day of coverage under the policy or contract.

(iii) *Waiting period* means the period that must pass before coverage for an employee or dependent who is otherwise eligible to enroll under the terms of a group health plan can become effective. If an employee or dependent enrolls as a late enrollee or special enrollee, any period before such late or special enrollment is not a waiting period. If an individual seeks coverage in the individual market, a waiting period begins on the date the individual submits a substantially complete application for coverage and ends on—

(A) If the application results in coverage, the date coverage begins;

(B) If the application does not result in coverage, the date on which the application is denied by the issuer or the date on which the offer of coverage lapses.

(iv) The rules of paragraphs (a)(3)(i), (ii), and (iii) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *V*'s group health plan provides for coverage to begin on the first day of the first payroll period following the date an employee is hired and completes the applicable enrollment forms, or on any subsequent January 1 after completion of the applicable enrollment forms. Employer *V*'s plan imposes a preexisting condition exclusion for 12 months (reduced by the individual's creditable coverage) following an individual's enrollment date. Employee *E* is hired by Employer *V* on October

13, 1998 and on October 14, 1998 *E* completes and files all the forms necessary to enroll in the plan. *E*'s coverage under the plan becomes effective on October 25, 1998 (which is the beginning of the first payroll period after *E*'s date of hire).

(ii) *Conclusion.* In this *Example 1*, *E*'s enrollment date is October 13, 1998 (which is the first day of the waiting period for *E*'s enrollment and is also *E*'s date of hire). Accordingly, with respect to *E*, the permissible 6-month period in paragraph (a)(2)(i) is the period from April 13, 1998 through October 12, 1998, the maximum permissible period during which Employer *V*'s plan can apply a preexisting condition exclusion under paragraph (a)(2)(ii) is the period from October 13, 1998 through October 12, 1999, and this period must be reduced under paragraph (a)(2)(iii) by *E*'s days of creditable coverage as of October 13, 1998.

Example 2. (i) *Facts.* A group health plan has two benefit package options, Option 1 and Option 2. Under each option a 12-month preexisting condition exclusion is imposed. Individual *B* is enrolled in Option 1 on the first day of employment with the employer maintaining the plan, remains enrolled in Option 1 for more than one year, and then decides to switch to Option 2 at open season.

(ii) *Conclusion.* In this *Example 2, B* cannot be subject to any preexisting condition exclusion under Option 2 because any preexisting condition exclusion period would have to begin on *B*'s enrollment date, which is *B*'s first day of coverage, rather than the date that *B* enrolled in Option 2. Therefore, the preexisting condition exclusion period expired before B switched to Option 2.

Example 3. (i) *Facts.* On May 13, 1997, Individual *E* is hired by an employer and enrolls in the employer's group health plan. The plan provides benefits solely through an insurance policy offered by Issuer *S*. On December 27, 1998, *E*'s leg is injured in an accident and the leg is amputated. On January 1, 1999, the plan switches coverage to a policy offered by Issuer *T*. Issuer *T*'s policy excludes benefits for any prosthesis if the body part was lost before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 3, E*'s enrollment date is May 13, 1997, *E*'s first day of coverage. Therefore, the permissible 6-month look-back period for the preexisting condition exclusion imposed under Issuer *T*'s policy begins on November 13, 1996 and ends on May 12, 1997. In addition, the 12-month maximum permissible preexisting condition exclusion period begins on May 13, 1997 and ends on May 12, 1998. Accordingly, because no medical advice, diagnosis, care, or treatment was recommended to or received by *E* for the leg during the 6-month look-back period (even though medical care was provided within the 6-month period preceding the effective date of *E*'s coverage under Issuer *T*'s policy), Issuer *T* may not impose any preexisting condition exclusion with respect to *E*. Moreover, even if *E* had received treatment during the 6-month look-back period, Issuer *T* still would not be permitted to impose a preexisting condition exclusion because the 12-month maximum permissible preexisting condition exclusion period expired on May 12, 1998 (before the effective date of *E*'s coverage under Issuer *T*'s policy).

Example 4. (i) *Facts.* A group health plan limits eligibility for coverage to full-time employees of Employer *Y*. Coverage becomes effective on the first day of the month following the date the employee becomes eligible. Employee *C* begins working full-time for Employer *Y* on April 11. Prior to this date, *C* worked part-time for *Y*. *C* enrolls in the plan and coverage is effective May 1.

(ii) *Conclusion.* In this *Example 4*, *C*'s enrollment date is April 11 and the period from April 11 through April 30 is a waiting period. The period while *C* was working part-time, and therefore not in an eligible class of employees, is not part of the waiting period.

Example 5. (i) *Facts.* To be eligible for coverage under a multiemployer group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the previous quarter. If the hours requirement is satisfied, coverage becomes effective on the first day of the current calendar quarter. Employee *D* begins work on January 28 and does not work 250 hours in covered employment during the first quarter (ending March 31). *D* works at least 250 hours in the second quarter (ending June 30) and is enrolled in the plan with coverage effective July 1 (the first day of the third quarter).

(ii) *Conclusion.* In this *Example 5*, *D*'s enrollment date is the first day of the quarter during which *D* satisfies the hours requirement, which is April 1. The period from April 1 through June 30 is a waiting period.

(v) *Late enrollee* means an individual whose enrollment in a plan is a late enrollment.

(vi) (A) *Late enrollment* means enrollment of an individual under a group health plan other than—

(*1*) On the earliest date on which coverage can become effective for the individual under the terms of the plan; or

(*2*) Through special enrollment. (For rules relating to special enrollment, see §146.117.)

(B) If an individual ceases to be eligible for coverage under the plan, and then subsequently becomes eligible for coverage under the plan, only the individual's most recent period of eligibility is taken into account in determining whether the individual is a late

enrollee under the plan with respect to the most recent period of coverage. Similar rules apply if an individual again becomes eligible for coverage following a suspension of coverage that applied generally under the plan.

(vii) *Examples.* The rules of paragraphs (a)(3)(v) and (vi) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Employee *F* first becomes eligible to be covered by Employer *W*'s group health plan on January 1, 1999 but elects not to enroll in the plan until a later annual open enrollment period, with coverage effective January 1, 2001. *F* has no special enrollment right at that time.

(ii) *Conclusion.* In this *Example 1*, *F* is a late enrollee with respect to *F*'s coverage that became effective under the plan on January 1, 2001.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *F* terminates employment with Employer *W* on July 1, 1999 without having had any health insurance coverage under the plan. *F* is rehired by Employer *W* on January 1, 2000 and is eligible for and elects coverage under Employer *W*'s plan effective on January 1, 2000.

(ii) *Conclusion.* In this *Example 2*, *F* would not be a late enrollee with respect to *F*'s coverage that became effective on January 1, 2000.

(b) *Exceptions pertaining to preexisting condition exclusions*—(1) *Newborns*—(i) *In general.* Subject to paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion on a child who, within 30 days after birth, is covered under any creditable coverage. Accordingly, if a child is enrolled in a group health plan (or other creditable coverage) within 30 days after birth and subsequently enrolls in another group health plan without a significant break in coverage (as described in §146.113(b)(2)(iii)), the other plan may not impose any preexisting condition exclusion on the child.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *E*, who has no prior creditable coverage, begins working for Employer *W* and has accumulated 210 days of creditable coverage under Employer *W*'s group health plan on the date *E* gives birth to a child. Within 30 days after the birth, the child is enrolled in the plan. Ninety days after the birth, both *E* and the child terminate coverage under the plan. Both *E* and the child then experience a break in coverage of 45 days before *E* is hired by Employer *X* and the two are enrolled in Employer *X*'s group health plan.

(ii) *Conclusion.* In this *Example 1,* because *E*'s child is enrolled in Employer *W*'s plan within 30 days after birth, no preexisting condition exclusion may be imposed with respect to the child under Employer *W*'s plan. Likewise, Employer *X*'s plan may not impose any preexisting condition exclusion on *E*'s child because the child was covered under creditable coverage within 30 days after birth and had no significant break in coverage before enrolling in Employer *X*'s plan. On the other hand, because *E* had only 300 days of creditable coverage prior to *E*'s enrollment date in Employer *X*'s plan, Employer *X*'s plan may impose a preexisting condition exclusion on *E* for up to 65 days (66 days if the 12-month period after *E*'s enrollment date in *X*'s plan includes February 29).

Example 2. (i) *Facts.* Individual *F* is enrolled in a group health plan in which coverage is provided through a health insurance issuer. *F* gives birth. Under State law applicable to the health insurance issuer, health care expenses incurred for the child during the 30 days following birth are covered as part of *F*'s coverage. Although *F* may obtain coverage for the child beyond 30 days by timely requesting special enrollment and paying an additional premium, the issuer is prohibited under State law from recouping the cost of any expenses incurred for the child within the 30-day period if the child is not later enrolled.

(ii) *Conclusion.* In this *Example 2,* the child is covered under creditable coverage within 30 days after birth, regardless of whether the child enrolls as a special enrollee under the plan. Therefore, no preexisting condition exclusion may be imposed on the child unless the child has a significant break in coverage.

(2) *Adopted children.* Subject to paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion on a child who is adopted or placed for adoption before attaining 18 years of age and who, within 30 days after the adoption or placement for adoption, is covered under any creditable coverage. Accordingly, if a child is enrolled in a group health plan (or other creditable coverage) within 30 days after adoption or placement for adoption and subsequently enrolls in another group health plan without a significant break in

coverage (as described in §146.113(b)(2)(iii)), the other plan may not impose any preexisting condition exclusion on the child. This rule does not apply to coverage before the date of such adoption or placement for adoption.

(3) *Significant break in coverage.* Paragraphs (b)(1) and (2) of this section no longer apply to a child after a significant break in coverage. (*See* §146.113(b)(2)(iii) for rules relating to the determination of a significant break in coverage.)

(4) *Special enrollment.* For special enrollment rules relating to new dependents, see §146.117(b).

(5) *Pregnancy.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not impose a preexisting condition exclusion relating to pregnancy.

(6) *Genetic information*—(i) A group health plan, and a health insurance issuer offering group health insurance coverage, may not impose a preexisting condition exclusion relating to a condition based solely on genetic information. However, if an individual is diagnosed with a condition, even if the condition relates to genetic information, the plan may impose a preexisting condition exclusion with respect to the condition, subject to the other limitations of this section.

(ii) The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) *Facts.* Individual *A* enrolls in a group health plan that imposes a 12-month maximum preexisting condition exclusion. Three months before *A*'s enrollment, *A*'s doctor told *A* that, based on genetic information, *A* has a predisposition towards breast cancer. *A* was not diagnosed with breast cancer at any time prior to *A*'s enrollment date in the plan. Nine months after *A*'s enrollment date in the plan, *A* is diagnosed with breast cancer.

(ii) *Conclusion.* In this *Example,* the plan may not impose a preexisting condition exclusion with respect to *A*'s breast cancer because, prior to *A*'s enrollment date, *A* was not diagnosed with breast cancer.

(c) *General notice of preexisting condition exclusion.* A group health plan imposing a preexisting condition exclusion, and a health insurance issuer offering group health insurance coverage subject to a preexisting condition exclusion, must provide a written general notice of preexisting condition exclusion to participants under the plan and cannot impose a preexisting condition exclusion with respect to a participant or a dependent of the participant until such a notice is provided.

(1) *Manner and timing.* A plan or issuer must provide the general notice of preexisting condition exclusion as part of any written application materials distributed by the plan or issuer for enrollment. If the plan or issuer does not distribute such materials, the notice must be provided by the earliest date following a request for enrollment that the plan or issuer, acting in a reasonable and prompt fashion, can provide the notice.

(2) *Content.* The general notice of preexisting condition exclusion must notify participants of the following:

(i) The existence and terms of any preexisting condition exclusion under the plan. This description includes the length of the plan's look-back period (which is not to exceed 6 months under paragraph (a)(2)(i) of this section); the maximum preexisting condition exclusion period under the plan (which cannot exceed 12 months (or 18-months for late enrollees) under paragraph (a)(2)(ii) of this section); and how the plan will reduce the maximum preexisting condition exclusion period by creditable coverage (described in paragraph (a)(2)(iii) of this section).

(ii) A description of the rights of individuals to demonstrate creditable coverage, and any applicable waiting periods, through a certificate of creditable coverage (as required by §146.115(a)) or through other means (as described in §146.115(c)). This must include a description of the right of the individual to request a certificate from a prior plan or issuer, if necessary, and a statement that the current plan or issuer will assist in obtaining a certificate from any prior plan or issuer, if necessary.

(iii) A person to contact (including an address or telephone number) for obtaining additional information or assistance regarding the preexisting condition exclusion.

(3) *Duplicate notices not required.* If a notice satisfying the requirements of

this paragraph (c) is provided to an individual, the obligation to provide a general notice of preexisting condition exclusion with respect to that individual is satisfied for both the plan and the issuer.

(4) *Example with sample language.* The rules of this paragraph (c) are illustrated by the following example, which includes sample language that plans and issuers can use as a basis for preparing their own notices to satisfy the requirements of this paragraph (c):

Example. (i) *Facts.* A group health plan makes coverage effective on the first day of the first calendar month after hire and on each January 1 following an open season. The plan imposes a 12-month maximum preexisting condition exclusion (18 months for late enrollees) and uses a 6-month look-back period. As part of the enrollment application materials, the plan provides the following statement:

This plan imposes a preexisting condition exclusion. This means that if you have a medical condition before coming to our plan, you might have to wait a certain period of time before the plan will provide coverage for that condition. This exclusion applies only to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within a six-month period. Generally, this six-month period ends the day before your coverage becomes effective. However, if you were in a waiting period for coverage, the six-month period ends on the day before the waiting period begins. The preexisting condition exclusion does not apply to pregnancy nor to a child who is enrolled in the plan within 30 days after birth, adoption, or placement for adoption.

This exclusion may last up to 12 months (18 months if you are a late enrollee) from your first day of coverage, or, if you were in a waiting period, from the first day of your waiting period. However, you can reduce the length of this exclusion period by the number of days of your prior ''creditable coverage.'' Most prior health coverage is creditable coverage and can be used to reduce the preexisting condition exclusion if you have not experienced a break in coverage of at least 63 days. To reduce the 12-month (or 18-month) exclusion period by your creditable coverage, you should give us a copy of any certificates of creditable coverage you have. If you do not have a certificate, but you do have prior health coverage, we will help you obtain one from your prior plan or issuer. There are also other ways that you can show you have creditable coverage. Please contact us if you need help demonstrating creditable coverage.

All questions about the preexisting condition exclusion and creditable coverage should be directed to Individual *B* at Address *M* or Telephone Number *N*.

(ii) *Conclusion.* In this *Example,* the plan satisfies the general notice requirement of this paragraph (c), and thus also satisfies this requirement for any issuer providing the coverage.

(d) *Determination of creditable coverage*—(1) *Determination within reasonable time.* If a group health plan or health insurance issuer offering group health insurance coverage receives creditable coverage information under §146.115, the plan or issuer is required, within a reasonable time following receipt of the information, to make a determination regarding the amount of the individual's creditable coverage and the length of any exclusion that remains. Whether this determination is made within a reasonable time depends on the relevant facts and circumstances. Relevant facts and circumstances include whether a plan's application of a preexisting condition exclusion would prevent an individual from having access to urgent medical care.

(2) *No time limit on presenting evidence of creditable coverage.* A plan or issuer may not impose any limit on the amount of time that an individual has to present a certificate or other evidence of creditable coverage.

(3) *Example.* The rules of this paragraph (d) are illustrated by the following example:

Example. (i) *Facts.* A group health plan imposes a preexisting condition exclusion period of 12 months. After receiving the general notice of preexisting condition exclusion, Individual *H* develops an urgent health condition before receiving a certificate of creditable coverage from *H*'s prior group health plan. *H* attests to the period of prior coverage, presents corroborating documentation of the coverage period, and authorizes the plan to request a certificate on *H*'s behalf in accordance with the rules of §146.115.

(ii) *Conclusion.* In this *Example,* the plan must review the evidence presented by *H* and make a determination of creditable coverage within a reasonable time that is consistent with the urgency of *H*'s health condition. (This determination may be modified as permitted under paragraph (f) of this section.)

(e) *Individual notice of period of preexisting condition exclusion.* After an individual has presented evidence of

creditable coverage and after the plan or issuer has made a determination of creditable coverage under paragraph (d) of this section, the plan or issuer must provide the individual a written notice of the length of preexisting condition exclusion that remains after offsetting for prior creditable coverage. This individual notice is not required to identify any medical conditions specific to the individual that could be subject to the exclusion. A plan or issuer is not required to provide this notice if the plan or issuer does not impose any preexisting condition exclusion on the individual or if the plan's preexisting condition exclusion is completely offset by the individual's prior creditable coverage.

(1) *Manner and timing.* The individual notice must be provided by the earliest date following a determination that the plan or issuer, acting in a reasonable and prompt fashion, can provide the notice.

(2) *Content.* A plan or issuer must disclose—

(i) Its determination of any preexisting condition exclusion period that applies to the individual (including the last day on which the preexisting condition exclusion applies);

(ii) The basis for such determination, including the source and substance of any information on which the plan or issuer relied;

(iii) An explanation of the individual's right to submit additional evidence of creditable coverage; and

(iv) A description of any applicable appeal procedures established by the plan or issuer.

(3) *Duplicate notices not required.* If a notice satisfying the requirements of this paragraph (e) is provided to an individual, the obligation to provide this individual notice of preexisting condition exclusion with respect to that individual is satisfied for both the plan and the issuer.

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

Example 1. (i) *Facts.* A group health plan imposes a preexisting condition exclusion period of 12 months. After receiving the general notice of preexisting condition exclusion, Individual *G* presents a certificate of creditable coverage indicating 240 days of creditable coverage. Within seven days of receipt of the certificate, the plan determines that *G* is subject to a preexisting condition exclusion of 125 days, the last day of which is March 5. Five days later, the plan notifies *G* that, based on the certificate *G* submitted, *G* is subject to a preexisting condition exclusion period of 125 days, ending on March 5. The notice also explains the opportunity to submit additional evidence of creditable coverage and the plan's appeal procedures. The notice does not identify any of *G*'s medical conditions that could be subject to the exclusion.

(ii) *Conclusion.* In this *Example 1*, the plan satisfies the requirements of this paragraph (e).

Example 2. (i) *Facts.* Same facts as in *Example 1*, except that the plan determines that *G* has 430 days of creditable coverage based on *G*'s certificate indicating 430 days of creditable coverage under *G*'s prior plan.

(ii) *Conclusion.* In this *Example 2*, the plan is not required to notify *G* that *G* will not be subject to a preexisting condition exclusion.

(f) *Reconsideration.* Nothing in this section prevents a plan or issuer from modifying an initial determination of creditable coverage if it determines that the individual did not have the claimed creditable coverage, provided that —

(1) A notice of the new determination (consistent with the requirements of paragraph (e) of this section) is provided to the individual; and

(2) Until the notice of the new determination is provided, the plan or issuer, for purposes of approving access to medical services (such as a pre-surgery authorization), acts in a manner consistent with the initial determination.

[69 FR 78783, Dec. 30, 2004, as amended at 75 FR 37235, June 28, 2010]

§ 146.113 Rules relating to creditable coverage.

(a) *General rules*—(1) *Creditable coverage.* For purposes of this section, except as provided in paragraph (a)(2) of this section, the term *creditable coverage* means coverage of an individual under any of the following:

(i) A group health plan as defined in § 146.145(a).

(ii) Health insurance coverage as defined in § 144.103 of this chapter (whether or not the entity offering the coverage is subject to the requirements of

this part and 45 CFR part 148 and without regard to whether the coverage is offered in the group market, the individual market, or otherwise).

(iii) Part A or B of Title XVIII of the Social Security Act (Medicare).

(iv) Title XIX of the Social Security Act (Medicaid), other than coverage consisting solely of benefits under section 1928 of the Social Security Act (the program for distribution of pediatric vaccines).

(v) Title 10 U.S.C. Chapter 55 (medical and dental care for members and certain former members of the uniformed services, and for their dependents; for purposes of Title 10 U.S.C. Chapter 55, *uniformed services* means the armed forces and the Commissioned Corps of the National Oceanic and Atmospheric Administration and of the Public Health Service).

(vi) A medical care program of the Indian Health Service or of a tribal organization.

(vii) A State health benefits risk pool. For purposes of this section, a *State health benefits risk pool* means—

(A) An organization qualifying under section 501(c)(26) of the Internal Revenue Code;

(B) A qualified high risk pool described in section 2744(c)(2) of the PHS Act; or

(C) Any other arrangement sponsored by a State, the membership composition of which is specified by the State and which is established and maintained primarily to provide health coverage for individuals who are residents of such State and who, by reason of the existence or history of a medical condition—

(*1*) Are unable to acquire medical care coverage for such condition through insurance or from an HMO, or

(*2*) Are able to acquire such coverage only at a rate which is substantially in excess of the rate for such coverage through the membership organization.

(viii) A health plan offered under Title 5 U.S.C. Chapter 89 (the Federal Employees Health Benefits Program).

(ix) A public health plan. For purposes of this section, a *public health plan* means any plan established or maintained by a State, the U.S. government, a foreign country, or any political subdivision of a State, the U.S. government, or a foreign country that provides health coverage to individuals who are enrolled in the plan.

(x) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

(xi) Title XXI of the Social Security Act (State Children's Health Insurance Program).

(2) *Excluded coverage.* Creditable coverage does not include coverage of solely excepted benefits (described in §146.145).

(3) *Methods of counting creditable coverage.* For purposes of reducing any preexisting condition exclusion period, as provided under §146.111(a)(2)(iii), the amount of an individual's creditable coverage generally is determined by using the standard method described in paragraph (b) of this section. A plan or issuer may use the alternative method under paragraph (c) of this section with respect to any or all of the categories of benefits described under paragraph (c)(3) of this section.

(b) *Standard method*—(1) *Specific benefits not considered.* Under the standard method, the amount of creditable coverage is determined without regard to the specific benefits included in the coverage.

(2) *Counting creditable coverage*—(i) *Based on days.* For purposes of reducing the preexisting condition exclusion period that applies to an individual, the amount of creditable coverage is determined by counting all the days on which the individual has one or more types of creditable coverage. Accordingly, if on a particular day an individual has creditable coverage from more than one source, all the creditable coverage on that day is counted as one day. Any days in a waiting period for coverage are not creditable coverage.

(ii) *Days not counted before significant break in coverage.* Days of creditable coverage that occur before a significant break in coverage are not required to be counted.

(iii) *Significant break in coverage defined*—A significant break in coverage means a period of 63 consecutive days during each of which an individual does not have any creditable coverage. (See also §146.143(c)(2)(iii) regarding the applicability to issuers of State insurance

laws that require a break of more than 63 days before an individual has a significant break in coverage for purposes of State insurance law.)

(iv) *Periods that toll a significant break.* Days in a waiting period and days in an affiliation period are not taken into account in determining whether a significant break in coverage has occurred. In addition, for an individual who elects COBRA continuation coverage during the second election period provided under the Trade Act of 2002, the days between the date the individual lost group health plan coverage and the first day of the second COBRA election period are not taken into account in determining whether a significant break in coverage has occurred.

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

Example 1. (i) *Facts.* Individual *A* has creditable coverage under Employer *P*'s plan for 18 months before coverage ceases. *A* is provided a certificate of creditable coverage on *A*'s last day of coverage. Sixty-four days after the last date of coverage under *P*'s plan, *A* is hired by Employer *Q* and enrolls in *Q*'s group health plan. *Q*'s plan has a 12-month preexisting condition exclusion.

(ii) *Conclusion.* In this *Example 1*, *A* has a break in coverage of 63 days. Because *A*'s break in coverage is a significant break in coverage, *Q*'s plan may disregard *A*'s prior coverage and *A* may be subject to a 12-month preexisting condition exclusion.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *A* is hired by *Q* and enrolls in *Q*'s plan on the 63rd day after the last date of coverage under *P*'s plan.

(ii) *Conclusion.* In this *Example 2*, *A* has a break in coverage of 62 days. Because *A*'s break in coverage is not a significant break in coverage, *Q*'s plan must count *A*'s prior creditable coverage for purposes of reducing the plan's preexisting condition exclusion period that applies to *A*.

Example 3. (i) *Facts.* Same facts as *Example 1*, except that *Q*'s plan provides benefits through an insurance policy that, as required by applicable State insurance laws, defines a significant break in coverage as 90 days.

(ii) *Conclusion.* In this *Example 3*, under State law, the issuer that provides group health insurance coverage to *Q*'s plan must count *A*'s period of creditable coverage prior to the 63-day break. (However, if *Q*'s plan was a self-insured plan, the coverage would not be subject to State law. Therefore, the health coverage would not be governed by the longer break rules and *A*'s previous health coverage could be disregarded.)

Example 4. [Reserved]

Example 5. (i) *Facts.* Individual *C* has creditable coverage under Employer *S*'s plan for 200 days before coverage ceases. *C* is provided a certificate of creditable coverage on *C*'s last day of coverage. *C* then does not have any creditable coverage for 51 days before being hired by Employer *T*. *T*'s plan has a 3-month waiting period. *C* works for *T* for 2 months and then terminates employment. Eleven days after terminating employment with *T*, *C* begins working for Employer *U*. *U*'s plan has no waiting period, but has a 6-month preexisting condition exclusion.

(ii) *Conclusion.* In this *Example 5*, *C* does not have a significant break in coverage because, after disregarding the waiting period under *T*'s plan, *C* had only a 62-day break in coverage (51 days plus 11 days). Accordingly, *C* has 200 days of creditable coverage, and *U*'s plan may not apply its 6-month preexisting condition exclusion with respect to *C*.

Example 6. [Reserved]

Example 7. (i) *Facts.* Individual *E* has creditable coverage under Employer *X*'s plan. *E* is provided a certificate of creditable coverage on *E*'s last day of coverage. On the 63rd day without coverage, *E* submits a substantially complete application for a health insurance policy in the individual market. *E*'s application is accepted and coverage is made effective 10 days later.

(ii) *Conclusion.* In this *Example 7*, because *E* applied for the policy before the end of the 63rd day, the period between the date of application and the first day of coverage is a waiting period and no significant break in coverage occurred even though the actual period without coverage was 73 days.

Example 8. (i) *Facts.* Same facts as *Example 7*, except that *E*'s application for a policy in the individual market is denied.

(ii) *Conclusion.* In this *Example 8*, even though *E* did not obtain coverage following application, the period between the date of application and the date the coverage was denied is a waiting period. However, to avoid a significant break in coverage, no later than the day after the application for the policy is denied *E* would need to do one of the following: submit a substantially complete application for a different individual market policy; obtain coverage in the group market; or be in a waiting period for coverage in the group market.

(vi) *Other permissible counting methods*—(A) *Rule.* Notwithstanding any other provisions of this paragraph (b)(2), for purposes of reducing a preexisting condition exclusion period (but not for purposes of issuing a certificate under §146.115), a group health

plan, and a health insurance issuer offering group health insurance coverage, may determine the amount of creditable coverage in any other manner that is at least as favorable to the individual as the method set forth in this paragraph (b)(2), subject to the requirements of other applicable law.

(B) *Example.* The rule of this paragraph (b)(2)(vi) is illustrated by the following example:

Example. (i) *Facts.* Individual *F* has coverage under Group Health Plan *Y* from January 3, 1997 through March 25, 1997. *F* then becomes covered by Group Health Plan *Z*. *F*'s enrollment date in Plan *Z* is May 1, 1997. Plan *Z* has a 12-month preexisting condition exclusion.

(ii) *Conclusion.* In this *Example,* Plan *Z* may determine, in accordance with the rules prescribed in paragraphs (b)(2)(i), (ii), and (iii) of this section, that *F* has 82 days of creditable coverage (29 days in January, 28 days in February, and 25 days in March). Thus, the preexisting condition exclusion will no longer apply to *F* on February 8, 1998 (82 days before the 12-month anniversary of *F*'s enrollment (May 1)). For administrative convenience, however, Plan *Z* may consider that the preexisting condition exclusion will no longer apply to *F* on the first day of the month (February 1).

(c) *Alternative method*—(1) *Specific benefits considered.* Under the alternative method, a group health plan, or a health insurance issuer offering group health insurance coverage, determines the amount of creditable coverage based on coverage within any category of benefits described in paragraph (c)(3) of this section and not based on coverage for any other benefits. The plan or issuer may use the alternative method for any or all of the categories. The plan or issuer may apply a different preexisting condition exclusion period with respect to each category (and may apply a different preexisting condition exclusion period for benefits that are not within any category). The creditable coverage determined for a category of benefits applies only for purposes of reducing the preexisting condition exclusion period with respect to that category. An individual's creditable coverage for benefits that are not within any category for which the alternative method is being used is determined under the standard method of paragraph (b) of this section.

(2) *Uniform application.* A plan or issuer using the alternative method is required to apply it uniformly to all participants and beneficiaries under the plan or health insurance coverage. The use of the alternative method is required to be set forth in the plan.

(3) *Categories of benefits.* The alternative method for counting creditable coverage may be used for coverage for the following categories of benefits—

(i) Mental health;

(ii) Substance abuse treatment;

(iii) Prescription drugs;

(iv) Dental care; or

(v) Vision care.

(4) *Plan notice.* If the alternative method is used, the plan is required to—

(i) State prominently that the plan is using the alternative method of counting creditable coverage in disclosure statements concerning the plan, and state this to each enrollee at the time of enrollment under the plan; and

(ii) Include in these statements a description of the effect of using the alternative method, including an identification of the categories used.

(5) *Issuer notice.* With respect to health insurance coverage offered by an issuer in the small or large group market, if the insurance coverage uses the alternative method, the issuer states prominently in any disclosure statement concerning the coverage, that the issuer is using the alternative method, and includes in such statements a description of the effect of using the alternative method. This applies separately to each type of coverage offered by the health insurance issuer.

(6) *Disclosure of information on previous benefits.* See §146.115(b) for special rules concerning disclosure of coverage to a plan, or issuer, using the alternative method of counting creditable coverage under this paragraph (c).

(7) *Counting creditable coverage*—(i) *In general.* Under the alternative method, the group health plan or issuer counts creditable coverage within a category if any level of benefits is provided within the category. Coverage under a reimbursement account or arrangement, such as a flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code),

does not constitute coverage within any category.

(ii) *Special rules.* In counting an individual's creditable coverage under the alternative method, the group health plan, or issuer, first determines the amount of the individual's creditable coverage that may be counted under paragraph (b) of this section, up to a total of 365 days of the most recent creditable coverage (546 days for a late enrollee). The period over which this creditable coverage is determined is referred to as the determination period. Then, for the category specified under the alternative method, the plan or issuer counts within the category all days of coverage that occurred during the determination period (whether or not a significant break in coverage for that category occurs), and reduces the individual's preexisting condition exclusion period for that category by that number of days. The plan or issuer may determine the amount of creditable coverage in any other reasonable manner, uniformly applied, that is at least as favorable to the individual.

(iii) *Example.* The rules of this paragraph (c)(7) are illustrated by the following example:

Example. (i) *Facts.* Individual *D* enrolls in Employer *V*'s plan on January 1, 2001. Coverage under the plan includes prescription drug benefits. On April 1, 2001, the plan ceases providing prescription drug benefits. *D*'s employment with Employer *V* ends on January 1, 2002, after *D* was covered under Employer *V*'s group health plan for 365 days. *D* enrolls in Employer *Y*'s plan on February 1, 2002 (*D*'s enrollment date). Employer *Y*'s plan uses the alternative method of counting creditable coverage and imposes a 12-month preexisting condition exclusion on prescription drug benefits.

(ii) *Conclusion.* In this *Example*, Employer *Y*'s plan may impose a 275-day preexisting condition exclusion with respect to *D* for prescription drug benefits because *D* had 90 days of creditable coverage relating to prescription drug benefits within *D*'s determination period.

[69 FR 78788, Dec. 30, 2004]

§ 146.115 Certification and disclosure of previous coverage.

(a) *Certificate of creditable coverage*—(1) *Entities required to provide certificate*—(i) *In General.* A group health plan, and each health insurance issuer offering group health insurance coverage under a group health plan, is required to furnish certificates of creditable coverage in accordance with this paragraph (a).

(ii) *Duplicate certificates not required.* An entity required to provide a certificate under this paragraph (a) with respect to an individual satisfies that requirement if another party provides the certificate, but only to the extent that the certificate contains the information required in paragraph (a)(3) of this section. For example, in the case of a group health plan funded through an insurance policy, the issuer satisfies the certification requirement with respect to an individual if the plan actually provides a certificate that includes all the information required under paragraph (a)(3) of this section with respect to the individual.

(iii) *Special rule for group health plans.* To the extent coverage under a plan consists of group health insurance coverage, the plan satisfies the certification requirements under this paragraph (a) if any issuer offering the coverage is required to provide the certificates pursuant to an agreement between the plan and the issuer. For example, if there is an agreement between an issuer and a plan sponsor under which the issuer agrees to provide certificates for individuals covered under the plan, and the issuer fails to provide a certificate to an individual when the plan would have been required to provide one under this paragraph (a), then the issuer, but not the plan, violates the certification requirements of this paragraph (a).

(iv) *Special rules for issuers*—(A)(*1*) *Responsibility of issuer for coverage period.* An issuer is not required to provide information regarding coverage provided to an individual by another party.

(*2*) *Example.* The rule of this paragraph (a)(1)(iv)(A) is illustrated by the following example:

Example. (i) *Facts.* A plan offers coverage with an HMO option from one issuer and an indemnity option from a different issuer. The HMO has not entered into an agreement with the plan to provide certificates as permitted under paragraph (a)(1)(iii) of this section.

(ii) *Conclusion.* In this *Example,* if an employee switches from the indemnity option to the HMO option and later ceases to be

covered under the plan, any certificate provided by the HMO is not required to provide information regarding the employee's coverage under the indemnity option.

(B)(*1*) *Cessation of issuer coverage prior to cessation of coverage under a plan.* If an individual's coverage under an issuer's policy or contract ceases before the individual's coverage under the plan ceases, the issuer is required to provide sufficient information to the plan (or to another party designated by the plan) to enable the plan (or other party), after cessation of the individual's coverage under the plan, to provide a certificate that reflects the period of coverage under the policy or contract. By providing that information to the plan, the issuer satisfies its obligation to provide an automatic certificate for that period of creditable coverage with respect to the individual under paragraph (a)(2)(ii) of this section. The issuer, however, must still provide a certificate upon request as required under paragraph (a)(2)(iii) of this section. In addition, the issuer is required to cooperate with the plan in responding to any request made under paragraph (b)(2) of this section (relating to the alternative method of counting creditable coverage). Moreover, if the individual's coverage under the plan ceases at the time the individual's coverage under the issuer's policy or contract ceases, the issuer must still provide an automatic certificate under paragraph (a)(2)(ii) of this section. If an individual's coverage under an issuer's policy or contract ceases on the effective date for changing enrollment options under the plan, the issuer may presume (absent information to the contrary) that the individual's coverage under the plan continues. Therefore, the issuer is required to provide information to the plan in accordance with this paragraph (a)(1)(iv)(B)(*1*) (and is not required to provide an automatic certificate under paragraph (a)(2)(ii) of this section).

(*2*) *Example.* The rule of this paragraph (a)(1)(iv)(B) is illustrated by the following example:

Example. (i) *Facts.* A group health plan provides coverage under an HMO option and an indemnity option through different issuers, and only allows employees to switch on each January 1. Neither the HMO nor the indemnity issuer has entered into an agreement with the plan to provide certificates as permitted under paragraph (a)(1)(iii) of this section.

(ii) *Conclusion.* In this *Example,* if an employee switches from the indemnity option to the HMO option on January 1, the indemnity issuer must provide the plan (or a person designated by the plan) with appropriate information with respect to the individual's coverage with the indemnity issuer. However, if the individual's coverage with the indemnity issuer ceases at a date other than January 1, the issuer is instead required to provide the individual with an automatic certificate.

(2) *Individuals for whom certificate must be provided; timing of issuance*—(i) *Individuals.* A certificate must be provided, without charge, for participants or dependents who are or were covered under a group health plan upon the occurrence of any of the events described in paragraph (a)(2)(ii) or (iii) of this section.

(ii) *Issuance of automatic certificates.* The certificates described in this paragraph (a)(2)(ii) are referred to as automatic certificates.

(A) *Qualified beneficiaries upon a qualifying event.* In the case of an individual who is a qualified beneficiary (as defined in section 607(3) of ERISA, section 4980(B)(g)(1) of the Internal Revenue Code, or section 2208 of the PHS Act) entitled to elect COBRA continuation coverage, an automatic certificate is required to be provided at the time the individual would lose coverage under the plan in the absence of COBRA continuation coverage or alternative coverage elected instead of COBRA continuation coverage. A plan or issuer satisfies this requirement if it provides the automatic certificate no later than the time a notice is required to be furnished for a qualifying event under section 606 of ERISA, section 4980(B)(f)(6) of the Internal Revenue Code, and section 2206 of the PHS Act (relating to notices required under COBRA).

(B) *Other individuals when coverage ceases.* In the case of an individual who is not a qualified beneficiary entitled to elect COBRA continuation coverage, an automatic certificate must be provided at the time the individual ceases to be covered under the plan. A plan or issuer satisfies the requirement to provide an automatic certificate at the

time the individual ceases to be covered if it provides the automatic certificate within a reasonable time after coverage ceases (or after the expiration of any grace period for nonpayment of premiums).

(*1*) The cessation of temporary continuation coverage (TCC) under Title 5 U.S.C. Chapter 89 (the Federal Employees Health Benefit Program) is a cessation of coverage upon which an automatic certificate must be provided.

(*2*) In the case of an individual who is entitled to elect to continue coverage under a State program similar to COBRA and who receives the automatic certificate not later than the time a notice is required to be furnished under the State program, the certificate is deemed to be provided within a reasonable time after coverage ceases under the plan.

(*3*) If an individual's coverage ceases due to the operation of a lifetime limit on all benefits, coverage is considered to cease for purposes of this paragraph (a)(2)(ii)(B) on the earliest date that a claim is denied due to the operation of the lifetime limit.

(C) *Qualified beneficiaries when COBRA ceases.* In the case of an individual who is a qualified beneficiary and has elected COBRA continuation coverage (or whose coverage has continued after the individual became entitled to elect COBRA continuation coverage), an automatic certificate is to be provided at the time the individual' s coverage under the plan ceases. A plan, or issuer, satisfies this requirement if it provides the automatic certificate within a reasonable time after coverage ceases (or after the expiration of any grace period for nonpayment of premiums). An automatic certificate is required to be provided to such an individual regardless of whether the individual has previously received an automatic certificate under paragraph (a)(2)(ii)(A) of this section.

(iii) *Any individual upon request.* A certificate must be provided in response to a request made by, or on behalf of, an individual at any time while the individual is covered under a plan and up to 24 months after coverage ceases. Thus, for example, a plan in which an individual enrolls may, if authorized by the individual, request a certificate of the individual's creditable coverage on behalf of the individual from a plan in which the individual was formerly enrolled. After the request is received, a plan or issuer is required to provide the certificate by the earliest date that the plan or issuer, acting in a reasonable and prompt fashion, can provide the certificate. A certificate is required to be provided under this paragraph (a)(2)(iii) even if the individual has previously received a certificate under this paragraph (a)(2)(iii) or an automatic certificate under paragraph (a)(2)(ii) of this section.

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

Example 1. (i) *Facts.* Individual *A* terminates employment with Employer *Q*. *A* is a qualified beneficiary entitled to elect COBRA continuation coverage under Employer *Q*'s group health plan. A notice of the rights provided under COBRA is typically furnished to qualified beneficiaries under the plan within 10 days after a covered employee terminates employment.

(ii) *Conclusion.* In this *Example 1,* the automatic certificate may be provided at the same time that *A* is provided the COBRA notice.

Example 2. (i) *Facts.* Same facts as *Example 1,* except that the automatic certificate for *A* is not completed by the time the COBRA notice is furnished to *A*.

(ii) *Conclusion.* In this *Example 2,* the automatic certificate may be provided after the COBRA notice but must be provided within the period permitted by law for the delivery of notices under COBRA.

Example 3. (i) *Facts.* Employer *R* maintains an insured group health plan. *R* has never had 20 employees and thus *R*'s plan is not subject to the COBRA continuation provisions. However, *R* is in a State that has a State program similar to COBRA. *B* terminates employment with *R* and loses coverage under *R*'s plan.

(ii) *Conclusion.* In this *Example 3,* the automatic certificate must be provided not later than the time a notice is required to be furnished under the State program.

Example 4. (i) *Facts.* Individual *C* terminates employment with Employer *S* and receives both a notice of *C*'s rights under COBRA and an automatic certificate. *C* elects COBRA continuation coverage under Employer *S*'s group health plan. After four months of COBRA continuation coverage and the expiration of a 30-day grace period, *S*'s group health plan determines that *C*'s COBRA continuation coverage has ceased

due to a failure to make a timely payment for continuation coverage.

(ii) *Conclusion.* In this *Example 4*, the plan must provide an updated automatic certificate to *C* within a reasonable time after the end of the grace period.

Example 5. (i) *Facts.* Individual *D* is currently covered under the group health plan of Employer *T*. *D* requests a certificate, as permitted under paragraph (a)(2)(iii) of this section. Under the procedure for *T*'s plan, certificates are mailed (by first class mail) 7 business days following receipt of the request. This date reflects the earliest date that the plan, acting in a reasonable and prompt fashion, can provide certificates.

(ii) *Conclusion.* In this *Example 5*, the plan's procedure satisfies paragraph (a)(2)(iii) of this section.

(3) *Form and content of certificate*—(i) *Written certificate*—(A) *In General.* Except as provided in paragraph (a)(3)(i)(B) of this section, the certificate must be provided in writing (or any other medium approved by the Secretary).

(B) *Other permissible forms.* No written certificate is required to be provided under this paragraph (a) with respect to a particular event described in paragraph (a)(2)(ii) or (iii) of this section, if—

(*1*) An individual who is entitled to receive the certificate requests that the certificate be sent to another plan or issuer instead of to the individual;

(*2*) The plan or issuer that would otherwise receive the certificate agrees to accept the information in this paragraph (a)(3) through means other than a written certificate (such as by telephone); and

(*3*) The receiving plan or issuer receives the information from the sending plan or issuer through such means within the time required under paragraph (a)(2) of this section.

(ii) *Required information.* The certificate must include the following—

(A) The date the certificate is issued;

(B) The name of the group health plan that provided the coverage described in the certificate;

(C) The name of the participant or dependent with respect to whom the certificate applies, and any other information necessary for the plan providing the coverage specified in the certificate to identify the individual, such as the individual's identification number under the plan and the name of the participant if the certificate is for (or includes) a dependent;

(D) The name, address, and telephone number of the plan administrator or issuer required to provide the certificate;

(E) The telephone number to call for further information regarding the certificate (if different from paragraph (a)(3)(ii)(D) of this section);

(F) Either—

(*1*) A statement that an individual has at least 18 months (for this purpose, 546 days is deemed to be 18 months) of creditable coverage, disregarding days of creditable coverage before a significant break in coverage, or

(*2*) The date any waiting period (and affiliation period, if applicable) began and the date creditable coverage began;

(G) The date creditable coverage ended, unless the certificate indicates that creditable coverage is continuing as of the date of the certificate; and

(H) An educational statement regarding HIPAA, which explains:

(*1*) The restrictions on the ability of a plan or issuer to impose a preexisting condition exclusion (including an individual's ability to reduce a preexisting condition exclusion by creditable coverage);

(*2*) Special enrollment rights;

(*3*) The prohibitions against discrimination based on any health factor;

(*4*) The right to individual health coverage;

(*5*) The fact that State law may require issuers to provide additional protections to individuals in that State; and

(*6*) Where to get more information.

(iii) *Periods of coverage under the certificate.* If an automatic certificate is provided pursuant to paragraph (a)(2)(ii) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate pursuant to paragraph (a)(2)(iii) of this section, the certificate provided must include each period of continuous coverage ending within the 24-month period ending on the date of the request (or continuing on the date of the request). A separate certificate may be

provided for each such period of continuous coverage.

(iv) *Combining information for families.* A certificate may provide information with respect to both a participant and the participant's dependents if the information is identical for each individual. If the information is not identical, certificates may be provided on one form if the form provides all the required information for each individual and separately states the information that is not identical.

(v) *Model certificate.* The requirements of paragraph (a)(3)(ii) of this section are satisfied if the plan or issuer provides a certificate in accordance with a model certificate authorized by the Secretary.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in §146.145(c). In addition, the information in the certificate regarding coverage is not required to specify categories of benefits described in §146.113(c) (relating to the alternative method of counting creditable coverage). However, if excepted benefits are provided concurrently with other creditable coverage (so that the coverage does not consist solely of excepted benefits), information concerning the benefits may be required to be disclosed under paragraph (b) of this section.

(4) *Procedures*—(i) *Method of delivery.* The certificate is required to be provided to each individual described in paragraph (a)(2) of this section or an entity requesting the certificate on behalf of the individual. The certificate may be provided by first-class mail. If the certificate or certificates are provided to the participant and the participant's spouse at the participant's last known address, then the requirements of this paragraph (a)(4) are satisfied with respect to all individuals residing at that address. If a dependent's last known address is different than the participant's last known address, a separate certificate is required to be provided to the dependent at the dependent's last known address. If separate certificates are being provided by mail to individuals who reside at the same address, separate mailings of each certificate are not required.

(ii) *Procedure for requesting certificates.* A plan or issuer must establish a written procedure for individuals to request and receive certificates pursuant to paragraph (a)(2)(iii) of this section. The written procedure must include all contact information necessary to request a certificate (such as name and phone number or address).

(iii) *Designated recipients.* If an automatic certificate is required to be provided under paragraph (a)(2)(ii) of this section, and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the plan or issuer responsible for providing the certificate is permitted to provide the certificate to the designated individual or entity. If a certificate is required to be provided upon request under paragraph (a)(2)(iii) of this section and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the plan or issuer responsible for providing the certificate is required to provide the certificate to the designated individual or entity.

(5) *Special rules concerning dependent coverage*—(i)(A) *Reasonable efforts.* A plan or issuer is required to use reasonable efforts to determine any information needed for a certificate relating to dependent coverage. In any case in which an automatic certificate is required to be furnished with respect to a dependent under paragraph (a)(2)(ii) of this section, no individual certificate is required to be furnished until the plan or issuer knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the plan.

(B) *Example.* The rules of this paragraph (a)(5)(i) are illustrated by the following example:

Example. (i) *Facts.* A group health plan covers employees and their dependents. The plan annually requests all employees to provide updated information regarding dependents, including the specific date on which an employee has a new dependent or on which a person ceases to be a dependent of the employee.

(ii) *Conclusion.* In this *Example,* the plan has satisfied the standard in this paragraph (a)(5)(i) of this section that it make reasonable efforts to determine the cessation of dependents' coverage and the related dependent coverage information.

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by a plan or issuer does not provide the name of any dependent covered by the certificate, the procedures described in paragraph (c)(5) of this section may be used to demonstrate dependent status. In addition, these procedures may be used to demonstrate that a child was covered under any creditable coverage within 30 days after birth, adoption, or placement for adoption. See also §146.111(b), under which such a child cannot be subject to a preexisting condition exclusion.

(6) *Special certification rules*—(i) *Issuers.* Issuers of group and individual health insurance are required to provide certificates of any creditable coverage they provide in the group or individual health insurance market, even if the coverage is provided in connection with an entity or program that is not itself required to provide a certificate because it is not subject to the group market provisions of this part, part 7 of subtitle B of title I of ERISA, or chapter 100 of subtitle K of the Internal Revenue Code. This would include coverage provided in connection with any of the following:

(A) Creditable coverage described in sections 2701(c)(1)(G), (I) and (J) of the PHS Act (coverage under a State health benefits risk pool, a public health plan, and a health benefit plan under section 5(e) of the Peace Corps Act).

(B) Coverage subject to section 2722(a)(1)(B) of the PHS Act (requiring certificates by issuers offering health insurance coverage in connection with any group health plan, including a church plan or a governmental plan (including the Federal Employees Health Benefits Program).

(C) Coverage subject to section 2743 of the PHS Act applicable to health insurance issuers in the individual market. (However, this section does not require a certificate to be provided with respect to short-term limited duration insurance, which is excluded from the definition of ''individual health insurance coverage'' in 45 CFR 144.103 that is not provided in connection with a group health plan, as described in paragraph (a)(6)(i)(B) of this section.)

(ii) *Other entities.* For special rules requiring that certain other entities, not subject to this part, provide certificates consistent with the rules of this section, see section 2791(a)(3) of the PHS Act applicable to entities described in sections 2701(c)(1)(C), (D), (E), and (F) of the PHS Act (relating to Medicare, Medicaid, TRICARE, and Indian Health Service), section 2722(a)(1)(A) of the PHS Act applicable to non-Federal governmental plans generally, section 2721(b)(2)(C)(ii) of the PHS Act applicable to non-Federal governmental plans that elect to be excluded from the requirements of subparts 1 through 3 of part A of title XXVII of the PHS Act, and section 9805(a) of the Internal Revenue Code applicable to group health plans, which includes church plans (as defined in section 414(e) of the Internal Revenue Code).

(b) *Disclosure of coverage to a plan or issuer using the alternative method of counting creditable coverage*—(1) *In general.* After an individual provides a certificate of creditable coverage to a plan or issuer using the alternative method under §146.113(c), that plan or issuer (requesting entity) must request that the entity that issued the certificate (prior entity) disclose the information set forth in paragraph (b)(2) of this section. The prior entity is required to disclose this information promptly.

(2) *Information to be disclosed.* The prior entity is required to identify to the requesting entity the categories of benefits with respect to which the requesting entity is using the alternative method of counting creditable coverage, and the requesting entity may identify specific information that the requesting entity reasonably needs in order to determine the individual's creditable coverage with respect to any such category.

(3) *Charge for providing information.* The prior entity may charge the requesting entity for the reasonable cost of disclosing such information.

(c) *Ability of an individual to demonstrate creditable coverage and waiting period information*—(1) *Purpose.* The rules in this paragraph (c) implement section 2701(c)(4) of the PHS Act, which permits individuals to demonstrate the duration of creditable coverage

through means other than certificates, and section 2701(e)(3) of the PHS Act, which requires the Secretary to establish rules designed to prevent an individual's subsequent coverage under a group health plan or health insurance coverage from being adversely affected by an entity's failure to provide a certificate with respect to that individual.

(2) *In general.* If the accuracy of a certificate is contested or a certificate is unavailable when needed by an individual, the individual has the right to demonstrate creditable coverage (and waiting or affiliation periods) through the presentation of documents or other means. For example, the individual may make such a demonstration when—

(i) An entity has failed to provide a certificate within the required time;

(ii) The individual has creditable coverage provided by an entity that is not required to provide a certificate of the coverage pursuant to paragraph (a) of this section;

(iii) The individual has an urgent medical condition that necessitates a determination before the individual can deliver a certificate to the plan; or

(iv) The individual lost a certificate that the individual had previously received and is unable to obtain another certificate.

(3) *Evidence of creditable coverage*—(i) *Consideration of evidence*—(A) A plan or issuer is required to take into account all information that it obtains or that is presented on behalf of an individual to make a determination, based on the relevant facts and circumstances, whether an individual has creditable coverage. A plan or issuer shall treat the individual as having furnished a certificate under paragraph (a) of this section if—

(*1*) The individual attests to the period of creditable coverage;

(*2*) The individual also presents relevant corroborating evidence of some creditable coverage during the period; and

(*3*) The individual cooperates with the plan's or issuer's efforts to verify the individual's coverage.

(B) For purposes of this paragraph (c)(3)(i), cooperation includes providing (upon the plan's or issuer's request) a written authorization for the plan or issuer to request a certificate on behalf of the individual, and cooperating in efforts to determine the validity of the corroborating evidence and the dates of creditable coverage. While a plan or issuer may refuse to credit coverage where the individual fails to cooperate with the plan's or issuer's efforts to verify coverage, the plan or issuer may not consider an individual's inability to obtain a certificate to be evidence of the absence of creditable coverage.

(ii) *Documents.* Documents that corroborate creditable coverage (and waiting or affiliation periods) include explanations of benefits (EOBs) or other correspondence from a plan or issuer indicating coverage, pay stubs showing a payroll deduction for health coverage, a health insurance identification card, a certificate of coverage under a group health policy, records from medical care providers indicating health coverage, third party statements verifying periods of coverage, and any other relevant documents that evidence periods of health coverage.

(iii) *Other evidence.* Creditable coverage (and waiting or affiliation periods) may also be corroborated through means other than documentation, such as by a telephone call from the plan or provider to a third party verifying creditable coverage.

(iv) *Example.* The rules of this paragraph (c)(3) are illustrated by the following example:

Example. (i) *Facts.* Individual *F* terminates employment with Employer *W* and, a month later, is hired by Employer *X*. *X*'s group health plan imposes a preexisting condition exclusion of 12 months on new enrollees under the plan and uses the standard method of determining creditable coverage. *F* fails to receive a certificate of prior coverage from the self-insured group health plan maintained by *F*'s prior employer, *W*, and requests a certificate. However, *F* (and *X*'s plan, on *F*'s behalf and with *F*'s cooperation) is unable to obtain a certificate from *W*'s plan. *F* attests that, to the best of *F*'s knowledge, *F* had at least 12 months of continuous coverage under *W*'s plan, and that the coverage ended no earlier than *F*'s termination of employment from *W*. In addition, *F* presents evidence of coverage, such as an explanation of benefits for a claim that was made during the relevant period.

(ii) *Conclusion.* In this *Example*, based solely on these facts, *F* has demonstrated creditable coverage for the 12 months of coverage

under *W*'s plan in the same manner as if *F* had presented a written certificate of creditable coverage.

(4) *Demonstrating categories of creditable coverage.* Procedures similar to those described in this paragraph (c) apply in order to determine the duration of an individual's creditable coverage with respect to any category under paragraph (b) of this section (relating to determining creditable coverage under the alternative method).

(5) *Demonstrating dependent status.* If, in the course of providing evidence (including a certificate) of creditable coverage, an individual is required to demonstrate dependent status, the group health plan or issuer is required to treat the individual as having furnished a certificate showing the dependent status if the individual attests to such dependency and the period of such status and the individual cooperates with the plan's or issuer's efforts to verify the dependent status.

[69 FR 78790, Dec. 30, 2004, as amended at 75 FR 27138, May 13, 2010]

§ 146.117 Special enrollment periods.

(a) *Special enrollment for certain individuals who lose coverage*—(1) *In General.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, is required to permit current employees and dependents (as defined in §144.103 of this chapter) who are described in paragraph (a)(2) of this section to enroll for coverage under the terms of the plan if the conditions in paragraph (a)(3) of this section are satisfied. The special enrollment rights under this paragraph (a) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan.

(2) *Individuals eligible for special enrollment*—(i) *When employee loses coverage.* A current employee and any dependents (including the employee's spouse) each are eligible for special enrollment in any benefit package under the plan (subject to plan eligibility rules conditioning dependent enrollment on enrollment of the employee) if—

(A) The employee and the dependents are otherwise eligible to enroll in the benefit package;

(B) When coverage under the plan was previously offered, the employee had coverage under any group health plan or health insurance coverage; and

(C) The employee satisfies the conditions of paragraph (a)(3)(i), (ii), or (iii) of this section and, if applicable, paragraph (a)(3)(iv) of this section.

(ii) *When dependent loses coverage*—(A) A dependent of a current employee (including the employee's spouse) and the employee each are eligible for special enrollment in any benefit package under the plan (subject to plan eligibility rules conditioning dependent enrollment on enrollment of the employee) if—

(*1*) The dependent and the employee are otherwise eligible to enroll in the benefit package;

(*2*) When coverage under the plan was previously offered, the dependent had coverage under any group health plan or health insurance coverage; and

(*3*) The dependent satisfies the conditions of paragraph (a)(3)(i), (ii), or (iii) of this section and, if applicable, paragraph (a)(3)(iv) of this section.

(B) However, the plan or issuer is not required to enroll any other dependent unless that dependent satisfies the criteria of this paragraph (a)(2)(ii), or the employee satisfies the criteria of paragraph (a)(2)(i) of this section.

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

Example 1. (i) *Facts.* Individual *A* works for Employer *X*. *A*, *A*'s spouse, and *A*'s dependent children are eligible but not enrolled for coverage under *X*'s group health plan. *A*'s spouse works for Employer *Y* and at the time coverage was offered under *X*'s plan, *A* was enrolled in coverage under *Y*'s plan. Then, *A* loses eligibility for coverage under *Y*'s plan.

(ii) *Conclusion.* In this *Example 1*, because *A* satisfies the conditions for special enrollment under paragraph (a)(2)(i) of this section, *A*, *A*'s spouse, and *A*'s dependent children are eligible for special enrollment under *X*'s plan.

Example 2. (i) *Facts.* Individual *A* and *A*'s spouse are eligible but not enrolled for coverage under Group Health Plan *P* maintained by *A*'s employer. When *A* was first presented with an opportunity to enroll *A* and *A*'s spouse, they did not have other coverage. Later, *A* and *A*'s spouse enroll in Group Health Plan *Q* maintained by the employer of *A*'s spouse. During a subsequent open enrollment period in *P*, *A* and *A*'s spouse did not enroll because of their coverage under *Q*.

They then lose eligibility for coverage under *Q*.

(ii) *Conclusion.* In this *Example 2,* because *A* and *A*'s spouse were covered under *Q* when they did not enroll in *P* during open enrollment, they satisfy the conditions for special enrollment under paragraphs (a)(2)(i) and (ii) of this section. Consequently, *A* and *A*'s spouse are eligible for special enrollment under *P*.

Example 3. (i) *Facts.* Individual *B* works for Employer *X*. *B* and *B*'s spouse are eligible but not enrolled for coverage under *X*'s group health plan. *B*'s spouse works for Employer *Y* and at the time coverage was offered under *X*'s plan, *B*'s spouse was enrolled in self-only coverage under *Y*'s group health plan. Then, *B*'s spouse loses eligibility for coverage under *Y*'s plan.

(ii) *Conclusion.* In this *Example 3,* because *B*'s spouse satisfies the conditions for special enrollment under paragraph (a)(2)(ii) of this section, both *B* and *B*'s spouse are eligible for special enrollment under *X*'s plan.

Example 4. (i) *Facts.* Individual *A* works for Employer *X*. *X* maintains a group health plan with two benefit packages—an HMO option and an indemnity option. Self-only and family coverage are available under both options. *A* enrolls for self-only coverage in the HMO option. *A*'s spouse works for Employer *Y* and was enrolled for self-only coverage under *Y*'s plan at the time coverage was offered under *X*'s plan. Then, *A*'s spouse loses coverage under *Y*'s plan. *A* requests special enrollment for *A* and *A*'s spouse under the plan's indemnity option.

(ii) *Conclusion.* In this *Example 4,* because *A*'s spouse satisfies the conditions for special enrollment under paragraph (a)(2)(ii) of this section, both *A* and *A*'s spouse can enroll in either benefit package under *X*'s plan. Therefore, if *A* requests enrollment in accordance with the requirements of this section, the plan must allow *A* and *A*'s spouse to enroll in the indemnity option.

(3) *Conditions for special enrollment*—(i) *Loss of eligibility for coverage.* In the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions of this paragraph (a)(3)(i) are satisfied at the time the coverage is terminated as a result of loss of eligibility (regardless of whether the individual is eligible for or elects COBRA continuation coverage). Loss of eligibility under this paragraph (a)(3)(i) does not include a loss due to the failure of the employee or dependent to pay premiums on a timely basis or termination of coverage for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). Loss of eligibility for coverage under this paragraph (a)(3)(i) includes (but is not limited to)—

(A) Loss of eligibility for coverage as a result of legal separation, divorce, cessation of dependent status (such as attaining the maximum age to be eligible as a dependent child under the plan), death of an employee, termination of employment, reduction in the number of hours of employment, and any loss of eligibility for coverage after a period that is measured by reference to any of the foregoing;

(B) In the case of coverage offered through an HMO, or other arrangement, in the individual market that does not provide benefits to individuals who no longer reside, live, or work in a service area, loss of coverage because an individual no longer resides, lives, or works in the service area (whether or not within the choice of the individual);

(C) In the case of coverage offered through an HMO, or other arrangement, in the group market that does not provide benefits to individuals who no longer reside, live, or work in a service area, loss of coverage because an individual no longer resides, lives, or works in the service area (whether or not within the choice of the individual), and no other benefit package is available to the individual;

(D) A situation in which an individual incurs a claim that would meet or exceed a lifetime limit on all benefits; and

(E) A situation in which a plan no longer offers any benefits to the class of similarly situated individuals (as described in §146.121(d)) that includes the individual.

(ii) *Termination of employer contributions.* In the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions of this paragraph (a)(3)(ii) are satisfied at the time employer contributions towards the employee's or dependent's coverage terminate. Employer contributions include contributions by any current or former employer that was contributing to coverage for the employee or dependent.

(iii) *Exhaustion of COBRA continuation coverage.* In the case of an employee or dependent who has coverage that is COBRA continuation coverage, the conditions of this paragraph (a)(3)(iii) are satisfied at the time the COBRA continuation coverage is exhausted. For purposes of this paragraph (a)(3)(iii), an individual who satisfies the conditions for special enrollment of paragraph (a)(3)(i) of this section, does not enroll, and instead elects and exhausts COBRA continuation coverage satisfies the conditions of this paragraph (a)(3)(iii). (*Exhaustion of COBRA continuation coverage* is defined in §144.103 of this chapter.)

(iv) *Written statement.* A plan may require an employee declining coverage (for the employee or any dependent of the employee) to state in writing whether the coverage is being declined due to other health coverage only if, at or before the time the employee declines coverage, the employee is provided with notice of the requirement to provide the statement (and the consequences of the employee's failure to provide the statement). If a plan requires such a statement, and an employee does not provide it, the plan is not required to provide special enrollment to the employee or any dependent of the employee under this paragraph (a)(3). A plan must treat an employee as having satisfied the plan requirement permitted under this paragraph (a)(3)(iv) if the employee provides a written statement that coverage was being declined because the employee or dependent had other coverage; a plan cannot require anything more for the employee to satisfy the plan's requirement to provide a written statement. (For example, the plan cannot require that the statement be notarized.)

(v) The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *D* enrolls in a group health plan maintained by Employer *Y*. At the time *D* enrolls, *Y* pays 70 percent of the cost of employee coverage and *D* pays the rest. *Y* announces that beginning January 1, *Y* will no longer make employer contributions towards the coverage. Employees may maintain coverage, however, if they pay the total cost of the coverage.

(ii) *Conclusion.* In this *Example 1*, employer contributions towards *D*'s coverage ceased on January 1 and the conditions of paragraph (a)(3)(ii) of this section are satisfied on this date (regardless of whether *D* elects to pay the total cost and continue coverage under *Y*'s plan).

Example 2. (i) *Facts.* A group health plan provides coverage through two options—Option 1 and Option 2. Employees can enroll in either option only within 30 days of hire or on January 1 of each year. Employee *A* is eligible for both options and enrolls in Option 1. Effective July 1 the plan terminates coverage under Option 1 and the plan does not create an immediate open enrollment opportunity into Option 2.

(ii) *Conclusion.* In this *Example 2*, A has experienced a loss of eligibility for coverage that satisfies paragraph (a)(3)(i) of this section, and has satisfied the other conditions for special enrollment under paragraph (a)(2)(i) of this section. Therefore, if *A* satisfies the other conditions of this paragraph (a), the plan must permit *A* to enroll in Option 2 as a special enrollee. (*A* may also be eligible to enroll in another group health plan, such as a plan maintained by the employer of *A*'s spouse, as a special enrollee.) The outcome would be the same if Option 1 was terminated by an issuer and the plan made no other coverage available to *A*.

Example 3. (i) *Facts.* Individual *C* is covered under a group health plan maintained by Employer *X*. While covered under *X*'s plan, *C* was eligible for but did not enroll in a plan maintained by Employer Z, the employer of *C*'s spouse. *C* terminates employment with *X* and loses eligibility for coverage under *X*'s plan. *C* has a special enrollment right to enroll in *Z*'s plan, but *C* instead elects COBRA continuation coverage under *X*'s plan. *C* exhausts COBRA continuation coverage under *X*'s plan and requests special enrollment in *Z*'s plan.

(ii) *Conclusion.* In this *Example 3*, *C* has satisfied the conditions for special enrollment under paragraph (a)(3)(iii) of this section, and has satisfied the other conditions for special enrollment under paragraph (a)(2)(i) of this section. The special enrollment right that *C* had into *Z*'s plan immediately after the loss of eligibility for coverage under *X*'s plan was an offer of coverage under *Z*'s plan. When *C* later exhausts COBRA coverage under *X*'s plan, *C* has a second special enrollment right in *Z*'s plan.

(4) *Applying for special enrollment and effective date of coverage*—(i) A plan or issuer must allow an employee a period of at least 30 days after an event described in paragraph (a)(3) of this section (other than an event described in paragraph (a)(3)(i)(D)) to request enrollment (for the employee or the employee's dependent). In the case of an event described in paragraph

(a)(3)(i)(D) of this section (relating to loss of eligibility for coverage due to the operation of a lifetime limit on all benefits), a plan or issuer must allow an employee a period of at least 30 days after a claim is denied due to the operation of a lifetime limit on all benefits.

(ii) Coverage must begin no later than the first day of the first calendar month beginning after the date the plan or issuer receives the request for special enrollment.

(b) *Special enrollment with respect to certain dependent beneficiaries*—(1) *General.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, that makes coverage available with respect to dependents is required to permit individuals described in paragraph (b)(2) of this section to be enrolled for coverage in a benefit package under the terms of the plan. Paragraph (b)(3) of this section describes the required special enrollment period and the date by which coverage must begin. The special enrollment rights under this paragraph (b) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan.

(2) *Individuals eligible for special enrollment.* An individual is described in this paragraph (b)(2) if the individual is otherwise eligible for coverage in a benefit package under the plan and if the individual is described in paragraph (b)(2)(i), (ii), (iii), (iv), (v), or (vi) of this section.

(i) *Current employee only.* A current employee is described in this paragraph (b)(2)(i) if a person becomes a dependent of the individual through marriage, birth, adoption, or placement for adoption.

(ii) *Spouse of a participant only.* An individual is described in this paragraph (b)(2)(ii) if either—

(A) The individual becomes the spouse of a participant; or

(B) The individual is a spouse of a participant and a child becomes a dependent of the participant through birth, adoption, or placement for adoption.

(iii) *Current employee and spouse.* A current employee and an individual who is or becomes a spouse of such an employee, are described in this paragraph (b)(2)(iii) if either—

(A) The employee and the spouse become married; or

(B) The employee and spouse are married and a child becomes a dependent of the employee through birth, adoption, or placement for adoption.

(iv) *Dependent of a participant only.* An individual is described in this paragraph (b)(2)(iv) if the individual is a dependent (as defined in §144.103 of this chapter) of a participant and the individual has become a dependent of the participant through marriage, birth, adoption, or placement for adoption.

(v) *Current employee and a new dependent.* A current employee and an individual who is a dependent of the employee, are described in this paragraph (b)(2)(v) if the individual becomes a dependent of the employee through marriage, birth, adoption, or placement for adoption.

(vi) *Current employee, spouse, and a new dependent.* A current employee, the employee's spouse, and the employee's dependent are described in this paragraph (b)(2)(vi) if the dependent becomes a dependent of the employee through marriage, birth, adoption, or placement for adoption.

(3) *Applying for special enrollment and effective date of coverage*—(i) *Request.* A plan or issuer must allow an individual a period of at least 30 days after the date of the marriage, birth, adoption, or placement for adoption (or, if dependent coverage is not generally made available at the time of the marriage, birth, adoption, or placement for adoption, a period of at least 30 days after the date the plan makes dependent coverage generally available) to request enrollment (for the individual or the individual's dependent).

(ii) *Reasonable procedures for special enrollment.* [Reserved]

(iii) *Date coverage must begin*—(A) *Marriage.* In the case of marriage, coverage must begin no later than the first day of the first calendar month beginning after the date the plan or issuer receives the request for special enrollment.

(B) *Birth, adoption, or placement for adoption.* Coverage must begin in the case of a dependent's birth on the date

of birth and in the case of a dependent's adoption or placement for adoption no later than the date of such adoption or placement for adoption (or, if dependent coverage is not made generally available at the time of the birth, adoption, or placement for adoption, the date the plan makes dependent coverage available).

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

Example 1. (i) *Facts.* An employer maintains a group health plan that offers all employees employee-only coverage, employee-plus-spouse coverage, or family coverage. Under the terms of the plan, any employee may elect to enroll when first hired (with coverage beginning on the date of hire) or during an annual open enrollment period held each December (with coverage beginning the following January 1). Employee *A* is hired on September 3. *A* is married to *B*, and they have no children. On March 15 in the following year a child *C* is born to *A* and *B*. Before that date, *A* and *B* have not been enrolled in the plan.

(ii) *Conclusion.* In this *Example 1*, the conditions for special enrollment of an employee with a spouse and new dependent under paragraph (b)(2)(vi) of this section are satisfied. If *A* satisfies the conditions of paragraph (b)(3) of this section for requesting enrollment timely, the plan will satisfy this paragraph (b) if it allows *A* to enroll either with employee-only coverage, with employee-plus-spouse coverage (for *A* and *B*), or with family coverage (for *A*, *B*, and *C*). The plan must allow whatever coverage is chosen to begin on March 15, the date of *C*'s birth.

Example 2. (i) *Facts.* Individual *D* works for Employer *X*. *X* maintains a group health plan with two benefit packages—an HMO option and an indemnity option. Self-only and family coverage are available under both options. *D* enrolls for self-only coverage in the HMO option. Then, a child, *E*, is placed for adoption with *D*. Within 30 days of the placement of *E* for adoption, *D* requests enrollment for *D* and *E* under the plan's indemnity option.

(ii) *Conclusion.* In this *Example 2*, *D* and *E* satisfy the conditions for special enrollment under paragraphs (b)(2)(v) and (b)(3) of this section. Therefore, the plan must allow *D* and *E* to enroll in the indemnity coverage, effective as of the date of the placement for adoption.

(c) *Notice of special enrollment.* At or before the time an employee is initially offered the opportunity to enroll in a group health plan, the plan must furnish the employee with a notice of special enrollment that complies with the requirements of this paragraph (c).

(1) *Description of special enrollment rights.* The notice of special enrollment must include a description of special enrollment rights. The following model language may be used to satisfy this requirement:

If you are declining enrollment for yourself or your dependents (including your spouse) because of other health insurance or group health plan coverage, you may be able to enroll yourself and your dependents in this plan if you or your dependents lose eligibility for that other coverage (or if the employer stops contributing towards your or your dependents' other coverage). However, you must request enrollment within [insert ''30 days'' or any longer period that applies under the plan] after your or your dependents' other coverage ends (or after the employer stops contributing toward the other coverage).

In addition, if you have a new dependent as a result of marriage, birth, adoption, or placement for adoption, you may be able to enroll yourself and your dependents. However, you must request enrollment within [insert ''30 days'' or any longer period that applies under the plan] after the marriage, birth, adoption, or placement for adoption.

To request special enrollment or obtain more information, contact [insert the name, title, telephone number, and any additional contact information of the appropriate plan representative].

(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 cost-

sharing 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. The length of any preexisting condition exclusion that may be applied to a special enrollee cannot exceed the length of any preexisting condition exclusion that is applied to similarly situated individuals who enroll when first eligible. For rules prohibiting the application of a preexisting condition exclusion to certain newborns, adopted children, and children placed for adoption, see §146.111(b).

(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]

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

(a) *In general.* A group health plan offering health insurance coverage through an HMO, or an HMO that offers health insurance coverage in connection with a group health plan, may impose an affiliation period only if each of the following requirements is satisfied—

(1) No preexisting condition exclusion is imposed with respect to any coverage offered by the HMO in connection with the particular group health plan.

(2) No premium is charged to a participant or beneficiary for the affiliation period.

(3) The affiliation period for the HMO coverage is imposed consistent with the requirements of §146.121 (prohibiting discrimination based on a health factor).

(4) The affiliation period does not exceed 2 months (or 3 months in the case of a late enrollee).

(5) The affiliation period begins on the enrollment date, or in the case of a late enrollee, the affiliation period begins on the day that would be the first day of coverage but for the affiliation period.

(6) The affiliation period for enrollment in the HMO under a plan runs concurrently with any waiting period.

(b) *Examples.* The rules of paragraph (a) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan. Benefits under the plan are provided through an HMO, which imposes a two-month affiliation period. In order to be eligible under the plan, employees must have worked for the employer for six months. Individual *A* begins working for the employer on February 1.

(ii) *Conclusion.* In this *Example 1,* Individual *A*'s enrollment date is February 1 (see §146.111(a)(2)), and both the waiting period and the affiliation period begin on this date and run concurrently. Therefore, the affiliation period ends on March 31, the waiting period ends on July 31, and *A* is eligible to have coverage begin on August 1.

Example 2. (i) *Facts.* A group health plan has two benefit package options, a fee-for-service option and an HMO option. The HMO imposes a 1-month affiliation period. Individual *B* is enrolled in the fee-for-service option for more than one month and then decides to switch to the HMO option at open season.

(ii) *Conclusion.* In this *Example 2*, the HMO may not impose the affiliation period with respect to *B* because any affiliation period would have to begin on *B*'s enrollment date in the plan rather than the date that *B* enrolled in the HMO option. Therefore, the affiliation period would have expired before *B* switched to the HMO option.

Example 3. (i) *Facts.* An employer sponsors a group health plan that provides benefits through an HMO. The plan imposes a two-month affiliation period with respect to salaried employees, but it does not impose an affiliation period with respect to hourly employees.

(ii) *Conclusion.* In this *Example 3*, the plan may impose the affiliation period with respect to salaried employees without imposing any affiliation period with respect to hourly employees (unless, under the circumstances, treating salaried and hourly employees differently does not comply with the requirements of §146.121).

(c) *Alternatives to affiliation period.* An HMO may use alternative methods in lieu of an affiliation period to address adverse selection, as approved by the State insurance commissioner or other official designated to regulate HMOs. However, an arrangement that is in the nature of a preexisting condition exclusion cannot be an alternative to an affiliation period. Nothing in this part requires a State to receive proposals for or approve alternatives to affiliation periods.

[69 FR 78797, Dec. 30, 2004]

§ 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.

(2) Evidence of insurability includes—

(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*—(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 is subject to the provisions of paragraph (b)(2) of this section (explaining how this rule applies to benefits), paragraph (b)(3) of this section (allowing plans to impose certain preexisting condition exclusions), 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 or through group health insurance coverage 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 or issuer 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 impose annual, lifetime, or other limits on benefits and 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 any other provision of ERISA, 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 $500,000 lifetime limit on all benefits 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)(i) because $500,000 of benefits are 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 $2 million lifetime limit on all benefits (and no other lifetime limits) for participants covered under the plan. Participant *B* files 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 $10,000 lifetime limit 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 (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. (This example does not address whether the plan provision is permissible under the Americans with Disabilities Act or any other applicable law.)

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.

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.

Example 8. (i) *Facts.* An employer sponsors a group health plan that is available to all current employees. Under the plan, the medical care expenses of each employee (and the employee's dependents) are reimbursed up to an annual maximum amount. The maximum reimbursement amount with respect to an employee for a year is $1500 multiplied by the number of years the employee has participated in the plan, reduced by the total reimbursements for prior years.

(ii) *Conclusion.* In this *Example 8*, the variable annual limit does not violate this paragraph (b)(2)(i). Although the maximum reimbursement amount for a year varies among employees within the same group of similarly situated individuals based on prior claims experience, employees who have participated in the plan for the same length of time are eligible for the same total benefit over that length of time (and the restriction on the maximum reimbursement amount is not directed at any individual participants or beneficiaries based on any health factor).

(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-of-injury 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.)

(3) *Relationship to §146.111.* (i) A preexisting condition exclusion is permitted under this section if it —

(A) Complies with §146.111;

(B) Applies uniformly to all similarly situated individuals (as described in paragraph (d) of this section); and

(C) Is not directed at individual participants or beneficiaries based on any health factor of the participants or

beneficiaries. For purposes of this paragraph (b)(3)(i)(C), a plan amendment relating to a preexisting condition exclusion 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.

(ii) The rules of this paragraph (b)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan imposes a preexisting condition exclusion on all individuals enrolled in the plan. The exclusion applies to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. In addition, the exclusion generally extends for 12 months after an individual's enrollment date, but this 12-month period is offset by the number of days of an individual's creditable coverage in accordance with §146.111. There is nothing to indicate that the exclusion is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1*, even though the plan's preexisting condition exclusion discriminates against individuals based on one or more health factors, the preexisting condition exclusion does not violate this section because it applies uniformly to all similarly situated individuals, is not directed at individual participants or beneficiaries, and complies with §146.111 (that is, the requirements relating to the six-month look-back period, the 12-month (or 18-month) maximum exclusion period, and the creditable coverage offset).

Example 2. (i) *Facts.* A group health plan excludes coverage for conditions with respect to which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. Under the plan, the preexisting condition exclusion generally extends for 12 months, offset by creditable coverage. However, if an individual has no claims in the first six months following enrollment, the remainder of the exclusion period is waived.

(ii) *Conclusion.* In this *Example 2*, the plan's preexisting condition exclusions violate this section because they do not meet the requirements of this paragraph (b)(3); specifically, they do not apply uniformly to all similarly situated individuals. The plan provisions do not apply uniformly to all similarly situated individuals because individuals who have medical claims during the first six months following enrollment are not treated the same as similarly situated individuals with no claims during that period. (Under paragraph (d) of this section, the groups cannot be treated as two separate groups of similarly situated individuals because the distinction is based on a health factor.)

(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 1*, 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 package.

(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 employer'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 part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus 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 between 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 dependent children. However, coverage is made available to a dependent child only if the dependent child is under age 19 (or under age 25 if the child is continuously enrolled full-time 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 dependent children differently by imposing an age limitation on dependent children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and dependent 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 dependent children who are under age 19 (or full-time students under age 25) as a group of similarly situated individuals separate from those who are age 25 or older (or age 19 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 lower lifetime dollar limit than in the benefit package made available to the other six employees.

(ii) *Conclusion.* Under the facts of this *Example 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-at-work 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-of-benefits 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.

(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 full-time 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) *Wellness programs.* A wellness program is any program designed to promote health or prevent disease. 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). 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, paragraph (f)(1) of this section clarifies that the wellness program does not violate this section if participation in the program is made available to all similarly situated individuals. If any 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, the wellness program does not violate this section if the requirements of paragraph (f)(2) of this section are met.

(1) *Wellness programs not subject to requirements.* If none of the conditions for obtaining a reward under a wellness program are 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 does not violate this section, if participation in the program is made available to all similarly situated individuals. Thus, for example, the following programs need not satisfy the requirements of paragraph (f)(2) of this section, if participation in the program is made available to all similarly situated individuals:

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

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

(iii) 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.

(iv) A program that reimburses employees for the costs of smoking cessation programs without regard to whether the employee quits smoking.

(v) A program that provides a reward to employees for attending a monthly health education seminar.

(2) *Wellness programs subject to requirements.* If any 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, the wellness program does not violate this section if the requirements of this paragraph (f)(2) are met.

(i) The reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed 20 percent of the 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 20 percent of the cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(2), the cost of coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward can be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan.

(ii) 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.

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

(iv) The reward under the program must be available to all similarly situated individuals. (A) A reward is not available to all similarly situated individuals for a period unless the program allows —

(1) 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) 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) A plan or issuer may seek verification, such as a statement from an individual's physician, that a health factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

(v)(A) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under paragraph (f)(2)(iv) of this section. However, if plan materials merely mention that a program is available, without describing its terms, this disclosure is not required.

(B) The following language, or substantially similar language, can be used to satisfy the requirement of this paragraph (f)(2)(v): ''If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward.'' In addition, other examples of language that would satisfy this requirement are set forth in Examples 3, 4, and 5 of paragraph (f)(3) of this section.

(3) *Examples.* The rules of paragraph (f)(2) of this section 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 $3,600 (of which the employer pays $2,700 per year and the employee pays $900 per year). The annual premium for family coverage is $9,000 (of which the employer pays $4,500 per year and the employee pays $4,500 per year). The plan offers a wellness program with an annual premium rebate of $360. The program is available only to employees.

(ii) *Conclusion.* In this *Example 1*, the program satisfies the requirements of paragraph (f)(2)(i) of this section because the reward for the wellness program, $360, does not exceed 20 percent of the total annual cost of employee-only coverage, $720. ($3,600 × 20% = $720.) If any class of dependents is allowed to participate in the program and the employee is enrolled in family coverage, the plan could offer the employee a reward of up to 20 percent of the cost of family coverage, $1,800. ($9,000 × 20% = $1,800.)

Example 2. (i) *Facts.* A group health plan gives an annual premium discount of 20 percent of the cost of employee-only coverage to participants who adhere to a wellness program. The wellness program consists solely of giving an annual cholesterol test to participants. Those participants who achieve a count under 200 receive the premium discount for the year.

(ii) *Conclusion.* In this *Example 2*,the program fails to satisfy the requirement of being available to all similarly situated individuals because some participants may be unable to achieve a cholesterol count of under 200 and the plan does not make available a reasonable alternative standard or waive the cholesterol standard. (In addition, plan materials describing the program are required to disclose the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) for obtaining the premium discount. Thus, the premium discount violates paragraph (c) of this section because it may require an individual to pay a higher premium based on a health factor of the individual than is required of a similarly situated individual under the plan.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that the plan provides that if it is unreasonably difficult due to a medical condition for a participant to achieve the targeted cholesterol count (or if it is medically inadvisable for a participant to attempt to achieve the targeted cholesterol count) within a 60-day period, the plan will make available a reasonable alternative standard that takes the relevant medical condition into account. In addition, all plan materials describing the terms of the program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a cholesterol count under 200, or if it is medically inadvisable for you to attempt to achieve a count under 200, call us at the number below and we will work with you to develop another way to get the discount.'' Individual *D* begins a diet and exercise program but is unable to achieve a cholesterol count under 200 within the prescribed period. D's doctor determines D requires prescription medication to achieve a medically advisable cholesterol count. In addition, the doctor determines that D must be monitored through periodic blood tests to continually reevaluate D's health status. The plan accommodates *D* by making the discount available to *D*, but only if *D* follows the advice of D's doctor regarding medication and blood tests.

(ii) *Conclusion.* In this *Example 3*, the program is a wellness program because it satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve the targeted count (or for whom it is medically inadvisable to attempt to achieve the targeted count) in the prescribed period by providing a reasonable alternative standard. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium discount does not violate this section.

Example 4. (i) *Facts.* A group health plan will waive the $250 annual deductible (which is less than 20 percent of the annual cost of employee-only coverage under the plan) for the following year for participants who have a body mass index between 19 and 26, determined shortly before the beginning of the year. However, any participant for whom it is unreasonably difficult due to a medical condition to attain this standard (and any participant for whom it is medically inadvisable to attempt to achieve this standard) during the plan year is given the same discount if the participant walks for 20 minutes three days a week. Any participant for whom it is unreasonably difficult due to a medical condition to attain either standard (and any participant for whom it is medically inadvisable to attempt to achieve either standard) during the year is given the same discount if the individual satisfies an alternative standard that is reasonable in the burden it imposes and is reasonable taking into consideration the individual's medical situation. All

plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a body mass index between 19 and 26 (or if it is medically inadvisable for you to attempt to achieve this body mass index) this year, your deductible will be waived if you walk for 20 minutes three days a week. If you cannot follow the walking program, call us at the number above and we will work with you to develop another way to have your deductible waived.'' Due to a medical condition, Individual E is unable to achieve a BMI of between 19 and 26 and is also unable to follow the walking program. *E* proposes a program based on the recommendations of *E*'s physician. The plan agrees to make the discount available to *E* if *E* follows the physician's recommendations.

(ii) *Conclusion.* In this *Example 4*, the program satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it generally accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve (or for whom it is medically inadvisable to attempt to achieve) the targeted body mass index by providing a reasonable alternative standard (walking) and it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to walk by providing an alternative standard that is reasonable for the individual. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard for every individual. Thus, the waiver of the deductible does not violate this section.

Example 5. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a form for participants to certify that they have not used tobacco products in the preceding twelve months. Participants who do not provide the certification are assessed a surcharge that is 20 percent of the cost of employee-only coverage. However, all plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a health factor for you to meet the requirements under this program (or if it is medically inadvisable for you to attempt to meet the requirements of this program), we will make available a reasonable alternative standard for you to avoid this surcharge.'' It is unreasonably difficult for Individual *F* to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates *F* by requiring *F* to participate in a smoking cessation program to avoid the surcharge. *F* can avoid the surcharge for as long as *F* participates in the program, regardless of whether *F* stops smoking (as long as *F* continues to be addicted to nicotine).

(ii) *Conclusion.* In this *Example 5*, the premium surcharge is permissible as a wellness program because it satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to quit using tobacco products by providing a reasonable alternative standard. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium surcharge does not violate this section.

Example 6. (i) *Facts.* Same facts as *Example 5*, except the plan accommodates *F* by requiring *F* to view, over a period of 12 months, a 12-hour video series on health problems associated with tobacco use. *F* can avoid the surcharge by complying with this requirement.

(ii) *Conclusion.* In this *Example 6*, the requirement to watch the series of video tapes is a reasonable alternative method for avoiding the surcharge.

(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 23. However, dependent children who are disabled are eligible for coverage beyond age 23.

(ii) *Conclusion.* In this *Example 1*, the plan provision allowing coverage for disabled dependent children beyond age 23 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 employee-only coverage and $250 per month for family coverage. (This extended period 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 2*, the plan provision allowing extended coverage for disabled 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.

(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 Americans with Disabilities Act. 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 nonfederal 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 self-funded 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 12-month 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 *E* may 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]

§ 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-grandchildren, 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.

(iii) The term *genetic information* includes—

(A) With respect to a pregnant woman (or a family member of the pregnant woman), genetic information of any fetus carried by the pregnant woman; and

(B) With respect to an individual (or a family member of the individual) who is utilizing an assisted reproductive technology, genetic information of any embryo legally held by the individual or family member.

(4) *Genetic services* means —

(i) A genetic test, as defined in paragraph (a)(5) of this section;

(ii) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(iii) Genetic education.

(5)(i) *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. However, a genetic test does not include an analysis of

proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a BRCA1 or BRCA2 variant is a genetic test. Similarly, a test to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer is a genetic test. However, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

(ii) The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* Individual *A* is a newborn covered under a group health plan. *A* undergoes a phenylketonuria (PKU) screening, which measures the concentration of a metabolite, phenylalanine, in *A*'s blood. In PKU, a mutation occurs in the phenylalanine hydroxylase (PAH) gene which contains instructions for making the enzyme needed to break down the amino acid phenylalanine. Individuals with the mutation, who have a deficiency in the enzyme to break down phenylalanine, have high concentrations of phenylalanine.

(ii) *Conclusion.* In this *Example*, the PKU screening is a genetic test with respect to *A* because the screening is an analysis of metabolites that detects a genetic mutation.

(6)(i) *Manifestation* or *manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this section, a disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.

(ii) The rules of this paragraph (a)(6) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* has a family medical history of diabetes. *A* begins to experience excessive sweating, thirst, and fatigue. *A*'s physician examines *A* and orders blood glucose testing (which is not a genetic test). Based on the physician's examination, *A*'s symptoms, and test results that show elevated levels of blood glucose, *A*'s physician diagnoses *A* as having adult onset diabetes mellitus (Type 2 diabetes).

(ii) *Conclusion.* In this *Example 1, A* has been diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. The diagnosis is not based principally on genetic information. Thus, Type 2 diabetes is manifested with respect to *A.*

Example 2. (i) *Facts.* Individual *B* has several family members with colon cancer. One of them underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). *B*'s physician, a health care professional with appropriate training and expertise in the field of medicine involved, recommends that *B* undergo a targeted genetic test to look for the specific mutation found in *B* 's relative to determine if *B* has an elevated risk for cancer. The genetic test with respect to *B* showed that *B* also carries the mutation and is at increased risk to develop colorectal and other cancers associated with HNPCC. *B* has a colonoscopy which indicates no signs of disease, and *B* has no symptoms.

(ii) *Conclusion.* In this *Example 2,* because *B* has no signs or symptoms of colorectal cancer, *B* has not been and could not reasonably be diagnosed with HNPCC. Thus, HNPCC is not manifested with respect to *B.*

Example 3. (i) *Facts.* Same facts as *Example 2*, except that *B*'s colonoscopy and subsequent tests indicate the presence of HNPCC. Based on the colonoscopy and subsequent test results, *B*'s physician makes a diagnosis of HNPCC.

(ii) *Conclusion.* In this *Example 3*, HNPCC is manifested with respect to *B* because a health care professional with appropriate training and expertise in the field of medicine involved has made a diagnosis that is not based principally on genetic information.

Example 4. (i) *Facts.* Individual *C* has a family member that has been diagnosed with Huntington's Disease. A genetic test indicates that *C* has the Huntington's Disease gene variant. At age 42, *C* begins suffering from occasional moodiness and disorientation, symptoms which are associated with Huntington's Disease. *C* is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's Disease). The examination includes a clinical neurological exam. The results of the examination do not support a diagnosis of Huntington's Disease.

(ii) *Conclusion.* In this *Example 4, C* is not and could not reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is not manifested with respect to *C.*

Example 5. (i) *Facts.* Same facts as *Example 4*, except that *C* exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's Disease with respect to *C*.

(ii) *Conclusion.* In this *Example 5*, *C* could reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is manifested with respect to *C*.

(7) *Underwriting purposes* has the meaning given in paragraph (d)(1) of this section.

(b) *No group-based discrimination based on genetic information*—(1) *In general.* For purposes of this section, a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not adjust premium or contribution amounts for the plan, or any group of similarly situated individuals under the plan, on the basis of genetic information. For this purpose, ''similarly situated individuals'' are those described in §146.121(d) of this part.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section (or in paragraph (d)(1) or (d)(2) of this section) limits the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for a group health plan or a group of similarly situated individuals under the plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such a case, however, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members to further increase the premium for a group health plan or a group of similarly situated individuals under the plan.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that provides coverage through 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 and other health status information of the individuals, including genetic information. The issuer finds that three individuals covered under the plan had unusually high claims experience. In addition, the issuer finds that the genetic information of two other individuals indicates the individuals have a higher probability of developing certain illnesses although the illnesses are not manifested at this time. The issuer quotes the plan a higher per-participant rate because of both the genetic information and the higher claims experience.

(ii) *Conclusion.* In this *Example 1*, the issuer violates the provisions of this paragraph (b) because the issuer adjusts the premium based on genetic information. However, if the adjustment related solely to claims experience, the adjustment would not violate the requirements of this section (nor would it violate the requirements of paragraph (c) of §146.121 of this part, which prohibits discrimination in individual premiums or contributions based on a health factor but permits increases in the group rate based on a health factor).

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage through 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 and other health status information of the individuals, including genetic information. The issuer finds that Employee *A* has made claims for treatment of polycystic kidney disease. *A* also has two dependent children covered under the plan. The issuer quotes the plan a higher per-participant rate because of both *A*'s claims experience and the family medical history of *A*'s children (that is, the fact that *A* has the disease).

(ii) *Conclusion.* In this *Example 2*, the issuer violates the provisions of this paragraph (b) because, by taking the likelihood that *A*'s children may develop polycystic kidney disease into account in computing the rate for the plan, the issuer adjusts the premium based on genetic information relating to a condition that has not been manifested in *A*'s children. However, it is permissible for the issuer to increase the premium based on *A*'s claims experience.

(c) *Limitation on requesting or requiring genetic testing*—(1) *General rule.* Except as otherwise provided in this paragraph (c), a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (c)(1) of this section limits the authority of a health care professional

who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples.* The rules of paragraphs (c)(1) and (2) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* goes to a physician for a routine physical examination. The physician reviews *A*'s family medical history and *A* informs the physician that *A*'s mother has been diagnosed with Huntington's Disease. The physician advises *A* that Huntington's Disease is hereditary and recommends that *A* undergo a genetic test.

(ii) *Conclusion.* In this *Example 1*, the physician is a health care professional who is providing health care services to *A*. Therefore, the physician's recommendation that *A* undergo the genetic test does not violate this paragraph (c).

Example 2. (i) *Facts.* Individual *B* is covered by a health maintenance organization (HMO). *B* is a child being treated for leukemia. *B*'s physician, who is employed by the HMO, is considering a treatment plan that includes six-mercaptopurine, a drug for treating leukemia in most children. However, the drug could be fatal if taken by a small percentage of children with a particular gene variant. *B*'s physician recommends that *B* undergo a genetic test to detect this variant before proceeding with this course of treatment.

(ii) *Conclusion.* In this *Example 2,* even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to *B*. Therefore, the physician's recommendation that *B* undergo the genetic test does not violate this paragraph (c).

(4) *Determination regarding payment.*

(i) *In general.* As provided in this paragraph (c)(4), nothing in paragraph (c)(1) of this section precludes a plan or issuer from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in §164.501 of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if a plan or issuer conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on the genetic makeup of a patient, then the plan or issuer is permitted to condition payment for the item or service on the outcome of a genetic test. The plan or issuer may also refuse payment if the patient does not undergo the genetic test.

(ii) *Limitation.* A plan or issuer is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in §164.502(b) of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples. See* paragraph (e) of this section for examples illustrating the rules of this paragraph (c)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (c)(1) of this section, a plan or issuer may request, but not require, that a participant or beneficiary undergo a genetic test if all of the conditions of this paragraph (c)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations.* The plan or issuer makes the request pursuant to research, as defined in §46.102(d) of this subtitle, that complies with part 46 of this subtitle or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research.* The plan or issuer makes the request in writing, and the request clearly indicates to each participant or beneficiary (or, in the case of a minor child, to the legal guardian of the beneficiary) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in §146.121(b)(1) of this part) or premium or contribution amounts.

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (c)(5) can be used for underwriting purposes (as described in paragraph (d)(1) of this section).

(iv) *Notice to Federal agencies.* The plan or issuer completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and provides the notice to

the address specified in the instructions thereto.

(d) *Prohibitions on collection of genetic information.*

(1) *For underwriting purposes.*

(i) *General rule.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect (as defined in paragraph (a)(1) of this section) genetic information for underwriting purposes. *See* paragraph (e) of this section for examples illustrating the rules of this paragraph (d)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (d)(1)(iii) of this section, *underwriting purposes* means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in §146.121(b)(1)(ii) of this part (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(B) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(C) The application of any preexisting condition exclusion under the plan or coverage; and

(D) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(iii) *Medical appropriateness.* If an individual seeks a benefit under a group health plan or health insurance coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an individual seeks a benefit under the plan and the plan or issuer conditions the benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on genetic information of the individual, then the plan or issuer is permitted to condition the benefit on the genetic information. A plan or issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness. The plan or issuer may deny the benefit if the patient does not provide the genetic information required to determine medical appropriateness. If an individual is not seeking a benefit, the medical appropriateness exception of this paragraph (d)(1)(iii) to the definition of underwriting purposes does not apply. *See* paragraph (e) of this section for examples illustrating the medical appropriateness provisions of this paragraph (d)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment.* (i) *In general.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect genetic information with respect to any individual prior to that individual's effective date of coverage under that plan or coverage, nor in connection with the rules for eligibility (as defined in §146.121(b)(1)(ii) of this part) that apply to that individual. Whether or not an individual's information is collected prior to that individual's effective date of coverage is determined at the time of collection.

(ii) *Incidental collection exception.*

(A) *In general.* If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (d)(2), as long as the collection is not for underwriting purposes in violation of paragraph (d)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (d)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided.

(3) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The health risk assessment includes questions about the individual's family medical history.

(ii) *Conclusion.* In this *Example 1*, the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information in paragraph (d)(1) of this section.

Example 2. (i) *Facts.* The same facts as *Example 1*, except there is no premium reduction or any other reward for completing the health risk assessment.

(ii) *Conclusion.* In this *Example 2*, the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 3. (i) *Facts.* A group health plan requests that enrollees complete a health risk assessment prior to enrollment, and includes questions about the individual's family medical history. There is no reward or penalty for completing the health risk assessment.

(ii) *Conclusion.* In this *Example 3*, because the health risk assessment includes a request for genetic information (that is, the individual's family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information in paragraph (d)(2) of this section. Moreover, because it is a request for genetic information, it is not an incidental collection under paragraph (d)(2)(ii) of this section.

Example 4. (i) *Facts.* The facts are the same as in *Example 1*, except there is no premium reduction or any other reward given for completion of the health risk assessment. However, certain people completing the health risk assessment may become eligible for additional benefits under the plan by being enrolled in a disease management program based on their answers to questions about family medical history. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history.

(ii) *Conclusion.* In this *Example 4*, the request for information about an individual's family medical history could result in the individual being eligible for benefits for which the individual would not otherwise be eligible. Therefore, the questions about family medical history on the health risk assessment are a request for genetic information for underwriting purposes and are prohibited under this paragraph (d). Although the plan conditions eligibility for the disease management program based on determinations of medical appropriateness, the exception for determinations of medical appropriateness does not apply because the individual is not seeking benefits.

Example 5. (i) *Facts.* A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

(ii) *Conclusion.* In this *Example 5*, no genetic information is collected in connection with the first HRA, which offers a reward, and no benefits or other rewards are conditioned on the request for genetic information in the second HRA. Consequently, the request for genetic information in the second HRA is not for underwriting purposes, and the two HRAs do not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 6. (i) *Facts.* A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual's genetic information (including family medical history). However, the last question reads, ''Is there anything else relevant to your health that you would like us to know or discuss with you?''

(ii) *Conclusion.* In this *Example 6*, the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to

the question is not within the incidental collection exception and is prohibited under this paragraph (d).

Example 7. (i) *Facts.* Same facts as *Example 6*, except that the last question goes on to state, ''In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk.''

(ii) *Conclusion.* In this *Example 7*, the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

Example 8. (i) *Facts.* Issuer *M* acquires Issuer *N*. *M* requests *N*'s records, stating that *N* should not provide genetic information and should review the records to excise any genetic information. *N* assembles the data requested by *M* and, although *N* reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, *M* receives genetic information about some of *N*'s covered individuals.

(ii) *Conclusion.* In this *Example 8*, *M*'s request for health information explicitly stated that genetic information should not be provided. Therefore, the collection of genetic information was within the incidental collection exception. However, *M* may not use the genetic information it obtained incidentally for underwriting purposes.

(e) *Examples regarding determinations of medical appropriateness.* The application of the rules of paragraphs (c) and (d) of this section to plan or issuer determinations of medical appropriateness is illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* group health plan covers genetic testing for celiac disease for individuals who have family members with this condition. After *A*'s son is diagnosed with celiac disease, *A* undergoes a genetic test and promptly submits a claim for the test to *A*'s issuer for reimbursement. The issuer asks *A* to provide the results of the genetic test before the claim is paid.

(ii) *Conclusion.* In this *Example 1*, under the rules of paragraph (c)(4) of this section the issuer is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for the issuer to make a decision regarding the payment of *A*'s claim, the issuer's request for the results of the genetic test violates paragraph (c) of this section.

Example 2. (i) *Facts.* Individual *B*'s group health plan covers a yearly mammogram for participants and beneficiaries starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. *B* is 33 years old and has the BRCA2 mutation. *B* undergoes a mammogram and promptly submits a claim to *B*'s plan for reimbursement. Following an established policy, the plan asks *B* for evidence of increased risk of breast cancer, such as the results of a genetic test or a family history of breast cancer, before the claim for the mammogram is paid. This policy is applied uniformly to all similarly situated individuals and is not directed at individuals based on any genetic information.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate paragraphs (c) or (d) of this section. Under paragraph (c), the plan is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the plan requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the genetic makeup of the patient, the minimum amount of information necessary includes the results of the genetic test. Similarly, the plan does not violate paragraph (d) of this section because the plan is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and if the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts.* Individual *C* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *C*'s physician, *C* has been taking a regular dose of tamoxifen to help prevent a recurrence. *C*'s group health plan adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients, those with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, the plan does not pay for the tamoxifen prescription.

(ii) *Conclusion.* In this *Example 3*, the plan does not violate paragraph (c) of this section if it conditions future payments for the tamoxifen prescription on *C*'s undergoing a genetic test to determine what genetic markers *C* has for making the CYP_2D6 enzyme. Nor does the plan violate paragraph (c) of this section if the plan refuses future

payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *C*.

Example 4. (i) *Facts*. A group health plan offers a diabetes disease management program to all similarly situated individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants that describes the diabetes disease management program and explains the terms for eligibility. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes. For individuals who do not currently have diabetes, genetic information may be used to demonstrate that an individual is at risk.

(ii) *Conclusion*. In this *Example 4*, the plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such showing may involve genetic information, provided that the plan requests genetic information only when necessary to make a determination regarding whether the disease management program is medically appropriate for the individual and only requests the minimum amount of information necessary to make that determination.

Example 5. (i) *Facts*. Same facts as *Example 4*, except that the plan includes a questionnaire that asks about the occurrence of diabetes in members of the individual's family as part of the notice describing the disease management program.

(ii) *Conclusion*. In this *Example 5*, the plan violates the requirements of paragraph (d)(1) of this section because the requests for genetic information are not limited to those situations in which it is necessary to make a determination regarding whether the disease management program is medically appropriate for the individuals.

Example 6. (i) *Facts*. Same facts as *Example 4*, except the disease management program provides an enhanced benefit in the form of a lower annual deductible to individuals under the program; the lower deductible applies with respect to all medical expenses incurred by the individual. Thus, whether or not a claim relates to diabetes, the individual is provided with a lower deductible based on the individual providing the plan with genetic information.

(ii) *Conclusion*. In this *Example 6*, because the enhanced benefits include benefits not related to the determination of medical appropriateness, making available the enhanced benefits is within the meaning of underwriting purposes. Accordingly, the plan may not request or require genetic information (including family history information) in determining eligibility for enhanced benefits under the program because such a request would be for underwriting purposes and would violate paragraph (d)(1) of this section.

(f) *Applicability date*. This section applies for plan years beginning on or after December 7, 2009.

[74 FR 51688, Oct. 7, 2009]

§ 146.125 Applicability dates.

Section 144.103, §§ 146.111 through 146.119, § 146.143, and § 146.145 are applicable for plan years beginning on or after July 1, 2005. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144 and 146, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2004.

[69 FR 78797, Dec. 30, 2004; 70 FR 21147, Apr. 25, 2005]

Subpart C—Requirements Related to Benefits

§ 146.130 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule*. Except as provided in paragraph (a)(5) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital*. If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital*. If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection

with childbirth is a medical decision to be made by the attending provider.

(3) *Examples.* The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In each example, the group health plan provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A pregnant woman covered under a group health plan goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion.* In this *Example 1,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts.* A woman covered under a group health plan gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion.* In this *Example 2,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts.* A woman covered under a group health plan gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion.* In this *Example 3,* the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general.* A plan or issuer is prohibited from requiring that a physician or other health care provider obtain authorization from the plan or issuer for prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example.* The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts.* In the case of a delivery by cesarean section, a group health plan subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the plan requires an attending provider to complete a certificate of medical necessity. The plan then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion.* In this *Example,* the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, a plan, hospital, managed care organization, or other issuer is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a group health plan subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The plan pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example,* the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital

stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll or renew coverage under the terms of the plan solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under the plan are discharged within 24 hours after the delivery, the plan will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1*, because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the plan violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the plan provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2*, because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* A group health plan subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the plan automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the participant or beneficiary must call the plan to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the plan will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example*, the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit a plan from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the plan based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a participant or beneficiary in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a participant or beneficiary in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any group health plan, or any group health insurance coverage, that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the plan or coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The plan covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1*, the plan violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the plan also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* A group health plan generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the plan will cover 80 percent of the cost of the stay if the participant or beneficiary notifies the plan of the pregnancy in advance of admission and uses whatever hospital the plan may designate.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the plan does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, a group health plan that provides benefits for hospital lengths of stay in connection with childbirth must meet the following requirements:

(1) *Required statement.* The plan document that provides a description of plan benefits to participants and beneficiaries, or that notifies participants and beneficiaries of plan benefit changes, must disclose information that notifies participants and beneficiaries of their rights under this section.

(2) *Disclosure notice.* To meet the disclosure requirement set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

STATEMENT OF RIGHTS UNDER THE NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT

Under federal law, group health plans and health insurance issuers offering group health insurance coverage generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the plan or issuer may pay for a shorter stay if the attending provider (*e.g.*, your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, plans and issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, a plan or issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up

to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your plan administrator.

(3) *Timing of disclosure.* The disclosure notice in paragraph (d)(2) of this section shall be furnished to each participant covered under a group health plan, and each beneficiary receiving benefits under a group health plan, not later than 60 days after the first day of the first plan year beginning on or after January 1, 2009. Each time a plan distributes one or both of the documents described in paragraph (d)(1) to participants and beneficiaries after providing this initial notice, the disclosure notice in paragraph (d)(2) must appear in at least one of those documents.

(4) *Exceptions.* The requirements of this paragraph (d) do not apply in the following situations.

(i) *Self-insured plans that have already provided notice.* If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has already provided an initial notice that complies with paragraphs (d)(1) and (d)(2) of this section, the group health plan is not automatically required to provide another such notice to participants and beneficiaries who have been provided with the initial notice. However, following the effective date of these regulations, whenever such a plan provides one or both of the documents described in paragraph (d)(1) of this section to participants and beneficiaries, the disclosure notice in paragraph (d)(2) of this section must appear in at least one of those documents.

(ii) *Self-insured plans that have elected exemption from this section.* If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has made the election described in Sec. 146.180 to be exempted from the requirements of this section, the group health plan is not subject to this paragraph (d).

(iii) *Insured plans.* If benefits for hospital lengths of stay in connection with childbirth are provided through health insurance coverage, and the coverage is regulated under a State law described in paragraph (e) of this section, the group health plan is not subject to this paragraph (d).

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 2725 of the PHS Act and this section do not apply with respect to health insurance coverage offered in connection with a group health plan if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Group health plans*—(i) *Fully-insured plans.* For a group health plan that provides benefits solely through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2725 of the PHS Act and this section do not apply.

(ii) *Self-insured plans.* For a group health plan that provides all benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the requirements of section 2725 of the PHS Act and this section apply.

(iii) *Partially-insured plans.* For a group health plan that provides some

benefits through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2725 of the PHS Act and this section apply only to the extent the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage.

(3) *Relation to section 2724 (a) of the PHS Act.* The preemption provisions contained in section 2724 (a)(1) of the PHS Act and Sec. 146.143(a) do not supersede a state law described in paragraph (e)(1) of this section.

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

Example 1. (i) *Facts.* A group health plan buys group health insurance coverage in a state that requires that the coverage provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) *Conclusion.* In this Example 1, the coverage is subject to state law, and the requirements of section 2725 of the PHS Act and this section do not apply.

Example 2. (i) *Facts.* A self-insured group health plan covers hospital lengths of stay in connection with childbirth in a state that requires health insurance coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

(ii) *Conclusion.* In this Example 2, even though the state law satisfies the criterion of paragraph (e)(1)(ii) of this section, because the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the plan is subject to the requirements of section 2725 of the PHS Act and this section.

(f) *Applicability date.* Section 2725 of the PHS Act applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 1998. This section applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 2009.

[73 FR 62424, Oct. 20, 2008, as amended at 75 FR 27138, May 13, 2010]

§ 146.136 Parity in mental health and substance use disorder benefits.

(a) *Meaning of terms.* For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Coverage unit means coverage unit as described in paragraph (c)(1)(iv) of this section.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Cumulative quantitative treatment limitations are treatment limitations that determine whether or to what extent benefits are provided based on accumulated amounts, such as annual or lifetime day or visit limits.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for medical or surgical services, as defined under the terms of the plan or health insurance coverage, but does not include mental health or substance use disorder benefits. Any condition defined by the plan as being or as not being a medical/surgical condition

must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

Mental health benefits means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any condition defined by the plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).

Substance use disorder benefits means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines).

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan. (*See* paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation.

(b) *Parity requirements with respect to aggregate lifetime and annual dollar limits*—(1)—*General*—(i) *General parity requirement.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (b)(2), (b)(3), or (b)(6) of this section.

(ii) *Exception.* The rule in paragraph (b)(1)(i) of this section does not apply if a plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(2) *Plan with no limit or limits on less than one-third of all medical/surgical benefits.* If a plan (or health insurance coverage) does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(3) *Plan with a limit on at least two-thirds of all medical/surgical benefits.* If a plan (or health insurance coverage) includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (c)(3)(v) of this section prohibiting separately accumulating cumulative financial requirements or cumulative quantitative treatment limitations.)

(4) *Examples.* The rules of paragraphs (b)(2) and (b)(3) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan has no annual limit on medical/surgical benefits and a $10,000 annual limit on mental health and substance use disorder benefits. To comply with the requirements of this paragraph (b), the plan sponsor is considering each of the following options—

(A) Eliminating the plan's annual dollar limit on mental health and substance use disorder benefits;

(B) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $500,000 annual limit on all benefits (including medical/surgical and mental health and substance use disorder benefits); and

(C) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $250,000 annual limit on medical/surgical benefits and a $250,000 annual limit on mental health and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 1,* each of the three options being considered by the plan sponsor would comply with the requirements of this paragraph (b).

Example 2. (i) *Facts.* A plan has a $100,000 annual limit on medical/surgical inpatient benefits and a $50,000 annual limit on medical/surgical outpatient benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options—

(A) Imposing a $150,000 annual limit on mental health and substance use disorder benefits; and

(B) Imposing a $100,000 annual limit on mental health and substance use disorder inpatient benefits and a $50,000 annual limit on mental health and substance use disorder outpatient benefits.

(ii) *Conclusion.* In this *Example 2,* each option under consideration by the plan sponsor would comply with the requirements of this section.

(5) *Determining one-third and two-thirds of all medical/surgical benefits.* For purposes of this paragraph (b), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(6) *Plan not described in paragraph (b)(2) or (b)(3) of this section*—(i) *In general.* A group health plan (or health insurance coverage) that is not described in paragraph (b)(2) or (b)(3) of this section with respect to aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(6)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

(ii) *Weighting.* For purposes of this paragraph (b)(6), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(5) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(iii) *Example.* The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) *Facts.* A group health plan that is subject to the requirements of this section includes a $100,000 annual limit on medical/

surgical benefits related to cardio-pulmonary diseases. The plan does not include an annual dollar limit on any other category of medical/surgical benefits. The plan determines that 40% of the dollar amount of plan payments for medical/surgical benefits are related to cardio-pulmonary diseases. The plan determines that $1,000,000 is a reasonable estimate of the upper limit on the dollar amount that the plan may incur with respect to the other 60% of payments for medical/surgical benefits.

(ii) *Conclusion.* In this *Example,* the plan is not described in paragraph (b)(3) of this section because there is not one annual dollar limit that applies to at least two-thirds of all medical/surgical benefits. Further, the plan is not described in paragraph (b)(2) of this section because more than one-third of all medical/surgical benefits are subject to an annual dollar limit. Under this paragraph (b)(6), the plan sponsor can choose either to include no annual dollar limit on mental health or substance use disorder benefits, or to include an annual dollar limit on mental health or substance use disorder benefits that is not less than the weighted average of the annual dollar limits applicable to each category of medical/surgical benefits. In this example, the minimum weighted average annual dollar limit that can be applied to mental health or substance use disorder benefits is $640,000 (40% × $100,000 + 60% × $1,000,000 = $640,000).

(c) *Parity requirements with respect to financial requirements and treatment limitations*—(1) *Clarification of terms*—(i) *Classification of benefits.* When reference is made in this paragraph (c) to a classification of benefits, the term ''classification'' means a classification as described in paragraph (c)(2)(ii) of this section.

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) *Level of a type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation. For example, different levels of coinsurance include 20 percent and 30 percent; different levels of a copayment include $15 and $20; different levels of a deductible include $250 and $500; and different levels of an episode limit include 21 inpatient days per episode and 30 inpatient days per episode.

(iv) *Coverage unit.* When reference is made in this paragraph (c) to a coverage unit, coverage unit refers to the way in which a plan (or health insurance coverage) groups individuals for purposes of determining benefits, or premiums or contributions. For example, different coverage units include self-only, family, and employee-plus-spouse.

(2) *General parity requirement*—(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) *Classifications of benefits used for applying rules*—(A) *In general.* If a plan (or health insurance coverage) provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided

in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c):

(*1*) *Inpatient, in-network.* Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.

(*2*) *Inpatient, out-of-network.* Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes inpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(*3*) *Outpatient, in-network.* Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.

(*4*) *Outpatient, out-of-network.* Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes outpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(*5*) *Emergency care.* Benefits for emergency care.

(*6*) *Prescription drugs.* Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(3)(iii) of this section.

(B) *Application to out-of-network providers.* See paragraph (c)(2)(ii)(A) of this section, under which a plan (or health insurance coverage) that provides mental health or substance use disorder benefits in any classification of benefits must provide mental health or substance use disorder benefits in every classification in which medical/surgical benefits are provided, including out-of-network classifications.

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 1,* because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

Example 2. (i) *Facts.* A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 2,* because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

Example 3. (i) *Facts.* Same facts as *Example 2,* except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 3,* because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for—

(A) Benefits in the emergency classification; and

(B) All other benefits.

Example 4. (i) *Facts.* Same facts as *Example 2*, except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this *Example 4*, because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for—

(A) Inpatient, out-of-network benefits; and

(B) All other benefits.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining ''substantially all'' and ''predominant''*—(A) *Substantially all.* For purposes of this paragraph (c), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For this purpose, benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) *Predominant—(1)* If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(*2*) If, with respect to a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) *Portion based on plan payments.* For purposes of this paragraph (c), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been

made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes.

(E) *Determining the dollar amount of plan payments.* Subject to paragraph (c)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) *Application to different coverage units.* If a plan (or health insurance coverage) applies different levels of a financial requirement or quantitative treatment limitation to different coverage units in a classification of medical/surgical benefits, the predominant level that applies to substantially all medical/surgical benefits in the classification is determined separately for each coverage unit.

(iii) *Special rule for multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(iv) *Examples.* The rules of paragraphs (c)(3)(i), (c)(3)(ii), and (c)(3)(iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Coinsurance rate	0%	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(ii) *Conclusion.* In this *Example 1*, the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

Example 2. (i) *Facts.* For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Copayment amount	$0	$10	$15	$20	$50	Total
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

The plan projects plan costs of $800x to be subject to copayments ($200x + $200x + $300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(ii) *Conclusion.* In this *Example 2*, the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels—the $50 copayment, the $20 copayment, and the $15 copayment—are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

Example 3. (i) *Facts.* A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 3*, because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

Example 4. (i) *Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as ''generic'', ''preferred brand name'', ''non-preferred brand name'', or ''specialty'' complies with the rules of paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations).

Tier description	Tier 1	Tier 2	Tier 3	Tier 4
	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives)	Specialty drugs
Percent paid by plan	90%	80%	60%	50%

(ii) *Conclusion.* In this *Example 4*, the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(v) *No separate cumulative financial requirements or cumulative quantitative treatment limitations*—(A) A group health plan (or health insurance coverage offered in connection with a group health plan) may not apply any cumulative financial requirement or cumulative quantitative treatment limitation for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(B) The rules of this paragraph (c)(3)(v) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan imposes a combined annual $500 deductible on all medical/surgical, mental health, and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 1*, the combined annual deductible complies with the requirements of this paragraph (c)(3)(v).

Example 2. (i) *Facts.* A plan imposes an annual $250 deductible on all medical/surgical benefits and a separate annual $250 deductible on all mental health and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 2*, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 3. (i) *Facts.* A plan imposes an annual $300 deductible on all medical/surgical benefits and a separate annual $100 deductible on all mental health or substance use disorder benefits.

(ii) *Conclusion.* In this *Example 3*, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 4. (i) *Facts.* A plan generally imposes a combined annual $500 deductible on all benefits (both medical/surgical benefits and mental health and substance use disorder benefits) except prescription drugs. Certain benefits, such as preventive care, are provided without regard to the deductible. The imposition of other types of financial requirements or treatment limitations varies with each classification. Using reasonable methods, the plan projects its payments for medical/surgical benefits in each classification for the upcoming year as follows:

Classification	Benefits subject to deductible	Total benefits	Percent subject to deductible
Inpatient, in-network	$1,800x	$2,000x	90
Inpatient, out-of-network	1,000x	1,000x	100
Outpatient, in-network	1,400x	2,000x	70
Outpatient, out-of-network	1,880x	2,000x	94
Emergency care	300x	500x	60

(ii) *Conclusion.* In this *Example 4*, the two-thirds threshold of the substantially all standard is met with respect to each classification except emergency care because in each of those other classifications at least two-thirds of medical/surgical benefits are subject to the $500 deductible. Moreover, the $500 deductible is the predominant level in each of those other classifications because it is the only level. However, emergency care mental health and substance use disorder benefits cannot be subject to the $500 deductible because it does not apply to substantially all emergency care medical/surgical benefits.

(4) *Nonquantitative treatment limitations*—(i) *General rule.* A group health plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical surgical/benefits in the classification, except to the extent that recognized clinically appropriate standards of care may permit a difference.

(ii) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Plan methods for determining usual, customary, and reasonable charges;

(E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols); and

(F) Exclusions based on failure to complete a course of treatment.

(iii) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* A group health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for inpatient, in-network mental health and substance use disorder benefits but does not require it for any inpatient, in-network medical/surgical benefits. The plan conducts retrospective review for inpatient, in-network medical/surgical benefits.

(ii) *Conclusion.* In this *Example 1,* the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical necessity—applies to both mental health and substance use disorder benefits and to medical/surgical benefits for inpatient, in-network services, the concurrent review process does not apply to medical/surgical benefits. The concurrent review process is not comparable to the retrospective review process. While such a difference might be permissible in certain individual cases based on recognized clinically appropriate standards of care, it is not permissible for distinguishing between all medical/surgical benefits and all mental health or substance use disorder benefits.

Example 2. (i) *Facts.* A plan requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance use disorder benefits. For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in the benefits the plan would otherwise pay.

(ii) *Conclusion.* In this *Example 2,* the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical necessity—is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, the penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 3. (i) *Facts.* A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that may differ based on clinically appropriate standards of care for a condition.

(ii) *Conclusion.* In this *Example 3,* the plan complies with the rules of this paragraph (c)(4) because the nonquantitative treatment limitation—medical appropriateness—is the same for both medical/surgical benefits and mental health and substance use disorder benefits, and the processes for developing the evidentiary standards and the application of them to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if, based on clinically appropriate standards of care, the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.

Example 4. (i) *Facts.* A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a black box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects). For other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion.* In this *Example 4,* the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 5. (i) *Facts.* An employer maintains both a major medical program and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. Participants are eligible for mental health or substance use disorder benefits under the major medical program only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with

respect to medical/surgical benefits provided under the major medical program.

(ii) *Conclusion.* In this *Example 5*, limiting eligibility for mental health and substance use disorder benefits only after EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because no comparable requirement applies to medical/surgical benefits, the requirement may not be applied to mental health or substance use disorder benefits.

(5) *Exemptions.* The rules of this paragraph (c) do not apply if a group health plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(d) *Availability of plan information*—(1) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits (or health insurance coverage offered in connection with the plan with respect to such benefits) must be made available by the plan administrator (or the health insurance issuer offering such coverage) to any current or potential participant, beneficiary, or contracting provider upon request.

(2) *Reason for denial.* The reason for any denial under a non-Federal governmental plan (or health insurance coverage offered in connection with such plan) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available within a reasonable time and in a reasonable manner by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary upon request. For this purpose, a non-Federal governmental plan (or health insurance coverage offered in connection with such plan) that provides the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503–1 for group health plans complies with the requirements of this paragraph (d)(2).

(e) *Applicability*—(1) *Group health plans.* The requirements of this section apply to a group health plan offering medical/surgical benefits and mental health or substance use disorder benefits. If, under an arrangement or arrangements to provide medical care benefits by an employer or employee organization (including for this purpose a joint board of trustees of a multiemployer trust affiliated with one or more multiemployer plans), any participant (or beneficiary) can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section (including the exemption provisions in paragraph (g) of this section) apply separately with respect to each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any participant (or beneficiary) can simultaneously receive from that employer's or employee organization's arrangement or arrangements to provide medical care benefits, and all such combinations are considered for purposes of this section to be a single group health plan.

(2) *Health insurance issuers.* The requirements of this section apply to a health insurance issuer offering health insurance coverage for mental health or substance use disorder benefits in connection with a group health plan subject to paragraph (e)(1) of this section.

(3) *Scope.* This section does not—

(i) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a plan (or health insurance coverage) for one or more mental health conditions or substance use disorders does not require the plan (or health insurance coverage) under this section to provide benefits for any other mental health condition or substance use disorder; or

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the plan (or health insurance coverage) except as specifically provided in paragraphs (b) and (c) of this section.

(f) *Small employer exemption*—(1) *In general.* The requirements of this section do not apply to a group health

plan (or health insurance issuer offering coverage in connection with a group health plan) for a plan year of a small employer. For purposes of this paragraph (f), the term *small employer* means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least two but not more than 50 employees on business days during the preceding calendar year and who employs at least two employees on the first day of the plan year (except that for purposes of this paragraph, a small employer shall include an employer with one employee in the case of an employer residing in a State that permits small groups to include a single individual). See also section 2721(a) of the PHS Act and §146.145(b) of this Part, which provide that this section (and certain other sections) does not apply to any group health plan (and health insurance issuer offering coverage in connection with a group health plan) for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(2) *Rules in determining employer size.* For purposes of paragraph (f)(1) of this section—

(i) All persons treated as a single employer under subsections (b), (c), (m), and (o) of section 414 of the Internal Revenue Code of 1986 (26 U.S.C. 414) are treated as one employer;

(ii) If an employer was not in existence throughout the preceding calendar year, whether it is a small employer is determined based on the average number of employees the employer reasonably expects to employ on business days during the current calendar year; and

(iii) Any reference to an employer for purposes of the small employer exemption includes a reference to a predecessor of the employer.

(g) *Increased cost exemption* [Reserved]

(h) *Sale of nonparity health insurance coverage.* A health insurance issuer may not sell a policy, certificate, or contract of insurance that fails to comply with paragraph (b) or (c) of this section, except to a plan for a year for which the plan is exempt from the requirements of this section because the plan meets the requirements of paragraph (f) or (g) of this section.

(i) *Applicability dates*—(1) *In general.* Except as provided in paragraph (i)(2) of this section, the requirements of this section are applicable for plan years beginning on or after July 1, 2010.

(2) *Special effective date for certain collectively-bargained plans.* For a group health plan maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of this section do not apply to the plan (or health insurance coverage offered in connection with the plan) for plan years beginning before the later of either—

(i) The date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension agreed to after October 3, 2008); or

(ii) July 1, 2010.

[75 FR 5444, Feb. 2, 2010]

Subpart D—Preemption and Special Rules

§146.143 Preemption; State flexibility; construction.

(a) *Continued applicability of State law with respect to health insurance issuers.* Subject to paragraph (b) of this section and except as provided in paragraph (c) of this section, part A of title XXVII of the PHS Act is not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

(b) *Continued preemption with respect to group health plans.* Nothing in part A of title XXVII of the PHS Act affects or modifies the provisions of section 514 of ERISA with respect to group health plans.

(c) *Special rules*—(1) *In general.* Subject to paragraph (c)(2) of this section, the provisions of part A of title XXVII of the PHS Act relating to health insurance coverage offered by a health

insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 2701 of the PHS Act which differs from the standards or requirements specified in section 2701 of the PHS Act.

(2) *Exceptions.* Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

(i) Shortens the period of time from the ''6-month period'' described in section 2701(a)(1) of the PHS Act and §146.111(a)(2)(i) (for purposes of identifying a preexisting condition);

(ii) Shortens the period of time from the ''12 months'' and ''18 months'' described in section 2701(a)(2) of the PHS Act and §146.111(a)(2)(ii) (for purposes of applying a preexisting condition exclusion period);

(iii) Provides for a greater number of days than the ''63-day period'' described in sections 2701(c)(2)(A) and (d)(4)(A) of the PHS Act and §§146.111(a)(2)(iii) and 146.113 (for purposes of applying the break in coverage rules);

(iv) Provides for a greater number of days than the ''30-day period'' described in sections 2701(b)(2) and (d)(1) of the PHS Act and §146.111(b) (for purposes of the enrollment period and preexisting condition exclusion periods for certain newborns and children that are adopted or placed for adoption);

(v) Prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) of the PHS Act or expands the exceptions described therein;

(vi) Requires special enrollment periods in addition to those required under section 2701(f) of the PHS Act; or

(vii) Reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B) of the PHS Act.

(d) *Definitions*—(1) *State law.* For purposes of this section the term *State law* includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia is treated as a State law rather than a law of the United States.

(2) *State.* For purposes of this section the term *State* includes a State (as defined in §144.103), any political subdivisions of a State, or any agency or instrumentality of either.

[69 FR 78797, Dec. 30, 2004; 70 FR 21147, Apr. 25, 2005]

§146.145 Special rules relating to group health plans.

(a) *Group health plan*—(1) *Definition.* A group health plan means an employee welfare benefit plan to the extent that the plan provides medical care (including items and services paid for as medical care) to employees (including both current and former employees) or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

(2) *Determination of number of plans.* [Reserved]

(b) *General exception for certain small group health plans.* The requirements of this part, other than §146.130 and the provisions with respect to genetic nondiscrimination (found in §146.111(b)(6), §146.121(b), §146.121(c), §146.121(e), §146.122(b), §146.122(c), §146.122(d), and §146.122(e)) do not apply to any group health plan (and group health insurance coverage) for any plan year, if on the first day of the plan year, the plan has fewer than two participants who are current employees.

(c) *Excepted benefits*—(1) *In general.* The requirements of subparts B and C of this part do not apply to any group health plan (or any group health insurance coverage) in relation to its provision of the benefits described in paragraph (c)(2), (3), (4), or (5) of this section (or any combination of these benefits).

(2) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances—

(i) Coverage only for accident (including accidental death and dismemberment);

(ii) Disability income coverage;

(iii) Liability insurance, including general liability insurance and automobile liability insurance;

(iv) Coverage issued as a supplement to liability insurance;

(v) Workers' compensation or similar coverage;

(vi) Automobile medical payment insurance;

(vii) Credit-only insurance (for example, mortgage insurance); and

(viii) Coverage for on-site medical clinics.

(3) *Limited excepted benefits*—(i) *In general.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan as described in paragraph (c)(3)(ii) of this section. In addition, benefits provided under a health flexible spending arrangement are excepted benefits if they satisfy the requirements of paragraph (c)(3)(v) of this section.

(ii) *Not an integral part of a group health plan.* For purposes of this paragraph (c)(3), benefits are not an integral part of a group health plan (whether the benefits are provided through the same plan or a separate plan) only if the following two requirements are satisfied—

(A) Participants must have the right to elect not to receive coverage for the benefits; and

(B) If a participant elects to receive coverage for the benefits, the participant must pay an additional premium or contribution for that coverage.

(iii) *Limited scope*—(A) *Dental benefits.* Limited scope dental benefits are benefits substantially all of which are for treatment of the mouth (including any organ or structure within the mouth).

(B) *Vision benefits.* Limited scope vision benefits are benefits substantially all of which are for treatment of the eye.

(iv) *Long-term care.* Long-term care benefits are benefits that are either—

(A) Subject to State long-term care insurance laws;

(B) For qualified long-term care services, as defined in section 7702B(c)(1) of the Internal Revenue Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Internal Revenue Code; or

(C) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(v) *Health flexible spending arrangements.* Benefits provided under a health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) are excepted for a class of participants only if they satisfy the following two requirements—

(A) Other group health plan coverage, not limited to excepted benefits, is made available for the year to the class of participants by reason of their employment; and

(B) The arrangement is structured so that the maximum benefit payable to any participant in the class for a year cannot exceed two times the participant's salary reduction election under the arrangement for the year (or, if greater, cannot exceed $500 plus the amount of the participant's salary reduction election). For this purpose, any amount that an employee can elect to receive as taxable income but elects to apply to the health flexible spending arrangement is considered a salary reduction election (regardless of whether the amount is characterized as salary or as a credit under the arrangement).

(4) *Noncoordinated benefits*—(i) *Excepted benefits that are not coordinated.* Coverage for only a specified disease or illness (for example, cancer-only policies) or hospital indemnity or other fixed indemnity insurance is excepted only if it meets each of the conditions specified in paragraph (c)(4)(ii) of this section. To be hospital indemnity or other fixed indemnity insurance, the insurance must pay a fixed dollar amount per day (or per other period) of hospitalization or illness (for example, $100/day) regardless of the amount of expenses incurred.

(ii) *Conditions.* Benefits are described in paragraph (c)(4)(i) of this section only if—

(A) The benefits are provided under a separate policy, certificate, or contract of insurance;

(B) There is no coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and

(C) The benefits are paid with respect to an event without regard to whether

benefits are provided with respect to the event under any group health plan maintained by the same plan sponsor.

(iii) *Example.* The rules of this paragraph (c)(4) are illustrated by the following example:

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage through an insurance policy. The policy provides benefits only for hospital stays at a fixed percentage of hospital expenses up to a maximum of $100 a day.

(ii) *Conclusion.* In this *Example,* even though the benefits under the policy satisfy the conditions in paragraph (c)(4)(ii) of this section, because the policy pays a percentage of expenses incurred rather than a fixed dollar amount, the benefits under the policy are not excepted benefits under this paragraph (c)(4). This is the result even if, in practice, the policy pays the maximum of $100 for every day of hospitalization.

(5) *Supplemental benefits.* (i) The following benefits are excepted only if they are provided under a separate policy, certificate, or contract of insurance—

(A) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act; also known as Medigap or MedSupp insurance);

(B) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as TRICARE supplemental programs); and

(C) Similar supplemental coverage provided to coverage under a group health plan. To be similar supplemental coverage, the coverage must be specifically designed to fill gaps in primary coverage, such as coinsurance or deductibles. Similar supplemental coverage does not include coverage that becomes secondary or supplemental only under a coordination-of-benefits provision.

(ii) The rules of this paragraph (c)(5) are illustrated by the following example:

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage for both active employees and retirees. The coverage for retirees supplements benefits provided by Medicare, but does not meet the requirements for a supplemental policy under section 1882(g)(1) of the Social Security Act.

(ii) *Conclusion.* In this *Example,* the coverage provided to retirees does not meet the definition of supplemental excepted benefits under this paragraph (c)(5) because the coverage is not Medicare supplemental insurance as defined under section 1882(g)(1) of the Social Security Act, is not a TRICARE supplemental program, and is not supplemental to coverage provided under a group health plan.

(d) *Treatment of partnerships.* For purposes of this part:

(1) *Treatment as a group health plan.* Any plan, fund, or program that would not be (but for this paragraph (d)) an employee welfare benefit plan and that is established or maintained by a partnership, to the extent that the plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, is treated (subject to paragraph (d)(2) of this section) as an employee welfare benefit plan that is a group health plan.

(2) *Employment relationship.* In the case of a group health plan, the term *employer* also includes the partnership in relation to any bona fide partner. In addition, the term *employee* also includes any bona fide partner. Whether or not an individual is a bona fide partner is determined based on all the relevant facts and circumstances, including whether the individual performs services on behalf of the partnership.

(3) *Participants of group health plans.* In the case of a group health plan, the term *participant* also includes any individual described in paragraph (d)(3)(i) or (ii) of this section if the individual is, or may become, eligible to receive a benefit under the plan or the individual's beneficiaries may be eligible to receive any such benefit.

(i) In connection with a group health plan maintained by a partnership, the individual is a partner in relation to the partnership.

(ii) In connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the individual is the self-employed individual.

(e) *Determining the average number of employees.* [Reserved]

[69 FR 78798, Dec. 30, 2004, as amended at 74 FR 51692, Oct. 7, 2009]

Subpart E—Provisions Applicable to Only Health Insurance Issuers

§ 146.150 Guaranteed availability of coverage for employers in the small group market.

(a) *Issuance of coverage in the small group market.* Subject to paragraphs (c) through (f) of this section, each health insurance issuer that offers health insurance coverage in the small group market in a State must—

(1) Offer, to any small employer in the State, all products that are approved for sale in the small group market and that the issuer is actively marketing, and must accept any employer that applies for any of those products; and

(2) Accept for enrollment under the coverage every eligible individual (as defined in paragraph (b) of this section) who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan, or during a special enrollment period, and may not impose any restriction on an eligible individual's being a participant or beneficiary, which is inconsistent with the nondiscrimination provisions of § 146.121.

(b) *Eligible individual defined.* For purposes of this section, the term ''eligible individual'' means an individual who is eligible—

(1) To enroll in group health insurance coverage offered to a group health plan maintained by a small employer, in accordance with the terms of the group health plan;

(2) For coverage under the rules of the health insurance issuer which are uniformly applicable in the State to small employers in the small group market; and

(3) For coverage in accordance with all applicable State laws governing the issuer and the small group market.

(c) *Special rules for network plans.* (1) In the case of a health insurance issuer that offers health insurance coverage in the small group market through a network plan, the issuer may—

(i) Limit the employers that may apply for the coverage to those with eligible individuals who live, work, or reside in the service area for the network plan; and

(ii) Within the service area of the plan, deny coverage to employers if the issuer has demonstrated to the applicable State authority (if required by the State authority) that—

(A) It will not have the capacity to deliver services adequately to enrollees of any additional groups because of its obligations to existing group contract holders and enrollees; and

(B) It is applying this paragraph (c)(1) uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies health insurance coverage to an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the small group market within the service area to any employer for a period of 180 days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(3) Coverage offered within a service area after the 180-day period specified in paragraph (c)(2) of this section is subject to the requirements of this section.

(d) *Application of financial capacity limits.* (1) A health insurance issuer may deny health insurance coverage in the small group market if the issuer has demonstrated to the applicable State authority (if required by the State authority) that it—

(i) Does not have the financial reserves necessary to underwrite additional coverage; and

(ii) Is applying this paragraph (d)(1) uniformly to all employers in the small group market in the State consistent with applicable State law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies group health insurance coverage to any small employer in a State under paragraph (d)(1) of this section may not offer coverage in connection with group health plans

in the small group market in the State before the later of the following dates:

(i) The 181st day after the date the issuer denies coverage.

(ii) The date the issuer demonstrates to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable State authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Exception to requirement for failure to meet certain minimum participation or contribution rules.* (1) Paragraph (a) of this section does not preclude a health insurance issuer from establishing employer contribution rules or group participation rules for the offering of health insurance coverage in connection with a group health plan in the small group market, as allowed under applicable State law.

(2) For purposes of paragraph (e)(1) of this section—

(i) The term ''employer contribution rule'' means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries; and

(ii) The term ''group participation rule'' means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(f) *Exception for coverage offered only to bona fide association members.* Paragraph (a) of this section does not apply to health insurance coverage offered by a health insurance issuer if that coverage is made available in the small group market only through one or more bona fide associations (as defined in 45 CFR 144.103).

(Approved by the Office of Management and Budget under control number 0938–0702)

[62 FR 16958, Apr. 8, 1997; 62 FR 31694, June 10, 1997, as amended at 62 FR 35906, July 2, 1997; 67 FR 48811, July 26, 2002]

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

(a) *General rule.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer offering health insurance coverage in the small or large group market is required to renew or continue in force the coverage at the option of the plan sponsor.

(b) *Exceptions.* An issuer may nonrenew or discontinue group health insurance coverage offered in the small or large group market based only on one or more of the following:

(1) *Nonpayment of premiums.* The plan sponsor has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* The plan sponsor has failed to comply with a material plan provision relating to any employer contribution or group participation rules permitted under § 146.150(e) in the case of the small group market or under applicable State law in the case of the large group market.

(4) *Termination of plan.* The issuer is ceasing to offer coverage in the market in accordance with paragraphs (c) and (d) of this section and applicable State law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the group health plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 146.150(c).

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the small or large group market, that product may be discontinued by the issuer in accordance with applicable State law in the particular market only if—

(1) The issuer provides notice in writing to each plan sponsor provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 days before the date the coverage will be discontinued;

(2) The issuer offers to each plan sponsor provided that particular product the option, on a guaranteed issue basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in that market; and

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* An issuer may elect to discontinue offering all health insurance coverage in the small or large group market or both markets in a State in accordance with applicable State law only if—

(1) The issuer provides notice in writing to the applicable State authority and to each plan sponsor (and all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 days prior to the date the coverage will be discontinued; and

(2) All health insurance policies issued or delivered for issuance in the State in the market (or markets) are discontinued and not renewed.

(e) *Prohibition on market reentry.* An issuer who elects to discontinue offering all health insurance coverage in a market (or markets) in a State as described in paragraph (d) of this section may not issue coverage in the market (or markets) and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(f) *Exception for uniform modification of coverage.* Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan in the—

(1) Large group market; and

(2) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(g) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to ''plan sponsor'' is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

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[62 FR 16958, Apr. 8, 1997; 62 FR 31670, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 146.160 Disclosure of information.

(a) *General rule.* In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer is required to—

(1) Make a reasonable disclosure to the employer, as part of its solicitation and sales materials, of the availability of information described in paragraph (b) of this section; and

(2) Upon request of the employer, provide that information to the employer.

(b) *Information described.* Subject to paragraph (d) of this section, information that must be provided under paragraph (a)(2) of this section is information concerning the following:

(1) Provisions of coverage relating to the following:

(i) The issuer's right to change premium rates and the factors that may affect changes in premium rates.

(ii) Renewability of coverage.

(iii) Any preexisting condition exclusion, including use of the alternative method of counting creditable coverage.

(iv) Any affiliation periods applied by HMOs.

(v) The geographic areas served by HMOs.

(2) The benefits and premiums available under all health insurance coverage for which the employer is qualified, under applicable State law. See §146.150(b) through (f) for allowable limitations on product availability.

(c) *Form of information.* The information must be described in language that is understandable by the average small employer, with a level of detail that is sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage. This requirement is satisfied if the issuer provides each of the following with respect to each product offered:

(1) An outline of coverage. For purposes of this section, outline of coverage means a description of benefits in summary form.

(2) The rate or rating schedule that applies to the product (with and without the preexisting condition exclusion or affiliation period).

(3) The minimum employer contribution and group participation rules that apply to any particular type of coverage.

(4) In the case of a network plan, a map or listing of counties served.

(5) Any other information required by the State.

(d) *Exception.* An issuer is not required to disclose any information that is proprietary and trade secret information under applicable law.

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[62 FR 16958, Apr. 8, 1997, as amended at 62 FR 35906, July 2, 1997]

Subpart F—Exclusion of Plans and Enforcement

§146.180 Treatment of non-Federal governmental plans.

(a) *Requirements subject to exemption—*(1) *Basic rule.* A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), from any or all of the following requirements:

(i) Limitations on preexisting condition exclusion periods described in §146.111.

(ii) Special enrollment periods for individuals and dependents described in §146.117.

(iii) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in §146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from the requirements in §146.121(a)(1)(vi) and §146.122 that prohibit discrimination with respect to genetic information.

(iv) Standards relating to benefits for mothers and newborns described in §146.130.

(v) Parity in the application of certain limits to mental health benefits described in §146.136.

(vi) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2706 of the PHS Act.

(2) *Limitations.* (i) An election under this section cannot circumvent a requirement of this part to the extent the requirement applied to the plan before the effective date of the election.

(A) *Example 1.* A plan is subject to requirements of section 2706 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An

enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2706 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

(B) *Example 2.* An individual is hired by a non-Federal governmental employer and reports to work on August 6. The individual has diabetes. Under the terms of the plan in effect on August 6, if an individual files an enrollment application within the first 30 days of employment, enrollment in the plan is effective as of the first day of employment. The individual timely files an enrollment application. The application is processed on September 10. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from §146.121, which prohibits enrollment discrimination based on health status-related factors, by requiring new enrollees to pass medical underwriting. The plan cannot decline to enroll the individual effective August 6, even if he would not pass medical underwriting under the terms of the plan in effect on September 1.

(ii) If a group health plan is co-sponsored by two or more employers, then only plan enrollees of the non-Federal governmental employer(s) with a valid election under this section are affected by the election.

(3) *Stop-loss or excess risk coverage.* For purposes of this section. (i) Subject to paragraph (a)(3)(ii), the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

(ii) Regardless of whether coverage offered by an issuer is designated as ''stop-loss'' coverage or ''excess risk'' coverage, if it is regulated as group health insurance under an applicable State law, then for purposes of this section, a non-Federal governmental plan that purchases the coverage is considered to be fully insured. In that event, a plan may not be exempted under this section from the requirements of this part.

(4) *Construction.* Nothing in this part should be construed as imposing collective bargaining obligations on any party to the collective bargaining process.

(b) *Form and manner of election*—(1) *Election requirements.* The election must meet the following requirements:

(i) Be made in writing.

(ii) Be made in conformance with all of the plan sponsor's rules, including any public hearing requirements.

(iii) Specify the beginning and ending dates of the period to which the election is to apply. This period can be either of the following periods:

(A) A single specified plan year, as defined in §144.103 of this subchapter.

(B) The ''term of the agreement,'' as specified in paragraph (b)(2) of this section, in the case of a plan governed by collective bargaining.

(iv) Specify the name of the plan and the name and address of the plan administrator, and include the name and telephone number of a person CMS may contact regarding the election.

(v) State that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through health insurance coverage.

(vi) Specify each requirement described in paragraph (a) of this section from which the plan sponsor elects to exempt the plan.

(vii) Certify that the person signing the election document, including (if applicable) a third party plan administrator, is legally authorized to do so by the plan sponsor.

(viii) Include, as an attachment, a copy of the notice described in paragraph (f) of this section.

(2) *''Term of the agreement'' defined.* Except as provided in paragraphs (b)(2)(i) and (b)(2)(ii), for purposes of this section ''term of the agreement'' means all group health plan years governed by a single collective bargaining agreement.

(i) In the case of a group health plan for which the last plan year governed by a prior collective bargaining agreement expires during the bargaining process for a new agreement, the term

of the prior agreement includes all plan years governed by the agreement plus the period of time that precedes the latest of the following dates, as applicable, with respect to the new agreement:

(A) The date of an agreement between the governmental employer and union officials.

(B) The date of ratification of an agreement between the governmental employer and the union.

(C) The date impasse resolution, arbitration or other closure of the collective bargaining process is finalized when agreement is not reached.

(ii) In the case of a group health plan governed by a collective bargaining agreement for which closure is not reached before the last plan year under the immediately preceding agreement expires, the term of the new agreement includes all plan years governed by the agreement excluding the period that precedes the latest applicable date specified in paragraph (b)(2)(i) of this section.

(3) *Construction*—(i) *Dispute resolution.* Nothing in paragraph (b)(1)(ii) of this section should be construed to mean that CMS arbitrates disputes between plan sponsors, participants, beneficiaries, or their representatives regarding whether an election complies with all of a plan sponsor's rules.

(ii) *Future elections not preempted.* If a plan must comply with one or more requirements of this part for a given plan year or period of plan coverage, nothing in this section should be construed as preventing a plan sponsor from submitting an election in accordance with this section for a subsequent plan year or period of plan coverage.

(c) *Mailing address.* The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Private Health Insurance Group, CMSO, 7500 Security Boulevard, S3–16–16, Baltimore, MD 21244–1850.

(d) *Filing a timely election*—(1) *Plan not governed by collective bargaining.* Subject to paragraph (d)(4) of this section, if a plan is not governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the plan year.

(2) *Plan governed by a collective bargaining agreement.* Subject to paragraph (d)(4) of this section, if a plan is governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the first plan year governed by a collective bargaining agreement, or by the 45th day after the latest applicable date specified in paragraph (b)(2)(i) of this section, if the 45th day falls on or after the first day of the plan year.

(3) *Verifying timely filing.* CMS uses the postmark on the envelope in which the election is submitted to determine that the election is timely filed as specified under paragraphs (d)(1) or (d)(2) of this section, as applicable. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(4) *Filing extension based on good cause.* CMS may extend the deadlines specified in paragraphs (d)(1) and (d)(2) of this section for good cause if the plan substantially complies with the requirements of paragraph (f) of this section.

(5) *Failure to file a timely election.* Absent an extension under paragraph (d)(4) of this section, a plan sponsor's failure to file a timely election under paragraph (d)(1) or (d)(2) of this section makes the plan subject to all requirements of this part for the entire plan year to which the election would have applied, or, in the case of a plan governed by a collective bargaining agreement, for any plan years under the agreement for which the election is not timely filed.

(e) *Additional information required*—(1) *Written notification.* If an election is timely filed, but CMS determines that the election document (or the notice to plan enrollees) does not meet all of the requirements of this section, CMS may notify the plan sponsor, or other entity that filed the election, that it must submit any additional information that CMS has determined is necessary to meet those requirements. The additional information must be filed with CMS by the later of the following dates:

(i) The last day of the plan year.

(ii) The 45th day after the date of CMS's written notification requesting additional information.

(2) *Timely response.* CMS uses the postmark on the envelope in which the additional information is submitted to determine that the information is timely filed as specified under paragraph (e)(1) of this section. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(3) *Failure to respond timely.* CMS may invalidate an election if the plan sponsor, or other entity that filed the election, fails to timely submit the additional information as specified under paragraph (e)(1) of this section.

(f) *Notice to enrollees*—(1) *Mandatory notification.* (i) A plan that makes the election described in this section must notify each affected enrollee of the election, and explain the consequences of the election. For purposes of this paragraph (f), if the dependent(s) of a participant reside(s) with the participant, a plan need only provide notice to the participant.

(ii) The notice must be in writing and, except as provided in paragraph (f)(2) of this section with regard to initial notices, must be provided to each enrollee at the time of enrollment under the plan, and on an annual basis no later than the last day of each plan year (as defined in §144.103 of this subchapter) for which there is an election.

(iii) A plan may meet the notification requirements of this paragraph (f) by prominently printing the notice in a summary plan description, or equivalent description, that it provides to each enrollee at the time of enrollment, and annually. Also, when a plan provides a notice to an enrollee at the time of enrollment, that notice may serve as the initial annual notice for that enrollee.

(2) *Initial notices.* (i) If a plan is not governed by a collective bargaining agreement, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of that plan year, and notice at the time of enrollment to all individuals who enroll during that plan year.

(ii) In the case of a collectively bargained plan (including a self-funded non-Federal governmental plan that has been exempted from requirements of this part under §146.125(a)(2)), with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of the plan year, or within 30 days after the latest applicable date specified in paragraph (b)(2)(i) of this section if the 30th day falls on or after the first day of the plan year. Also, the plan must provide a notice at the time of enrollment to individuals who—

(A) Enroll on or after the first day of the plan year, when closure of the collective bargaining process is reached before the plan year begins; or

(B) Enroll on or after the latest applicable date specified in paragraph (b)(2)(i) of this section if that date falls on or after the first day of the plan year.

(3) *Notice content.* The notice must include at least the following information:

(i) The specific requirements described in paragraph (a)(1) of this section from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

(ii) A statement that Federal law gives the plan sponsor of a self-funded non-Federal governmental plan the right to exempt the plan in whole, or in part, from the listed requirements, and that the plan sponsor has elected to do so.

(iii) A statement identifying which parts of the plan are subject to the election.

(iv) A statement identifying which of the listed requirements, if any, apply under the terms of the plan, or as required by State law, without regard to an exemption under this section.

(v) A statement informing plan enrollees that the plan provides for certification and disclosure of creditable coverage for covered employees and their dependents who lose coverage under the plan.

(g) *Subsequent elections*—(1) *Election renewal.* A plan sponsor may renew an

election under this section through subsequent elections. The timeliness standards described in paragraph (d) apply to election renewals under this paragraph (g).

(2) *Form and manner of renewal.* Except for the requirement to forward to CMS a copy of the notice to enrollees under paragraph (b)(1)(viii) of this section, the plan sponsor must comply with the election requirements of paragraph (b)(1) of this section. In lieu of providing a copy of the notice under (b)(1)(viii), the plan sponsor may include a statement that the notice has been, or will be, provided to enrollees as specified under paragraph (f) of this section.

(3) *Election renewal includes provisions from which plan not previously exempted.* If an election renewal includes a requirement described in paragraph (a) of this section from which the plan sponsor did not elect to exempt the plan for the preceding plan year, the advance notification requirements of paragraph (f)(2) of this section apply with respect to the additional requirement(s) of paragraph (a) from which the plan sponsor is electing to exempt the plan.

(4) *Special rules regarding renewal of an election under a collective bargaining agreement.* (i) If protracted negotiations with respect to a new agreement result in an extension of the term of the prior agreement (as provided under paragraph (b)(2)(i)) under which an election under this section was in effect, the plan must comply with the enrollee notification requirements of paragraph (f)(1), and, following closure of the collective bargaining process, must file an election renewal with CMS as provided under paragraph (d)(2) of this section.

(ii) If a single plan applies to more than one bargaining unit, and the plan is governed by collective bargaining agreements of varying lengths, paragraph (d)(2) of this section, with respect to an election renewal, applies to the plan as governed by the agreement that results in the earliest filing date.

(h) *Requirements not subject to exemption.*

(1) *Certification and disclosure of creditable coverage.* Without regard to an election under this section, a non-Federal governmental plan must provide for certification and disclosure of creditable coverage under the plan with respect to participants and their dependents as specified under §146.115 of this part.

(2) *Genetic information.* Without regard to an election under this section that exempts a non-Federal governmental plan from any or all of the provisions of §146.111 and §146.121 of this part, the exemption election must not be construed to exempt the plan from any provisions of this part 146 that pertain to genetic information.

(3) *Enforcement.* CMS enforces these requirements as provided under paragraph (k) of this section.

(4) *Examples.*

(i)

Example 1. (A) Individual *A* is hired by a county that has elected to exempt its self-funded group health plan from certain requirements of paragraph (a)(1) of this section, including prohibitions against enrollment discrimination based on health status-related factors. Individual *A* applies for enrollment in the county's group health plan. Applicants must pass medical underwriting before being allowed to enroll in the plan. The plan requires an applicant to complete a medical history form and to authorize the plan to contact physicians regarding any medical treatments the applicant has received in the past 5 years. Individual *A* has Type 2 diabetes. He submits the required form, which reflects that condition. The plan also receives information from Individual *A*'s physicians. While the plan's request to Individual *A's* physicians did not include a request for genetic information, the plan received information from a physician in response to its request for health information about Individual *A*, that one of Individual *A*'s parents has Huntington's Disease. The Plan denies enrollment to Individual *A*.

(B) Individual *A* files a complaint with CMS that he has been denied enrollment in the plan because of genetic information the plan received. CMS investigates the complaint and determines that the plan uniformly denies enrollment to anyone who has Type II diabetes. CMS resolves the complaint in favor of the plan on the basis that the plan permissibly denied enrollment to Individual *A* under its exemption election because of the existence of a medical condition that uniformly disqualifies individuals from participating in the plan.

(ii)

Example 2. (A) Same facts as in *Example 1*, except Individual *A* does not have diabetes or any other preexisting medical condition; that is, there is no manifestation of a disease

or disorder with respect to Individual *A* at the time of his application for enrollment in the county's group health plan.

(B) In these circumstances, CMS resolves the complaint in favor of Individual *A* because CMS determines that the plan impermissibly denied enrollment to Individual *A* on the basis of genetic information. CMS instructs the plan to permit Individual *A* to enroll in the plan retroactive to the earliest date coverage would be effective under the terms of the plan based on the date of Individual *A*'s enrollment application or hire, as applicable. CMS may impose a civil money penalty, as determined under subpart C of part 150.

(i) *Effect of failure to comply with certification and notification requirements*—(1) *Substantial failure.* (i) *General rule.* Except as provided in paragraph (i)(1)(iii) of this section, a substantial failure to comply with paragraphs (f) or (h)(1) of this section results in the invalidation of an election under this section with respect to all plan enrollees for the entire plan year. That is, the plan is subject to all requirements of this part for the entire plan year to which the election otherwise would have applied.

(ii) *Determination of substantial failure.* CMS determines whether a plan has substantially failed to comply with a requirement of paragraph (f) or paragraph (h)(1) of this section based on all relevant facts and circumstances, including previous record of compliance, gravity of the violation and whether a plan corrects the failure, as warranted, within 30 days of learning of the violation. However, in general, a plan's failure to provide a notice of the fact and consequences of an election under this section to an individual at the time of enrollment, or on an annual basis before a given plan year expires, constitutes a substantial failure.

(iii) *Exceptions*—(A) *Multiple employers.* If the plan is sponsored by multiple employers, and only certain employers substantially fail to comply with the requirements of paragraphs (f) or (h)(1) of this section, then the election is invalidated with respect to those employers only, and not with respect to other employers that complied with those requirements, unless the plan chooses to cancel its election entirely.

(B) *Limited failure to provide notice.* If a substantial failure to notify enrollees of the fact and consequences of an election is limited to certain individuals, the election under this section is valid only if, for the plan year with respect to which the failure has occurred, the plan agrees not to apply the election with respect to the individuals who were not notified and so informs those individuals in writing.

(2) *Examples.* (i) *Example 1:* A self-funded non-Federal group health plan is co-sponsored by 10 school districts. Nine of the school districts have fully complied with the requirements of paragraph (f) of this section, including providing notice to new employees at the time of their enrollment in the plan, regarding the group health plan's exemption under this section from requirements of this part. One school district, which hired 10 new teachers during the summer for the upcoming school year, neglected to notify three of the new hires about the group health plan's exemption election at the time they enrolled in the plan. The school district has substantially failed to comply with a requirement of paragraph (f) with respect to these individuals.

The school district learned of the oversight six weeks into the school year, and promptly (within 30 days of learning of the oversight) provided notice to the three teachers regarding the plan's exemption under this section and that the exemption does not apply to them, or their dependents, during the plan year of their enrollment because of the plan's failure to timely notify them of its exemption. The plan complies with the requirements of this part for these individuals for the plan year of their enrollment. CMS would not require the plan to come into compliance with the requirements of this part for other enrollees.

(ii) *Example 2:* Same facts as in Example 1, except the noncompliant school district failed to notify any enrollees regarding an election under this section. That is, the school district failed to provide the annual notice to current plan enrollees as well as the notice at the time of enrollment to new enrollees. The school district has substantially failed to comply with the requirements of paragraph (f) of this section. At a minimum, the election is invalidated with respect to all enrollees

of the noncompliant school district for the plan year for which the substantial failure has occurred. In this example, the plan decides not to cancel its election entirely. The election with regard to the other nine school districts remains in effect.

(iii) *Example 3.* Two non-Federal governmental employers cosponsor a self-funded group health plan. One employer substantially fails to comply with the requirements of paragraph (f) of this section. While the plan may limit the invalidation of the election to enrollees of the plan sponsor that is responsible for the substantial failure, the plan sponsors determine that administering the plan in that manner would be too burdensome. Accordingly, in this example, the plan sponsors choose to cancel the election entirely. Both plan sponsors come into compliance with the requirements of this part with respect to all enrollees for the plan year for which the substantial failure has occurred.

(iv) *Example 4:* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from certain requirements of this part. The collective bargaining agreement applies to five plan years, 2001 through 2005. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2001 through December 31, 2005. Prior to the dissemination of the annual notice for the 2004 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2001 through December 31, 2005. Accordingly, CMS would not invalidate the election for the 2004 plan year.

(v) *Example 5:* A non-Federal governmental employer has elected to exempt its self-funded plan from certain requirements of this part. An individual terminates employment with the governmental employer, which fails to automatically provide a certificate of creditable coverage within the period specified in §146.115(a)(2)(ii)(A). (The governmental employer generally provides certificates to terminated employees on an automatic basis, but neglected to do so in this case.) The oversight is brought to the employer's attention when the individual inquires as to why he has not received his certificate of creditable coverage. The governmental employer promptly (within 30 days) forwards a certificate to the individual. CMS would not view that situation as constituting a substantial failure and would not invalidate the election under this section.

(j) *Election invalidated.* If CMS finds cause to invalidate an election under this section, the following rules apply:

(1) CMS notifies the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) in writing that CMS has made a preliminary determination that an election is invalid, and states the basis for that determination.

(2) CMS's notice informs the plan sponsor that it has 45 days after the date of CMS's notice to explain in writing why it believes its election is valid. The plan sponsor should provide applicable statutory and regulatory citations to support its position.

(3) CMS verifies that the plan sponsor's response is timely filed as provided under paragraph (d)(3) of this section. CMS will not consider a response that is not timely filed.

(4) If CMS's preliminary determination that an election is invalid remains unchanged after CMS considers the plan sponsor's timely response (or in the event that the plan sponsor fails to respond timely), CMS provides written notice to the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) of CMS's final determination that the election is invalid. Also, CMS informs the plan sponsor that, within 45 days of the date of the notice of final determination, the plan, subject to paragraph (i)(1)(iii) of this section, must comply with all

requirements of this part for the specified period for which CMS has determined the election to be invalid.

(k) *Enforcement.* To the extent that an election under this section has not been filed or a non-Federal governmental plan otherwise is subject to one or more requirements of this part, CMS enforces those requirements under part 150 of this subchapter. This may include imposing a civil money penalty against the plan or plan sponsor, as determined under subpart C of part 150.

(l) *Construction.* Nothing in this section should be construed to prevent a State from taking the following actions:

(1) Establishing, and enforcing compliance with, the requirements of State law (as defined in §146.143(d)(1)), including requirements that parallel provisions of title XXVII of the PHS Act, that apply to non-Federal governmental plans or sponsors.

(2) Prohibiting a sponsor of a non-Federal governmental plan within the State from making an election under this section.

[67 FR 48811, July 26, 2002, as amended at 74 FR 51693, Oct. 7, 2009]

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

Sec.

AUTHORITY: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

SOURCE: 75 FR 27138, May 13, 2010, unless otherwise noted.

§147.100 Basis and scope.

Part 147 of this subchapter implements the requirements of the Patient Protection and Affordable Care Act that apply to group health plans and health insurance issuers in the Group and Individual markets.

§147.108 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions*—(1) *In general.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in §144.103).

(2) *Examples.* The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, *see* §146.111(a)(1)(ii)):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P*. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N*. *N*'s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1,* the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) *Facts.* Individual *C* applies for individual health insurance coverage with Issuer *M*. *M* denies *C*'s application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion.* In this *Example 2, M*'s denial of *C*'s application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) *Applicability*—(1) *General applicability date.* Except as provided in paragraph (b)(2) of this section, the rules of this section apply for plan years beginning on or after January 1, 2014; in the case of individual health insurance coverage, for policy years beginning, or