

## SUBCHAPTER B—REQUIREMENTS RELATING TO HEALTH CARE ACCESS

### PARTS 140–143 [RESERVED]

### PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

#### Subpart A—General Provisions

Sec.	
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#### Subpart B [Reserved]

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

SOURCE: 62 FR 16955, Apr. 8, 1997, unless otherwise noted.

#### Subpart A—General Provisions

##### § 144.101 Basis and purpose.

(a) Part 146 of this subchapter implements sections 2701 through 2723 of the Public Health Service Act (PHS Act, 42 U.S.C. 300gg, *et seq.*). Its purpose is to improve access to group health insurance coverage, guarantee the renewability of all coverage in the group market, provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth, and provide parity between the application of annual and lifetime dollar limits to mental health benefits and those limits for other health benefits and to provide certain protections for patients who elect breast reconstruction in connection with a mastectomy.

(b) Part 148 of this subchapter implements sections 2741 through 2763 of the PHS Act. Its purpose is to improve access to individual health insurance coverage for certain individuals who previously had group coverage, guarantee the renewability of all health insurance coverage in the individual market, and provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth, and to provide

certain protections for patients who elect breast reconstruction in connection with a mastectomy.

(c) Part 150 of this subchapter implements the enforcement provisions of sections 2722 and 2761 of the PHS Act with respect to the following:

(1) States that fail to substantially enforce one or more provisions of part 146 concerning group health insurance or the requirements of part 148 of this subchapter concerning individual health insurance.

(2) Insurance issuers in States described in paragraph (c)(1) of this section.

(3) Group health plans that are non-Federal governmental plans.

(d) 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.

[64 FR 45795, Aug. 20, 1999]

##### § 144.102 Scope and applicability.

(a) For purposes of 45 CFR parts 144 through 148, all health insurance coverage is generally divided into two markets—the group market (set forth in 45 CFR part 146) and the individual market (set forth in 45 CFR part 148). 45 CFR part 146 limits the group market to insurance sold to employment-related group health plans and further divides the group market into the large group market and the small group market. Federal law further defines the small group market as insurance sold to employer plans with 2 to 50 employees. State law, however, may expand the definition of the small group market to include certain coverage that would otherwise, under the Federal law, be considered coverage in the large group market or the individual market.

(b) The protections afforded under 45 CFR parts 144 through 148 to individuals and employers (and other sponsors of health insurance offered in connection with a group health plan) are determined by whether the coverage involved is obtained in the small group market, the large group market, or the

individual market. Small employers, and individuals who are eligible to enroll under the employer's plan, are guaranteed availability of insurance coverage sold in the small group market. Small and large employers are guaranteed the right to renew their group coverage, subject to certain exceptions. Eligible individuals are guaranteed availability of coverage sold in the individual market, and all coverage in the individual market must be guaranteed renewable. All coverage issued in the small or large group market, and in the individual market, must provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth.

(c) Coverage that is provided to associations, but is not related to employment, is not considered group coverage under 45 CFR parts 144 through 148. The coverage is considered coverage in the individual market, regardless of whether it is considered group coverage under State law.

(d) Provisions relating to CMS enforcement of one or more provisions of part 146 or the requirements of part 148, or both, are contained in part 150 of this subchapter.

[62 FR 16955, Apr. 8, 1997, as amended at 63 FR 57558, Oct. 27, 1998; 64 FR 45795, Aug. 20, 1999]

#### § 144.103 Definitions.

For purposes of parts 146 (group market), 148 (individual market), and 150 (enforcement) of this subchapter, the following definitions apply unless otherwise provided:

*Affiliation period* means a period of time that must expire before health insurance coverage provided by an HMO becomes effective, and during which the HMO is not required to provide benefits.

*Applicable State authority* means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of 45 CFR parts 146 and 148 for the State involved with respect to the issuer.

*Beneficiary* has the meaning given the term under section 3(8) of the Employee Retirement Income Security

Act of 1974 (ERISA), which states, "a person designated by a participant, or by the terms of an employee benefit plan, who is or may become entitled to a benefit" under the plan.

*Bona fide association* means, with respect to health insurance coverage offered in a State, an association that meets the following conditions:

(1) Has been actively in existence for at least 5 years.

(2) Has been formed and maintained in good faith for purposes other than obtaining insurance.

(3) Does not condition membership in the association on any health status-related factor relating to an individual (including an employee of an employer or a dependent of any employee).

(4) Makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to the members (or individuals eligible for coverage through a member).

(5) Does not make health insurance coverage offered through the association available other than in connection with a member of the association.

(6) Meets any additional requirements that may be imposed under State law.

*Church plan* means a Church plan within the meaning of section 3(33) of ERISA.

*COBRA definitions:*

(1) *COBRA* means Title X of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(2) *COBRA continuation coverage* means coverage, under a group health plan, that satisfies an applicable COBRA continuation provision.

(3) *COBRA continuation provision* means sections 601 through 608 of the Employee Retirement Income Security Act of 1974, section 4980B of the Internal Revenue Code of 1986 (other than paragraph (f)(1) of section 4980B insofar as it relates to pediatric vaccines), and Title XXII of the PHS Act.

(4) *Continuation coverage* means coverage under a COBRA continuation provision or a similar State program. Coverage provided by a plan that is subject to a COBRA continuation provision or similar State program, but that does not satisfy all the requirements of that provision or program,

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will be deemed to be continuation coverage if it allows an individual to elect to continue coverage for a period of at least 18 months. Continuation coverage does not include coverage under a conversion policy required to be offered to an individual upon exhaustion of continuation coverage, nor does it include continuation coverage under the Federal Employees Health Benefits Program.

(5) *Exhaustion of COBRA continuation coverage* means that an individual's COBRA continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). An individual is considered to have exhausted COBRA continuation coverage if such coverage ceases—

(i) Due to the failure of the employer or other responsible entity to remit premiums on a timely basis; or

(ii) When the individual no longer resides, lives, or works in a service area of an HMO or similar program (whether or not within the choice of the individual) and there is no other COBRA continuation coverage available to the individual.

(6) *Exhaustion of continuation coverage* means that an individual's continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). An individual is considered to have exhausted continuation coverage if—

(i) Coverage ceases due to the failure of the employer or other responsible entity to remit premiums on a timely basis; or

(ii) When the individual no longer resides, lives, or works in a service area of an HMO or similar program (whether or not within the choice of the individual) and there is no other continuation coverage available to the individual.

*Condition* means a medical condition. *Creditable coverage* has the meaning given the term under 45 CFR 146.113(a).

*Eligible individual*, for purposes of—

(1) The group market provisions in 45 CFR part 146, subpart E, the term is defined in 45 CFR 146.150(b); and

(2) The individual market provisions in 45 CFR part 148, the term is defined in 45 CFR 148.103.

*Employee* has the meaning given the term under section 3(6) of ERISA, which states, "any individual employed by an employer."

*Employer* has the meaning given the term under section 3(5) of ERISA, which states, "any person acting directly as an employer, or indirectly in the interest of an employer, in relation to an employee benefit plan; and includes a group or association of employers acting for an employer in such capacity."

*Enroll* means to become covered for benefits under a group health plan (that is, when coverage becomes effective), without regard to when the individual may have completed or filed any forms that are required in order to enroll in the plan. For this purpose, an individual who has health insurance coverage under a group health plan is enrolled in the plan regardless of whether the individual elects coverage, the individual is a dependent who becomes covered as a result of an election by a participant, or the individual becomes covered without an election.

*Enrollment date* definitions (*enrollment date* and *first day of coverage*) are set forth in 45 CFR 146.111(a)(2)(i) and (a)(2)(ii).

*ERISA* stands for the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*).

*Excepted benefits*, for purposes of the—

(1) Group market provisions in 45 CFR part 146 subpart D, the term is defined in 45 CFR 146.145(b); and

(2) Individual market provisions in 45 CFR part 148, the term is defined in 45 CFR 148.220.

*Federal governmental plan* means a governmental plan established or maintained for its employees by the Government of the United States or by any agency or instrumentality of such Government.

*Genetic information* means information about genes, gene products, and inherited characteristics that may derive from the individual or a family

member. This includes information regarding carrier status and information derived from laboratory tests that identify mutations in specific genes or chromosomes, physical medical examinations, family histories, and direct analysis of genes or chromosomes.

*Governmental plan* means a governmental plan within the meaning of section 3(32) of ERISA.

*Group health insurance coverage* means health insurance coverage offered in connection with a group health plan.

*Group health plan* means an employee welfare benefit plan (as defined in section 3(1) of ERISA) to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the PHS Act and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

*Group market* means the market for health insurance coverage offered in connection with a group health plan. (However, unless otherwise provided under State law, certain very small plans may be treated as being in the individual market, rather than the group market; see the definition of "individual market" in this section.)

*CMS* means the Centers for Medicare & Medicaid Services.

*Health insurance coverage* means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer.

*Health insurance issuer* or *issuer* means an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of ERISA). This term does not include a group health plan.

*Health maintenance organization* or *HMO* means—

(1) A Federally qualified health maintenance organization (as defined in section 1301(a) of the PHS Act);

(2) An organization recognized under State law as a health maintenance organization; or

(3) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

*Health status-related factor* means health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence) and disability.

*Individual health insurance coverage* means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited-duration insurance. Individual health insurance coverage can include dependent coverage.

*Individual market* means the market for health insurance coverage offered to individuals other than in connection with a group health plan. Unless a State elects otherwise in accordance with section 2791(e)(1)(B)(ii) of the PHS Act, such term also includes coverage offered in connection with a group health plan that has fewer than two participants as current employees on the first day of the plan year.

*Internal Revenue Code (Code)* means the Internal Revenue Code of 1986, as amended (Title 26, United States Code).

*Issuer* means a health insurance issuer.

*Large 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 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year, unless otherwise provided under State law.

*Large group market* means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer, unless otherwise provided under State law.

*Late enrollment definitions (late enrollee and late enrollment)* are set forth

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in 45 CFR 146.111 (a)(2)(iii) and (a)(2)(iv).

*Medical care* means amounts paid for any of the following:

(1) The diagnosis, cure, mitigation, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body.

(2) Transportation primarily for and essential to medical care referred to in paragraph (1) of this definition.

(3) Insurance covering medical care referred to in paragraphs (1) and (2) of this definition.

*Medical condition* or *condition* means any condition, whether physical or mental, including, but not limited to, any condition resulting from illness, injury (whether or not the injury is accidental), pregnancy, or congenital malformation. However, genetic information is not a condition.

*NAIC* stands for the National Association of Insurance Commissioners.

*Network plan* means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

*Non-Federal governmental plan* means a governmental plan established or maintained for its employees by the government of any State or political subdivision thereof, or by any agency or instrumentality of either.

*Participant* has the meaning given the term under section 3(7) of ERISA, which states, “any employee or former employee of an employer, or any member or former member of an employee organization, who is or may become eligible to receive a benefit of any type from an employee benefit plan which covers employees of such employer or members of such organization, or whose beneficiaries may be eligible to receive any such benefit.”

*PHS Act* stands for the Public Health Service Act (42 U.S.C. 201 *et seq.*).

*Placement, or being placed, for adoption* means the assumption and retention of a legal obligation for total or partial support of a child by a person with whom the child has been placed in anticipation of the child’s adoption. The child’s placement for adoption with the

person terminates upon the termination of the legal obligation.

*Plan sponsor* has the meaning given the term under section 3(16)(B) of ERISA, which states “(i) the employer in the case of an employee benefit plan established or maintained by a single employer, (ii) the employee organization in the case of a plan established or maintained by an employee organization, or (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan.”

*Plan year* means the year that is designated as the plan year in the plan document of a group health plan, except that if the plan document does not designate a plan year or if there is no plan document, the plan year is:

(1) The deductible/limit year used under the plan.

(2) If the plan does not impose deductibles or limits on a yearly basis, the plan year is the policy year.

(3) If the plan does not impose deductibles or limits on a yearly basis, and either the plan is not insured or the insurance policy is not renewed on an annual basis, the plan year is the employer’s taxable year.

(4) In any other case, the plan year is the calendar year.

*Preexisting condition exclusion* means a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the first day of coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any exclusion applicable to an individual as a result of information that is obtained relating to an individual’s health status before the individual’s first day of coverage, such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

*Public health plan* has the meaning given the term under 45 CFR 146.113(a)(1)(ix).

*Short-term limited duration insurance* means health insurance coverage provided under a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer's consent) that is within 12 months of the date the contract becomes effective.

*Significant break in coverage* has the meaning given the term in 45 CFR 146.113(b)(2)(iii).

*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 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year, unless otherwise provided under State law.

*Small group market* means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer.

*Special enrollment date* has the meaning given the term in 45 CFR 146.117(d).

*State* means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

*State health benefits risk pool* has the meaning given the term under 45 CFR 146.113(a)(1)(vii).

*Waiting period* means the period that must pass before an employee or dependent is eligible to enroll under the terms of a group health plan. If an employee or dependent enrolls as a late enrollee or on a special enrollment date, any period before such late or special enrollment is not a waiting period. If an individual seeks and obtains coverage in the individual market, any period after the date the individual files a substantially complete application for coverage and before the first day of coverage is a waiting period.

[62 FR 16955, Apr. 8, 1997; 62 FR 31670, 31693, June 10, 1997; 64 FR 45795, Aug. 20, 1999]

**Subpart B [Reserved]**

**PART 145 [RESERVED]**

**PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET**

**Subpart A—General Provisions**

Sec.  
146.101 Basis and scope.

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

- 146.111 Limitations on preexisting condition exclusion periods.
- 146.113 Rules relating to creditable coverage.
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- 146.117 Special enrollment periods.
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- 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.
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- 146.143 Preemption; State flexibility; construction.
- 146.145 Special rules relating to group health plans.

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- 146.150 Guaranteed availability of coverage for employers in the small group market.
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- 146.160 Disclosure of information.

**Subpart F—Exclusion of Plans and Enforcement**

- 146.180 Treatment of non-Federal governmental plans.

AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as added by HIPAA (Pub. L. 104-191), and

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amended by MHPA (Pub. L. 104-204, as amended by Pub. L. 107-116, Pub. L. 107-313, and Pub. L. 108-197), NMHPA (Pub. L. 104-204), and WHCRA (Pub. L. 105-277), sec. 102(c) of HIPAA.

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 sections 2701 through 2723 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.

(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 require-

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ments of Subpart B for certain plans and certain types of benefits.

(4) *Subpart E.* Subpart E of this part implements sections 2711 through 2713 of the PHS Act, which set forth requirements that apply only to health insurance issuers offering health insurance coverage in connection with a group health plan.

(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]

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

#### § 146.111 Limitations on preexisting condition exclusion periods.

(a) *Preexisting condition exclusion—(1) General.* Subject to paragraph (b) of this section, 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) are satisfied.

(1)(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 ending on the enrollment date.

(A) For purposes of this paragraph (a)(1)(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)(1)(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 following examples illustrate the requirements of this paragraph (a)(1)(i):

*Example 1:* (i) Individual *A* is treated for a medical condition 7 months before the enrollment date in Employer *R*'s group health plan. As part of such treatment, *A*'s physician recommends that a follow-up examination be given 2 months later. Despite this recommendation, *A* does not receive a follow-up examination and no other medical advice, diagnosis, care, or treatment for that condition is recommended to *A* or received by *A* during the 6-month period ending on *A*'s enrollment date in Employer *R*'s plan.

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

*Example 2:* (i) Same facts as *Example 1* except that Employer *R*'s plan learns of the condition and attaches a rider to *A*'s policy excluding coverage for the condition. Three months after enrollment, *A*'s condition recurs, and Employer *R*'s plan denies payment under the rider.

(ii) In this *Example*, the rider is a preexisting condition exclusion and Employer *R*'s plan may not impose a preexisting condition exclusion with respect to the condition for which *A* received treatment 7 months prior to the enrollment date.

*Example 3:* (i) Individual *B* has asthma and is treated for that condition several times during the 6-month period before *B*'s enrollment date in Employer *S*'s plan. The plan imposes a 12-month preexisting condition exclusion. *B* has no prior creditable coverage to reduce the exclusion period. Three months after the enrollment date, *B* begins coverage under Employer *S*'s plan. *B* is hospitalized for asthma.

(ii) In this *Example*, Employer *S*'s plan may exclude payment for the hospital stay and the physician services associated with this illness because the care is related to a medical condition for which treatment was received by *B* during the 6-month period before the enrollment date.

*Example 4:* (i) Individual *D*, who is subject to a preexisting condition exclusion imposed by Employer *U*'s plan, has diabetes, as well as a foot condition caused by poor circulation and retinal degeneration (both of which are conditions that may be directly attrib-

uted to diabetes). After enrolling in the plan, *D* stumbles and breaks a leg.

(ii) In this *Example*, the leg fracture is not a condition related to *D*'s diabetes, even though poor circulation in *D*'s extremities and poor vision may have contributed towards the accident. However, any additional medical services that may be needed because of *D*'s preexisting diabetic condition that would not be needed by another patient with a broken leg who does not have diabetes may be subject to the preexisting condition exclusion imposed under Employer *U*'s plan.

(ii) *Maximum length of preexisting condition exclusion (the look-forward rule).* 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 purposes of this paragraph (a)(1)(ii), the 12-month and 18-month periods after the enrollment date are determined by reference to the anniversary of 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.

(iii) *Reducing a preexisting condition exclusion period by creditable coverage.* 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. For purposes of this part, the phrase "days of creditable coverage" has the same meaning as the phrase "the aggregate of the periods of creditable coverage" as such phrase is used in section 2701(a)(3) of the PHS Act.

(iv) *Other standards.* See § 146.121 for other standards that may apply with respect to certain benefit limitations or restrictions under a group health plan.

(2) *Enrollment definitions—*(i) *Enrollment date* means the first day of coverage or, if there is a waiting period, the first day of the waiting period.

(ii) (A) *First day of coverage* means, in the case of an individual covered for benefits under a group health plan in the group market, 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.

(B) *Example.* The following example illustrates the requirements of paragraph (a)(2)(ii)(A) of this section:

*Example:* (i) 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 then on October 14, 1998 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) In this *Example*, *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 6-month period in paragraph (a)(1)(i) would be the period from April 13, 1998 through October 12, 1998, the maximum permissible period during which Employer *V*'s plan could apply a preexisting condition exclusion under paragraph (a)(1)(ii) would be the period from October 13, 1998 through October 12, 1999, and this period would be reduced under paragraph (a)(1)(iii) by *E*'s days of creditable coverage as of October 13, 1998.

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

(iv) *Late enrollment* means enrollment under a group health plan other than on—

(A) The earliest date on which coverage can become effective under the terms of the plan; or

(B) A special enrollment date for the individual. If an individual ceases to be eligible for coverage under the plan by terminating employment, and subsequently becomes eligible for coverage under the plan by resuming employment, only eligibility during the individual's most recent period of employment 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 fol-

lowing a suspension of coverage that applied generally under the plan.

(v) *Examples.* The following examples illustrate the requirements of this paragraph (a)(2):

*Example 1:* (i) 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 April 1, 1999. April 1, 1999 is not a special enrollment date for *F*.

(ii) In this *Example*, *F* would be a late enrollee with respect to *F*'s coverage that became effective under the plan on April 1, 1999.

*Example 2:* (i) Same as *Example 1*, except that *F* does not enroll in the plan on April 1, 1999 and 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) In this *Example*, *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) General rule.* 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 with regard to a child who, as of the last day of the 30-day period beginning with the date of birth, is covered under any creditable coverage. Accordingly, if a newborn 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, the other plan may not impose any preexisting condition exclusion with regard to the child.

(ii) *Example.* The following example illustrates the requirements of this paragraph (b)(1):

*Example:* (i) Seven months after enrollment in Employer *W*'s group health plan, Individual *E* has a child born with a birth defect. Because the child is enrolled in Employer *W*'s plan within 30 days of birth, no preexisting condition exclusion may be imposed with respect to the child under Employer *W*'s plan. Three months after the child's birth, *E* commences employment with Employer *X* and enrolls with the child in Employer *X*'s plan within 45 days of leaving Employer *W*'s plan. Employer *X*'s plan imposes a 12-month exclusion for any preexisting condition.

(ii) In this *Example*, Employer X's plan may not impose any preexisting condition exclusion with respect to E's child because the child was covered within 30 days of birth and had no significant break in coverage. This result applies regardless of whether E's child is included in the certificate of creditable coverage provided to E by Employer W indicating 300 days of dependent coverage or receives a separate certificate indicating 90 days of coverage. Employer X's plan may impose a preexisting condition exclusion with respect to E for up to 65 days for any preexisting condition of E for which medical advice, diagnosis, care, or treatment was recommended or received by E within the 6-month period ending on E's enrollment date in Employer X's plan.

(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 in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. This rule does not apply to coverage before the date of such adoption or placement for adoption.

(3) *Break in coverage.* Paragraphs (b)(1) and (b)(2) of this section no longer apply to a child after a significant break in coverage.

(4) *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 as a preexisting condition.

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

(c) *Notice of plan's preexisting condition exclusion.* A group health plan, and a health insurance issuer offering group health insurance under the plan, may not impose a preexisting condition exclusion with respect to a participant or dependent of the participant before notifying the participant, in writing, of the existence and terms of any preexisting condition exclusion under the plan and of the rights of individuals to demonstrate creditable coverage (and any applicable waiting periods) as required by §146.115. The description of the rights of individuals to dem-

onstrate creditable coverage includes 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.

(Approved by the Office of Management and Budget under control number 0938-0702)

[62 FR 16958, Apr. 8, 1997; 62 FR 31670, 31693, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

#### § 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), the term creditable coverage means coverage of an individual under any of the following:

(i) A group health plan as defined in §144.103.

(ii) Health insurance coverage as defined in §144.103 (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 part 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 Code;

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(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 insurance 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, county, or other political subdivision of a State that provides health insurance 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)).

(2) *Excluded coverage.* Creditable coverage does not include coverage consisting solely of coverage of 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)(1)(iii), a group health plan, and a health insurance issuer offering group health insurance coverage, determines the amount of an individual's creditable coverage by using the standard method described in paragraph (b), except that the plan, or issuer, may use the alternative method under paragraph (c) with respect to any or all of the categories of benefits described under paragraph (c)(3).

(b) *Standard method—(1) Specific benefits not considered.* Under the standard method, a group health plan, and a health insurance issuer offering group health insurance coverage, determines the amount of creditable coverage

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, a group health plan, and a health insurance issuer offering group health insurance coverage, determines the amount of creditable coverage by counting all the days that the individual has under 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. Further, any days in a waiting period for a plan or policy are not creditable coverage under the plan or policy.

(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) *Definition of significant break in coverage.* A significant break in coverage means a period of 63 consecutive days during all of which the individual does not have any creditable coverage, except that neither a waiting period nor an affiliation period is taken into account in determining a significant break in coverage. (See section 731(b)(2)(iii) of ERISA and section 2723(b)(2)(iii) of the PHS Act, which exclude from preemption 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 law.)

(iv) *Examples.* The following examples illustrate how creditable coverage is counted in reducing preexisting condition exclusion periods:

*Example 1:* (i) Individual *A* works for Employer *P* and has creditable coverage under Employer *P*'s plan for 18 months before *A*'s employment terminates. *A* is hired by Employer *O*, and enrolls in Employer *O*'s group health plan, 64 days after the last date of coverage under Employer *P*'s plan. Employer *O*'s plan has a 12-month preexisting condition exclusion period.

(ii) In this *Example*, because *A* had a break in coverage of 63 days, Employer *O*'s plan may disregard *A*'s prior coverage and *A* may be subject to a 12-month preexisting condition exclusion period.

*Example 2:* (i) Same facts as *Example 1*, except that *A* is hired by Employer *O*, and enrolls in Employer *O*'s plan, on the 63rd day

after the last date of coverage under Employer *P*'s plan.

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

*Example 3:* (i) Same facts as *Example 1*, except that Employer *O*'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) In this *Example*, the issuer that provides group health insurance to Employer *O*'s plan must count *A*'s period of creditable coverage prior to the 63-day break.

*Example 4:* (i) Same facts as *Example 3*, except that Employer *O*'s plan is a self-insured plan, and thus is not subject to State insurance laws.

(ii) In this *Example*, the plan is not governed by the longer break rules under State insurance law and *A*'s previous coverage may be disregarded.

*Example 5:* (i) Individual *B* begins employment with Employer *R* 45 days after terminating coverage under a prior group health plan. Employer *R*'s group health plan has a 30-day waiting period before coverage begins. *B* enrolls in Employer *R*'s plan when first eligible.

(ii) In this *Example*, *B* does not have a significant break in coverage for purposes of determining whether *B*'s prior coverage must be counted by Employer *R*'s plan. *B* has only a 44-day break in coverage because the 30-day waiting period is not taken into account in determining a significant break in coverage.

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

(ii) In this *Example*, *C* does not have a significant break in coverage because, after disregarding the waiting period under Employer *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 Employer *U*'s plan may not apply its 6-month preexisting condition exclusion period with respect to *C*.

*Example 7:* (i) Individual *D* terminates employment with Employer *V* on January 13,

1998 after being covered for 24 months under Employer *V*'s group health plan. On March 17, the 63rd day without coverage, *D* applies for a health insurance policy in the individual market. *D*'s application is accepted and the coverage is made effective May 1.

(ii) In this *Example*, because *D* applied for the policy before the end of the 63rd day, and coverage under the policy ultimately became effective, 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 107 days.

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

(ii) In this *Example*, because *D* did not obtain coverage following application, *D* incurred a significant break in coverage on the 64th day.

(v) *Other permissible counting methods—(A) General 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 following example illustrates the requirements of this paragraph (b)(2)(v):

*Example:* (i) 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 period.

(ii) In this *Example*, Plan *Z* may determine, in accordance with the rules prescribed in paragraph (b)(2) (i), (ii), and (iii), 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 period 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 period 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) 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 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 policy. The use of the alternative method is set forth in the plan.

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

- (i) Mental health.
- (ii) Substance abuse treatment.
- (iii) Prescription drugs.
- (iv) Dental care.
- (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, and to each employer at the time of the offer or sale of 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) 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 following example illustrates the requirements of this paragraph (c)(7):

*Example:* (i) 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, 2001 (*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) 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.

[62 FR 16958, Apr. 8, 1997; 62 FR 31670, 31693, June 10, 1997]

**§ 146.115 Certification and disclosure of previous coverage.**

(a) *Certificate of creditable coverage—*  
(1) *Entities required to provide certificate—*(i) *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)(1) for an individual is deemed to have satisfied the certification requirements for that individual if another party provides the certificate, but only to the extent that information relating to the individual's creditable coverage and waiting or affiliation period is provided by the other party. For example, in the case of a group health plan funded through an insurance policy, the issuer is deemed to have satisfied the certification requirement with respect to a participant or beneficiary if the plan actually provides a certificate that includes the information required under paragraph (a)(3) of this section with respect to the participant or beneficiary.

(iii) *Special rule for group health plans.* To the extent coverage under a plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirements under this paragraph (a)(1) 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 the 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) *Responsibility of issuer for coverage period—*  
(1) *General rule.* An issuer is not required to provide information regarding coverage provided to an individual by another party.

(2) *Example.* The following example illustrates the requirements of this paragraph (a)(1)(iv)(A):

*Example.* (i) 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) 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) *Cessation of issuer coverage prior to cessation of coverage under a plan—*  
(1) *General rule.* If an individual's coverage under an issuer's policy 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 a certificate to be provided by the plan (or other party), after cessation of the individual's coverage under the plan, that reflects the period of coverage under the policy. The provision of that information to the plan will satisfy the issuer's obligation to provide an automatic certificate for that period of creditable coverage for the individual under paragraphs (a)(2)(ii) and (a)(3) of this section. In addition, an issuer providing that information is required to cooperate with the plan in responding to any request made under paragraph (b)(1) of this section (relating to the alternative

method of counting creditable coverage). If the individual's coverage under the plan ceases at the time the individual's coverage under the issuer's policy ceases, the issuer must provide an automatic certificate under paragraph (a)(2)(ii) of this section. An issuer may presume that an individual whose coverage ceases at a time other than the effective date for changing enrollment options has ceased to be covered under the plan.

(2) *Example.* The following example illustrates the requirements of this paragraph (a)(1)(iv)(B):

*Example:* (i) A group health plan provides coverage under an HMO option and an indemnity option with a different issuer, 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) In this *Example*, if an employee switches from the indemnity option to the HMO option on January 1, the 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 a 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 (a)(2)(iii) of this section.

(ii) *Issuance of automatic certificates.* The certificates described in this paragraph (a)(2)(i) 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 4980B(g)(1) of the 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 elect-

ed 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 4980B(f)(6) of the 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 is required to be provided at the time the individual ceases to be covered under the plan. A plan or issuer satisfies this requirement if it provides the automatic certificate within a reasonable time period thereafter. 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 period after the cessation of coverage under the plan.

(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.* Requests for certificates are permitted to be made by, or on behalf of, an individual within 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 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 following examples illustrate the requirements of this paragraph (a)(2):

*Example 1:* (i) Individual *A* terminates employment with Employer *O*. *A* is a qualified beneficiary entitled to elect COBRA continuation coverage under Employer *O*'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) In this *Example*, the automatic certificate may be provided at the same time that *A* is provided the COBRA notice.

*Example 2:* (i) 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) In this *Example*, the automatic certificate may be provided within the period permitted by law for the delivery of notices under COBRA.

*Example 3:* (i) 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 coverage 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) In this *Example*, the automatic certificate may be provided not later than the time a notice is required to be furnished under the State program.

*Example 4:* (i) 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, Employer *S*'s group health plan determines that *C*'s COBRA continuation coverage has ceased due to failure to make a timely payment for continuation coverage.

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

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

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

(B) *Other permissible forms.* No written certificate is required to be provided under this paragraph (a) with respect to a particular event described in paragraphs (a)(2)(ii) and (a)(2)(iii) of this section if all the following conditions are met:

(1) An individual is entitled to receive a certificate.

(2) The individual requests that the certificate be sent to another plan or issuer instead of to the individual.

(3) 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 (for example, by telephone).

(4) The receiving plan or issuer receives the information from the sending plan or issuer in such form within the time periods required under paragraph (a)(2) of this section.

(ii) *Required information.* The certificate must include all of 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.

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(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)).

(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.

(iii) *Periods of coverage under certificate.* If an automatic certificate is provided under 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 under paragraph (a)(2)(iii) of this section, a certificate must be provided for 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 or, 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 CMS.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted ben-

efits described in §146.145. 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 procedure for individuals to request and receive certificates under paragraph (a)(2)(iii) of this section.

(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 party. 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 party.

(5) *Special rules concerning dependent coverage—(i) Reasonable efforts—(A) General rule.* 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 following example illustrates the requirements of this paragraph (a)(5)(i):

*Example:* (i) 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) In this *Example*, the plan has satisfied the standard in this paragraph (a)(5)(i) 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 of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (c)(4) of this section for demonstrating dependent status. In addition, an individual may, if necessary, use these procedures to demonstrate that a child was enrolled within 30 days of birth, adoption, or placement for adoption. See § 146.111(b), under which such a child would not be subject to a preexisting condition exclusion.

(iii) *Transition rule for dependent coverage through June 30, 1998—(A) General.* A group health plan or health insurance issuer that cannot provide the names of dependents (or related coverage information) for purposes of providing a certificate of coverage for a dependent may satisfy the requirements of paragraph (a)(3)(ii)(C) of this section by providing the name of the participant covered by the group

health plan or health insurance issuer and specifying that the type of coverage described in the certificate is for dependent coverage (for example, family coverage or employee-plus-spouse coverage).

(B) *Certificates provided on request.* For purposes of certificates provided on the request of, or on behalf of, an individual under paragraph (a)(2)(iii) of this section, a plan or issuer must make reasonable efforts to obtain and provide the names of any dependent covered by the certificate where such information is requested to be provided. If a certificate does not include the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (c) of this section for submitting documentation to establish that the creditable coverage in the certificate applies to the dependent.

(C) *Demonstrating a dependent's creditable coverage.* See paragraph (c)(4) of this section for special rules to demonstrate dependent status.

(D) *Duration.* This paragraph (a)(5)(iii) is only effective for certifications provided with respect to events occurring through June 30, 1998.

(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) through (c)(1)(J) of the PHS Act (coverage under a State health benefits risk pool, the Federal Employees Health Benefits Program, a public health plan, and a health benefit plan under section 5(e) of the Peace Corps Act).

(B) Coverage subject to section 2721(b)(1)(B) of the PHS Act (requiring certificates by issuers offering health

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insurance coverage in connection with any group health plan, including a church plan or a governmental plan (including the Federal Employees Health Benefits Program (FEHBP)).

(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 in 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, CHAMPUS, and Indian Health Service), section 2721(b)(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) General.* If an individual enrolls in a group health plan with respect to which the plan, or issuer, uses the alternative method of counting creditable coverage described in section 2701(c)(3)(B) of the PHS Act and §146.113(c), the individual provides a certificate of coverage under paragraph (a) of this section, and the plan or issuer in which the individual enrolls so requests, the entity that issued the certificate (the “prior entity”) is required to disclose promptly to a requesting plan or issuer (the “requesting entity”) the information set forth in paragraph (b)(2) of this section.

(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. The prior entity is required to disclose promptly to the requesting entity the creditable coverage information so requested.

(3) *Charge for providing information.* The prior entity furnishing the information under paragraph (b) of this section 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) General.* The rules in this paragraph (c) implement section 2701(c)(4) of the PHS Act, which permits individuals to establish 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. If the accuracy of a certificate is contested or a certificate is unavailable when needed by the 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 period;

(ii) The individual has creditable coverage but an entity may not be required to provide a certificate of the coverage under paragraph (a) of this section;

(iii) The coverage is for a period before July 1, 1996;

(iv) The individual has an urgent medical condition that necessitates a

determination before the individual can deliver a certificate to the plan; or

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

(2) *Evidence of creditable coverage*—(i) *Consideration of evidence.* 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 and is entitled to offset all or a portion of any preexisting condition exclusion period. A plan or issuer shall treat the individual as having furnished a certificate under paragraph (a) of this section if the individual attests to the period of creditable coverage, the individual also presents relevant corroborating evidence of some creditable coverage during the period, and the individual cooperates with the plan's or issuer's efforts to verify the individual's coverage. For this purpose, 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 may establish creditable coverage (and waiting periods or affiliation periods) in the absence of a certificate include explanations of benefit claims (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 period or affiliation period information) may also be established 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 following example illustrates the requirements of this paragraph (c)(2):

*Example:* (i) Individual *F* terminates employment with Employer *W* and, a month later, is hired by Employer *X*. Employer *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, Employer *W*, and requests a certificate. However, *F* (and Employer *X*'s plan, on *F*'s behalf) is unable to obtain a certificate from Employer *W*'s plan. *F* attests that, to the best of *F*'s knowledge, *F* had at least 12 months of continuous coverage under Employer *W*'s plan, and that the coverage ended no earlier than *F*'s termination of employment from Employer *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) In this *Example*, based solely on these facts, *F* has demonstrated creditable coverage for the 12 months of coverage under Employer *W*'s plan in the same manner as if *F* had presented a written certificate of creditable coverage.

(3) *Demonstrating categories of creditable coverage.* Procedures similar to those described in this paragraph (c) apply in order to determine 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).

(4) *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.

(d) *Determination and notification of creditable coverage*—(1) *Reasonable time period.* In the event that a group health plan or health insurance issuer offering group health insurance coverage receives information in this section under paragraph (a) (certifications), paragraph (b) (disclosure of information relating to the alternative method), or paragraph (c) (other evidence of creditable coverage), the entity is required, within a reasonable time period following receipt of the information, to make a determination regarding the individual's period of creditable coverage and notify the individual of the determination in accordance with paragraph (d)(2) of this section. Whether a determination and notification regarding an individual's creditable coverage is made within a reasonable time period is determined based 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 services.

(2) *Notification to individual of period of preexisting condition exclusion.* A plan issuer seeking to impose a preexisting condition exclusion is required to disclose to the individual, in writing, its determination of any preexisting condition exclusion period that applies to the individual, and the basis for such determination, including the source and substance of any information on which the plan or issuer relied. In addition, the plan or issuer is required to provide the individual with a written explanation of any appeal procedures established by the plan or issuer, and with a reasonable opportunity to submit additional evidence of creditable coverage. However, nothing in this paragraph (d) or paragraph (c) of 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—

(i) A notice of the reconsideration is provided to the individual; and

(ii) Until the final determination is made, 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.

(3) *Examples.* The following examples illustrate this paragraph (d):

*Example 1:* (i) Individual *F* terminates employment with Employer *W* and, a month later, is hired by Employer *X*. *Example 1:* Individual *G* is hired by Employer *Y*. Employer *Y*'s group health plan imposes a preexisting condition exclusion for 12 months with respect to new enrollees and uses the standard method of determining creditable coverage. Employer *Y*'s plan determines that *G* is subject to a 4-month preexisting condition exclusion, based on a certificate of creditable coverage that is provided by *G* to Employer *Y*'s plan indicating 8 months of coverage under *G*'s prior group health plan.

(ii) In this *Example*, Employer *Y*'s plan must notify *G* within a reasonable period of time following receipt of the certificate that *G* is subject to a 4-month preexisting condition exclusion beginning on *G*'s enrollment date in *Y*'s plan.

*Example 2:* (i) Same facts as in *Example 1*, except that Employer *Y*'s plan determines that *G* has 14 months of creditable coverage based on *G*'s certificate indicating 14 months of creditable coverage under *G*'s prior plan.

(ii) In this *Example*, Employer *Y*'s plan is not required to notify *G* that *G* will not be subject to a preexisting condition exclusion.

*Example 3:* (i) Individual *H* is hired by Employer *Z*. Employer *Z*'s group health plan imposes a preexisting condition exclusion for 12 months with respect to new enrollees and uses the standard method of determining creditable coverage. *H* develops an urgent health condition before receiving a certificate of prior coverage. *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.

(ii) In this *Example*, Employer *Z*'s plan must review the evidence presented by *H*. In addition, the plan must make a determination and notify *H* regarding any preexisting condition exclusion period that applies to *H* (and the basis of such determination) within a reasonable time period following receipt of the evidence that is consistent with the urgency of *H*'s health condition. (This determination may be modified as permitted under paragraph (d)(2)).

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[62 FR 16958, Apr. 8, 1997; 62 FR 31693, 31694, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

#### § 146.117 Special enrollment periods.

(a) *Special enrollment for certain individuals who lose coverage*—(1) *General.* A

group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, is required to permit employees and dependents described in this section in paragraph (a)(2), (a)(3), or (a)(4) to enroll for coverage under the terms of the plan if the conditions in paragraph (a)(5) are satisfied and the enrollment is requested within the period described in paragraph (a)(6). The enrollment is effective at the time described in paragraph (a)(7). 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) *Special enrollment of an employee only.* An employee is described in this paragraph (a)(2) if the employee is eligible, but not enrolled, for coverage under the terms of the plan and, when enrollment was previously offered to the employee under the plan and was declined by the employee, the employee was covered under another group health plan or had other health insurance coverage.

(3) *Special enrollment of dependents only.* A dependent is described in this paragraph (a)(3) if the dependent is a dependent of an employee participating in the plan, the dependent is eligible, but not enrolled, for coverage under the terms of the plan, and, when enrollment was previously offered under the plan and was declined, the dependent was covered under another group health plan or had other health insurance coverage.

(4) *Special enrollment of both employee and dependent.* An employee and any dependent of the employee are described in this paragraph (a)(4) if they are eligible, but not enrolled, for coverage under the terms of the plan and, when enrollment was previously offered to the employee or dependent under the plan and was declined, the employee or dependent was covered under another group health plan or had other health insurance coverage.

(5) *Conditions for special enrollment.* An employee or dependent is eligible to enroll during a special enrollment period if each of the following applicable conditions is met:

(i) When the employee declined enrollment for the employee or the dependent, the employee stated in writing that coverage under another group health plan or other health insurance coverage was the reason for declining enrollment. This paragraph (a)(5)(i) applies only if—

(A) The plan required such a statement when the employee declined enrollment; and

(B) The employee is provided with notice of the requirement to provide the statement in paragraph (a)(5)(i) (and the consequences of the employee's failure to provide the statement) at the time the employee declined enrollment.

(ii)(A) When the employee declined enrollment for the employee or dependent under the plan, the employee or dependent had COBRA continuation coverage under another plan and COBRA continuation coverage under that other plan has since been exhausted; or

(B) If the other coverage that applied to the employee or dependent when enrollment was declined was not under a COBRA continuation provision, either the other coverage has been terminated as a result of loss of eligibility for the coverage or employer contributions towards the other coverage have been terminated. For this purpose, loss of eligibility for coverage includes a loss of coverage as a result of legal separation, divorce, death, termination of employment, reduction in the number of hours of employment, and any loss of eligibility after a period that is measured by reference to any of the foregoing. Thus, for example, if an employee's coverage ceases following a termination of employment and the employee is eligible for but fails to elect COBRA continuation coverage, this is treated as a loss of eligibility under this paragraph (a)(5)(ii)(B). However, loss of eligibility does not include a loss due to failure of the individual or the participant 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). In addition, for purposes of this paragraph (a)(5)(ii)(B), employer contributions include contributions by any current or

former employer (of the individual or another person) that was contributing to coverage for the individual.

(6) *Length of special enrollment period.* The employee is required to request enrollment (for the employee or the employee's dependent, as described in this section in paragraph (a)(2), paragraph (a)(3), or paragraph (a)(4)) not later than 30 days after the exhaustion of the other coverage described in paragraph (a)(5)(ii)(A) or termination of the other coverage as a result of the loss of eligibility for the other coverage for items described in paragraph (a)(5)(ii)(B) or following the termination of employer contributions toward that other coverage. The plan may impose the same requirements that apply to employees who are otherwise eligible under the plan to immediately request enrollment for coverage (for example, that the request be made in writing).

(7) *Effective date of enrollment.* Enrollment is effective not later than the first day of the first calendar month beginning after the date the completed request for enrollment is received.

(b) *Special enrollment with respect to certain dependent beneficiaries—(1) General.* A group health plan that makes coverage available with respect to dependents of a participant is required to provide a special enrollment period to permit individuals described in this section in paragraph (b)(2), (b)(3), (b)(4), (b)(5), or (b)(6) to be enrolled for coverage under the terms of the plan if the enrollment is requested within the time period described in paragraph (b)(7). The enrollment is effective at the time described in paragraph (b)(8). 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) *Special enrollment of an employee who is eligible but not enrolled.* An individual is described in this paragraph (b)(2) if the individual is an employee who is eligible, but not enrolled, for coverage under the terms of the plan, the individual would be a participant but for a prior election by the individual not to enroll in the plan during a previous enrollment period, and a person becomes a dependent of the in-

dividual through marriage, birth, or adoption or placement for adoption.

(3) *Special enrollment of a spouse of a participant.* An individual is described in this paragraph (b)(3) if either—

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

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

(4) *Special enrollment of an employee who is eligible, but not enrolled, for coverage under the terms of the spouse of such employee.* An employee who is eligible, but not enrolled, in the plan, and an individual who is a dependent of such employee, are described in this paragraph (b)(4) if the employee would be a participant but for a prior election by the employee not to enroll in the plan during a previous enrollment period, and either—

(i) The employee and the individual become married; or

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

(5) *Special enrollment of a dependent of a participant.* An individual is described in this paragraph (b)(5) if the individual is a dependent of a participant and the individual becomes a dependent of such participant through marriage, birth, or adoption or placement for adoption.

(6) *Special enrollment of an employee who is eligible but not enrolled and a new dependent.* An employee who is eligible, but not enrolled, for coverage under the terms of the plan, and an individual who is a dependent of the employee, are described in this paragraph (b)(6) if the employee would be a participant but for a prior election by the employee not to enroll in the plan during a previous enrollment period, and the dependent becomes a dependent of the employee through marriage, birth, or adoption or placement for adoption.

(7) *Length of special enrollment period.* The special enrollment period under paragraph (b)(1) of this section is a period of not less than 30 days and begins on the date of the marriage, birth, or adoption or placement for adoption (except that such period does not begin

earlier than the date the plan makes dependent coverage generally available).

(8) *Effective date of enrollment.* Enrollment is effective—

(i) In the case of marriage, not later than the first day of the first calendar month beginning after the date the completed request for enrollment is received by the plan;

(ii) In the case of a dependent's birth, the date of such birth; and

(iii) In the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

(9) *Example.* The following example illustrates the requirements of this paragraph (b):

*Example:* (i) Employee *A* is hired on September 3, 1998 by Employer *X*, which has a group health plan in which *A* can elect to enroll either for employee-only coverage, for employee-plus-spouse coverage, or for family coverage, effective on the first day of any calendar quarter thereafter. *A* is married and has no children. *A* does not elect to join Employer *X*'s plan (for employee-only coverage, employee-plus-spouse coverage, or family coverage) on October 1, 1998 or January 1, 1999. On February 15, 1999, a child is placed for adoption with *A* and *A*'s spouse.

(ii) In this *Example*, the conditions for special enrollment of an employee with a new dependent under paragraph (b)(2) are satisfied, the conditions for special enrollment of an employee and a spouse with a new dependent under paragraph (b)(4) are satisfied, and the conditions for special enrollment of an employee and a new dependent under paragraph (b)(6) are satisfied. Accordingly, Employer *X*'s plan will satisfy this paragraph (b) if and only if it allows *A* to elect, by filing the required forms by March 16, 1999, to enroll in Employer *X*'s plan either with employee-only coverage, with employee-plus-spouse coverage, or with family coverage, effective as of February 15, 1999.

(c) *Notice of enrollment rights.* On or before the time an employee is offered the opportunity to enroll in a group health plan, the plan is required to provide the employee with a description of the plan's special enrollment rules under this section. For this purpose, the plan may use the following model description of the special enrollment rules under this section:

If you are declining enrollment for yourself or your dependents (including your spouse) because of other health insurance

coverage, you may in the future be able to enroll yourself or your dependents in this plan, provided that you request enrollment within 30 days after your other coverage ends. 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, provided that you request enrollment within 30 days after the marriage, birth, adoption, or placement for adoption.

(d) *Special enrollment date definition.*

(1) *General rule.* A special enrollment date for an individual means any date in paragraph (a)(7) or paragraph (b)(8) of this section on which the individual has a right to have enrollment in a group health plan become effective under this section.

(2) *Examples.* The following examples illustrate the requirements of this paragraph (d):

*Example 1:* (i) Employer *Y* maintains a group health plan that allows employees to enroll in the plan either (a) effective on the first day of employment by an election filed within three days thereafter, (b) effective on any subsequent January 1 by an election made during the preceding months of November or December, or (c) effective as of any special enrollment date described in this section. Employee *B* is hired by Employer *Y* on March 15, 1998 and does not elect to enroll in Employer *Y*'s plan until January 31, 1999 when *B* loses coverage under another plan. *B* elects to enroll in Employer *Y*'s plan effective on February 1, 1999 by filing the completed request form by January 31, 1999, in accordance with the special rule set forth in paragraph (a).

(ii) In this *Example*, *B* has enrolled on a special enrollment date because the enrollment is effective at a date described in paragraph (a)(7).

*Example 2:* (i) Same facts as *Example 1*, except that *B*'s loss of coverage under the other plan occurs on December 31, 1998 and *B* elects to enroll in Employer *Y*'s plan effective on January 1, 1999 by filing the completed request form by December 31, 1998, in accordance with the special rule set forth in paragraph (a).

(ii) In this *Example*, *B* has enrolled on a special enrollment date because the enrollment is effective at a date described in paragraph (a)(7) (even though this date is also a regular enrollment date under the plan).

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

(a) *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 requirements in paragraph (b) of this section is satisfied.

(b) *Requirements for affiliation period.*

(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 applied uniformly without regard to any health status-related factors.

(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.

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

(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. Nothing in this section requires a State to receive proposals for or approve alternatives to affiliation periods.

**§ 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;

(iii) Claims experience;

(iv) Receipt of health care;

(v) Medical history;

(vi) Genetic information, as defined in 45 CFR 144.103;

(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 bona fide 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 (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 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 bona fide 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.* Under the facts of this *Example 2*, the plan violates this paragraph (b)(2)(i) because the plan modification is directed at *B* based on *B*'s claim.

*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.

*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.

(ii) *Cost-sharing mechanisms and wellness programs.* A group health plan or group health insurance coverage with a cost-sharing mechanism (such as a deductible, copayment, or coinsurance) that requires a higher payment from an individual, based on a health factor of that individual or a dependent of that individual, than for a similarly situated individual under the plan (and thus does not apply uniformly to all similarly situated individuals) does not violate the requirements of this paragraph (b)(2) if the payment differential is based on whether an individual has complied with the requirements of a bona fide wellness program.

(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 (includ-

ing both physical and mental health conditions).

(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. Individual *D* suffers from depression and attempts suicide. As a result, *D* sustains injuries and is hospitalized for treatment of the injuries. Pursuant to 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 pre-existing 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

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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

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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.

(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.

*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 bona fide wellness programs.* Notwithstanding paragraphs (c)(1) and (2) of this section, a plan may establish a premium or contribution differential based on whether an individual has complied with the requirements of a bona fide wellness program.

(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 (e.g., 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 (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 di-

rected 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 (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. This section does not affect any obligation Issuer *M* may have under applicable State law to provide any extension of benefits and does not affect any State law governing coordination of benefits.

(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 (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) *Bona fide wellness programs.* [Reserved]

(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) Paragraphs applicable May 8, 2001.* Paragraphs (a)(1), (a)(2)(i), (b)(1)(i), (b)(1)(iii) *Example 1*, (b)(2)(i)(A), (b)(2)(ii), (c)(1)(i), (c)(2)(i), and (c)(3) of this section and this paragraph (j)(1) apply to group health plans and health insurance issuers offering group health insurance coverage May 8, 2001.

(2) *Paragraphs applicable for plan years beginning on or after July 1, 2001.* Except as provided in paragraph (j)(3) or (j)(4) of this section, the provisions of this section not listed in paragraph (j)(1) of this section apply to group health plans and health insurance issuers offering group health insurance coverage for plan years beginning on or after July 1, 2001. Except as provided in paragraph (j)(3) or (j)(4) of this section, with respect to efforts to comply with section 2702 of the PHS Act before the first plan year beginning on or after July 1, 2001, the Secretary will not take any enforcement action against an issuer or plan that has sought to comply in good faith with section 2702 of the PHS Act.

(3) *Transitional rules for individuals previously denied coverage based on a health factor.* This paragraph (j)(3) provides rules relating to individuals previously denied coverage under a group health plan or group health insurance coverage based on a health factor of the individual. Paragraph (j)(3)(i) clarifies what constitutes a denial of coverage under this paragraph (j)(3). Paragraph (j)(3)(ii) of this section applies with respect to any individual who was denied coverage if the denial was not based on a good faith interpretation of section 2702 of the PHS Act or the Secretary's published guidance. Under that paragraph, such an individual must be allowed to enroll retroactively to the effective date of section 2702 of

the PHS Act, or, if later, the date the individual meets eligibility criteria under the plan that do not discriminate based on any health factor. Paragraph (j)(3)(iii) of this section applies with respect to any individual who was denied coverage based on a good faith interpretation of section 2702 of the PHS Act or the Secretary's published guidance. Under that paragraph, such an individual must be given an opportunity to enroll effective July 1, 2001. In either event, whether under paragraph (j)(3)(ii) or (iii) of this section, the Secretary will not take any enforcement action with respect to denials of coverage addressed in this paragraph (j)(3) if the issuer or plan has complied with the transitional rules of this paragraph (j)(3).

(i) *Denial of coverage clarified.* For purposes of this paragraph (j)(3), an individual is considered to have been denied coverage if the individual—

(A) Failed to apply for coverage because it was reasonable to believe that an application for coverage would have been futile due to a plan provision that discriminated based on a health factor; or

(B) Was not offered an opportunity to enroll in the plan and the failure to give such an opportunity violates this section.

(ii) *Individuals denied coverage without a good faith interpretation of the law—*

(A) *Opportunity to enroll required.* If a plan or issuer has denied coverage to any individual based on a health factor and that denial was not based on a good faith interpretation of section 2702 of the PHS Act or any guidance published by the Secretary, the plan or issuer is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days. This opportunity must be presented not later than May 8, 2001.

(j) If this enrollment opportunity was presented before or within the first plan year beginning on or after July 1, 1997 (or in the case of a collectively bargained plan, before or within the first plan year beginning on the effective date for the plan described in section 102(c) (3) of the Health Insurance Portability and Accountability Act of

1996), the coverage must be effective within that first plan year.

(2) If this enrollment opportunity is presented after such plan year, the individual must be given the choice of having the coverage effective on either of the following two dates—

(j) The date the plan receives a request for enrollment in connection with the enrollment opportunity; or

(ii) Retroactively to the first day of the first plan year beginning on the effective date for the plan described in sections 102(c)(1) and (3) of the Health Insurance Portability and Accountability Act of 1996 (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan). If an individual elects retroactive coverage, the plan or issuer is required to provide the benefits it would have provided if the individual had been enrolled for coverage during that period (irrespective of any otherwise applicable plan provisions governing timing for the submission of claims). The plan or issuer may require the individual to pay whatever additional amount the individual would have been required to pay for the coverage (but the plan or issuer cannot charge interest on that amount).

(B) *Relation to preexisting condition rules.* For purposes of section 2701 of the PHS Act, the individual may not be treated as a late enrollee or as a special enrollee. Moreover, the individual's enrollment date is the effective date for the plan described in sections 102(c)(1) and (3) of the Health Insurance Portability and Accountability Act (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan), even if the individual chooses under paragraph (j)(3)(ii)(A) of this section to have coverage effective only prospectively. In addition, any period between the individual's enrollment date and the effective date of coverage is treated as a waiting period.

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

*Example 1.* (i) *Facts.* Employer *X* maintains a group health plan with a plan year beginning October 1 and ending September 30. Individual *F* was hired by Employer *X* before the effective date of section 2702 of the PHS Act. Before the effective date of section 2702 of the PHS Act for this plan (October 1, 1997), the terms of the plan allowed employees and their dependents to enroll when the employee was first hired, and on each January 1 thereafter, but in either case, only if the individual could pass a physical examination. *F*'s application to enroll when first hired was denied because *F* had diabetes and could not pass a physical examination. Upon the effective date of section 2702 of the PHS Act for this plan (October 1, 1997), the plan is amended to delete the requirement to pass a physical examination. In November of 1997, the plan gives *F* an opportunity to enroll in the plan (including notice of the opportunity to enroll) without passing a physical examination, with coverage effective January 1, 1998.

(ii) *Conclusion.* In this *Example 1*, the plan complies with the requirements of this paragraph (i)(3)(ii).

*Example 2.* (i) *Facts.* The plan year of a group health plan begins January 1 and ends December 31. Under the plan, a dependent who is unable to engage in normal life activities on the date coverage would otherwise become effective is not enrolled until the dependent is able to engage in normal life activities. Individual *G* is a dependent who is otherwise eligible for coverage, but is unable to engage in normal life activities. The plan has not allowed *G* to enroll for coverage.

(ii) *Conclusion.* In this *Example 2*, beginning on the effective date of section 2702 of the PHS Act for the plan (January 1, 1998), the plan provision is not permitted under any good faith interpretation of section 2702 of the PHS Act or any guidance published by the Secretary. Therefore, the plan is required, not later than May 8, 2001, to give *G* an opportunity to enroll (including notice of the opportunity to enroll), with coverage effective, at *G*'s option, either retroactively from January 1, 1998 or prospectively from the date *G*'s request for enrollment is received by the plan. If *G* elects coverage to be effective beginning January 1, 1998, the plan can require *G* to pay any required employee premiums for the retroactive coverage.

(iii) *Individuals denied coverage based on a good faith interpretation of the law—(A) Opportunity to enroll required.* If a plan or issuer has denied coverage to any individual before the first day of the first plan year beginning on or after July 1, 2001 based in part on a health factor and that denial was based on a good faith interpretation of sec-

tion 2702 of the PHS Act or guidance published by the Secretary, the plan or issuer is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days, with coverage effective no later than July 1, 2001. Individuals required to be offered an opportunity to enroll include individuals previously offered enrollment without regard to a health factor but subsequently denied enrollment due to a health factor.

(B) *Relation to preexisting condition rules.* For purposes of section 2701 of the PHS Act, the individual may not be treated as a late enrollee or as a special enrollee. Moreover, the individual's enrollment date is the effective date for the plan described in sections 102(c)(1) and (3) of the Health Insurance Portability and Accountability Act (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan). In addition, any period between the individual's enrollment date and the effective date of coverage is treated as a waiting period.

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

*Example.* (i) *Facts.* Individual *H* was hired by Employer *Y* on May 3, 1995. *Y* maintains a group health plan with a plan year beginning on February 1. Under the terms of the plan, employees and their dependents are allowed to enroll when the employee is first hired (without a requirement to pass a physical examination), and on each February 1 thereafter if the individual can pass a physical examination. *H* chose not to enroll for coverage when hired in May of 1995. On February 1, 1997, *H* tried to enroll for coverage under the plan. However, *H* was denied coverage for failure to pass a physical examination. Shortly thereafter, *Y*'s plan eliminated late enrollment, and *H* was not given another opportunity to enroll in the plan. There is no evidence to suggest that *Y*'s plan was acting in bad faith in denying coverage under the plan beginning on the effective date of section 2702 of the PHS Act (February 1, 1998).

(ii) *Conclusion.* In this *Example*, because coverage previously had been made available with respect to *H* without regard to any health factor of *H* and because *Y*'s plan was acting in accordance with a good faith interpretation of section 2702 of the PHS Act (and guidance published by the Secretary), the

failure of *Y*'s plan to allow *H* to enroll effective February 1, 1998 was permissible on that date. However, under the transitional rules of this paragraph (i)(3)(iii), *Y*'s plan must give *H* an opportunity to enroll that continues for at least 30 days, with coverage effective no later than July 1, 2001. (In addition, February 1, 1998 is *H*'s enrollment date under the plan and the period between February 1, 1998 and July 1, 2001 is treated as a waiting period. Accordingly, any preexisting condition exclusion period permitted under § 146.111 will have expired before July 1, 2001.)

(4) *Special transitional rule for self-funded non-Federal governmental plans exempted under 45 CFR 146.180*—(i) If coverage has been denied to any individual because the sponsor of a self-funded non-Federal 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 (with regard to this section) is no longer in effect (or July 1, 2001, if later, and the plan was acting in accordance with a good faith interpretation of section 2702 of the PHS Act and guidance published by CMS); and

(D) May not treat the individual as a late enrollee or a special enrollee.

(ii) For purposes of this paragraph (i)(4), 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, 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)(4) are illustrated by the following examples:

*Example 1. (i) Facts.* Individual *D* was hired by a non-Federal governmental employer in June 1996. The employer maintains a self-funded group health plan with a plan year beginning on October 1. Under the terms of the plan, employees and their dependents are allowed to enroll when the employee is first hired without regard to any health factor. If an individual declines to enroll when first eligible, the individual may enroll effective October 1 of any plan year if the individual can pass a physical examination. 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, 1997, and renewed the exemption election for the plan year beginning October 1, 1998. That is, the plan sponsor elected to retain the evidence of good health requirement for late enrollees which, absent an exemption election under § 146.180 of this part, would have been in violation of this section as of October 1, 1997. *D* chose not to enroll for coverage when first hired. In February of 1998, *D* was treated for skin cancer but did not apply for coverage under the plan for the plan year beginning October 1, 1998, because *D* assumed *D* could not meet the evidence of good health requirement. With the plan year beginning October 1, 1999, the plan sponsor chose not to renew its exemption election and brought the plan into compliance with this section. However, the terms of the plan, effective October 1, 1999, were amended to permit enrollment only during the initial 30-day period of employment. The plan no longer permits late enrollment under any circumstances, including with respect to current employees not enrolled in the plan. Therefore, *D* was not given another opportunity to enroll in the plan. There is no evidence to suggest that the plan was acting in bad faith in denying *D* coverage under the plan beginning on the effective date of § 146.121 for the plan (October 1, 1999).

(ii) *Conclusion.* In this *Example 1*, because the plan under § 146.180 was previously excluded from the requirements of § 146.121 and thereafter was acting in accordance with a good faith interpretation of § 146.121 and guidance published by CMS, the failure of the plan to give *D* an opportunity to enroll effective October 1, 1999 was permissible on that date. However, under the transitional rules of this paragraph (i)(4), the plan must give *D* an opportunity to enroll that continues for at least 30 days, with coverage effective no later than July 1, 2001. (Additionally, October 1, 1999 is *D*'s enrollment date under the plan and the period between October 1, 1999 and July 1, 2001 is treated as a waiting period. Furthermore, if the plan sponsor has not elected to exempt the plan

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from limitations on preexisting condition exclusion periods, any preexisting condition exclusion period must be administered in accordance with § 146.111. Accordingly, any preexisting condition exclusion period permitted under § 146.111 will have expired before July 1, 2001.)

*Example 2.* (i) *Facts.* Individual *E* was hired by a non-Federal governmental employer in February 1995. The employer maintains a self-funded group health plan with a plan year beginning on September 1. Under the terms of the plan, employees and their dependents are allowed to enroll when the employee is first hired without regard to any health factor. If an individual declines to enroll when first eligible, the individual may enroll effective September 1 of any plan year if the individual can pass a physical examination. All enrollees are subject to a 12-month preexisting condition exclusion period. 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, 1997, and renews the exemption election for the plan years beginning September 1, 1998, September 1, 1999, and September 1, 2000. *E* chose not to enroll for coverage when first hired. In June of 2001, *E* is diagnosed as having multiple sclerosis (MS). With the plan year beginning September 1, 2001, 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 affords *E* an opportunity to enroll, without a physical examination, effective September 1, 2001. *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, 2002, 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.)

[66 FR 1412, Jan. 8, 2001, as amended at 66 FR 14078, Mar. 9, 2001]

### § 146.125 Applicability dates.

(a) *General applicability dates—(1) Non-collectively bargained plans.* Part A of title XXVII of the PHS Act and §§ 146.101 through 146.119, § 146.143, § 146.145, 45 CFR part 150, and this section apply with respect to group health plans, and health insurance coverage offered in connection with group health

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plans, for plan years beginning after June 30, 1997, except as otherwise provided in this section.

(2) *Collectively-bargained plans.* Except as otherwise provided in this section (other than paragraph (a)(1) of this section), in the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before August 21, 1996, Part A of Title XXVII of the PHS Act and §§ 146.101 through 146.119, § 146.143, § 146.145, 45 CFR part 150, and this section do not apply to plan years beginning before the later of July 1, 1997, or the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after August 21, 1996). For these purposes, any plan amendment made under a collective bargaining agreement relating to the plan, that amends the plan solely to conform to any requirement of such part, is not treated as a termination of the collective bargaining agreement.

(3) *Preexisting condition exclusion periods for current employees.* (i) *General rule.* Any preexisting condition exclusion period permitted under § 146.111 is measured from the individual's enrollment date in the plan. This exclusion period, as limited under § 146.111, may be completed before the effective date of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for his or her plan. Therefore, on the date the individual's plan becomes subject to part A of title XXVII of the PHS Act, no preexisting condition exclusion may be imposed with respect to an individual beyond the limitation in § 146.111. For an individual who has not completed the permitted exclusion period under HIPAA, upon the effective date for his or her plan, the individual may use creditable coverage that the person had as of the enrollment date to reduce the remaining preexisting condition exclusion period applicable to the individual.

(ii) *Examples.* The following examples illustrate the requirements of this paragraph (a)(3):

*Example 1:* (i) Individual *A* has been working for Employer *X* and has been covered under Employer *X*'s plan since March 1, 1997.

Under Employer X's plan, as in effect before January 1, 1998, there is no coverage for any preexisting condition. Employer X's plan year begins on January 1, 1998. A's enrollment date in the plan is March 1, 1997, and A has no creditable coverage before this date.

(i) In this *Example*, Employer X may continue to impose the preexisting condition exclusion under the plan through February 28, 1998 (the end of the 12-month period using anniversary dates).

*Example 2:* (i) Same facts as in *Example 1*, except that A's enrollment date was August 1, 1996, instead of March 1, 1997.

(ii) In this *Example*, on January 1, 1998, Employer X's plan may no longer exclude treatment for any preexisting condition that A may have; however, because Employer X's plan is not subject to HIPAA until January 1, 1998, A is not entitled to claim reimbursement for expenses under the plan for treatments for any preexisting condition received before January 1, 1998.

(b) *Effective date for certification requirement—(1) General.* Subject to the transitional rule in §146.115(a)(5)(iii), the certification rules of §146.115 apply to events occurring on or after July 1, 1996.

(2) *Period covered by certificate.* A certificate is not required to reflect coverage before July 1, 1996.

(3) *No certificate before June 1, 1997.* Notwithstanding any other provision of this part, in no case is a certificate required to be provided before June 1, 1997.

(c) *Limitation on actions.* No enforcement action is to be taken, under, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by part A of title XXVII of the PHS Act before January 1, 1998, if the plan or issuer has sought to comply in good faith with such requirements. Compliance with this part is deemed to be good faith compliance with the requirements of part A of title XXVII of the PHS Act.

(d) *Transition rules for counting creditable coverage.* An individual who seeks to establish creditable coverage for periods before July 1, 1996 is entitled to establish such coverage through the presentation of documents or other means in accordance with the provisions of §146.115(c). For coverage relating to an event occurring before July 1, 1996, a group health plan and a health insurance issuer are not subject to any

penalty or enforcement action with respect to the plan's or issuer's counting (or not counting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under §146.115(c).

(e) *Transition rules for certification of creditable coverage—(1) Certificates only upon request.* For events occurring on or after July 1, 1996 but before October 1, 1996, a certificate is required to be provided only upon a written request by or on behalf of the individual to whom the certificate applies.

(2) *Certificates before June 1, 1997.* For events occurring on or after October 1, 1996 and before June 1, 1997, a certificate must be furnished no later than June 1, 1997, or any later date permitted under §146.115(a)(2)(ii) and (iii).

(3) *Optional notice—(i) General.* This paragraph (e)(3) applies with respect to events described in §146.115(a)(2)(ii), that occur on or after October 1, 1996 but before June 1, 1997. A group health plan or health insurance issuer offering group health coverage is deemed to satisfy §§146.115(a)(2) and (a)(3) if a notice is provided in accordance with the provisions of paragraphs (e)(3)(i) through (e)(3)(iv) of this section.

(ii) *Time of notice.* The notice must be provided no later than June 1, 1997.

(iii) *Form and content of notice.* A notice provided under this paragraph (e)(3) must be in writing and must include information substantially similar to the information included in a model notice authorized by CMS. Copies of the model notice are available at the following website—[www.cms.gov](http://www.cms.gov) (or call (410) 786-1565).

(iv) *Providing certificate after request.* If an individual requests a certificate following receipt of the notice, the certificate must be provided at the time of the request as set forth in §146.115(a)(2)(iii).

(v) *Other certification rules apply.* The rules set forth in §146.115(a)(4)(i) (method of delivery) and (a)(1) (entities required to provide a certificate) apply with respect to the provision of the notice.

[62 FR 16958, Apr. 8, 1997; 62 FR 31694, June 10, 1997, as amended at 66 FR 1420, Jan. 8, 2001; 66 FR 14078, Mar. 9, 2001]

**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 (a)(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) 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) 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) 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) 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) 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) 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 may not require that a physician or other health care provider obtain authorization from the plan or issuer for prescribing the hospital length of stay required under 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) 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) 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.

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

*Example.* (i) 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) 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) 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 de-

livery, the plan will waive the copayment and deductible.

(ii) 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) 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) 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 required under 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) 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) In this *Example*, the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour

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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, if the plan's utilization reviewer denied any mother or her newborn benefits within the 96-hour stay, the plan 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

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portion of the hospital length of stay required under 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) 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) 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) 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) 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 paragraph (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 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, 1999.

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

(i) *Self-insured plans.* The 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 §146.180 to be exempted from the requirements of this section.

(ii) *Insured plans.* The 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.

(e) *Applicability in certain States—(1) Health insurance coverage.* The requirements of section 2704 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 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 2704 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 2704 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 2704 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 2723(a) of the PHS Act.* The preemption provisions contained in section 2723(a)(1) of the PHS Act and § 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) 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) In this *Example 1*, the coverage is subject to State law, and the requirements of section 2704 of the PHS Act and this section do not apply.

*Example 2.* (i) 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 care in accordance with guidelines established by the American College of Obstetricians and Gynecologists and to provide for pediatric care in accordance with guidelines established by the American Academy of Pediatrics.

(ii) 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 2704 of the PHS Act and this section.

(f) *Effective date.* Section 2704 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, 1999.

[63 FR 57559, Oct. 27, 1998]

**§ 146.136 Parity in the application of certain limits to mental health benefits.**

(a) *Definitions.* For purposes of this section, except where the context clearly indicates otherwise, the following definitions apply:

*Aggregate lifetime limit* means a dollar limitation on the total amount of specified benefits that may be paid under a group health plan (or group health insurance coverage offered in connection with such plan) for an individual (or for a group of individuals considered a single unit in applying this dollar limitation, such as a family or an employee plus spouse).

*Annual limit* means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a plan (or group health insurance coverage offered in connection with such plan) for an individual (or for a group of individuals considered a single unit in applying this dollar limitation, such as a family or an employee plus spouse).

*Medical/surgical benefits* means benefits for medical or surgical services, as defined under the terms of the plan or group health insurance coverage, but does not include mental health benefits.

*Mental health benefits* means benefits for mental health services, as defined under the terms of the plan or group health insurance coverage, but does not include benefits for treatment of substance abuse or chemical dependency.

(b) *Requirements regarding limits on benefits—(1) In 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 benefits must comply with paragraph (b)(2), paragraph (b)(3), or paragraph (b)(6) of this section.

(ii) *Exception.* The rule in paragraph (b)(1)(i) of this section does not apply if a plan, or coverage, satisfies the requirements of paragraph (e) or paragraph (f) of this section.

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

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

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

(ii) Not include an aggregate lifetime or annual limit on mental health benefits that is less than the aggregate lifetime or annual limit, respectively, on the medical/surgical benefits.

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

*Example 1.* (i) Prior to the effective date of the mental health parity provisions, a group health plan had no annual limit on medical/surgical benefits and had a \$10,000 annual limit on mental health benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options:

(A) Eliminating the plan's annual limit on mental health benefits;

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

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

(ii) In this *Example 1*, each of the three options being considered by the plan sponsor would comply with the requirements of this section because they offer parity in the dollar limits placed on medical/surgical and mental health benefits.

*Example 2.* (i) Prior to the effective date of the mental health parity provisions, a group

health plan had a \$100,000 annual limit on medical/surgical inpatient benefits, a \$50,000 annual limit on medical/surgical outpatient benefits, and a \$100,000 annual limit on all mental health benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options:

(A) Replacing the plan's previous annual limit on mental health benefits with a \$150,000 annual limit on mental health benefits; and

(B) Replacing the plan's previous annual limit on mental health benefits with a \$100,000 annual limit on mental health inpatient benefits and a \$50,000 annual limit on mental health outpatient benefits.

(ii) In this *Example 2*, each option under consideration by the plan sponsor would comply with the requirements of this section because they offer parity in the dollar limits placed on medical/surgical and mental health benefits.

*Example 3.* (i) A group health plan that is subject to the requirements of this section has no aggregate lifetime or annual limit for either medical/surgical benefits or mental health benefits. While the plan provides medical/surgical benefits with respect to both network and out-of-network providers, it does not provide mental health benefits with respect to out-of-network providers.

(ii) In this *Example 3*, the plan complies with the requirements of this section because they offer parity in the dollar limits placed on medical/surgical and mental health benefits.

*Example 4.* (i) Prior to the effective date of the mental health parity provisions, a group health plan had an annual limit on medical/surgical benefits and a separate but identical annual limit on mental health benefits. The plan included benefits for treatment of substance abuse and chemical dependency in its definition of mental health benefits. Accordingly, claims paid for treatment of substance abuse and chemical dependency were counted in applying the annual limit on mental health benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options:

(A) Making no change in the plan so that claims paid for treatment of substance abuse and chemical dependency continue to count in applying the annual limit on mental health benefits;

(B) Amending the plan to count claims paid for treatment of substance abuse and chemical dependency in applying the annual limit on medical/surgical benefits (rather than counting those claims in applying the annual limit on mental health benefits);

(C) Amending the plan to provide a new category of benefits for treatment of chemical dependency and substance abuse that is subject to a separate, lower limit and under

which claims paid for treatment of substance abuse and chemical dependency are counted only in applying the annual limit on this separate category; and

(D) Amending the plan to eliminate distinctions between medical/surgical benefits and mental health benefits and establishing an overall limit on benefits offered under the plan under which claims paid for treatment of substance abuse and chemical dependency are counted with medical/surgical benefits and mental health benefits in applying the overall limit.

(ii) In this *Example 4*, the group health plan is described in paragraph (b)(3) of this section. Because mental health benefits are defined in paragraph (a) of this section as excluding benefits for treatment of substance abuse and chemical dependency, the inclusion of benefits for treatment of substance abuse and chemical dependency in applying an aggregate lifetime limit or annual limit on mental health benefits under option (A) of this *Example 4* would not comply with the requirements of paragraph (b)(3) of this section. However, options (B), (C), and (D) of this *Example 4* would comply with the requirements of paragraph (b)(3) of this section because they offer parity in the dollar limits placed on medical/surgical and mental health benefits.

(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 a 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 limits). Any reasonable method may be used to determine whether the dollar amounts 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 paragraph (b)(3) of this section—*

(i) *In general.* A group health plan (or group health insurance coverage) that is not described in paragraph (b)(2) or paragraph (b)(3) of this section, must either impose—

(A) No aggregate lifetime or annual limit, as appropriate, on mental health benefits; or

(B) An aggregate lifetime or annual limit on mental health benefits that is no less than an average limit for medical/surgical benefits calculated in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual 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 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) *Examples.* The rules of this paragraph (b)(6) are illustrated by the following example:

*Example.* (i) 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 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) In this *Example*, the plan is not described in paragraph (b)(3) of this section because there is not one annual 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 limit.

Under this paragraph (b)(6), the plan sponsor can choose either to include no annual limit on mental health benefits, or to include an annual limit on mental health benefits that is not less than the weighted average of the annual limits applicable to each category of medical/surgical benefits. In this example, the minimum weighted average annual limit that can be applied to mental health benefits is \$640,000 (40% " \$100,000 + 60% " \$1,000,000 = \$640,000).

(c) *Rule in the case of separate benefit packages.* If a group health plan offers two or more benefit packages, the requirements of this section, including the exemption provisions in paragraph (f) of this section, apply separately to each benefit package. Examples of a group health plan that offers two or more benefit packages include a group health plan that offers employees a choice between indemnity coverage or HMO coverage, and a group health plan that provides one benefit package for retirees and a different benefit package for current employees.

(d) *Applicability—(1) Group health plans.* The requirements of this section apply to a group health plan offering both medical/surgical benefits and mental health benefits regardless of whether the mental health benefits are administered separately under the plan.

(2) *Health insurance issuers.* The requirements of this section apply to a health insurance issuer offering health insurance coverage for both medical/surgical benefits and mental health benefits in connection with a group health plan.

(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

(ii) Affect the terms and conditions (including cost sharing, limits on the number of visits or days of coverage, requirements relating to medical necessity, requiring prior authorization for treatment, or requiring primary care physicians' referrals for treatment) relating to the amount, duration, or scope of the mental health benefits under the plan (or coverage) except as specifically provided in paragraph (b) of this section.

(e) *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 (e), 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. See regulations at § 146.145(a), 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 (e)(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.

(f) *Increased cost exemption—(1) In general.* A group health plan (or health insurance coverage offered in connection with a group health plan) is not subject to the requirements of this section if the requirements of this paragraph (f) are satisfied. If a plan offers more than one benefit package, this paragraph (f) applies separately to each benefit package. Except as provided in paragraph (h) of this section, a plan must comply with the requirements of paragraph (b)(1)(i) of this section for the

first plan year beginning on or after January 1, 1998, and must continue to comply with the requirements of paragraph (b)(1)(i) of this section until the plan satisfies the requirements in this paragraph (f). In no event is the exemption of this paragraph (f) effective until 30 days after the notice requirements in paragraph (f)(3) of this section are satisfied. If the requirements of this paragraph (f) are satisfied with respect to a plan, the exemption continues in effect (at the plan's discretion) until December 31, 2004, even if the plan subsequently purchases a different policy from the same or a different issuer and regardless of any other changes to the plan's benefit structure.

(2) *Calculation of the one-percent increase*—(i) *Ratio*. A group health plan (or group health insurance coverage) satisfies the requirements of this paragraph (f)(2) if the application of paragraph (b)(1)(i) of this section to the plan (or to such coverage) results in an

increase in the cost under the plan (or for such coverage) of at least one percent. The application of paragraph (b)(1)(i) of this section results in an increased cost of at least one percent under a group health plan (or for such coverage) only if the ratio below equals or exceeds 1.01000. The ratio is determined as follows:

(A) The incurred expenditures during the base period, divided by,

(B) The incurred expenditures during the base period, reduced by—

(1) The claims incurred during the base period that would have been denied under the terms of the plan absent plan amendments required to comply with this section, and

(2) Administrative expenses attributable to complying with the requirements of this section.

(ii) *Formula*. The ratio of paragraph (f)(2)(i) is expressed mathematically as follows:

$$\frac{IE}{IE - (CE + AE)} \geq 1.01000$$

(A) *IE* means the incurred expenditures during the base period.

(B) *CE* means the claims incurred during the base period that would have been denied under the terms of the plan absent plan amendments required to comply with this section.

(C) *AE* means administrative costs related to claims in *CE* and other administrative costs attributable to complying with the requirements of this section.

(iii) *Incurred expenditures*. *Incurred expenditures* means actual claims incurred during the base period and reported within two months following the base period, and administrative costs for all benefits under the group health plan, including mental health benefits and medical/surgical benefits, during the base period. Incurred expenditures do not include premiums.

(iv) *Base period*. *Base period* means the period used to calculate whether the plan may claim the one-percent increased cost exemption in this paragraph (f). The base period must begin

on the first day in any plan year that the plan complies with the requirements of paragraph (b)(1)(i) of this section and must extend for a period of at least six consecutive calendar months. However, in no event may the base period begin prior to September 26, 1996 (the date of enactment of the Mental Health Parity Act (Pub. L. 104-204, 110 Stat. 2944)).

(v) *Rating pools*. For plans that are combined in a pool for rating purposes, the calculation under this paragraph (f)(2) for each plan in the pool for the base period is based on the incurred expenditures of the pool, whether or not all the plans in the pool have participated in the pool for the entire base period. (However, only the plans that have complied with paragraph (b)(1)(i) of this section for at least six months as a member of the pool satisfy the requirements of this paragraph (f)(2).) Otherwise, the calculation under this paragraph (f)(2) for each plan is calculated by the plan administrator (or

issuer) based on the incurred expenditures of the plan.

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

*Example 1.* (i) A group health plan has a plan year that is the calendar year. The plan satisfies the requirements of paragraph (b)(1)(i) of this section as of January 1, 1998. On September 15, 1998, the plan determines that \$1,000,000 in claims have been incurred during the period between January 1, 1998 and June 30, 1998 and reported by August 30, 1998. The plan also determines that \$100,000 in administrative costs have been incurred for all benefits under the group health plan, including mental health benefits. Thus, the plan determines that its incurred expenditures for the base period are \$1,100,000. The plan also determines that the claims incurred during the base period that would have been denied under the terms of the plan absent plan amendments required to comply with this section are \$40,000 and that administrative expenses attributable to complying with the requirements of this section are \$10,000. Thus, the total amount of expenditures for the base period had the plan not been amended to comply with the requirements of paragraph (b)(1)(i) of this section are \$1,050,000 ( $\$1,100,000 - (\$40,000 + \$10,000) = \$1,050,000$ ).

(ii) In this *Example 1*, the plan satisfies the requirements of this paragraph (f)(2) because the application of this section results in an increased cost of at least one percent under the terms of the plan ( $\$1,100,000/\$1,050,000 = 1.04762$ ).

*Example 2.* (i) A health insurance issuer sells a group health insurance policy that is rated on a pooled-basis and is sold to 30 group health plans. One of the group health plans inquires whether it qualifies for the one percent increased cost exemption. The issuer performs the calculation for the pool as a whole and determines that the application of this section results in an increased cost of 0.500 percent (for a ratio under this paragraph (f)(2) of 1.00500) for the pool. The issuer informs the requesting plan and the other plans in the pool of the calculation.

(ii) In this *Example 2*, none of the plans satisfy the requirements of this paragraph (f)(2) and a plan that purchases a policy not complying with the requirements of paragraph (b)(1)(i) of this section violates the requirements of this section. In addition, an issuer that issues to any of the plans in the pool a policy not complying with the requirements of paragraph (b)(1)(i) of this section violates the requirements of this section.

*Example 3.* (i) A partially-insured plan is collecting the information to determine whether it qualifies for the exemption. The plan administrator determines the incurred expenses for the base period for the self-fund-

ed portion of the plan to be \$2,000,000 and the administrative expenses for the base period for the self-funded portion to be \$200,000. For the insured portion of the plan, the plan administrator requests data from the insurer. For the insured portion of the plan, the plan's own incurred expenses for the base period are \$1,000,000 and the administrative expenses for the base period are \$100,000. The plan administrator determines that under the self-funded portion of the plan, the claims incurred for the base period that would have been denied under the terms of the plan absent the amendment are \$0 because the self-funded portion does not cover mental health benefits and the plan's administrative costs attributable to complying with the requirements of this section are \$1,000. The issuer determines that under the insured portion of the plan, the claims incurred for the base period that would have been denied under the terms of the plan absent the amendment are \$25,000 and the administrative costs attributable to complying with the requirements of this section are \$1,000. Thus, the total incurred expenditures for the plan for the base period are \$3,300,000 ( $\$2,000,000 + \$200,000 + \$1,000,000 + \$100,000 = \$3,300,000$ ) and the total amount of expenditures for the base period had the plan not been amended to comply with the requirements of paragraph (b)(1)(i) of this section are \$3,273,000 ( $\$3,300,000 - (\$0 + \$1,000 + \$25,000 + \$1,000) = \$3,273,000$ ).

(ii) In this *Example 3*, the plan does not satisfy the requirements of this paragraph (f)(2) because the application of this section does not result in an increased cost of at least one percent under the terms of the plan ( $\$3,300,000/\$3,273,000 = 1.00825$ ).

(3) *Notice of exemption—(i) Participants and beneficiaries—(A) In general.* A group health plan must notify participants and beneficiaries of the plan's decision to claim the one percent increased cost exemption. The notice must include the following information:

(1) A statement that the plan is exempt from the requirements of this section and a description of the basis for the exemption.

(2) The name and telephone number of the individual to contact for further information.

(3) The plan name and plan number (PN).

(4) The plan administrator's name, address, and telephone number.

(5) For single-employer plans, the plan sponsor's name, address, and telephone number (if different from paragraph (f)(3)(i)(A)(3) of this section) and

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the plan sponsor's employer identification number (EIN).

(6) The effective date of such exemption.

(7) The ability of participants and beneficiaries to contact the plan administrator to see how benefits may be affected as a result of the plan's election of the exemption.

(8) The availability, upon request and free of charge, of a summary of the information required under paragraph (f)(4) of this section.

(B) *Use of summary of material reductions in covered services or benefits.* A plan may satisfy the requirements of paragraph (f)(3)(i)(A) by providing participants and beneficiaries (in accordance with paragraph (f)(3)(i)(C)) with a summary of material reductions in covered services or benefits consistent with Department of Labor regulations at 29 CFR 2520.104b-3(d) that also includes the information of this paragraph (f)(3)(i). However, in all cases, the exemption is not effective until 30 days after notice has been sent.

(C) *Delivery.* The notice described in this paragraph (f)(3)(i) is required to be provided to all participants and beneficiaries. The notice may be furnished by any method of delivery that satisfies the requirements of section 104(b)(1) of ERISA (29 U.S.C. 1024(b)(1)) (e.g., first-class mail). If the notice is provided to the participant at the participant's last known address, then the requirements of this paragraph (f)(3)(i) are satisfied with respect to the participant and all beneficiaries residing at that address. If a beneficiary's last known address is different from the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

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

*Example.* (i) A group health plan has a plan year that is the calendar year and has an open enrollment period every November 1 through November 30. The plan determines on September 15 that it satisfies the requirements of paragraph (f)(2) of this section. As part of its open enrollment materials, the plan mails, on October 15, to all participants and beneficiaries a notice satisfying the requirements of this paragraph (f)(3)(i).

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(ii) In this *Example*, the plan has sent the notice in a manner that complies with this paragraph (f)(3)(i).

(ii) *Federal agencies—(A) Church plans.* A church plan (as defined in section 414(e) of the Internal Revenue Code) claiming the exemption of this paragraph (f) for any benefit package must provide notice to the Department of the Treasury. This requirement is satisfied if the plan sends a copy, to the address designated by the Secretary in generally applicable guidance, of the notice described in paragraph (f)(3)(i) of this section identifying the benefit package to which the exemption applies.

(B) *Group health plans subject to Part 7 of Subtitle B of Title I of ERISA.* A group health plan subject to Part 7 of Subtitle B of Title I of ERISA, and claiming the exemption of this paragraph (f) for any benefit package, must provide notice to the Department of Labor. This requirement is satisfied if the plan sends a copy, to the address designated by the Secretary in generally applicable guidance, of the notice described in paragraph (f)(3)(i) of this section identifying the benefit package to which the exemption applies.

(C) *Non-Federal governmental plans.* A group health plan that is a non-Federal governmental plan claiming the exemption of this paragraph (f) for any benefit package must provide notice to the Department of Health and Human Services (HHS). This requirement is satisfied if the plan sends a copy, to the address designated by the Secretary in generally applicable guidance, of the notice described in paragraph (f)(3)(i) of this section identifying the benefit package to which the exemption applies.

(4) *Availability of documentation.* The plan (or issuer) must make available to participants and beneficiaries (or their representatives), on request and at no charge, a summary of the information on which the exemption was based. An individual who is not a participant or beneficiary and who presents a notice described in paragraph (f)(3)(i) of this section is considered to be a representative. A representative may request the summary of information by providing the plan a copy of the notice

provided to the participant under paragraph (f)(3)(i) of this section with any individually identifiable information redacted. The summary of information must include the incurred expenditures, the base period, the dollar amount of claims incurred during the base period that would have been denied under the terms of the plan absent amendments required to comply with paragraph (b)(1)(i) of this section, the administrative costs related to those claims, and other administrative costs attributable to complying with the requirements for the exemption. In no event should the summary of information include any individually identifiable information.

(g) *Special rules for group health insurance coverage*—(1) *Sale of nonparity policies.* An issuer may sell a policy without parity (as described in paragraph (b) of this section) only to a plan that meets the requirements of paragraph (e) or paragraph (f) of this section.

(2) *Duration of exemption.* After a plan meets the requirements of paragraph (f) of this section, the plan may change issuers without having to meet the requirements of paragraph (f) of this section again before December 31, 2004.

(h) *Effective dates*—(1) *In general.* The requirements of this section are applicable for plan years beginning on or after January 1, 1998.

(2) *Limitation on actions.* (i) Except as provided in paragraph (h)(3) of this section, no enforcement action is to be taken by the Secretary against a group health plan that has sought to comply in good faith with the requirements of section 2705 of the PHS Act, with respect to a violation that occurs before the earlier of—

(A) The first day of the first plan year beginning on or after April 1, 1998; or

(B) January 1, 1999.

(ii) Compliance with the requirements of this section is deemed to be good faith compliance with the requirements of section 2705 of the PHS Act.

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

*Example 1.* (i) A group health plan has a plan year that is the calendar year. The plan complies with section 2705 of the PHS Act in

good faith using assumptions inconsistent with paragraph (b)(6) of this section relating to weighted averages for categories of benefits.

(ii) In this *Example 1*, no enforcement action may be taken against the plan with respect to a violation resulting solely from those assumptions and occurring before January 1, 1999.

*Example 2.* (i) A group health plan has a plan year that is the calendar year. For the entire 1998 plan year, the plan applies a \$1,000,000 annual limit on medical/surgical benefits and a \$100,000 annual limit on mental health benefits.

(ii) In this *Example 2*, the plan has not sought to comply with the requirements of section 2705 of the PHS Act in good faith and this paragraph (h)(2) does not apply.

(3) *Transition period for increased cost exemption*—(i) *In general.* No enforcement action will be taken against a group health plan that is subject to the requirements of this section based on a violation of this section that occurs before April 1, 1998 solely because the plan claims the increased cost exemption under section 2705(c)(2) of the PHS Act based on assumptions inconsistent with the rules under paragraph (f) of this section, provided that a plan amendment that complies with the requirements of paragraph (b)(1)(i) of this section is adopted and effective no later than March 31, 1998 and the plan complies with the notice requirements in paragraph (h)(3)(ii) of this section.

(ii) *Notice of plan's use of transition period.* (A) A group health plan satisfies the requirements of this paragraph (h)(3)(ii) only if the plan provides notice to the applicable federal agency and posts the notice at the location(s) where documents must be made available for examination by participants and beneficiaries under section 104(b)(2) of ERISA and the regulations thereunder (29 CFR 2520.104b-1(b)(3)). The notice must indicate the plan's decision to use the transition period in paragraph (h)(3)(i) of this section by 30 days after the first day of the plan year beginning on or after January 1, 1998, but in no event later than March 31, 1998. For a group health plan that is a church plan, the applicable federal agency is the Department of the Treasury. For a group health plan that is subject to Part 7 of Subtitle B of Title I of ERISA, the applicable federal agency is the Department of Labor.

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For a group health plan that is a non-federal governmental plan, the applicable federal agency is the Department of Health and Human Services. The notice must include—

(1) The name of the plan and the plan number (PN);

(2) The name, address, and telephone number of the plan administrator;

(3) For single-employer plans, the name, address, and telephone number of the plan sponsor (if different from the plan administrator) and the plan sponsor's employer identification number (EIN);

(4) The name and telephone number of the individual to contact for further information; and

(5) The signature of the plan administrator and the date of the signature.

(B) The notice must be provided at no charge to participants or their representative within 15 days after receipt of a written or oral request for such notification, but in no event before the notice has been sent to the applicable federal agency.

(i) *Sunset.* This section does not apply to benefits for services furnished on or after December 31, 2004.

[62 FR 66961, Dec. 22, 1997, as amended at 68 FR 38208, June 27, 2003; 69 FR 43926, July 23, 2004]

### 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 part A of title XXVII of the PHS Act.

(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

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514 of ERISA with respect to group health plans.

(c) *Special rules—*(1) *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 such section.

(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)(1)(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)(1)(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)(1)(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 in that section;

(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 701(g)(1)(B).

(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, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

**§ 146.145 Special rules relating to group health plans.**

(a) *General exception for certain small group health plans*. The requirements of this part do not apply to any group health plan (and group health insurance coverage offered 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 2 participants who are current employees.

(b) *Excepted benefits*—(1) *General*. The requirements of subpart B of this part do not apply to any group health plan (or any group health insurance coverage offered in connection with a group health plan) in relation to its provision of the benefits described in paragraph (b)(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 insurance.

(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 insurance.

(vi) Automobile medical payment insurance.

(vii) Credit-only insurance (for example, mortgage insurance).

(viii) Coverage for on-site medical clinics.

(3) *Limited excepted benefits*—(1) *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 the plan, as defined in paragraph (b)(3)(ii) of this section.

(ii) *Integral*. For purposes of paragraph (b)(3)(i) of this section, benefits are deemed to be an integral part of a plan unless a participant has the right to elect not to receive coverage for the benefits and, if the participant elects to receive coverage for the benefits, the participant pays an additional premium or contribution for that coverage.

(iii) *Limited scope*. Limited scope dental or vision benefits are dental or vision benefits that are sold under a separate policy or rider and that are limited in scope to a narrow range or type of benefits that are generally excluded from hospital/medical/surgical benefits packages.

(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 insurance 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.

(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 dollar indemnity insurance (for example, \$100/day) is excepted only if it meets each of the conditions specified in paragraph (b)(4)(ii) of this section.

(ii) *Conditions*. Benefits are described in paragraph (b)(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

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(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.

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

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

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

(iii) Similar supplemental coverage provided to coverage under a group health plan.

[62 FR 16958, Apr. 8, 1997; 62 FR 31670, June 10, 1997]

**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

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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.

(Approved by the Office of Management and Budget under control number 0938-0702)

[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 cov-

erage 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.

(Approved by the Office of Management and Budget under control number 0938-0702)

[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.

(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.

§ 146.180

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(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, para-

graph (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) *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. CMS enforces this requirement as provided under paragraph (k) of this section.

(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) 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) 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) 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 in-

validated 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 the plan sponsor, as determined under § 150.305.

(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]

## PART 147 [RESERVED]

## PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

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AUTHORITY: Secs. 2741 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg-41 through 300gg-63, 300gg-91, and 300gg-92).

SOURCE: 62 FR 16995, Apr. 8, 1997, unless otherwise noted.

**Subpart A—General Provisions**

**§ 148.101 Basis and purpose.**

This part implements sections 2741 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to improve access to individual health insurance coverage for certain eligible individuals who previously had group coverage, and to guarantee the renewability of all coverage in the individual market. It also provides certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth.

[63 FR 57561, Oct. 27, 1998]

**§ 148.102 Scope, applicability, and effective dates.**

(a) *Scope and applicability.* (1) Individual health insurance coverage includes all health insurance coverage (as defined in §144.103) that is neither health insurance coverage sold in connection with an employment-related group health plan, nor short-term, limited-duration coverage as defined in §144.103 of this subchapter. In some cases, coverage that may be considered group coverage under State law (such

as coverage sold through certain associations) is considered individual coverage.

(2) The requirements of this part that pertain to guaranteed availability of individual health insurance coverage for certain eligible individuals apply to all issuers of individual health insurance coverage in a State, unless the State implements an acceptable alternative mechanism as described in §148.128. The requirements that pertain to guaranteed renewability for all individuals, and to protections for mothers and newborns with respect to hospital stays in connection with childbirth, apply to all issuers of individual health insurance coverage in the State, regardless of whether a State implements an alternative mechanism.

(b) *Effective date.* Except as provided in §§148.124 (certificate of coverage), 148.128 (alternative State mechanisms), and 148.170 (standards relating to benefits for mothers and newborns), the requirements of this part apply to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs.

[62 FR 16995, Apr. 8, 1997; 62 FR 31695, June 10, 1997, as amended at 63 FR 57562, Oct. 27, 1998]

**§ 148.103 Definitions.**

Unless otherwise provided, the following definition applies:

*Eligible individual* means an individual who meets the following conditions:

(1) The individual has at least 18 months of creditable coverage (as determined under §146.113 of this subchapter) as of the date on which the individual seeks coverage under this part.

(2) The individual's most recent prior creditable coverage was under a group health plan, governmental plan, or church plan (or health insurance coverage offered in connection with any of these plans).

(3) The individual is not eligible for coverage under any of the following:

- (i) A group health plan.
- (ii) Part A or Part B of Title XVIII (Medicare) of the Social Security Act.

(iii) A State plan under Title XIX (Medicaid) of the Social Security Act (or any successor program).

(4) The individual does not have other health insurance coverage.

(5) The individual's most recent coverage was not terminated because of nonpayment of premiums or fraud. (For more information about nonpayment of premiums or fraud, see §146.152(b)(1) and (b)(2) of this subchapter.)

(6) If the individual has been offered the option of continuing coverage under a COBRA continuation provision or a similar State program, the individual has both elected and exhausted the continuation coverage.

**Subpart B—Requirements Relating to Access and Renewability of Coverage**

**§ 148.120 Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage.**

(a) *General rule.* Except as provided for in paragraph (c) of this section, an issuer that furnishes health insurance coverage in the individual market must meet the following requirements with respect to any eligible individual who requests coverage:

(1) May not decline to offer coverage or deny enrollment under any policy forms that it actively markets in the individual market, except as permitted in paragraph (c) of this section concerning alternative coverage when no State mechanism exists. An issuer is deemed to meet this requirement if, upon the request of an eligible individual, it acts promptly to do the following:

(i) Provide information about all available coverage options.

(ii) Enroll the individual in any coverage option the individual selects.

(2) May not impose any preexisting condition exclusion on the individual.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to health insurance coverage offered in the individual market in a State that chooses to implement an acceptable alternative mechanism described in §148.128.

(c) *Alternative coverage permitted where no State mechanism exists.* (1) *General rule.* If the State does not implement an acceptable alternative mechanism under §148.128, an issuer may elect to limit the coverage required under paragraph (a) of this section if it offers eligible individuals at least two policy forms that meet the following requirements:

(i) Each policy form must be designed for, made generally available to, and actively marketed to, and enroll, both eligible and other individuals.

(ii) The policy forms must be either the issuer's two most popular policy forms (as described in paragraph (c)(2) of this section) or representative samples of individual health insurance offered by the issuer in the State (as described in paragraph (c)(3) of this section).

(2) *Most popular policies.* The *two most popular policy forms* means the policy forms with the largest, and the second largest, premium volume for the last reporting year, for policies offered in that State. In the absence of applicable State standards, *premium volume* means earned premiums for the last reporting year. In the absence of applicable State standards, the last reporting year is the period from October 1 through September 30 of the preceding year. Blocks of business closed under applicable State law are not included in calculating premium volume.

(3) *Representative policy forms—(i) Definition of weighted average.* Weighted average means the average actuarial value of the benefits provided by all the health insurance coverage issued by one of the following:

(A) An issuer in the individual market in a State during the previous calendar year, weighted by enrollment for each policy form, but not including coverage issued to eligible individuals.

(B) All issuers in the individual market in a State if the data are available for the previous calendar year, weighted by enrollment for each policy form.

(ii) *Requirements.* The two representative policy forms must meet the following requirements:

(A) Include a lower-level coverage policy form under which the actuarial value of benefits under the coverage is

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at least 85 percent but not greater than 100 percent of the weighted average.

(B) Include a higher-level coverage policy form under which the actuarial value of the benefits under the coverage is at least 15 percent greater than the actuarial value of the lower-level coverage policy form offered by an issuer in that State and at least 100 percent, but not greater than 120 percent, of the weighted average.

(C) Include benefits substantially similar to other individual health insurance coverage offered by the issuer in the State.

(D) Provide for risk adjustment, risk spreading, or a risk spreading mechanism, or otherwise provide some financial subsidization for eligible individuals.

(E) Meet all applicable State requirements.

(iii) *Actuarial value of benefits.* The actuarial value of benefits provided under individual health insurance coverage must be calculated based on a standardized population, and a set of standardized utilization and cost factors under applicable State law.

(4) *Election.* All issuer elections must be applied uniformly to all eligible individuals in the State and must be effective for all policies offered during a period of at least 2 years.

(5) *Documentation.* The issuer must document the actuarial calculations it makes as follows:

(i) *Enforcement by State.* In a State that elects to enforce the provisions of this section in lieu of an alternative mechanism under § 148.128, the issuer must provide the appropriate State authorities with the documentation required by the State.

(ii) *Enforcement by CMS.* If CMS acts to enforce the provisions of this section under § 148.200, the issuer must provide to CMS, within the following time frames, any documentation CMS requests:

(A) For policy forms already being marketed as of July 1, 1997—no later than September 1, 1997.

(B) For other policy forms—90 days before the beginning of the calendar year in which the issuer wants to market the policy form.

(d) *Special rules for network plans.* (1) An issuer that offers coverage in the

individual market through a network plan may take the following actions:

(i) Specify that an eligible individual may only enroll if he or she lives, resides, or works within the service area for the network plan.

(ii) Deny coverage to an eligible individual if the issuer has demonstrated the following to the applicable State authority (if required by the State):

(A) It does not have the capacity to deliver services adequately to additional individual enrollees because of its obligations to provide services to current group contract holders and enrollees, and to current individual enrollees.

(B) It uniformly denies coverage to individuals without regard to any health status-related factor, and without regard to whether the individuals are eligible individuals.

(iii) Not offer any coverage in the individual market, within the service area identified for purposes of paragraph (d)(1)(ii) of this section, for a period of 180 days after the coverage is denied.

(2) In those States in which CMS is enforcing the individual market provisions of this part in accordance with § 148.200, the issuer must make the demonstration described in paragraph (d)(1)(ii) of this section to CMS rather than to the State, and the issuer may not deny coverage to any eligible individual until 30 days after CMS receives and approves the information.

(e) *Application of financial capacity limits.* (1) An issuer may deny coverage to an eligible individual if the issuer has demonstrated the following to the applicable State authority (if required by the State):

(i) It does not have the financial reserves necessary to underwrite additional coverage.

(ii) It uniformly denies coverage to all individuals in the individual market, consistent with applicable State law, without regard to any health status-related factor of the individuals, and without regard to whether the individuals are eligible individuals.

(2) In those States in which CMS is enforcing the individual market provisions of this part in accordance with § 148.200, the issuer must make the demonstration described in paragraph

(e)(1) of this section to CMS rather than to the State, and the issuer may not deny coverage to any eligible individual until 30 days after CMS receives and approves the information.

(3) An issuer that denies coverage in any service area according to paragraph (e)(1) of this section is prohibited from offering that coverage in the individual market for a period of 180 days after the later of the date—

(i) The coverage is denied; or

(ii) 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.

(4) A State may apply the 180-day suspension described in paragraph (e)(3) of this section on a service-area-specific basis.

(f) *Rules for dependents*—(1) *General rule.* If an eligible individual elects to enroll in individual health insurance coverage that provides coverage for dependents, the issuer may apply a preexisting condition exclusion on any dependent who is not an eligible individual.

(2) *Exception for certain children.* A child is deemed to be an eligible individual if the following conditions are met:

(i) The child was covered under any creditable coverage within 30 days of birth, adoption, or placement for adoption (or longer if the State provides for a longer special enrollment period than required under § 146.117(a)(6) of this subchapter).

(ii) The child has not had a significant break in coverage.

(3) *Examples.* The following examples illustrate the requirements of this paragraph (f) for certain children:

*Example 1:* Individual *A* had self-only coverage under his employer's group health plan for five years. *A* has two children, ages 11 and 15, but never enrolled in family coverage. *A* leaves his job to become self-employed, and qualifies as an eligible individual because he is not entitled to any continuation coverage, Medicare or Medicaid, and has no other health insurance coverage. He applies to Issuer *R* for coverage in the individual market under a policy with family coverage that *R* makes available to eligible individuals. *R* must sell *A* the policy, but he may refuse coverage to *A*'s children, or may apply a preexisting condition exclusion to them if allowed under applicable State law,

because they did not have prior creditable coverage, and therefore do not qualify as eligible individuals.

*Example 2:* Individual *B* was also covered under a group health plan for 5 years before losing his job. He originally had coverage only for himself and his wife, but 3 months before his employment ended, his wife had a baby. *B* took advantage of the special enrollment period that applied, changed to family coverage, and enrolled the baby in the group health plan within 20 days. Immediately after losing his job, *B* applied to Issuer *R* for family coverage. *B* and his wife qualify as eligible individuals, and the baby is deemed to be an eligible individual even though she has less than 3 months of creditable coverage. Therefore *R* must make the policy available to all three members of the family, and cannot impose any preexisting condition exclusions.

(g) *Clarification of applicability.* (1) An issuer in the individual market is not required to offer a family coverage option with any policy form.

(2) An issuer offering health insurance coverage only in connection with group health plans, or only through one or more bona fide associations, or both, is not required to offer that type of coverage in the individual market.

(3) An issuer offering health insurance coverage in connection with a group health plan is not deemed to be a health insurance issuer offering individual health insurance coverage solely because the issuer offers a conversion policy.

(4) This section does not restrict the amount of the premium rates that an issuer may charge an individual under State law for health insurance coverage provided in the individual market.

(5) This section does not prevent an issuer offering health insurance coverage in the individual market from establishing premium discounts or rebates, or modifying otherwise applicable copayments or deductibles, in return for adherence to programs of health promotion and disease prevention.

(6) This section does not require issuers to reopen blocks of business closed under applicable State law.

(Approved by the Office of Management and Budget under control number 0938-0703)

[62 FR 16996, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

**§ 148.122 Guaranteed renewability of individual health insurance coverage.**

(a) *Applicability.* This section applies to all health insurance coverage in the individual market.

(b) *General rules.* (1) Except as provided in paragraph (c) of this section, an issuer must renew or continue in force the coverage at the option of the individual.

(2) Medicare eligibility or entitlement is not a basis for nonrenewal or termination of an individual's health insurance coverage in the individual market.

(c) *Exceptions to renewing coverage.* An issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market based only on one or more of the following:

(1) *Nonpayment of premiums.* The individual has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The individual has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

(3) *Termination of plan.* The issuer is ceasing to offer coverage in the individual market in accordance with paragraphs (d) and (e) of this section and applicable State law.

(4) *Movement outside the service area.* For network plans, the individual no longer resides, lives, or works in the service area of the issuer, or area for which the issuer is authorized to do business, but only if coverage is terminated uniformly without regard to any health status-related factor of covered individuals.

(5) *Association membership ceases.* For coverage made available in the individual market only through one or more bona fide associations, the individual's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor of covered individuals.

(d) *Discontinuing a particular type of coverage.* An issuer may discontinue offering a particular type of health insurance coverage offered in the individual

market only if it meets the following requirements:

(1) Provides notice in writing to each individual provided coverage of that type of health insurance at least 90 days before the date the coverage will be discontinued.

(2) Offers to each covered individual, on a guaranteed issue basis, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in that market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(e) *Discontinuing all coverage.* An issuer may discontinue offering all health insurance coverage in the individual market in a State only if it meets the following requirements.

(1) Provides notice in writing to the applicable State authority and to each individual of the discontinuation at least 180 days before the date the coverage will expire.

(2) Discontinues and does not renew all health insurance policies it issues or delivers for issuance in the State in the individual market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(f) *Prohibition on market reentry.* An issuer who elects to discontinue offering all health insurance coverage under paragraph (e) of this section may not issue coverage in the market and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(g) *Exception for uniform modification of coverage.* An issuer may, only at the time of coverage renewal, modify the health insurance coverage for a policy form offered in the individual market if the modification is consistent with State law and is effective uniformly for all individuals with that policy form.

(h) *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 individual market only through one or more associations, any reference

in this section to an “individual” is deemed to include a reference to the association of which the individual is a member.

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[62 FR 16998, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

**§ 148.124 Certification and disclosure of coverage.**

(a) *Applicability*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to all issuers of health insurance coverage.

(2) *Exception.* The provisions of this section do not apply to issuers of the following types of coverage:

(i) Health insurance coverage furnished in connection with a group health plan defined in §144.103 of this subchapter. (These issuers are required under §146.115 of this subchapter to provide a certificate of coverage.)

(ii) Excepted benefits described in §148.220.

(iii) Short-term, limited duration coverage defined in §144.103 of this subchapter.

(b) *General rules*—(1) *Individuals for whom a certificate must be provided; timing of issuance.* A certificate must be provided, without charge, for individuals and dependents who are or were covered under an individual health insurance policy as follows:

(i) *Issuance of automatic certificates.* An automatic certificate must be provided within a reasonable time period consistent with State law after the individual ceases to be covered under the policy.

(ii) *Any individual upon request.* Requests for certificates may be made by, or on behalf of, an individual within 24 months after coverage ends. For example, an entity that provides coverage to an individual in the future may, if authorized by the individual, request a certificate of the individual’s creditable coverage on behalf of the individual from the issuer of the individual’s prior coverage. After the request is received, an issuer must provide the certificate by the earliest date the issuer, acting in a reasonable and prompt fashion, can provide the certificate. A certificate must be provided under this paragraph even if the indi-

vidual has previously received a certificate under this paragraph (b)(1)(ii) or an automatic certificate under paragraph (a)(1)(i) of this section.

(2) *Form and content of certificate*—(i) *Written certificate*—(A) *General rule.* Except as provided in paragraph (b)(2)(i)(B) of this section, the issuer must provide the certificate in writing (including any form approved by CMS).

(B) *Other permissible forms.* No written certificate must be provided if all of the following occur:

(1) An individual is entitled to receive a certificate.

(2) The individual requests that the certificate be sent to another plan or issuer instead of to the individual.

(3) The plan or issuer that would otherwise receive the certificate agrees to accept the information in paragraph (a)(3) of this section through means other than a written certificate (for example, by telephone).

(4) The receiving plan or issuer receives the information from the sending issuer in the prescribed form within the time periods required under paragraph (b)(1) of this section.

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

(A) The date the certificate is issued.

(B) The name of the individual or dependent for whom the certificate applies, and any other information necessary for the issuer providing the coverage specified in the certificate to identify the individual, such as the individual’s identification number under the policy and the name of the policyholder if the certificate is for (or includes) a dependent.

(C) The name, address, and telephone number of the issuer required to provide the certificate.

(D) The telephone number to call for further information regarding the certificate (if different from paragraph (b)(2)(ii)(C) of this section).

(E) Either one of the following:

(1) A statement that the 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 as defined in §146.113(b)(2)(iii) of this subchapter.

(2) Both the date the individual first sought coverage, as evidenced by a substantially complete application, and the date creditable coverage began.

(F) The date creditable coverage ended, unless the certificate indicates that creditable coverage is continuing as of the date of the certificate.

(iii) *Periods of coverage under a certificate.* If an automatic certificate is provided under paragraph (b)(1)(i) 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 under paragraph (b)(1)(ii) of this section, a certificate must be provided for 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 period of continuous coverage.

(iv) *Single certificate permitted for families.* An issuer may provide a single certificate for both an individual and the individual's dependents if it provides all the required information for each individual and dependent, and separately states the information that is not identical.

(v) *Model certificate.* The requirements of paragraph (b)(2)(ii) of this section are satisfied if the issuer provides a certificate in accordance with a model certificate as provided by CMS.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in §148.220. 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 (c) of this section.

(3) *Procedures—(i) Method of delivery.* The certificate is required to be provided, without charge, to each individual described in paragraph (b)(1) 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 individual and the individual's spouse at the individual's last known address,

the requirements of this paragraph (b)(3) are satisfied with respect to all individuals and dependents residing at that address. If a dependent's last known address is different than the individual's last known address, a separate certificate must be provided to the dependent at the dependent's last known address. If separate certificates are provided by mail to individuals and dependents who reside at the same address, separate mailings of each certificate are not required.

(ii) *Procedure for requesting certificates.* An issuer must establish a procedure for individuals and dependents to request and receive certificates under paragraph (b)(1)(ii) of this section.

(iii) *Designated recipients.* If an automatic certificate is required to be provided under paragraph (b)(1)(i) of this section, and the individual or dependent entitled to receive the certificate designates another individual or entity to receive the certificate, the issuer responsible for providing the certificate may provide the certificate to the designated party. If a certificate must be provided upon request under paragraph (b)(1)(ii) of this section, and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the issuer responsible for providing the certificates must provide the certificate to the designated party.

(4) *Special rules concerning dependent coverage—(i) Reasonable efforts.* An issuer must use reasonable efforts to determine any information needed for a certificate relating to dependent coverage. If an automatic certificate must be furnished with respect to a dependent under paragraph (b)(1)(i) of this section, no individual certificate must be furnished until the issuer knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the policy.

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by an issuer does not provide the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (d)(3) of this section for demonstrating dependent status. An individual may, if necessary, use these procedures to demonstrate that a child

was enrolled within 30 days of birth, adoption, or placement for adoption, in which case the child would not be subject to a preexisting condition exclusion under § 148.120(f)(2).

(iii) *Transition rule for dependent coverage through June 30, 1998*—(A) *General rule.* An issuer that cannot provide the names of dependents (or related coverage information) for purposes of providing a certificate of coverage for a dependent may satisfy the requirements of paragraph (b)(2)(ii)(C) of this section by providing the name of the policyholder and specifying that the type of coverage described in the certificate is for dependent coverage (for example, family coverage or individual-plus-spouse coverage).

(B) *Certificates provided on request.* For purposes of certificates provided on the request of, or on behalf of, an individual under paragraph (b)(1)(ii) of this section, an issuer must make reasonable efforts to obtain and provide the names of any dependent covered by the certificate if the information is requested. If a certificate does not include the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (d)(3) of this section for submitting documentation to establish that the creditable coverage in the certificate applies to the dependent.

(C) *Demonstrating a dependent's creditable coverage.* See paragraph (d)(3) of this section for special rules to demonstrate dependent status.

(D) *Duration.* The transitional rules of this paragraph (b)(4)(iii) are effective for certifications provided with respect to an event occurring before July 1, 1998.

(5) *Optional notice.* This paragraph applies to events described in paragraph (b)(1)(i) of this section, that occur after September 30, 1996, but before June 30, 1997. An issuer offering individual health insurance coverage is deemed to satisfy paragraphs (b)(1) and (b)(2) of this section if a notice is provided in accordance with the provisions of § 146.125(e)(3)(ii) through (e)(3)(iv) of this subchapter.

(c) *Disclosure of coverage to a plan, or issuer, electing the alternative method of creating coverage*—(1) *General rule.* If an

individual enrolls in a group health plan and the plan or issuer uses the alternative method of determining creditable coverage described in § 146.113(c) of this subchapter, the individual provides a certificate of coverage under paragraph (b) of this section or demonstrates creditable coverage under paragraph (d) of this section, and the plan or coverage in which the individual enrolls requests from the prior entity, the prior entity must disclose promptly to the requesting plan or issuer (“requesting entity”) the information set forth in paragraph (c)(2) of this section.

(2) *Information to be disclosed.* The prior entity must identify to the requesting entity the categories of benefits under which the individual was covered and 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 to determine the individual's creditable coverage with respect to any of those categories. The prior entity must promptly disclose to the requesting entity the creditable coverage information that was requested.

(3) *Charge for providing information.* The prior entity furnishing the information under paragraph (c)(2) of this section may charge the requesting entity for the reasonable cost of disclosing the information.

(d) *Ability of an individual to demonstrate creditable coverage and waiting period information*—(1) *General rule.* Individuals may establish creditable coverage through means other than certificates. If the accuracy of a certificate is contested or a certificate is unavailable when needed by the 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 a demonstration if one of the following occurs:

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

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(ii) The individual has creditable coverage but an entity may not be required to provide a certificate of the coverage.

(iii) The coverage is for a period before July 1, 1996.

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

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

(2) *Evidence of creditable coverage—(i) Consideration of evidence.* An issuer must 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 or not an individual has 18 months of creditable coverage. An issuer must treat the individual as having furnished a certificate if the individual attests to the period of creditable coverage, the individual presents relevant corroborating evidence of some creditable coverage during the period, and the individual cooperates with the issuer's efforts to verify the individual's coverage. For this purpose, cooperation includes providing (upon the issuer's request) a written authorization for the 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 an issuer may refuse to credit coverage if the individual fails to cooperate with the issuer's efforts to verify coverage, the 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 may establish creditable coverage (and waiting periods or affiliation periods) in the absence of a certificate include explanations of benefit claims (EOB) 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 state-

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ments verifying periods of coverage, and any other relevant documents that evidence periods of health coverage.

(iii) *Other evidence.* Creditable coverage (and waiting period or affiliation period information) may be established through means other than documentation, such as by a telephone call from the issuer to a third party verifying creditable coverage.

(3) *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 issuer must treat the individual as having furnished a certificate showing the dependent status if the individual attests to the dependency and the period of the status and the individual cooperates with the issuer's efforts to verify the dependent status.

(Approved by the Office of Management and Budget under control number 0938-0703)

[62 FR 16998, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 148.126 **Determination of an eligible individual.**

(a) *General rule.* Each issuer offering health insurance coverage in the individual market is responsible for determining whether an applicant for coverage is an eligible individual as defined in § 148.103.

(b) *Specific requirements.* (1) The issuer must exercise reasonable diligence in making this determination.

(2) The issuer must promptly determine whether an applicant is an eligible individual.

(3) If an issuer determines that an individual is an eligible individual, the issuer must promptly issue a policy to that individual.

(c) *Insufficient information—(1) General rule.* If the information presented in or with an application is substantially insufficient for the issuer to make the determination described in paragraph (b)(2) of this section, the issuer may immediately request additional information from the individual, and must act promptly to make its determination after receipt of the requested information

(2) *Failure to provide a certification of creditable coverage.* If an entity fails to provide the certificate that is required

under this part or part 146 of this subchapter to the applicant, the issuer is subject to the procedures set forth in § 148.124(d)(1) concerning an individual's right to demonstrate creditable coverage.

[62 FR 17000, Apr. 8, 1997]

EFFECTIVE DATE NOTE: At 62 FR 17000, Apr. 8, 1997, § 148.126 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

**§ 148.128 State flexibility in individual market reforms—alternative mechanisms.**

(a) *Waiver of requirements.* The requirements of § 148.120, which set forth Federal requirements for guaranteed availability in the individual market, do not apply in a State that implements an acceptable alternative mechanism in accordance with the following criteria:

(1) The alternative mechanism meets the following conditions:

(i) Offers health insurance coverage to all eligible individuals.

(ii) Prohibits imposing preexisting condition exclusions and affiliation periods for coverage of an eligible individual.

(iii) Offers an eligible individual a choice of coverage that includes at least one policy form of coverage that is comparable to either one of the following:

(A) Comprehensive coverage offered in the individual market in the State.

(B) A standard option of coverage available under the group or individual health insurance laws of the State.

(2) The State is implementing one of the following provisions relating to risk:

(i) One of the following model acts, as adopted by the NAIC on June 3, 1996, but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

(A) The Small Employer and Individual Health Insurance Availability Model Act to the extent it applies to individual health insurance coverage.

(B) The Individual Health Insurance Portability Model Act.

(ii) A qualified high risk pool, which, for purposes of this section, is a high risk pool that meets the following conditions:

(A) Provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion or affiliation periods for coverage of an eligible individual.

(B) Provides for premium rates and covered benefits for the coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect as of August 21, 1996), but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

(iii) One of the following mechanisms:

(A) Any other mechanism that provides for risk adjustment, risk spreading, or a risk-spreading mechanism (among issuers or policies of an issuer) or otherwise provides for some financial subsidization for eligible individuals, including through assistance to participating issuers.

(B) A mechanism that provides a choice for each eligible individual of all individual health insurance coverage otherwise available.

(b) *Permissible forms of mechanisms.* A private or public individual health insurance mechanism (such as a health insurance coverage pool or program, a mandatory group conversion policy, guaranteed issue of one or more plans of individual health insurance coverage, or open enrollment by one or more health insurance issuers), or combination of these mechanisms, that is designed to provide access to health benefits for individuals in the individual market in the State, in accordance with this section, may constitute an acceptable alternative mechanism.

(c) *Establishing an acceptable alternative mechanism—transition rules.* CMS presumes a State to be implementing an acceptable alternative mechanism as of July 1, 1997 if the following conditions are met:

(1) By not later than April 1, 1997, as evidenced by a postmark date, or other such date, the chief executive officer of the State takes the following actions:

(i) Notifies CMS that the State has enacted or intends to enact by not later than January 1, 1998 (unless it is a State described in paragraph (d) of this section), any legislation necessary to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998.

(ii) Provides CMS with the information necessary to review the mechanism and its implementation (or proposed implementation).

(2) CMS has not made a determination, in accordance with the procedure in paragraph (e)(4) of this section, that the State will not be implementing a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998.

(d) *Delay permitted for certain States.* If a State notifies CMS that its legislature is not meeting in a regular session between August 21, 1996 and August 20, 1997, CMS continues to presume until July 1, 1998 that the State is implementing an acceptable alternative mechanism, if the chief executive officer of the State takes the following actions:

(1) Notifies CMS by April 1, 1997, that the State intends to submit an alternative mechanism and intends to enact any necessary legislation to provide for the implementation of an acceptable alternative mechanism as of July 1, 1998.

(2) Notifies CMS by April 1, 1998, that the State has enacted any necessary legislation to provide for the implementation of an acceptable alternative mechanism as of July 1, 1998.

(3) Provides CMS with the information necessary to review the mechanism and its implementation (or proposed implementation).

(e) *Submitting an alternative mechanism after April 1, 1997—(1) Notice with information.* A State that wishes to implement an acceptable alternative mechanism must take the following actions:

(i) Notify CMS that it has enacted legislation necessary to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism, and

(ii) Provide CMS with the information necessary for CMS to review the

mechanism and its implementation (or proposed implementation).

(2) *An acceptable alternative mechanism.* If the State takes the actions described in paragraph (e)(1) of this section, the mechanism is considered to be an acceptable alternative mechanism unless CMS makes a preliminary determination (under paragraph (e)(4)(i) of this section), within the review period (defined in paragraph (e)(3) of this section), that the mechanism is not an acceptable alternative mechanism.

(3) *Review period—(i) General.* The review period begins on the date the State's notice and information are received by CMS, and ends 90 days later, not counting any days during which the review period is suspended under paragraph (e)(3)(ii) of this section.

(ii) *Suspension of review period.* During any review period, if CMS notifies the State of the need for additional information or further discussion on its submission, CMS suspends the review period until the State provides the necessary information.

(4) *Determination by CMS—(i) Preliminary determination.* If CMS finds after reviewing the submitted information, and after consultation with the chief executive officer of the State and the chief insurance regulatory official of the State, that the mechanism is not an acceptable alternative mechanism, CMS takes the following actions:

(A) Notifies the State, in writing, of the preliminary determination.

(B) Informs the State that if it fails to implement an acceptable alternative mechanism, the Federal guaranteed availability provisions of §148.120 will take effect.

(C) Permits the State a reasonable opportunity to modify the mechanism (or to adopt another mechanism).

(ii) *Final determination.* If, after providing notice and a reasonable opportunity for the State to modify its mechanism, CMS makes a final determination that the design of the State's alternative mechanism is not acceptable or that the State is not substantially enforcing an acceptable alternative mechanism, CMS notifies the State in writing of the following:

(A) CMS's final determination.

(B) That the requirements of §148.120 concerning guaranteed availability

apply to health insurance coverage offered in the individual market in the State as of a date specified in the notice from CMS.

(iii) *State request for early notice.* A State may request that CMS notify the State before the end of the review period if CMS is not making a preliminary determination.

(5) *Effective date.* If CMS does not make a preliminary determination within the review period, the acceptable alternative mechanism is effective 90 days after the end of the 90-day review period described in paragraph (e)(3)(i) of this section.

(f) *Continued application.* A State alternative mechanism may continue to be presumed to be acceptable, if the State provides information to CMS that meets the following requirements:

(1) If the State makes a significant change to its alternative mechanism, it provides the information before making a change.

(2) Every 3 years from the later of implementing the alternative mechanism or implementing a significant change, it provides CMS with information.

(g) *Review criteria.* CMS reviews each State's submission to determine whether it addresses all of the following requirements:

(1) Is the mechanism reasonably designed to provide all eligible individuals with a choice of health insurance coverage?

(2) Does the choice offered to eligible individuals include at least one policy form that meets one of the following requirements?

(i) Is the policy form comparable to comprehensive health insurance coverage offered in the individual market in the State?

(ii) Is the policy form comparable to a standard option of coverage available under the group or individual health insurance laws of the State?

(3) Does the mechanism prohibit pre-existing condition exclusions for all eligible individuals?

(4) Is the State implementing one of the following:

(i) The NAIC Small Employer and Individual Health Insurance Availability Model Act (Availability Model), adopted

on June 3, 1996, revised to reflect HIPAA requirements.

(ii) The Individual Health Insurance Portability Model Act (Portability Model), adopted on June 3, 1996, revised to reflect HIPAA requirements.

(iii) A qualified high-risk pool that provides eligible individuals health insurance or comparable coverage without a preexisting condition exclusion, and with premiums and benefits consistent with the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect August 21, 1996), revised to reflect HIPAA requirements.

(iv) A mechanism that provides for risk spreading or provides eligible individuals with a choice of all available individual health insurance coverage.

(5) Has the State enacted all legislation necessary for implementing the alternative mechanism?

(6) If the State has not enacted all legislation necessary for implementing the alternative mechanism, will the necessary legislation be enacted by January 1, 1998?

(h) *Limitation of CMS's authority.* CMS does not make a preliminary or final determination on any basis other than that a mechanism is not considered an acceptable alternative mechanism or is not being implemented.

(Approved by the Office of Management and Budget under control number 0938-0703)

[62 FR 16995, Apr. 8, 1997; 62 FR 17005, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

**Subpart C—Requirements Related to Benefits**

**§148.170 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, an issuer offering health insurance coverage in the individual market 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 (a)(2) of this section are illustrated by the following examples. In each example, the issuer 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) A pregnant woman covered under a policy issued in the individual market 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) 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) A woman covered under a policy issued in the individual market 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) 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) A woman covered under a policy issued in the individual market 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) 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.* An issuer may not require that a physician or other health care provider obtain authorization from the issuer for prescribing the hospital length of stay required under 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) In the case of a delivery by cesarean section, an issuer 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 issuer requires an attending provider to complete a certificate of medical necessity. The issuer then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) 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.

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

*Example.* (i) A pregnant woman covered under a policy offered by an issuer 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 issuer pays for the 72-hour hospital stays.

(ii) 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*. An issuer may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll in or renew coverage 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 issuer is subject to the requirements of this section, as follows:

*Example 1.* (i) An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under a policy issued in the individual market are discharged within 24 hours after the delivery, the issuer will waive the copayment and deductible.

(ii) 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 issuer 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) An issuer 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 issuer 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) 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, an issuer may not restrict the benefits for any portion of a hospital length of stay required under 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) An issuer 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 issuer automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the covered individual must call the issuer 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 issuer will not provide benefits for any succeeding 24-hour period.

(ii) 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 an issuer from requiring precertification for any period after the first 96 hours.) In addition, if the issuer's utilization reviewer denied any mother or her newborn benefits within the 96-hour stay, the issuer would also violate paragraph (a) of this section.

(3) *With respect to attending providers*. An issuer 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 covered individual 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 covered individual in a manner inconsistent with this section, including providing any incentive that could induce

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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 issuer 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 an issuer 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 coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay required under 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 issuer is subject to the requirements of this section, as follows:

*Example 1.* (i) An issuer provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The issuer 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) In this *Example 1*, the issuer 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 issuer also violates the similar rule in paragraph (b)(2) of this section.)

*Example 2.* (i) An issuer generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the issuer will cover 80 percent of the cost of the stay if the covered individual notifies the issuer of the pregnancy in advance of admission and uses whatever hospital the issuer may designate.

(ii) In this *Example 2*, the issuer does not violate the rules of this paragraph (c)(3) be-

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cause 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 issuer does not violate the rules in paragraph (a)(4) or paragraph (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent an issuer 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).

(5) *Applicability.* This section applies to all health insurance coverage issued in the individual market, and is not limited in its application to coverage that is provided to eligible individuals as defined in section 2741(b) of the PHS Act.

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, an issuer offering health insurance in the individual market must meet the following requirements with respect to benefits for hospital lengths of stay in connection with childbirth:

(1) *Required statement.* The insurance contract must disclose information that notifies covered individuals 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, health insurance issuers 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 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, 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, an 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 issuer.

(3) *Timing of disclosure.* The disclosure notice in paragraph (d)(2) of this section shall be furnished to the covered individuals in the form of a copy of the contract, or a rider (or equivalent amendment to the contract), not later than March 1, 1999.

(4) *Exception.* The requirements of this paragraph (d) do not apply with respect to coverage regulated under a State law described in paragraph (e) of this section.

(e) *Applicability in certain States—(1) Health insurance coverage.* The requirements of section 2751 of the PHS Act and this section do not apply with respect to health insurance coverage in the individual market 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 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) *Relation to section 2762(a) of the PHS Act.* The preemption provisions contained in section 2762(a) of the PHS Act and §148.210(b) do not supersede a State law described in paragraph (e)(1) of this section.

(f) *Effective date.* Section 2751 of the PHS Act applies to health insurance coverage offered, sold, issued, renewed,

in effect, or operated in the individual market on or after January 1, 1998. This section applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1999.

[63 FR 57562, Oct. 27, 1998]

### Subpart D—Enforcement; Penalties; Preemption

#### § 148.210 Preemption.

(a) *Scope.* (1) This section describes the effect of sections 2741 through 2763 and 2791 of the PHS Act on a State's authority to regulate health insurance issuers in the individual market. This section makes clear that States remain subject to section 514 of ERISA, which generally preempts State law that relates to ERISA-covered plans.

(2) Sections 2741 through 2763 and 2791 of the PHS Act cannot be construed to affect or modify the provisions of section 514 of ERISA.

(b) *Regulation of insurance issuers.* The individual market rules of this part do not prevent a State law from establishing, implementing, or continuing in effect standards or requirements unless the standards or requirements prevent the application of a requirement of this part.

#### § 148.220 Excepted benefits.

The requirements of this part do not apply to individual health insurance coverage in relation to its provision of the benefits described in paragraphs (a) and (b) of this section (or any combination of the benefits).

(a) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances:

(1) Coverage only for accident (including accidental death and dismemberment).

(2) Disability income insurance.

(3) Liability insurance, including general liability insurance and automobile liability insurance.

(4) Coverage issued as a supplement to liability insurance.

(5) Workers' compensation or similar insurance.

(6) Automobile medical payment insurance.

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(7) Credit-only insurance (for example, mortgage insurance).

(8) Coverage for on-site medical clinics.

(b) *Other excepted benefits.* The requirements of this part do not apply to individual health insurance coverage described in paragraphs (b)(1) through (b)(6) of this section if the benefits are provided under a separate policy, certificate, or contract of insurance. These benefits include the following:

(1) Limited scope dental or vision benefits. These benefits are dental or vision benefits that are limited in scope to a narrow range or type of benefits that are generally excluded from benefit packages that combine hospital, medical, and surgical benefits.

(2) Long-term care benefits. These benefits are benefits that are either—

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

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

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

(3) Coverage only for a specified disease or illness (for example, cancer policies), or hospital indemnity or other fixed indemnity insurance (for example, \$100/day) if the policies meet the requirements of § 146.145(b)(4)(ii)(B) and (b)(4)(ii)(C) of this subchapter regarding noncoordination of benefits.

(4) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act, 42 U.S.C. 1395ss, also known as Medigap or MedSupp insurance).

(5) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as CHAMPUS supplemental programs).

(6) Similar supplemental coverage provided to coverage under a group health plan.

[62 FR 16995, Apr. 8, 1997; 62 FR 31696, June 10, 1997]

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### Subpart E—Grants to States for Operation of Qualified High Risk Pools

SOURCE: 68 FR 23414, May 2, 2003, unless otherwise noted.

#### § 148.306 Basis and scope.

This subpart implements section 2745 of the Public Health Service Act (the PHS Act). It provides for grants to States that have qualified high risk pools that meet the specific requirements described in § 148.310. It also provides specific instructions on how to apply for the grants and outlines the grant review and grant award processes.

#### § 148.308 Definitions.

For the purposes of this subpart, the following definitions apply:

*CMS* stands for Centers for Medicare & Medicaid Services.

*Loss* means the difference between expenses incurred by a qualified high risk pool, including payment of claims and administrative expenses, and the premiums collected by the pool.

*Qualified high risk pool* means a high risk pool that meets the conditions described in § 148.128(a)(2)(ii):

(1) It provides to all eligible individuals, as defined in § 148.103, health insurance coverage (or comparable coverage) that does not impose any pre-existing condition exclusion or affiliation periods for coverage of an eligible individual; and

(2) Provides for premium rates and covered benefits for the coverage consistent with the standards included in the National Association of Insurance Commissioners (NAIC) Model Health Plan for Uninsurable Individuals Act (as in effect as of August 21, 1996) but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

*Standard risk rate* means a rate developed by a State using reasonable actuarial techniques and taking into account the premium rates charged by other insurers offering health insurance coverage to individuals in the same geographical service area to which the rate applies. The standard

rate may be adjusted based upon age, sex, and geographical location.

*State*, for purposes of this subpart, means any of the 50 States and the District of Columbia or any entity to which a State has delegated the authority to conduct risk pool operations.

*State fiscal year*, for purposes of this subpart, means the fiscal year used for accounting purposes by either a State or a risk pool entity to which a State has delegated the authority to conduct risk pool operations.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004]

**§ 148.310 Eligibility requirements for a grant.**

A State must meet all of the following requirements to be eligible for a grant:

(a) The State has a qualified high risk pool as defined in § 148.308.

(b) The pool restricts premiums charged under the pool to no more than 150 percent of the premium for applicable standard risk rates for the State.

(c) The pool offers a choice of two or more coverage options through the pool.

(d) The pool has in effect a mechanism reasonably designed to ensure continued funding of losses incurred by the State after the end of fiscal year 2004 in connection with the operation of the pool.

(e) The pool has incurred a loss in a period described in § 148.314.

**§ 148.312 Amount of grant payment.**

(a) An eligible State may receive a grant to fund up to 50 percent of the losses incurred in the operation of its qualified high risk pool during the period for which it is applying.

(b) Funds will be allocated to each eligible State in accordance with the following formula:

(1) The number of uninsured individuals is calculated for each eligible State by taking a 3-year average of the number of uninsured individuals in that State in the Current Population Survey (CPS) of the Census Bureau. For grants based upon State fiscal years 2002 and 2003, a 3-year average was calculated using numbers available as of September 30, 2003. For grants

based upon State fiscal year 2004, a 3-year average will be calculated using numbers available as of September 30, 2004.

(2) Based upon the CPS numbers, the State's percentage of the total uninsured population of eligible States is calculated and then multiplied by \$40 million to determine the State's maximum allotment for the fiscal year in question. The following example illustrates the formula in paragraph (b):

(i) The most current 3-year average of uninsured individuals in State A is one million, and the 3-year average of uninsured individuals for all eligible States is 10 million. State A has 10 percent of the uninsured population of the eligible States.

(ii) Under this example, State A's allotment would be 10 percent of \$40 million, or \$4 million, for the fiscal year in question.

(c) The amount awarded to each eligible State will be the lesser of the 50 percent of losses incurred by its qualified risk pool for the fiscal year in question or its allotment under the formula.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004]

**§ 148.314 Periods during which eligible States may apply for a grant.**

(a) *General rule.* A State that meets the eligibility requirements in § 148.310 may apply for a grant to fund losses that were incurred during the State's fiscal year 2002, 2003, or 2004 in connection with the operation of its qualified high risk pool. If a State becomes eligible for a grant in the middle of its fiscal year, a State may apply for losses incurred in a partial fiscal year if a partial year audit is done. Only losses that are incurred after eligibility is established will qualify for a grant.

(b) *Maximum number of grants.* An eligible State may only be awarded a maximum of two grants, with one grant per fiscal year. A grant for a partial fiscal year counts as a full grant.

(c) *Deadline for submitting grant applications.* The deadlines for submitting grant applications are stated in § 148.316(d).

(d) *Initial distribution of grant funds.* States that meet all of the eligibility requirements in § 148.310 and submit

timely requests in accordance with paragraph (c) of this section will receive an initial distribution of grant funds using the following methodology:

(1) *Initial grant applications submitted for losses incurred in State fiscal year 2002 (hereafter referred to as 02 States)*. Initial grants to States that submitted an application for losses incurred in State fiscal year 2002 were funded out of the \$40 million appropriation for Federal fiscal year (FFY) 2003, which is available for obligation until the end of FFY 2004. (This is referred to as the “initial \$40 million appropriation.”)

(2) *Initial grant applications submitted for losses incurred in State fiscal year 2003 (hereafter referred to as 03 States)*. Initial grants to States that did not submit an application for losses in State fiscal year 2002 (or submitted an application but did not qualify) and first qualified for a grant for losses incurred in State fiscal year 2003 will be funded out of the initial \$40 million appropriation.

(3) *Initial grant allocations*. Initial grant allocations will be determined by taking all grant applications described in paragraphs (d)(1) and (2) of this section, and allocating in accordance with § 148.312.

(4) *Other applications*. All other grants, including the initial grants for the 04 States (States that initially qualify based upon losses incurred in their fiscal year 2004), will be funded out of the \$40 million appropriation for FFY 2004, which is available for obligation until the end of FFY 2005. (This is referred to as the “second \$40 million appropriation.”)

(e) *Allocation of funds*. Grants to States described in paragraphs (d)(1) and (d)(2) of this section will be allocated in accordance with paragraphs (e)(1) and (e)(2) of this section.

(1) *Initial allocation*. (i) *Reserves*. We will first determine the projected number of 03 States (those that are expected to submit their initial grant requests after the deadline for grants relating to a State’s 2002 losses). We will reserve the portion of the initial \$40 million appropriation that we estimate will be needed to fund grants for 03 States.

(ii) *Initial allocation to 02 States*. The remainder of the initial \$40 million ap-

propriation will be allotted to the 02 States.

(iii) *Excess reserves*. If the initial allotments for any of the 02 or 03 States are less than 50 percent of the losses incurred by those States, any reserved funds that remain after allotments have been made to all 02 and 03 States will be proportionally redistributed to the 02 and 03 States, but not to exceed 50 percent of losses incurred by the States. The size of the initial grants will be increased retroactively for those States.

(2) *Second allocation*. The procedure described in paragraph (e)(1) of this section will also be applied to allocate the second \$40 million appropriation. A reserve will be established based on the amounts expected to be needed to fund grants to 04 States before funds are allocated for second year grants for 02 and 03 States. If any excess funds remain after States receive their full allotments, the funds will be proportionally distributed to States whose allotments were less than 50 percent of their losses.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15701, Mar. 26, 2004]

#### § 148.316 Grant application instructions.

(a) *Application package*. Each State must compile an application package that documents that it has met the requirements for a grant. If a risk pool entity applies on behalf of a State, it must provide documentation that it has been delegated appropriate authority by the State. At a minimum, the application package must include a completed standard form application kit (see paragraph (b) of this section) along with the following information:

(1) *History and description of the qualified high risk pool*. Provide a detailed description of the qualified high risk pool that includes the following:

(i) Brief history, including date of inception.

(ii) Enrollment criteria (including provisions for the admission of eligible individuals as defined in § 148.103) and number of enrollees.

(iii) Description of how coverage is provided administratively in the qualified high risk pool (that is, self-insured, through a private carrier, etc.).

(iv) Benefits options and packages offered in the qualified high risk pool to both eligible individual (as defined in § 148.103) and other applicants.

(v) Outline of plan benefits and coverage offered in the pool. Provide evidence that the level of plan benefits is consistent with either Alternative One or Alternative Two in Section 8 of the NAIC Model Health Plan for Uninsurable Individuals Act. See Appendix for the text of Section 8 of the NAIC Model.

(vi) Premiums charged (in terms of dollars and in percentage of standard risk rate) and other cost-sharing mechanisms, such as co-pays and deductibles, imposed on enrollees (both eligible individuals (as defined in § 148.103) and non-eligible individuals if a distinction is made).

(vii) How the standard risk rate for the State is calculated and when it was last calculated.

(viii) Revenue sources for the qualified high risk pool, including current funding mechanisms and, if different, future funding mechanisms. Provide current projections of future income.

(ix) Copies of all governing authorities of the pool, including statutes, regulations and plan of operation.

(2) *Accounting of risk pool losses.* Provide a detailed accounting of claims paid, administrative expenses, and premiums collected for the fiscal year for which the grant is being requested. Indicate the timing of the fiscal year upon which the accounting is based. Provide the methodology of projecting losses and expenses, and include current projections of future operating losses (this information is needed to judge compliance with the requirements in § 148.310(d)).

(3) *Contact person.* Identify the name, position title, address, e-mail address, and telephone number of the person to contact for further information and questions.

(b) *Standard form application kit—(1) Forms.* (i) The following standard forms must be completed with an original signature and enclosed as part of the application package:

- SF-424 Application for Federal Assistance
- SF-424A Budget Information
- SF-424B Assurances “Non-Construction Program

SF-LLL Disclosure of Lobbying Activities  
Biographical Sketch  
Additional Assurances

(ii) These forms can be downloaded from the following Web site:

<http://www.cms.hhs.gov/researchers/priorities/grants.asp>

(2) *Other narrative.* All other narrative in the application must be submitted on 8½ x 11” white paper.

(c) *Submission of application package.*

(1) Applicants are required to submit an original and two copies of the application. Submissions by facsimile (fax) transmissions will not be accepted.

(2) Applications mailed through the U.S. Postal Service or a commercial delivery service will be considered “on time” if received by the close of business on the closing date, or postmarked (first class mail) by the date specified in the paragraph (d) of this section. If express, certified, or registered mail is used, the applicant should obtain a legible dated mailing receipt from the U.S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailings.

(d) *Application deadlines—(1) Deadline for States to submit an application for losses incurred in their fiscal year 2002.* States must submit an application to us by no later than September 30, 2003.

(2) *Deadline for States to submit an application for losses incurred in their fiscal year 2003.* States must submit an application to us by no later than June 30, 2004.

(3) *Deadline for States to submit an application for losses incurred in their fiscal year 2004.* States must submit an application to us by no later than June 30, 2005.

(e) *Where to submit an application.* All initial applications and supplemental applications must be submitted to:

Centers for Medicare & Medicaid Services,  
Acquisition and Grants Group, Mail Stop  
C2-21-15, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: Nicole Nicholson.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15701, Mar. 26, 2004]

**§ 148.318 Grant application review.**

(a) *Executive Order 12372.* This grant program is not listed by the Secretary under § 100.3 of this title, and therefore

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the grant program is not subject to review by States under part 100 of this title, which implements Executive Order 12372, “Intergovernmental Review of Federal Programs” (see part 100 of this title).

(b) *Review team.* A team consisting of staff from CMS and the Department of Health and Human Services will review all applications. The team will meet as necessary on an ongoing basis as applications are received.

(c) *Eligibility criteria.* To be eligible for a grant, a State must submit sufficient documentation that its high risk pool meets the eligibility requirements described in §148.310. A State must include sufficient documentation of the losses incurred in the operation of the qualified high risk pool in the period for when it is applying.

(d) *Review criteria.* If the review team determines that a State meets the eligibility requirements described in §148.310, the review team will use the following additional criteria in reviewing the applications:

(1) *Documentation of expenses incurred during operation of the qualified high risk pool.* The losses and expenses incurred in the operation of a State’s pool are sufficiently documented.

(2) *Funding mechanism.* The State has outlined funding sources, such as assessments and State general revenues, which can cover the projected costs and are reasonably designed to ensure continued funding of losses a State incurs in connection with the operation of the qualified high risk pool after fiscal year 2004.

### § 148.320 Grant awards.

(a) *Notification and award letter.* (1) Each State applicant will be notified in writing of CMS’s decision on its application.

(2) If the State applicant is awarded a grant, the award letter will contain the following terms and conditions:

(i) All funds awarded to the grantee under this program must be used exclusively for the operation of a qualified high risk pool that meets the eligibility requirements for this program.

(ii) The grantee must keep sufficient records of the grant expenditures for audit purposes (see part 92 of this title).

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(iii) The grantee may be required to submit quarterly progress and financial reports under part 92 of this title.

(b) *Grantees letter of acceptance.* Grantees must submit a letter of acceptance to CMS’ Acquisition and Grants Group within 30 days of the date of the award agreeing to the terms and conditions of the award letter.

### PART 149 [RESERVED]

## PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

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AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92).

SOURCE: 64 FR 45795, Aug. 20, 1999, unless otherwise noted.

**Subpart A—General Provisions**

**§ 150.101 Basis and scope.**

(a) *Basis.* CMS's enforcement authority under sections 2722 and 2761 of the

PHS Act and its rulemaking authority under section 2792 of the PHS Act provide the basis for issuing regulations under this part 150.

(b) *Scope*—(1) *Enforcement with respect to group health plans.* The provisions of title XXVII of the PHS Act that apply to group health plans that are non-Federal governmental plans are enforced by CMS using the procedures described in § 150.301 *et seq.*

(2) *Enforcement with respect to health insurance issuers.* The States have primary enforcement authority with respect to the requirements of title XXVII of the PHS Act that apply to health insurance issuers offering coverage in the group or individual health insurance market. If CMS determines under subpart B of this part that a State is not substantially enforcing title XXVII of the PHS Act, including the implementing regulations in part 146 and part 148 of this subchapter, CMS enforces them under subpart C of this part.

**§ 150.103 Definitions.**

The definitions that appear in part 144 of this subchapter apply to this part 150, unless stated otherwise. As used in this part:

*Amendment, endorsement, or rider* means a document that modifies or changes the terms or benefits of an individual policy, group policy, or certificate of insurance.

*Application* means a signed statement of facts by a potential insured that an issuer uses as a basis for its decision whether, and on what basis to insure an individual, or to issue a certificate of insurance, or that a non-Federal governmental health plan uses as a basis for a decision whether to enroll an individual under the plan.

*Certificate of insurance* means the document issued to a person or entity covered under an insurance policy issued to a group health plan or an association or trust that summarizes the benefits and principal provisions of the policy.

*Complaint* means any expression, written or oral, indicating a potential denial of any right or protection contained in HIPAA requirements (whether ultimately justified or not) by an individual, a personal representative or

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other entity acting on behalf of an individual, or any entity that believes such a right is being or has been denied an individual.

*Group health insurance policy or group policy* means the legal document or contract issued by an issuer to a plan sponsor with respect to a group health plan (including a plan that is a non-Federal governmental plan) that contains the conditions and terms of the insurance that covers the group.

*HIPAA requirements* means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146 and 148 of this subchapter.

*Individual health insurance policy or individual policy* means the legal document or contract issued by the issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in §144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual coverage subject to the requirements of part 148 of this subchapter. The term “individual health insurance policy” includes a policy that is—

(1) Issued to an association that makes coverage available to individuals other than in connection with one or more group health plans; or

(2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of part 146 of this subchapter.

*Plan document* means the legal document that provides the terms of the plan to individuals covered under a group health plan, such as a non-Federal governmental health plan.

*State law* means all laws, decisions, rules, regulations, or other State action having the effect of law, of any State as defined in §144.103 of this subchapter. A law of the United States applicable to the District of Columbia is treated as a State law rather than a law of the United States.

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### Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing to Substantially Enforce HIPAA Requirements

#### § 150.201 State enforcement.

Except as provided in subpart C of this part, each State enforces HIPAA requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.

#### § 150.203 Circumstances requiring CMS enforcement.

CMS enforces HIPAA requirements to the extent warranted (as determined by CMS) in any of the following circumstances:

(a) *Notification by State.* A State notifies CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing HIPAA requirements.

(b) *Determination by CMS.* If CMS receives or obtains information that a State may not be substantially enforcing HIPAA requirements, it may initiate the process described in this subchapter to determine whether the State is failing to substantially enforce these requirements.

(c) *Special rule for guaranteed availability in the individual market.* If a State has notified CMS that it is implementing an acceptable alternative mechanism in accordance with §148.128 of this subchapter instead of complying with the guaranteed availability requirements of §148.120, CMS’s determination focuses on the following:

(1) Whether the State’s mechanism meets the requirements for an acceptable alternative mechanism.

(2) Whether the State is implementing the acceptable alternative mechanism.

(d) *Consequence of a State not implementing an alternative mechanism.* If a State is not implementing an acceptable alternative mechanism, CMS determines whether the State is substantially enforcing the requirements of §§148.101 through 148.126 and §148.170 of this subchapter.

**§ 150.205 Sources of information triggering an investigation of State enforcement.**

Information that may trigger an investigation of State enforcement includes, but is not limited to, any of the following:

- (a) A complaint received by CMS.
- (b) Information learned during informal contact between CMS and State officials.
- (c) A report in the news media.
- (d) Information from the governors and commissioners of insurance of the various States regarding the status of their enforcement of HIPAA requirements.
- (e) Information obtained during periodic review of State health care legislation. CMS may review State health care and insurance legislation and regulations to determine whether they are:
  - (1) Consistent with HIPAA requirements.
  - (2) Not pre-empted as provided in §146.143 (relating to group market provisions) and §148.120 (relating to individual market requirements) on the basis that they prevent the application of a HIPAA requirement.
- (f) Any other information that indicates a possible failure to substantially enforce.

**§ 150.207 Procedure for determining that a State fails to substantially enforce HIPAA requirements.**

Sections 150.209 through 150.219 describe the procedures CMS follows to determine whether a State is substantially enforcing HIPAA requirements.

**§ 150.209 Verification of exhaustion of remedies and contact with State officials.**

If CMS receives a complaint or other information indicating that a State is failing to enforce HIPAA requirements, CMS assesses whether the affected individual or entity has made reasonable efforts to exhaust available State remedies. As part of its assessment, CMS may contact State officials regarding the questions raised.

**§ 150.211 Notice to the State.**

If CMS is satisfied that there is a reasonable question whether there has

been a failure to substantially enforce HIPAA requirements, CMS sends, in writing, the notice described in §150.213 of this part, to the following State officials:

- (a) The governor or chief executive officer of the State.
- (b) The insurance commissioner or chief insurance regulatory official.
- (c) If the alleged failure involves HMOs, the official responsible for regulating HMOs if different from the official listed in paragraph (b) of this section.

**§ 150.213 Form and content of notice.**

The notice provided to the State is in writing and does the following:

- (a) Identifies the HIPAA requirement or requirements that have allegedly not been substantially enforced.
- (b) Describes the factual basis for the allegation of a failure or failures to enforce HIPAA requirements.
- (c) Explains that the consequence of a State's failure to substantially enforce HIPAA requirements is that CMS enforces them.
- (d) Advises the State that it has 30 days from the date of the notice to respond, unless the time for response is extended as described in §150.215 of this subpart. The State's response should include any information that the State wishes CMS to consider in making the preliminary determination described in § 150.217.

**§ 150.215 Extension for good cause.**

CMS may extend, for good cause, the time the State has for responding to the notice described in §150.213 of this subpart. Examples of good cause include an agreement between CMS and the State that there should be a public hearing on the State's enforcement, or evidence that the State is undertaking expedited enforcement activities.

**§ 150.217 Preliminary determination.**

If, at the end of the 30-day period (and any extension), the State has not established to CMS's satisfaction that it is substantially enforcing the HIPAA requirements described in the notice, CMS takes the following actions:

- (a) Consults with the appropriate State officials identified in §150.211 (or their designees).

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(b) Notifies the State of CMS's preliminary determination that the State has failed to substantially enforce the requirements and that the failure is continuing.

(c) Permits the State a reasonable opportunity to show evidence of substantial enforcement.

**§ 150.219 Final determination.**

If, after providing notice and a reasonable opportunity for the State to show that it has corrected any failure to substantially enforce, CMS finds that the failure to substantially enforce has not been corrected, it will send the State a written notice of its final determination. The notice includes the following:

(a) Identification of the HIPAA requirements that CMS is enforcing.

(b) The effective date of CMS's enforcement.

**§ 150.221 Transition to State enforcement.**

(a) If CMS determines that a State for which it has assumed enforcement authority has enacted and implemented legislation to enforce HIPAA requirements and also determines that it is appropriate to return enforcement authority to the State, CMS will enter into discussions with State officials to ensure that a transition is effected with respect to the following:

(1) Consumer complaints and inquiries.

(2) Instructions to issuers.

(3) Any other pertinent aspect of operations.

(b) CMS may also negotiate a process to ensure that, to the extent practicable, and as permitted by law, its records documenting issuer compliance and other relevant areas of CMS's enforcement operations are made available for incorporation into the records of the State regulatory authority that will assume enforcement responsibility.

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**Subpart C—CMS Enforcement With Respect to Issuers and Non-Federal Governmental Plans—Civil Money Penalties**

**§ 150.301 General rule regarding the imposition of civil money penalties.**

If any health insurance issuer that is subject to CMS's enforcement authority under § 150.101(b)(2), or any non-Federal governmental plan (or employer that sponsors a non-Federal governmental plan) that is subject to CMS's enforcement authority under § 150.101(b)(1), fails to comply with HIPAA requirements, it may be subject to a civil money penalty as described in this subpart.

**§ 150.303 Basis for initiating an investigation of a potential violation.**

(a) *Information.* Any information that indicates that any issuer may be failing to meet the HIPAA requirements or that any non-Federal governmental plan that is a group health plan as defined in section 2791(a)(1) of the PHS Act and 45 CFR § 144.103 may be failing to meet an applicable HIPAA requirement, may warrant an investigation. CMS may consider, but is not limited to, the following sources or types of information:

(1) Complaints.

(2) Reports from State insurance departments, the National Association of Insurance Commissioners, and other Federal and State agencies.

(3) Any other information that indicates potential noncompliance with HIPAA requirements.

(b) *Who may file a complaint.* Any entity or individual, or any entity or personal representative acting on that individual's behalf, may file a complaint with CMS if he or she believes that a right to which the aggrieved person is entitled under HIPAA requirements is being, or has been, denied or abridged as a result of any action or failure to act on the part of an issuer or other responsible entity as defined in § 150.305.

(c) *Where a complaint should be directed.* A complaint may be directed to any CMS regional office.

**§ 150.305 Determination of entity liable for civil money penalty.**

If a failure to comply is established under this Part, the responsible entity, as determined under this section, is liable for any civil money penalty imposed.

(a) *Health insurance issuer is responsible entity*—(1) *Group health insurance policy*. To the extent a group health insurance policy issued, sold, renewed, or offered to a private plan sponsor or a non-Federal governmental plan sponsor is subject to applicable HIPAA requirements, a health insurance issuer is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraphs (b) or (c) of this section, if the policy itself or the manner in which the policy is marketed or administered fails to comply with an applicable HIPAA requirement.

(2) *Individual health insurance policy*. To the extent an individual health insurance policy is subject to an applicable HIPAA requirement, a health insurance issuer is subject to a civil money penalty if the policy itself, or the manner in which the policy is marketed or administered, violates any applicable HIPAA requirement.

(b) *Non-Federal governmental plan is responsible entity*. (1) *Basic rule*. If a non-Federal governmental plan is sponsored by two or more employers and fails to comply with an applicable HIPAA requirement, the plan is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraph (a) of this section. The plan is the responsible entity irrespective of whether the plan is administered by a health insurance issuer, an employer sponsoring the plan, or a third-party administrator.

(2) *Exception*. In the case of a non-Federal governmental plan that is not provided through health insurance coverage, this paragraph (b) does not apply to the extent that the non-Federal governmental employers have elected under § 146.180 to exempt the plan from applicable HIPAA requirements.

(c) *Employer is responsible entity*. (1) *Basic rule*. If a non-Federal governmental plan is sponsored by a single employer and fails to comply with an applicable HIPAA requirement, the employer is subject to a civil money

penalty, irrespective of whether a civil money penalty is imposed under paragraph (a) of this section. The employer is the responsible entity irrespective of whether the plan is administered by a health insurance issuer, the employer, or a third-party administrator.

(2) *Exception*. In the case of a non-Federal governmental plan that is not provided through health insurance coverage, this paragraph (c) does not apply to the extent the non-Federal governmental employer has elected under § 146.180 to exempt the plan from applicable HIPAA requirements.

(d) *Actions or inactions of agent*. A principal is liable for penalties assessed for the actions or inactions of its agent.

**§ 150.307 Notice to responsible entities.**

If an investigation under § 150.303 indicates a potential violation, CMS provides written notice to the responsible entity or entities identified under § 150.305. The notice does the following:

(a) Describes the substance of any complaint or other information. (See Appendix A to this subpart for examples of violations.)

(b) Provides 30 days from the date of the notice for the responsible entity or entities to respond with additional information, including documentation of compliance as described in § 150.311.

(c) States that a civil money penalty may be assessed.

**§ 150.309 Request for extension.**

In circumstances in which an entity cannot prepare a response to CMS within the 30 days provided in the notice, the entity may make a written request for an extension from CMS detailing the reason for the extension request and showing good cause. If CMS grants the extension, the responsible entity must respond to the notice within the time frame specified in CMS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in CMS's imposition of a civil money penalty based upon the complaint or other information alleging or indicating a violation of HIPAA requirements.

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### § 150.311 Responses to allegations of noncompliance.

In determining whether to impose a civil money penalty, CMS reviews and considers documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with HIPAA requirements. The following are examples of documentation that a potential responsible entity may submit for CMS's consideration in determining whether a civil money penalty should be assessed and the amount of any civil money penalty:

(a) Any individual policy, group policy, certificate of insurance, application, rider, amendment, endorsement, certificate of creditable coverage, advertising material, or any other documents if those documents form the basis of a complaint or allegation of noncompliance, or the basis for the responsible entity to refute the complaint or allegation.

(b) Any other evidence that refutes an alleged noncompliance.

(c) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(d) Documentation that the policies, certificates of insurance, or non-Federal governmental plan documents have been amended to comply with HIPAA requirements either by revision of the contracts or by the development of riders, amendments, or endorsements.

(e) Documentation of the entity's issuance of conforming policies, certificates of insurance, plan documents, or amendments to policyholders or certificate holders before the issuance of the notice of intent to assess a penalty described in § 150.307.

(f) Evidence documenting the development and implementation of internal policies and procedures by an issuer, or non-Federal governmental health plan or employer, to ensure compliance with HIPAA requirements. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's, or non-

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Federal governmental health plan's or employer's, commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with HIPAA requirements and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(g) Evidence documenting the entity's record of previous compliance with HIPAA requirements.

### § 150.313 Market conduct examinations.

(a) *Definition.* A market conduct examination means the examination of health insurance operations of an issuer, or the operation of a non-Federal governmental plan, involving the review of one or more (or a combination) of a responsible entity's business or operational affairs, or both, to verify compliance with HIPAA requirements.

(b) *General.* If, based on the information described in § 150.303, CMS finds evidence that a specific entity may be in violation of a HIPAA requirement, CMS may initiate a market conduct examination to determine whether the entity is out of compliance. CMS may conduct the examinations either at the site of the issuer or other responsible entity or a site CMS selects. When CMS selects a site, it may direct the issuer or other responsible entity to forward any documentation CMS considers relevant for purposes of the examination to that site.

(c) *Appointment of examiners.* When CMS identifies an issue that warrants investigation, CMS will appoint one or more examiners to perform the examination and instruct them as to the scope of the examination.

(d) *Appointment of professionals and specialists.* When conducting an examination under this part, CMS may retain attorneys, independent actuaries, independent market conduct examiners, or other professionals and specialists as examiners.

(e) *Report of market conduct examination.* (1) *CMS review.* When CMS receives a report, it will review the report, together with the examination work papers and any other relevant information, and prepare a final report. The final examination report will be provided to the issuer or other responsible entity.

(2) *Response from issuer or other responsible entity.* With respect to each examination issue identified in the report, the issuer or other responsible entity may:

(i) Concur with CMS's position(s) as outlined in the report, explaining the plan of correction to be implemented.

(ii) Dispute CMS's position(s), clearly outlining the basis for its dispute and submitting illustrative examples where appropriate.

(3) *CMS's reply to a response from an issuer or other responsible entity.* Upon receipt of a response from the issuer or other responsible entity, CMS will provide a letter containing its reply to each examination issue. CMS's reply will consist of one of the following:

(i) Concurrence with the issuer's or non-Federal governmental plan's position.

(ii) Approval of the issuer's or non-Federal governmental plan's proposed plan of correction.

(iii) Conditional approval of the issuer's or non-Federal governmental plan's proposed plan of correction, which will include any modifications CMS requires.

(iv) Notice to the issuer or non-Federal governmental plan that there exists a potential violation of HIPAA requirements.

**§ 150.315 Amount of penalty—General.**

A civil money penalty for each violation of 42 U.S.C. 300gg *et seq.* may not exceed \$100 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this part are in addition to any other penalties prescribed or allowed by law.

**§ 150.317 Factors CMS uses to determine the amount of penalty.**

In determining the amount of any penalty, CMS takes into account the following:

(a) *The entity's previous record of compliance.* This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation or violations, CMS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of HIPAA requirements.

(2) Documentation that the responsible entity has submitted its policy forms to CMS for compliance review.

(3) Evidence that the responsible entity has never had a complaint for non-compliance with HIPAA requirements filed with a State or CMS.

(4) Such other factors as justice may require.

(b) *The gravity of the violation.* This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

**§ 150.319 Determining the amount of the penalty—mitigating circumstances.**

For every violation subject to a civil money penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by § 150.315 to reflect that fact. As guidelines for taking into account the factors listed in § 150.317, CMS considers the following:

(a) *Record of prior compliance.* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under § 150.307, implemented and followed a compliance plan as described in § 150.311(f).

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s).* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

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(1) Made adjustments to its business practices to come into compliance with HIPAA requirements so that the following occur:

(i) All employers, employees, individuals and non-Federal governmental entities are identified that are or were issued any policy, certificate of insurance or plan document, or any form used in connection therewith that failed to comply.

(ii) All employers, employees, individuals, and non-Federal governmental plans are identified that were denied coverage or were denied a right provided under HIPAA requirements.

(iii) Each employer, employee, individual, or non-Federal governmental plan adversely affected by the violation has been, for example, offered coverage or provided a certificate of creditable coverage in a manner that complies with HIPAA requirements that were violated so that, to the extent practicable, that employer, employee, individual, or non-Federal governmental entity is in the same position that he, she, or it would have been in had the violation not occurred.

(iv) The adjustments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from CMS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the non-compliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the non-compliance is correctable and that a high percentage of the violations were corrected.

### **§ 150.321 Determining the amount of penalty—aggravating circumstances.**

For every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS sets the aggregate amount of the

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penalty at an amount sufficiently close to or at the maximum permitted by § 150.315 to reflect that fact. CMS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

### **§ 150.323 Determining the amount of penalty—other matters as justice may require.**

CMS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

### **§ 150.325 Settlement authority.**

Nothing in §§ 150.315 through 150.323 limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with § 150.307 or to compromise on any penalty provided for in §§ 150.315 through 150.323.

### **§ 150.341 Limitations on penalties.**

(a) *Circumstances under which a civil money penalty is not imposed.* CMS does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. CMS also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to CMS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

**§ 150.343 Notice of proposed penalty.**

If CMS proposes to assess a penalty in accordance with this part, it delivers to the responsible entity, or sends to that entity by certified mail, return receipt requested, written notice of its intent to assess a penalty. The notice includes the following:

(a) A description of the HIPAA requirements that CMS has determined that the responsible entity violated.

(b) A description of any complaint or other information upon which CMS based its determination, including the basis for determining the number of affected individuals and the number of days for which the violations occurred.

(c) The amount of the proposed penalty as of the date of the notice.

(d) Any circumstances described in §§ 150.317 through 150.323 that were considered when determining the amount of the proposed penalty.

(e) A specific statement of the responsible entity's right to a hearing.

(f) A statement that failure to request a hearing within 30 days permits the assessment of the proposed penalty without right of appeal in accordance with § 150.347.

**§ 150.345 Appeal of proposed penalty.**

Any entity against which CMS has assessed a penalty may appeal that penalty in accordance with § 150.401 *et seq.*

**§ 150.347 Failure to request a hearing.**

If the responsible entity does not request a hearing within 30 days of the issuance of the notice described in § 150.343, CMS may assess the proposed civil money penalty, a less severe penalty, or a more severe penalty. CMS notifies the responsible entity in writing of any penalty that has been assessed and of the means by which the responsible entity may satisfy the judgment. The responsible entity has no right to appeal a penalty with respect to which it has not requested a

hearing in accordance with § 150.405 unless the responsible entity can show good cause, as determined under § 150.405(b), for failing to timely exercise its right to a hearing.

APPENDIX A TO SUBPART C OF PART 150—EXAMPLES OF VIOLATIONS

This appendix lists actions in the group and individual markets for which CMS may impose civil money penalties. This list is not all-inclusive.

NOTE 1: All cross-references to sections of the Code of Federal Regulations are cross-references to sections in parts 144, 146, or 148 of this subchapter.

NOTE 2: Except as otherwise expressly noted, all references to non-Federal governmental plans refer to non-Federal governmental plans that are *not* exempt from HIPAA requirements (as defined in § 150.103) under section 2721(b)(2) of the PHS Act and § 146.180.

*I. Basis for Imposition of Civil Money Penalties—Actions in the Group Market*

a. Failure to comply with the limitations on pre-existing condition exclusions (§ 146.111).

Violations of the limitations on pre-existing condition exclusions, set forth in § 146.111, includes those circumstances in which a non-Federal governmental plan or health insurance issuer offering group health insurance coverage does the following:

(1) Imposes a preexisting condition exclusion period that exceeds 12 months or, in the case of a late enrollee, 18 months, from the enrollment date (the first day of coverage or the first day of the waiting period, if any).

(2) Fails to reduce a pre-existing condition exclusion period by creditable coverage as provided in §§ 146.111(a)(1)(iii) and 146.113.

(3) Imposes a pre-existing condition exclusion period without first giving the two written notices required in §§ 146.111(c) and 146.115(d). The first notice is a general notice to all plan participants of the existence and terms of any pre-existing condition exclusion under the plan, and the rights of individuals to demonstrate creditable coverage. The notice should explain the right of an individual to request a certificate from a previous plan or issuer, if necessary, and include a statement that the current plan or issuer will assist in obtaining a certificate from a previous plan or issuer, if necessary. The second notice is required to be sent to any individual who has presented evidence of creditable coverage, and to whom a pre-existing condition exclusion period will be applied. This second notice informs the individual of the plan's determination of any pre-existing condition exclusion period, the basis for such determination, a written explanation of any

appeals procedures established by the plan or issuer, and a reasonable opportunity to submit additional evidence of creditable coverage.

(4) Treats pregnancy as a pre-existing condition, as prohibited by § 146.111(b)(4). For example, an issuer may not refuse to pay for prenatal care and delivery effective with the date maternity coverage began because the individual did not have maternity coverage at the time the pregnancy began.

(5) Imposes a pre-existing condition exclusion with regard to a child who enrolls in a group health plan within 30 days of birth, adoption, or placement for adoption.

(6) Imposes a pre-existing condition exclusion with regard to a child who was enrolled in another group health plan within 30 days of birth, adoption, or placement for adoption and who does not experience significant break in coverage.

(7) Uses a pre-existing condition look-back period that exceeds the six-month period ending on the enrollment date in violation of § 146.111(a)(1) of this chapter.

(8) Determines whether a pre-existing condition exclusion applies by using a standard other than whether medical advice, diagnosis, care, or treatment was actually recommended or received during the look-back period. A determination that a reasonably prudent person would or should have sought medical care for the condition is an unacceptable standard by which to determine whether a pre-existing condition exclusion applies.

(9) Uses genetic information as part of the definition of pre-existing condition in the absence of a diagnosis of the condition related to the genetic information.

(10) Otherwise fails to comply with § 146.111.

b. Failure to comply with the provisions relating to creditable coverage (§ 146.113).

Failure to comply with the § 146.113 rules relating to creditable coverage includes those circumstances in which a non-Federal governmental plan or issuer offering group health insurance coverage does the following:

(1) Fails to treat all forms of coverage listed in § 146.113(a) as creditable coverage.

(2) Counts creditable coverage in a manner inconsistent with the standard method described in § 146.113(b) or the alternative method described in § 146.113(c), if it elects to use the alternative method.

(3) Treats an individual with fewer than 63 consecutive days without creditable coverage as having a significant break in coverage in violation of § 146.113(b)(2)(iii).

(4) Takes either a waiting period or an affiliation period into account when calculating a significant break in coverage, as prohibited by § 146.113(b)(2)(iii).

(5) Otherwise fails to comply with § 146.113.

c. Failure to comply with the provisions regarding certification and disclosure of previous coverage (§ 146.115).

Except as provided in paragraph (c)(b), the plan sponsor of a self-funded non-Federal governmental plan may not elect to exempt its plan from the requirements of this paragraph.

Failure to comply with the requirements in § 146.115 regarding certification and disclosure of previous coverage includes those circumstances in which a non-Federal governmental plan or issuer offering group health insurance coverage does the following:

(1) Fails to ensure that individuals who request certification receive it.

(2) Fails to automatically provide certificates of creditable coverage promptly, either—

(i) When the individual ceases to be covered under the plan (whether or not COBRA continuation coverage is offered or elected); or

(ii) When the COBRA continuation coverage is exhausted or is terminated by the individual, if COBRA continuation coverage was offered and was elected.

(3) Fails to provide certificates of creditable coverage promptly upon request.

(4) Fails to provide the required information in certificates of creditable coverage.

(5) Fails to provide certificates of creditable coverage to dependents.

(6) Fails to accept other evidence of creditable coverage as provided in § 146.115(c). (The plan sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan from the requirements of this paragraph (6)).

(7) Otherwise fails to comply with § 146.115.

d. Failure to comply with the provisions regarding special enrollment periods (§ 146.117).

Failure to comply with the § 146.117 requirements regarding special enrollment periods includes those circumstances in which an issuer or a non-Federal governmental plan does the following:

(1) Fails to permit employees and dependents to enroll for coverage if they satisfy the conditions of § 146.117(a) or (b).

(2) Fails to provide coverage on a timely basis to individuals protected by a special enrollment period as provided in § 146.117.

(3) Fails to provide the employee with a description of the plan's or issuer's special enrollment rules on or before the time the employee is offered the opportunity to enroll as provided in § 146.117(c).

(4) Otherwise fails to comply with § 146.117.

e. Failure to comply with the HMO affiliation period provisions (§ 146.119).

Failure to comply with the § 146.119 affiliation period requirements includes those circumstances in which an HMO that offers group health insurance coverage does the following:

(1) Imposes a pre-existing condition exclusion period.

(2) Charges a premium for months in an affiliation period.

(3) Fails to impose an affiliation period uniformly without regard to any health status-related factor.

(4) Imposes an affiliation period that is longer than 2 months (or 3 months for late enrollees), or one that begins later than the enrollment date or does not run concurrently with any waiting period.

(5) Otherwise fails to comply with § 146.119.

f. Failure to comply with the provisions regarding nondiscrimination (§ 146.121).

Failure to comply with the § 146.121 prohibitions regarding nondiscrimination includes those circumstances in which an issuer or a non-Federal governmental plan does the following:

(1) Applies rules of eligibility (including continued eligibility) to enroll under the terms of the plan based any of the health-status related factors described in § 146.121(a).

(2) Requires an individual as a condition of enrollment or re-enrollment to pay a higher premium than others similarly situated by reason of a health-status related factor of the individual or the individual's dependent.

(3) Otherwise fails to comply with § 146.121.

g. Failure to comply with the provisions relating to benefits for mothers and newborns (§ 146.130) in States where the § 146.130 standards are applicable.

Failure of an issuer or a non-Federal governmental plan to comply with the standards in § 146.130 relating to benefits for mothers and newborns includes the following:

(1) Restricts benefits for a mother or her newborn to less than 48 hours following a vaginal delivery or less than 96 hours following a delivery by cesarean section, unless the attending provider decides, in consultation with the mother, to discharge the mother or newborn earlier.

(2) Fails to calculate the length of stay from the time of delivery when delivery occurs in a hospital, or from the time of admission when delivery occurs outside the hospital.

(3) Penalizes an attending provider for complying with the law.

(4) Offers incentives to an attending provider to provide care in a manner inconsistent with the provisions of § 146.130.

(5) Denies the mother or newborn eligibility or continued eligibility to enroll under the plan to avoid complying with § 146.130.

(6) Provides payments or rebates to mothers to encourage them to accept less than the minimum stay required.

(7) Requires an attending provider to obtain authorization to prescribe a hospital length of stay of up to 48 hours (or 96 hours) after delivery.

(8) Imposes deductibles, coinsurance, or other cost-sharing measures for any portion of a 48-hour (or 96-hour) hospital stay that are less favorable than those imposed on any preceding portion of the stay.

(9) In the case of a non-Federal governmental plan, fails to provide participants and beneficiaries with a statement describing the requirements of the Newborns' and Mothers' Health Protection Act of 1996, using the language provided at § 146.130(d)(2), not later than 60 days after the first day of the first plan year beginning on or after January 1, 1999.

(10) Otherwise fails to comply with § 146.130.

h. Failure to comply with the provisions pertaining to parity in the application of certain limits to mental health benefits in the large group market (§ 146.136).

Failure of a non-Federal governmental plan offered by a large employer or health insurance issuer offering health insurance coverage to large employers to comply with the § 146.136 provisions pertaining to parity in the application of certain limits to mental health benefits (with respect to a plan that must comply with such provisions) includes the following:

(1) Sale of a product by a health insurance issuer that fails to comply with the mental health parity provisions of § 146.136.

(2) Failure of a non-Federal governmental plan to comply with the annual and lifetime dollar limits provisions concerning mental health parity.

i. Failure to comply with the Women's Health and Cancer Rights Act of 1998 (section 2706 of the PHS Act, 42 U.S.C. 300gg-06).

j. Failure to comply with the provisions regarding guaranteed availability of coverage in the small group market (§ 146.150).

Failure to provide guaranteed availability in the small group market as provided in § 146.150 includes those circumstances in which a health insurance issuer offering any health insurance coverage to group health plans in the small group market does the following:

(1) Fails to offer all products on a guaranteed availability basis to all small employers.

(2) Fails to define a small employer using the definition at § 144.103, unless otherwise provided under State law; that is, generally an employer with between 2 and 50 employees.

(3) Fails to count as employees all individual employees that an employer wants to include in the group by applying a more restrictive definition of "employee" than is permitted by § 144.103.

(4) Fails to accept all employee dependents who are qualified under the terms of the employer's group health plan.

(5) Sets agent commissions for sales to small employers so low as to discourage

agents from marketing policies to, or enrolling, these groups so that a failure to offer coverage results.

(6) Unreasonably delays the processing of applications submitted by small employers, so that a break in coverage of more than 63 days results.

(7) Fails to offer to any small employer on a guaranteed availability basis any product that the issuer sells to small employers through one or more associations that are not bona fide associations, as defined in §144.103. The requirement to guarantee availability of such products to all small employers applies whether or not the small employer is a member of, or could qualify for membership in, that association.

(8) Otherwise fails to comply with §146.150.

k. Failure to comply with the requirements regarding guaranteed renewability in either the large or small group market (§146.152).

Failure to provide guaranteed renewability of coverage as provided in §146.152 includes those circumstances in which a health insurance issuer offering health insurance coverage to a group health plan in the small or large group market does the following:

(1) Fails to renew or continue in force coverage at the option of the plan sponsor unless one of the specific exceptions in §146.152(b) is met.

(2) Fails to follow the requirements as described in §146.152(c)–(e) relating to the discontinuance of a particular product or withdrawal from the market of a particular product.

(3) Fails to renew coverage of an individual employer who has been a member of an association when the individual employer ceases to be a member of the association, unless it is a bona fide association as defined in §144.103, and the issuer terminates coverage for all former members on a uniform basis.

(4) Fails to act uniformly if the issuer cancels coverage.

(5) Otherwise fails to comply with §146.152.

l. Failure to comply with the requirements relating to disclosure of information (§146.160).

Failure to make reasonable disclosure as provided in §146.160 includes those circumstances in which an issuer offering group health insurance coverage to a small employer, as defined in §144.103, does the following:

(1) Fails to disclose all information concerning all products available from the issuer in the small group market as defined in §144.103.

(2) Otherwise fails to comply with §146.160.

#### *II. Basis for Imposition of Civil Money Penalties—Actions in the Individual Market*

a. Failure to comply with the requirements regarding guaranteed availability of coverage (§148.120).

In States that are not implementing an acceptable alternative mechanism described in §148.128, failure to provide guaranteed availability with no preexisting condition exclusion period as provided in §148.120 includes those circumstances in which an issuer does the following:

(1) Fails to provide to eligible individuals, on a guaranteed availability basis, at least one of the following:

(i) Enrollment in all individual market policies it actually markets.

(ii) The two most popular policies described in §148.120(c)(2).

(iii) Two representative policy forms as described in §148.120(c)(3).

(2) Imposes any preexisting condition exclusion or affiliation period on eligible individuals under any policy that it sells on a guaranteed availability basis.

(3) Sets agent commissions for sales to eligible individuals so low as to discourage agents from marketing policies to, or enrolling, these individuals so that a failure to offer coverage results.

(4) Unreasonably delays the processing of applications submitted by eligible individuals.

(5) Fails to offer to any eligible individual as defined in §148.103 (on a guaranteed availability basis with no preexisting condition exclusions) any product the issuer sells to individuals through one or more associations that are not bona fide associations, as defined in §144.103, unless the issuer has designated at least two other products (as its two most popular or its two representative policies) that it will sell to eligible individuals.

(6) Denies an eligible individual a policy on the basis that the individual has had a significant break in coverage even though a substantially complete application was filed on or before the 63rd day after the prior group coverage ended.

(7) Otherwise fails to comply with §148.120.

b. Failure to comply with the requirements regarding guaranteed renewability of coverage (§148.122).

Failure to provide guaranteed renewability as provided in §148.122 includes those circumstances in which an issuer does the following:

(1) Fails to renew or continue in force coverage at the option of the individual, unless one of the specific exceptions in §148.122 is met.

(2) Fails to follow the requirements relating to the discontinuance of a particular product or withdrawal from the market of a particular product as described in §148.122(d).

(3) Fails to continue coverage at the option of the individual after the individual becomes eligible for Medicare.

(4) Fails to renew coverage for an individual who has been a member of an association when the individual ceases to be a member of the association, unless the association is a bona fide association as defined in § 144.103 and the issuer uniformly terminates coverage for all former members.

(5) Otherwise fails to comply with § 148.122.

c. Failure to comply with the requirements regarding certification and disclosure of coverage (§ 148.124).

Failure to comply with the requirements of § 148.124 regarding certification and disclosure of previous coverage includes those circumstances in which an issuer does any of the following:

(1) Fails to provide automatic certificates of creditable coverage promptly.

(2) Fails to disclose the required information in certificates of creditable coverage as provided in § 148.124(b).

(3) Fails to provide certificates of creditable coverage to dependents who are insured in the individual market and whose coverage ceases under an individual policy.

(4) Fails to credit coverage or establish eligibility as provided in § 148.124 solely because the individual is unable to obtain a certificate. This includes failing to accept, acknowledge, consider, or otherwise use other evidence of creditable coverage described in § 146.115(c) submitted by, or on behalf of, an individual to establish that person is an eligible individual.

(5) Otherwise fails to comply with § 148.124.

d. Failure to comply with the requirements regarding determination of an eligible individual (§ 148.126).

Failure to determine, as provided in § 148.126, that an applicant for health insurance is an eligible individual includes those circumstances in which an issuer does the following:

(1) Fails to identify eligible individuals, to provide information regarding all coverage options, and to issue policies promptly.

(2) Requires eligible individuals to specify their desire to invoke the requirements of part 148 or to explicitly request their rights under the law in order to obtain information about products available to them.

(3) Otherwise fails to comply with § 148.126.

e. Failure to comply with the standards relating to benefits for mothers and newborns (§ 148.170).

In States where the § 148.170 standards are applicable (see § 148.170(e)), failure to comply with the § 148.170 standards relating to benefits for mothers and newborns includes those circumstances in which a health insurance issuer does the following:

(1) Restricts benefits for a mother or her newborn to fewer than 48 hours following a vaginal delivery or fewer than 96 hours following a delivery by cesarean section, unless the attending provider decides, in consulta-

tion with the mother, to discharge the mother or newborn earlier.

(2) Fails to calculate the length of stay from the time of delivery when delivery occurs in a hospital, or from the time of admission when delivery occurs outside the hospital.

(3) Requires an attending provider to obtain authorization to prescribe a hospital length of stay of up to 48 hours (or 96 hours, if applicable) after delivery.

(4) Imposes deductibles, coinsurance, or other cost-sharing measures for any portion of a 48-hour (or 96-hour, if applicable) hospital stay that are less favorable than those imposed on any preceding portion of the stay.

(5) [Reserved]

(6) Penalizes a provider for complying with the law.

(7) Offers incentives to a provider to provide care in a manner inconsistent with the provisions of § 148.170 to avoid complying with § 148.170.

(8) Denies the mother or newborn eligibility or continued eligibility solely to avoid the requirements of § 148.170.

(9) Provides incentives to mothers to encourage them to accept less than the minimum stay requirement.

(10) Fails to provide participants and beneficiaries with a statement describing the requirements of the Newborns' and Mothers' Health Protection Act of 1996, using the language provided at § 148.170 (d)(2), not later than March 1, 1999.

(11) Otherwise fails to comply with § 148.170.

f. Failure to comply with the Women's Health and Cancer Rights Act of 1998 (section 2752 of the PHS Act, 42 U.S.C. 300gg-52) and any additional implementing regulations.

### Subpart D—Administrative Hearings

#### § 150.401 Definitions.

In this subpart, unless the context indicates otherwise:

*ALJ* means administrative law judge of the Departmental Appeals Board of the Department of Health and Human Services.

*Filing date* means the date post-marked by the U.S. Postal Service, deposited with a carrier for commercial delivery, or hand delivered.

*Hearing* includes a hearing on a written record as well as an in-person or telephone hearing.

*Party* means CMS or the respondent.

*Receipt date* means five days after the date of a document, unless there is a

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showing that it was in fact received later.

*Respondent* means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to § 150.343.

#### § 150.403 Scope of ALJ's authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedure Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

#### § 150.405 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with § 150.407(a), within 30 days after the date of issuance of either CMS's notice of proposed assessment under § 150.343 or notice that an alternative dispute resolution process has terminated. The request for hearing should be addressed as instructed in the notice of proposed determination. "Date of issuance" is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

#### § 150.407 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment with which the respondent disagrees.

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(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) The request for hearing must identify the relevant notice of assessment by date and attach a copy of the notice.

#### § 150.409 Amendment of notice of assessment or request for hearing.

The ALJ may permit CMS to amend its notice of assessment, or permit the respondent to amend a request for hearing that complies with § 150.407(a), if the ALJ finds that no undue prejudice to either party will result.

#### § 150.411 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by § 150.405(a) or any extension of time granted by the ALJ pursuant to § 150.405(b).

(b) The request for hearing fails to meet the requirements of § 150.407.

(c) The entity that filed the request for hearing is not a respondent under § 150.401.

(d) The respondent has abandoned its request.

(e) The respondent withdraws its request for hearing.

#### § 150.413 Settlement.

CMS has exclusive authority to settle any issue or any case, without the consent of the administrative law judge at any time before or after the administrative law judge's decision.

#### § 150.415 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

(1) The entity has a significant interest relating to the subject matter of the case.

(2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.

(3) The entity's interest is not adequately represented by the existing parties.

(4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor or the IRS may intervene without regard to paragraphs (a)(1) through (a)(3) of this section.

**§ 150.417 Issues to be heard and decided by ALJ.**

(a) The ALJ has the authority to hear and decide the following issues:

(1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Applies the factors that are identified in § 150.317.

(2) May consider evidence of record relating to any factor that CMS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that CMS assessed.

**§ 150.419 Forms of hearing.**

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, or by telephone. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

(b) The ALJ may decide a case based solely on the written record where there is no disputed issue of material

fact the resolution of which requires the receipt of oral testimony.

**§ 150.421 Appearance of counsel.**

Any attorney who is to appear on behalf of a party must promptly file, with the ALJ, a notice of appearance.

**§ 150.423 Communications with the ALJ.**

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

**§ 150.425 Motions.**

(a) Any request to the ALJ for an order or ruling must be by motion, stating the relief sought, the authority relied upon, and the facts alleged. All motions must be in writing, with a copy served on the opposing party, except in either of the following situations:

(1) The motion is presented during an oral proceeding before an ALJ at which both parties have the opportunity to be present.

(2) An extension of time is being requested by agreement of the parties or with waiver of objections by the opposing party.

(b) Unless otherwise specified in this subpart, any response or opposition to a motion must be filed within 20 days of the party's receipt of the motion. The ALJ does not rule on a motion before the time for filing a response to the motion has expired except where the response is filed at an earlier date, where the opposing party consents to the motion being granted, or where the ALJ determines that the motion should be denied.

**§ 150.427 Form and service of submissions.**

(a) Every submission filed with the ALJ must be filed in triplicate, including one original of any signed documents, and include:

(1) A caption on the first page, setting forth the title of the case, the

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docket number (if known), and a description of the submission (such as “Motion for Discovery”).

(2) The signatory’s name, address, and telephone number.

(3) A signed certificate of service, specifying each address to which a copy of the submission is sent, the date on which it is sent, and the method of service.

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. Service must be made by mailing or hand delivering a copy of the submission to the opposing party. If a party is represented by an attorney, service must be made on the attorney.

### § 150.429 Computation of time and extensions of time.

(a) For purposes of this subpart, in computing any period of time, the time begins with the day following the act, event, or default and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government are excluded from the computation.

(b) The period of time for filing any responsive pleading or papers is determined by the date of receipt (as defined in § 150.401) of the submission to which a response is being made.

(c) The ALJ may grant extensions of the filing deadlines specified in these regulations or set by the ALJ for good cause shown (except that requests for extensions of time to file a request for hearing may be granted only on the grounds specified in section § 150.405(b)).

### § 150.431 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a letter to the parties that acknowledges receipt of the request for

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hearing, identifies the docket number assigned to the case, provides instructions for filing submissions and other general information concerning procedures, and sets out the next steps in the case.

### § 150.435 Discovery.

(a) The parties must identify any need for discovery from the opposing party as soon as possible, but no later than the time for the reply specified in § 150.437(c). Upon request of a party, the ALJ may stay proceedings for a reasonable period pending completion of discovery if the ALJ determines that a party would not be able to make the submissions required by § 150.437 without discovery. The parties should attempt to resolve any discovery issues informally before seeking an order from the ALJ.

(b) Discovery devices may include requests for production of documents, requests for admission, interrogatories, depositions, and stipulations. The ALJ orders interrogatories or depositions only if these are the only means to develop the record adequately on an issue that the ALJ must resolve to decide the case.

(c) Each discovery request must be responded to within 30 days of receipt, unless that period of time is extended for good cause by the ALJ.

(d) A party to whom a discovery request is directed may object in writing for any of the following reasons:

(1) Compliance with the request is unduly burdensome or expensive.

(2) Compliance with the request will unduly delay the proceedings.

(3) The request seeks information that is wholly outside of any matter in dispute.

(4) The request seeks privileged information. Any party asserting a claim of privilege must sufficiently describe the information or document being withheld to show that the privilege applies. If an asserted privilege applies to only part of a document, a party withholding the entire document must state why the nonprivileged part is not segregable.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party’s discovery request, within 10 days after the

time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

**§ 150.437 Submission of briefs and proposed hearing exhibits.**

(a) Within 60 days of its receipt of the acknowledgment provided for in § 150.431, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment that the respondent did not identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments, tabbed and organized chronologically and accompanied by an indexed list identifying each document (respondent's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing

and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

**§ 150.439 Effect of submission of proposed hearing exhibits.**

(a) Any proposed hearing exhibit submitted by a party in accordance with § 150.437 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in § 150.441 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in § 150.437 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

**§ 150.441 Prehearing conferences.**

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by § 150.437 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

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(f) Discussing whether the issues for a hearing can be simplified or narrowed.

(g) Discussing potential settlement of the case.

(h) Discussing any other procedural or substantive issues.

#### § 150.443 Standard of proof.

(a) In all cases before an ALJ—

(1) CMS has the burden of coming forward with evidence sufficient to establish a prima facie case;

(2) The respondent has the burden of coming forward with evidence in response, once CMS has established a prima facie case; and

(3) CMS has the burden of persuasion regarding facts material to the assessment; and

(4) The respondent has the burden of persuasion regarding facts relating to an affirmative defense.

(b) The preponderance of the evidence standard applies to all cases before the ALJ.

#### § 150.445 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate; for example, to exclude unreliable evidence.

(c) The ALJ excludes irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence is excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in the Federal Rules of Evidence.

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under §§ 150.317 and 150.323 of this part to consider the entity's prior

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record of compliance, or to show motive, opportunity, intent, knowledge, preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether CMS's notice sent in accordance with §§ 150.307 and 150.343 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless the ALJ orders otherwise for good cause shown.

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after CMS's notice under § 150.307.

#### § 150.447 The record.

(a) Any testimony that is taken in-person or by telephone is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

(b) The transcript of any testimony, exhibits and other evidence that is admitted, and all pleadings and other documents that are filed in the case constitute the record for purposes of an ALJ decision.

(c) For good cause, the ALJ may order appropriate redactions made to the record.

#### § 150.449 Cost of transcripts.

Generally, each party is responsible for 50 percent of the transcript cost. Where there is an intervenor, the ALJ determines what percentage of the transcript cost is to be paid for by the intervenor.

#### § 150.451 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed.

The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

**§ 150.453 ALJ decision.**

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under § 150.457.

**§ 150.455 Sanctions.**

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

- (1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.
- (2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.
- (3) Striking pleadings, in whole or in part.
- (4) Staying the case.
- (5) Dismissing the case.
- (6) Entering a decision by default.
- (7) Refusing to consider any motion or other document that is not filed in a timely manner.
- (8) Taking other appropriate action.

**§ 150.457 Review by Administrator.**

(a) The Administrator of CMS (which for purposes of this subsection may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under § 150.453.

(b) The Administrator may decide to review an initial agency decision if it appears from a preliminary review of

the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

- (1) The ALJ made an erroneous interpretation of law or regulation.
- (2) The initial agency decision is not supported by substantial evidence.
- (3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.
- (4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.
- (5) The ALJ decision otherwise requires modification, reversal, or remand.
- (c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.
- (d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.
- (e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.
- (f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.
- (g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.
- (h) The Administrator's decision may rely on decisions of any courts and

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other applicable law, whether or not cited in the initial agency decision.

**§ 150.459 Judicial review.**

(a) *Filing of an action for review.* Any responsible entity against whom a final order imposing a civil money penalty is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

(1) Filing a notice of appeal in that court within 30 days from the date of a final order.

(2) Simultaneously sending a copy of the notice of appeal by registered mail to CMS.

(b) *Certification of administrative record.* CMS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) *Standard of review.* The findings of CMS and the ALJ may not be set aside unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

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**§ 150.461 Failure to pay assessment.**

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who brings an action against the entity in the appropriate United States district court to recover the amount assessed.

**§ 150.463 Final order not subject to review.**

In an action brought under § 150.461, the validity and appropriateness of the final order described in § 150.459 is not subject to review.

**§ 150.465 Collection and use of penalty funds.**

(a) Any funds collected under § 150.461 are paid to CMS.

(b) The funds are available without appropriation until expended.

(c) The funds may be used only for the purpose of enforcing the HIPAA requirements for which the penalty was assessed.

**PARTS 151-159 [RESERVED]**