

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

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DEPARTMENT OF LABOR**Pension and Welfare Benefits Administration****29 CFR Part 2590**

RIN 1210-AA54

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Care Financing Administration****45 CFR Subtitle A, Parts 144 and 146**

RIN 0938-AI08

Interim Rules for Health Insurance Portability for Group Health Plans

AGENCIES: Internal Revenue Service, Department of the Treasury; Pension and Welfare Benefits Administration, Department of Labor; Health Care Financing Administration, Department of Health and Human Services.

ACTION: Interim rules with request for comments.

SUMMARY: This document contains interim rules governing access, portability and renewability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. The rules contained in this document implement changes made to certain provisions of the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974 (ERISA), and the Public Health Service Act (PHS Act) enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Interested persons are invited to submit comments on the interim rules for consideration by the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury (Departments) in developing final rules. The rules contained in this document are being adopted in an interim basis to accommodate statutorily established time frames intended to ensure that sponsors and administrators of group health plans, participants and beneficiaries, States, and issuers of group health insurance coverage have timely guidance concerning compliance with the recently enacted requirements of HIPAA.

DATES: *Effective date:* These interim rules are effective on June 7, 1997.

Comment dates: Written comments on these interim rules are invited and must be received by the Departments on or before July 7, 1997.

Applicability dates: For group health plans maintained pursuant to one or more collective bargaining agreements ratified before August 21, 1996, the rules (other than the certification requirements) do not apply to plan years beginning before the later of July 1, 1997 or the date on which the last collective bargaining agreement relating to the plan terminates without regard to any extension agreed to after August 21, 1996.

The rules implementing the certification provisions do not require any action to be taken before June 1, 1997, although certain certification requirements apply to periods of coverage and events that occur after June 30, 1996. The certification requirement for events that occurred on or after October 1, 1996 and before June 1, 1997 may be satisfied using an optional notice described in this preamble.

Information collection: Affected parties do not have to comply with the information collection requirements in these interim rules until the Departments publish in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB) to these information collection requirements. Publication of the control numbers notifies the public that OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995. The Departments have asked for OMB clearance as soon as possible, and OMB approval is anticipated by the applicable effective date.

ADDRESSES: Written comments should be submitted with a signed original and three copies to any of the addresses specified below. All comments will be available for public inspection and copying in their entirety. Interested persons are invited to submit written comments on these interim rules to: Health Care Financing Administration, Department of Health and Human Services, Attention: [BPD-890-IFC], P.O. Box 26688, Baltimore, Maryland 21207

Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N-5669, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Interim Portability and Renewability Rules

CC:DOM:CORP:T:R (REG-253578-96), Room 5228, Internal Revenue Service,

POB 7604, Ben Franklin Station, Washington, DC 20044

Alternatively, comments may be submitted electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.ustreas.gov/tax_regs/comments.html

In the alternative:

Written comments for the Department of Health and Human Services may be hand delivered from 8:30 a.m. to 5:00 p.m. to:

Room 309-G, Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850

Written comments for the Department of Labor may be hand delivered from 8:15 a.m. to 4:45 p.m. to the above address for the Pension and Welfare Benefits Administration, U.S. Department of Labor.

Written comments for the Internal Revenue Service may be hand delivered between the hours of 8 a.m. and 5 p.m. to:

CC:DOM:CORP:T:R(REG-253578-96), Courier's Desk, Internal Revenue Service, room 5228, 1111 Constitution Avenue, NW., Washington, DC.

All submissions to the Department of Health and Human Services will be open to public inspection as they are received, generally beginning three weeks after publication, in room 309-G of the Department of Health and Human Services offices at 200 Independence Avenue, SW., Washington, DC, from 8:30 a.m. to 5:00 p.m. All submissions to the Department of Labor will be open to public inspection at the Public Documents Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N-5638, 200 Constitution Avenue NW., Washington, DC, from 8:30 a.m. to 5:30 p.m. All submissions to the Internal Revenue Service will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC, from 9:00 a.m. to 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: Julie Walton, Health Care Financing Administration, at 410-786-1565; Mark Connor, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, Department of Labor, at 202-219-4377; Diane Pedulla, Plan Benefits Security Division, Office of the Solicitor, Department of Labor, at 202-219-4377; or Russ Weinheimer, Internal Revenue Service, at 202-622-

4695. These are not toll-free numbers.

CUSTOMER SERVICE INFORMATION:

Individuals interested in obtaining a copy of the Department of Labor's booklet entitled "Questions and Answers: Recent Changes in Health Care Law" may obtain a copy by calling the following toll-free number 1-800-998-7542.

SUPPLEMENTARY INFORMATION:

A. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, was enacted on August 21, 1996. HIPAA amended the Public Health Service Act (PHS Act), the Employee Retirement Income Security Act of 1974 (ERISA), and the Internal Revenue Code of 1986 (Code) to provide for, among other things, improved portability and continuity of health insurance coverage in the group and individual insurance markets, and group health plan coverage provided in connection with employment. Sections 102(c)(4), 101(g)(4), and 401(c)(4) of HIPAA require the Secretaries of Health and Human Services, Labor, and the Treasury, each to issue regulations necessary to carry out these provisions.¹

B. Overview of HIPAA and the Interim Rules

Area of Guidance. The access, portability, and renewability provisions of HIPAA affect group health plans and health insurance issuers. Group health plans are generally plans sponsored by employers or employee organizations or both. These HIPAA provisions are designed to improve the availability and portability of health coverage by:

- Limiting exclusions for preexisting medical conditions;
- Providing credit for prior health coverage and a process for transmitting certificates and other information concerning prior coverage to a new group health plan or issuer;
- Providing new rights that allow individuals to enroll for health coverage when they lose other health coverage or have a new dependent;
- Prohibiting discrimination in enrollment and premiums against employees and their dependents based on health status;
- Guaranteeing availability of health insurance coverage for small employers and renewability of health insurance

coverage in both the small and large group markets; and

- Preserving, through narrow preemption provisions, the States' traditional role in regulating health insurance, including State flexibility to provide greater protections.

The regulations provide guidance with respect to these provisions. In implementing these new rules, the regulations provide protections for individuals seeking health coverage while minimizing burdens on employers and insurers.

Reducing Burdens. The regulations reduce burdens by:

- Providing for a simple model certificate that can be used by plans and issuers;
- Reducing unnecessary duplication in the issuance of certificates;
- Including flexible rules for dependents to receive the coverage information they need;
- Allowing coverage information to be provided by telephone if all parties agree;
- Relieving plans and issuers of the need to report the starting date of coverage and waiting period information where a certificate shows 18 months of credible coverage;
- Including a transition rule permitting plans and issuers to give individuals a notice in lieu of a certificate where coverage ended before June 1, 1997; and
- Providing for a model notice that may be used to satisfy the transition rule and a model notice for information relating to categories of benefits provided under a plan.

Implementing Individual Protections. The regulations protect and assist participants and their dependents by:

- Ensuring that individuals are notified of the length of time that a preexisting condition exclusion clause in any new health plan may apply to them after taking into account their prior creditable coverage;
- Ensuring that individuals are notified of their rights to special enrollment under a plan;
- Permitting individuals to obtain a certificate before coverage under a plan ceases; and
- Creating practical ways for individuals to demonstrate creditable coverage to a new plan (where the individual's prior plan fails to provide the certificate).

C. Overview of Coordination of Group Market Regulation Among Departments

The HIPAA portability provisions relating to group health plans and health insurance coverage offered in connection with group health plans

(referred to below as the "group market" provisions) are set forth under a new Part A of Title XXVII of the PHS Act, a new Part 7 of Subtitle B of Title I of ERISA, and a new Subtitle K of the Internal Revenue Code. HIPAA also added provisions governing insurance in the individual market that are contained only in the PHS Act, and thus are not within the regulatory jurisdiction of the Department of Labor or the Department of the Treasury. (These portability provisions are referred to below as the "individual market" provisions.)

In general, the group market provisions create concurrent jurisdiction for the Secretaries of Health and Human Services, Labor, and the Treasury. The provisions include similar rules relating to preexisting conditions exclusions, special enrollment rights, and prohibition of discrimination against individuals based on health status-related factors. (These group market provisions are referred to below as the "shared group market" provisions.) Accordingly, the three Departments share regulatory responsibility for most, but not all, of the group market provisions.

The shared group market provisions are substantially similar, except as follows:

- The shared group market provisions in the PHS Act apply generally to insurance issuers that offer health insurance in connection with group health plans (subject to an exception that may apply for plans with fewer than two participants who are current employees ("very small plans")), and certain State and local government plans. Only the PHS Act contains group market provisions relating to availability and renewability of health insurance.² In addition, the PHS Act imposes certification requirements on certain federal entities not otherwise subject to the HIPAA portability provisions. Further, the States, in the first instance, will enforce the PHS Act with respect to issuers. In addition, individuals may be able to pursue claims through State mechanisms. Only if a State does not substantially enforce any provisions under its insurance laws, will the Department of Health and Human Services enforce the provisions, through the imposition of civil money penalties. (The group market provisions relating to guaranteed renewability for multiemployer plans and multiple employer welfare arrangements

¹ In addition to the group market regulations in this document, the Department of the Treasury is issuing a proposed Treasury regulation that cross-references these regulations and the Department of Labor is issuing an interim regulation relating to certain disclosure requirements under HIPAA. Each of these regulations appears separately in this issue of the **Federal Register**.

² The PHS Act does not include requirements on availability of insurance for employers in the large group market. Under section 2711(b)(3) of the PHS Act, however, the General Accounting Office (GAO) is to report to Congress on such availability in 1998.

(MEWAs) are in ERISA and the Internal Revenue Code, but not the PHS Act.)

- The ERISA shared group market provisions apply generally to all group health plans other than governmental plans, church plans, very small plans, and certain other plans. The shared group market provisions of ERISA also apply to health insurance issuers that offer health insurance in connection with such group health plans. Generally, the Secretary of Labor enforces the Provisions of HIPAA that amend ERISA, except that no enforcement action may be taken by the Secretary against issuers relating to the new shared group market provisions in part 7 of ERISA. However, individuals may generally pursue actions against issuers under ERISA and, in some circumstances, under State laws.

- The shared group market provisions in the Internal Revenue Code generally apply to all group health plans other than governmental plans and very small plans, but not to health insurance issuers. A taxpayer that fails to comply with these provisions may be subject to an excise tax under section 4980D of the Code. (The group market provisions relating to preemption and affiliation periods for HMOs are in the PHS Act and ERISA, but not in the Internal Revenue Code.)

The regulation being issued today by the Secretaries of Health and Human Services, Labor, and the Treasury have been developed on a coordinated basis by the Departments. Except to the extent needed to reflect the statutory differences described above, the shared group market provisions in these regulations of each Department are substantively identical. However, there are certain nonsubstantive differences. The PHS Act regulations are numbered and organized differently. Also, there are differences in the regulations that are necessary because of statutory provisions that are not common to all three Departments (in the definitions sections, for example). Further, the regulations reflect certain stylistic differences in language and structure to conform to conventions used by a particular Department. These differences have been minimized and any differences in wording are not intended to create any substantive difference, so that these regulations will have the same effect with respect to overlapping statutory provisions, as required by section 104 of HIPAA.

D. Special Information Concerning State Insurance Law

For purposes of the PHS Act and sections 144 through 148 in the PHS Act regulations, all health insurance

coverage in a State generally is sold in one of two markets: the group market (See section 146) and the individual market (see section 148). The group market is further divided into the large group market and the small group market. Section 146 of the PHS Act regulations applies the group market provisions only to insurance sold to group health plans (which are generally plans sponsored by employers or employee organizations or both), regardless of whether State law provides otherwise. State law may expand the definition of the small group market to include certain coverage that, under the federal law, would otherwise be considered coverage in the large group market or the individual market.

The protections provided in the PHS Act to particular individuals and employers are different depending on whether the coverage involved is obtained in the small group market, the large group market, or the individual market. Small employers are guaranteed availability of insurance coverage sold in the small group market under the PHS Act. Small and large employers are guaranteed the right to renew their group coverage under the PHS Act, subject to certain exceptions. Eligible individuals are guaranteed availability of coverage sold in the individual market under the PHS Act, and all coverage in the individual market must be guaranteed renewable under the PHS Act.

Coverage that is provided to associations, but is not related to employment (so that the coverage is not in connection with a group health plan), is not coverage in the group market under HIPAA. This coverage is instead coverage in the individual market under the PHS Act, regardless of whether it is considered group coverage under State law.

E. Discussion of the Shared Group Market Provisions in the Regulations

The most significant items relating to the shared group market in these regulations are discussed in detail below.

Definitions—26 CFR 54.9801–2, 29 CFR 2590.701–2, 45 CFR 144.103

This section provides most of the definitions used in the regulations implementing the provisions of HIPAA that were added to the PHS Act, ERISA, and the Code, relating to the group market.³ The definitions in this section

³The regulations for the PHS Act also contain certain definitions relating to those provisions added under the PHS Act regarding the individual market, in order to create a single, comprehensive

of the regulations include both statutory definitions provided in HIPAA, as well as certain others used in the regulations.

Limitation on Preexisting Condition Exclusion Period—26 CFR 54.9801–3, 29 CFR 2590.71–3, 45 CFR 146.111

Definition of Preexisting Condition Exclusion

A preexisting condition exclusion is defined broadly to be any limitation or exclusion of benefits based on the fact 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. HIPAA imposes certain limitations (described below) on the use of such an exclusion in the group market (and also uses this definition for purposes of the individual market rules, under which no preexisting condition exclusion is permitted to be imposed on an eligible individual). HIPAA's broad definition of a preexisting condition exclusion is at variance with some State laws and regulations because the relevant National Association of Insurance Commissioners (NAIC) models, on which many State laws are based, have imposed limitations on coverage for preexisting conditions without use of such a definition.

New Limitations on Preexisting Condition Exclusions. Paragraph (a) of this section⁴ of the regulations describes the limitations on the preexisting condition exclusion period. A group health plan, and a health insurance issuer offering group health insurance coverage, is permitted to impose a preexisting condition exclusion with respect to a participant or beneficiary only if the following conditions are met:

1. *6-month look-back rule.* The preexisting condition exclusion must relate to a condition (whether physical or mental, and 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. For these purposes, genetic information is not a condition.⁵ In order

reference for the definitions necessary under the PHS Act regulations.

⁴References to paragraphs of a section refer to paragraphs of each regulation section identified in the heading. For example, this reference is to paragraph (a) in each of 45 CFR 146.111, 29 CFR 2590.701–3, and 26 CFR 54.9801–3.

⁵The definition of genetic information in the regulations was developed taking into account hearing testimony related to genetic information given in connection with Senate Report 104–156, other legislative initiatives, and public comments (including those submitted in response to the request for information published by the Departments on December 30, 1996).

to be taken into account, the medical advice, diagnosis, care, or treatment must have been recommended 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 the State law. Under the new HIPAA standard, a plan would generally determine that an individual has a preexisting condition through medical records (such as diagnosis codes on bills, a physician's notes of a visit or telephone call, pharmacy prescription records, HMO encounter data, or other records indicating that medical services were actually recommended or received during the 6-month look-back period). The "prudent person" standard of some State laws (under which a condition is taken into account if a prudent person would have sought care whether or not care is actually received) no longer may be used to determine a preexisting condition.

This 6-month "look-back" period is based on the 6-month "anniversary date" of the enrollment date. As a result, an individual whose enrollment date is August 1, 1998 has a 6-month look-back period from February 1, 1998 through July 31, 1998.

2. *Length of preexisting condition exclusion period.* The exclusion period cannot extend for more than 12 months (18 months for late enrollees) after the enrollment date. The 12- or 18-month "look-forward" period is also based on the anniversary date of the enrollment date. A late enrollee is defined as an individual who enrolls in a plan at a time other than at the first time the individual is eligible to enroll or during a special enrollment period (described below). If an individual loses eligibility for coverage as a result of terminating employment or a general suspension of coverage under the plan, then upon becoming eligible again due to resumption of employment or due to resumption of plan coverage, only the most recent period of eligibility is considered for purposes of determining whether the individual is a late enrollee.

3. *Reduction of preexisting condition exclusion period by prior coverage.* In general, the preexisting condition exclusion period is reduced by the individual's days of creditable coverage⁶ as of the enrollment date. Creditable coverage is defined as coverage of an individual from a wide

range of specified sources, including group health plans, health insurance coverage, Medicare, and Medicaid.

Definition of Enrollment Date. The limitations on preexisting condition exclusions are measured from an individual's "enrollment date." The enrollment date is defined as the first day of coverage or, if there is a waiting period, the first day of the waiting period (typically the date employment begins).

The term "first day of coverage" is used in the regulations in place of the term "date of enrollment" in the statute, such as in the definitions of the terms "preexisting condition exclusion" and "enrollment date." This is intended to clarify the difference between the statutory terms "date of enrollment" and "enrollment date" (which have no difference in common usage).

The term "waiting period" generally refers to the period in which there is a delay between the first day of employment and the first day of coverage under the plan. Accordingly, because the preexisting condition exclusion period runs from the enrollment date, any waiting period would run concurrently with any preexisting condition exclusion period. Further:

- The enrollment date for a late enrollee or anyone who enrolls on a special enrollment date (see the section on special enrollment periods below) is the first date of coverage. Thus, the time between the date a late enrollee or special enrollee first becomes eligible for enrollment under the plan and the first day of coverage is not treated as a waiting period.

- Because the 6-month look-back limitation runs from the beginning of any applicable waiting period, the current practice of some plans that require physical examinations prior to commencement of coverage for the purpose of identifying preexisting conditions may be affected. If the examination is conducted during the waiting period (after employment begins and before enrollment), rather than before employment begins, a plan may not exclude coverage for any condition identified in the examination (unless, independent of the examination, medical advice, diagnosis, care, or treatment was in fact recommended or received for the condition during the 6-month look-back period). The use of such examinations for other purposes, such as worker safety, is not affected.⁷

Elimination of Preexisting Condition Exclusion for Pregnancy and for Certain Children. A preexisting condition exclusion cannot apply to pregnancy. In addition, a preexisting condition exclusion period cannot be applied to a newborn, an adopted child under age 18, or a child placed for adoption under age 18, if the child becomes covered within 30 days of birth, adoption, or placement for adoption. This exception does not apply after the child has a significant break in coverage (63 or more consecutive days). (An example in paragraph (b)(1) of the regulations illustrates these rules.)

Rules Relating to Creditable Coverage—26 CFR 54.9801-4, 29 CFR 2590.701-4, 45 CFR 146.113

As noted above, a plan or issuer that imposes a preexisting condition exclusion must reduce the length of the exclusion by an individual's creditable coverage. This section defines the term "creditable coverage" and sets forth the rules for how creditable coverage is applied to reduce such an exclusion period.

Creditable coverage includes health insurance coverage and other health coverage, such as coverage under group health plans (whether or not provided through an issuer), Medicaid, Medicare, and public health plans, as well as other types of coverage set forth in HIPAA and the regulations. Comments are requested on whether the definition of a public health plan should include the public health systems of other countries.

Under the definition of creditable coverage, all forms of health insurance coverage are included, whether in the individual market or group market, and whether the coverage is short-term, limited-duration coverage or other coverage for benefits for medical care for which no certificate of creditable coverage is required. Creditable coverage does not include coverage consisting solely of excepted benefits as defined in the regulations and described below.⁸

Under paragraph (a)(3) of this section of the regulation, a group health plan or health insurance issuer offering group

⁶ The phrase "days of creditable coverage" is used instead of the statutory phrase "aggregate periods of creditable coverage" for administrative ease in the calculation of creditable coverage. Use of days of creditable coverage also conforms to the practice of many States for crediting prior coverage under pre-HIPAA small group market reforms.

⁷ However, to avoid violating the Americans with Disabilities Act, Pub. L. 101-336, as amended by Pub. L. 102-166, the examination should generally be conducted only after the employer has offered employment to the individual.

⁸ However, if an individual has coverage of excepted benefits in addition to other forms of creditable coverage, coverage of excepted benefits is creditable coverage. This would make a difference only if a plan or issuer uses the alternative method of determining creditable coverage (described below) with respect to a category that includes excepted benefits. For example, coverage of excepted benefits such as limited vision or limited dental benefits, when offered in combination with other creditable coverage, may be used to offset a preexisting condition exclusion period for a category that includes those benefits under the alternative method in paragraph (c).

health insurance coverage may determine the amount of creditable coverage of an individual for purposes of reducing the period of a preexisting condition exclusion by using either the standard method described in paragraph (b) or the alternative method described in paragraph (c).

Standard Method

1. *Counting.* Under the standard method, the plan or issuer determines the amount of an individual's creditable coverage by determining all days during which the individual had one or more types of creditable coverage. This determination is made without regard to the specific benefits included in the coverage. If creditable coverage is derived from more than one source on a particular day, all of the creditable coverage that the individual had on that day is counted as one day of creditable coverage.

2. *Significant break in coverage.* Days of creditable coverage that occur before a significant break in coverage are not required to be counted by the plan or issuer in reducing a preexisting condition exclusion. A significant break in coverage means a period of 63 consecutive days during all of which the individual did not have any creditable coverage.

a. *Waiting and affiliation periods.* Waiting periods and affiliation periods, as defined in the regulation, are not taken into account in determining a significant break in coverage. This is the case regardless of whether the person ultimately fails to obtain coverage under the plan (such as, where termination of employment occurs before coverage begins). However, days in a waiting period or affiliation period are not counted as creditable coverage.

The regulations specify that the period between the date an individual files a substantially complete application for coverage in the individual market and the effective date of such coverage is a waiting period, so that the period is not taken into account in determining a significant break in coverage. In this way, an application processing delay or omission of details on a form would not cause an applicant to incur a significant break in coverage, which could adversely affect an individual who seeks coverage under a group health plan after purchasing coverage in the individual market.

However, the waiting period for purchase of an individual policy tolls a break in coverage only if the filing of the application for the individual market insurance actually results in purchase of the coverage by the individual. (See Examples 7 and 8 in paragraph

(b)(2)(iv)). By contrast, days in a waiting period for coverage under a group health plan toll a significant break in coverage regardless of whether coverage under the plan is ultimately obtained. (See Example 6.) The rule regarding the individual market prevents an individual from avoiding a significant break in coverage by repeatedly submitting applications to individual market issuers without ever purchasing coverage. This rule responds to comments sent to the Departments in response to the December 30, 1996 request for public comments. The comments asked for clear rules on when a significant break is tolled in the case of an application for individual market insurance.

Issuers of health insurance coverage in the individual market are subject to the same certification requirements that apply to plans and issuers in the group market. Therefore, issuers in the individual market must provide individuals with certificates that reflect information regarding the beginning of the waiting period (the date of application), the effective date of coverage, and the date coverage ends. This will assist people with coverage in the individual market who later become covered by a group health plan in demonstrating their creditable coverage to the plan or issuer in the group market.

b. *Effect of State insurance law.* HIPAA provides that the significant break in coverage rule does not preempt State insurance laws that provide longer periods than 63 days for a break in coverage. (The preemption provisions are described more fully below.) Accordingly, while federal law may allow a plan to disregard prior coverage before a 63-day significant break in coverage, an issuer may be required to take such coverage into account in order to comply with State insurance law. As a result, application of the break rules can vary between issuers located in different States. Similarly, the break rules may vary between insured plans and self-insured plans (which are not subject to State insurance laws) within a State, as well as between the insured and self-insured portions of a single plan. As illustrated by Example 3 in paragraph (b)(2)(iv), the laws of the State applicable to the insurance policy that has the preexisting condition exclusion are determinative of which break rule applies.

Alternative Method. Under the alternative method of counting creditable coverage, the plan or issuer determines the amount of an individual's creditable coverage for any of five identified categories of benefits.

Those categories are coverage for mental health, substance abuse treatment, prescription drugs, dental care, and vision care. The plan or issuer may use the alternative method for any or all of the categories and may apply a different preexisting condition exclusion period with respect to each category (as well as to coverage not within a 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. The standard method is used to determine an individual's creditable coverage for benefits that are not within any category for which the alternative method is being used. Disclosure statements concerning the plan must indicate that the alternative method is being used, and this disclosure must also be given to each enrollee at the time of enrollment. These statements must include a description of the effect of using the alternative method. Any issuer in the group market must provide similar statements to each employer at the time of offer or sale of the coverage.

For purposes of reducing the preexisting condition exclusion period under the alternative method, the plan or issuer determines under the standard method the amount of the individual's creditable coverage that can be counted, up to a total of 365 days of the most recent creditable coverage of the individual (546 days for a late enrollee). The period of this creditable coverage is referred to as the "determination period." The plan or issuer counts all days of coverage within the applicable category that occurred during the determination period (without regard to any significant breaks in that category of coverage). Those days reduce the preexisting condition exclusion for coverage within that category.

The regulations do not provide detailed definitions of the benefit categories. Comments are invited on whether additional guidance is needed.

The regulations under the alternative method of counting creditable coverage do not include a category relating to significant differences in deductible amounts. Commentators expressed concerns about adverse selection if individuals can change from a high deductible plan when they become ill and obtain "first dollar" coverage from an HMO or other issuer that provides broad, comprehensive care with only low deductibles or copayments.⁹ However, it is unclear how such a

⁹ See also the discussion below under the heading "HMO Affiliation as Alternative to Preexisting Condition Exclusion."

category would be defined or applied. Accordingly, the Departments solicit comments on this issue.

Certificates and Disclosure of Previous Coverage—26 CFR 54.9801–5, 29 CFR 2590.701–5, 45 CFR 146.115

This section of the regulations sets forth guidance regarding the certification requirements and other requirements concerning disclosure of information relating to prior creditable coverage. The provision of a certificate and other disclosures of information are intended to enable an individual to establish his or her prior creditable coverage for purposes of reducing any preexisting condition exclusion imposed on the individual by any subsequent group health plan coverage.

Form of Certificate. In general, the certificate must be provided in writing, including any form approved by the Secretaries as a writing. In certain circumstances, where the individual requests that the certificate be sent to another plan or issuer instead of to the individual, and the other plan or issuer agrees, the certification information may be provided by other means, such as by telephone. In some States, issuers transfer coverage information by telephone. Comments are requested as to whether, and under what conditions, other methods of transmitting certification information (including electronic communication) should be permitted in future guidance.

Information in Certificate. Paragraph (a)(3) of this section of the regulations sets forth the information that must be included in a certificate. The regulations allow a plan or issuer in an appropriate case simply to state in the certificate that the individual has at least 18 months of creditable coverage that was not interrupted by a significant break in coverage and to indicate the date coverage ended. (A certificate would never have to reflect coverage in excess of 18 months without a 63-day break because this is the maximum creditable coverage that an individual could need under the preexisting condition exclusion rules and the rules for access to the individual market.) In any other case, the certificate must disclose (1) the date any waiting or affiliation period began,¹⁰ (2) the date coverage began, and (3) the date coverage ended (or indicate if coverage is continuing).¹¹ For

individuals with fewer than 18 months of coverage without a significant break in coverage, the information about specific dates is essential in order for a subsequent plan or issuer in the group or individual market to be able to apply the break rules, especially in light of the possibility that an individual may have other coverage from various sources and the potential differences among State break rules (described above).

Certification Events and Timing. Paragraph (a)(5) describes the rights of participants and dependents to receive certificates. In general, individuals have the right to receive a certificate automatically (an “automatic certificate”) when they lose coverage under a plan and when they have a right to elect COBRA continuation coverage. The certificate must be furnished within the time periods described below:

- *First*, for an individual who is a qualified beneficiary entitled to elect COBRA continuation coverage, the certificate is required to be provided no later than when a notice is required to be provided for a qualifying event under COBRA.

- *Second*, for an individual who loses coverage under a group health plan and who is not a qualified beneficiary entitled to elect COBRA continuation coverage, the certificate is required to be provided within a reasonable time after the coverage ceases. (Typically, this would apply to small employers’ plans that are not subject to COBRA.) This requirement is satisfied if the certificate is provided by the time a notice is required to be provided under a State program similar to COBRA.

- *Third*, for an individual who is a qualified beneficiary and has elected COBRA continuation coverage, the certificate is required to be provided within a reasonable time after either cessation of COBRA continuation coverage or, if applicable, after the expiration of any grace period for the payment of COBRA premiums. In each of these three events, the regulations require the certificate to reflect only the most recent period of continuous coverage under the plan.

Under COBRA, multiemployer plans may provide notices within such longer period of time as provided for such notices under the terms of the plan. Under the general certification timing rule described above, multiemployer plans may use the same extended time period for providing certificates. Comments are requested on how this may affect a multiemployer plan and its participants and their families.

A certificate may be mailed by first class mail to the participant’s last known address. A certificate for a

participant’s spouse with an address different from the participant’s is to be sent to the spouse’s address. 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, a certificate may provide information sufficient to satisfy the requirements of the regulations with respect to each individual on one document.

A certificate is also required to be provided upon the request of, or on behalf of, an individual (whether the individual is a participant, the participant’s spouse, or any other dependent) if the request is made within 24 months after the individual loses coverage under the plan. The certificate is required to be provided at the earliest time that the plan or issuer, acting in a reasonable and prompt fashion, can provide the certificate. In this case, the certificate reflects each period of continuous coverage ending within the 24 months prior to the date of request.¹²

Responsibilities of Plans and Issuers. Paragraph (a)(1) clarifies the statutory obligation of plans and issuers to provide certificates. The statutory obligation to furnish a written certificate of information regarding creditable coverage is imposed on both the group health plan and the health insurance issuer offering group health insurance coverage. This dual obligation was the subject of many of the comments received by the three Departments in response to the December 30, 1996 request for public comments published in the **Federal Register**. Concerns were raised about superfluous, duplicate certificates being issued and the potential responsibility of issuers for reporting on an individual’s coverage under the plan after one issuer has been replaced by another.

Paragraph (a)(1) addresses these concerns by providing that the obligation to furnish a certificate is imposed on both the plan and each health insurance issuer that provides group health insurance coverage under the plan, subject to four exceptions.

First, paragraph (a)(1)(ii) provides that an entity required to provide a certificate is deemed to have satisfied this requirement to the extent that any other party provides the certificate and the certificate discloses the creditable coverage (including the waiting period

¹⁰ Because the ending date for a waiting or affiliation period will always be the date coverage begins, the ending date does not have to be separately stated in a certificate.

¹¹ These dates would include any period of COBRA continuation coverage. A COBRA continuation coverage period does not have to be separately identified.

¹² For example, for participation who has had a number of interruptions in coverage, a requested certificate could consist of copies of all of the automatic certificates that were previously provided to the individual for each of these periods.

information) that was to be provided by the entity.

Second, paragraph (a)(1)(iii) provides that a plan is deemed to have satisfied its obligation if there is an agreement between an issuer and a plan under which the issuer agrees to provide certificates for individuals covered under the plan.

Third, paragraph (a)(1)(iv)(A) provides that an issuer is not required to provide any coverage information regarding coverage periods for which it was not responsible.

Fourth, paragraph (a)(1)(iv)(B) provides that if an individual switches from one issuer to another option allowed under the plan, or an issuer is replaced by another before an individual's coverage in the plan ceases, the first issuer is required to provide sufficient information to the plan (or to another party designated by the plan), so that when the individual leaves the plan, a certificate can be provided that includes the period of coverage under the policy of the first issuer. In this situation, no certificate is required to be provided to the individual, but the issuer must also cooperate with the plan by providing any information that may be requested later pursuant to the alternative method. (This rule will reduce unnecessary and potentially misleading information from being received while the individual's coverage under the plan is uninterrupted.) An issuer may presume that it is the final issuer for an individual if the individual's coverage under the policy ends at a time other than in connection with the plan's open season.

Other Entities Issuing Certificates. Paragraph (a)(6) identifies the various statutory authorities that create responsibility for other entities (that are not subject to a particular Department's regulations) to provide certificates. As described above, there are forms of creditable coverage other than coverage provided by group health plans and health insurance coverage offered in connection with a group health plan. Accordingly, individuals who leave coverage provided by any such other entity are entitled to have that coverage counted by a group health plan and may in many cases receive certificates for their creditable coverage. This information is included in the regulations because plans that impose a preexisting condition exclusion may find it helpful to know when creditable coverage will be provable through presentation of a certificate and when other forms of documentation or attestation may be needed.

In cases where certifications are provided by entities not subject to

ERISA's requirements, such as Medicaid, the Indian Health Service, and CHAMPUS, certain adjustments in the certification rules may be appropriate. The regulations do not address how the certification process applies to these other programs. Comments are requested on how the certification requirements may be adapted to entities responsible for providing this coverage.

Dependent Coverage Information. Dependents are entitled to a written certificate of creditable coverage. Concerns were raised in comments received from the public regarding the certification of dependent coverage where information regarding dependents of participants in plans was not available. Plans and issuers, the commenters stated, often do not know the existence of dependents or their coverage periods until claims are filed. To address these concerns, the regulations have adopted two special rules.

First, under a transition rule that lasts through June 30, 1998, a plan or issuer may satisfy its obligation to provide a written certificate regarding the coverage of a dependent of a participant by providing the name of the participant covered by the plan and specifying the type of coverage provided in the certificate (such as family coverage or employee-plus-spouse coverage). However, if asked to provide a certificate relating to a dependent, the plan must make reasonable efforts to obtain and provide the name of the dependent. This rule will provide plans and issuers with a transition period to update their data systems to include information on dependents.

Second, the regulations include a special rule regarding dependent coverage that is not limited to the transition period. Under this rule, a plan or issuer must make a reasonable effort to collect the necessary information for dependents and include it on the certificate. However, under this special rule, an automatic certificate is not required to be issued until the plan or issuer knows (or, making reasonable efforts, should know) of the dependent's cessation of coverage. This information can be collected annually (during open enrollment).

Under the transition rule and the special rule, an individual may use the provisions described below to establish creditable coverage (and waiting and affiliation period information).

Information for Alternative Method of Counting Creditable Coverage. Following receipt of the certificate, an entity that uses the alternative method of counting creditable coverage may

request that the entity that issued the certificate disclose additional information in order for the requesting entity to determine the individual's creditable coverage with respect to any category of benefits described in paragraph (b). The requested entity may charge the requesting entity the reasonable cost of disclosing the information. The requesting entity may ask for a copy of the summary plan description (SPD) that applied to the individual's coverage or may ask for more specific information. Set forth below is a model form that may be used for specific coverage information about the categories of benefits:

Information on Categories of Benefits

1. Date of original certificate: _____
2. Name of group health plan providing the coverage: _____
3. Name of participant: _____
4. Identification number of participant: _____
5. Name of individual(s) to whom this information applies: _____
6. The following information applies to the coverage in the certificate that was provided to the individual(s) identified above:
 - a. Mental Health: _____
 - b. Substance Abuse Treatment: _____
 - c. Prescription Drugs: _____
 - d. Dental Care: _____
 - e. Vision Care: _____

For each category above, enter "N/A" if the individual had no coverage within the category and either (i) enter both the date that the individual's coverage within the category began and the date that the individual's coverage within the category ended (or indicate if continuing), or (ii) enter "same" on the line if the beginning and ending dates for coverage within the category are the same as the beginning and ending dates for the coverage in the certificate.

Demonstration of Coverage if Certificate is Not Provided. Under HIPAA, in order to prevent an individual from being adversely affected if the individual does not receive a certificate, the individual has a right to demonstrate creditable coverage through the presentation of documentation or other means. For example, an individual may not have a certificate because: an entity failed to provide a certificate within the required time period; an entity was not required to provide a certificate; the coverage of the individual was for a period before July 1, 1996; or, the individual has an urgent medical condition that necessitates an immediate determination of creditable coverage by the plan or issuer. Under these circumstances, an individual may present evidence of creditable coverage through documents, records, third party statements, or other means, including telephone calls by the plan or issuer to a third party provider. The plan administrator is required to take into

account all information presented in determining whether to offset any or all of a preexisting condition exclusion. A plan or issuer is required to treat the individual as having furnished a certificate provided by a plan or issuer 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 plan's or issuer's efforts to verify the individual's coverage.

If an individual needs to demonstrate his or her status as a dependent of a participant, the plan or issuer is required to treat the individual as having furnished a certificate if an attestation to such dependency and the period of such status is provided, and if the individual cooperates with the plan's or issuer's efforts to verify the dependent status.

Similar rules apply relating to determining creditable coverage under the alternative method.

Notice to Individual of Period of Preexisting Condition Exclusion. Within a reasonable time following the receipt of the certificate, information relating to the alternative method, or other evidence of coverage, a plan or issuer is required to make a determination regarding the length of any preexisting condition exclusion period that applies to the individual and notify the individual of its determination. Whether a determination and notification is made within a reasonable period of time depends upon the relevant facts and circumstances including whether the application of the preexisting condition exclusion period would prevent access to urgent medical services. The plan or issuer is required to notify the individual, however, only if, after considering the evidence, it has determined that a preexisting condition exclusion period will still be imposed on the individual. The basis of the determination, including the source and substance of any information on which the plan or issuer relied, must be included in the notification. The notification must also explain the plan's appeals procedures and the opportunity of the individual to present additional evidence.

The plan or issuer may reconsider and modify its initial determination if it determines that the individual did not have the claimed creditable coverage. In this circumstance, the plan or issuer must notify the individual of such reconsideration and, until a final determination is made, must act in accordance with its initial determination for purposes of approving medical services.

Model Certificate. The following model certificate has been authorized by the Secretary of each of the Departments. Use of the model certificate will satisfy the requirements of paragraph (a)(3)(ii) of the regulations.

Certificate of Group Health Plan Coverage

*** IMPORTANT**—This certificate provides evidence of your prior health coverage. You may need to furnish this certificate if you become eligible under a group health plan that excludes coverage for certain medical conditions that you have before you enroll. This certificate may need to be provided if medical advice, diagnosis, care, or treatment was recommended or received for the condition within the 6-month period prior to your enrollment in the new plan. If you become covered under another group health plan, check with the plan administrator to see if you need to provide this certificate. You may also need this certificate to buy, for yourself or your family, an insurance policy that does not exclude coverage for medical conditions that are present before you enroll.

1. Date of this certificate: _____
2. Name of group health plan: _____
3. Name of participant: _____
4. Identification number of participant: _____
5. Name of any dependents to whom this certificate applies: _____
6. Name, address, and telephone number of plan administrator or issuer responsible for providing this certificate: _____

7. For further information, call: _____
8. If the individual(s) identified in line 3 and line 5 has at least 18 months of creditable coverage (disregarding periods of coverage before a 63-day break), check here _____ and skip lines 9 and 10.
9. Date waiting period or affiliation period (if any) began: _____
10. Date coverage began: _____
11. Date coverage ended: _____ (or check if coverage is continuing as of the date of this certificate: _____).

Note: Separate certificates will be furnished if information is not identical for the participant and each beneficiary.

Special Enrollment Periods—26 CFR 54.9801-6, 29 CFR 2590.701-6, 45 CFR 146.117

This section of the regulations provides guidance regarding the new enrollment rights provided to employees and dependents under HIPAA. A group health plan and a health insurance issuer offering group health insurance coverage are required to provide for special enrollment periods during which individuals who previously declined coverage are allowed to enroll (without having to wait until the plan's next regular open enrollment period). A special enrollment period can occur if a person with other health coverage loses that coverage or if a person becomes a

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

A plan must provide a description of the special enrollment rights to anyone who declines coverage. The regulations provide a model of such a description.

A person who enrolls during a special enrollment period (even if the period also corresponds to a regular open enrollment period) is not treated as a late enrollee. (Accordingly, the plan or issuer may not impose a preexisting condition exclusion period longer than 12 months with respect to the person.)

Special Enrollment for Loss of Other Coverage. The special enrollment period for loss of other coverage is available to employees and their dependents who meet certain requirements. The employee or dependent must otherwise be eligible for coverage under the terms of the plan. When the coverage was previously declined, the employee or dependent must have been covered under another group health plan or must have had other health insurance coverage. The plan can require that, when coverage in the plan was previously declined, the employee must have declared in writing that the reason was other coverage, in which case the plan must at that time have provided notice of this requirement and the consequences of the employee's failure to provide the statement.

The special enrollment rights may apply with respect to an employee, a dependent of the employee, or both. An employee who has not previously enrolled can enroll under these rules if it is the employee who loses other coverage. An employee's dependent can be enrolled under these rules if it is the dependent who loses other coverage and the employee is already enrolled. In addition, both the employee and a dependent can be enrolled together under these rules if either the employee or the dependent loses other coverage.

If the other coverage is COBRA continuation coverage, the special enrollment can only be requested after exhausting COBRA continuation coverage. If the other coverage is not COBRA continuation coverage, special enrollment can only be requested after losing eligibility for the other coverage or after cessation of employer contributions for the other coverage. In each case, the employee has 30 days to request special enrollment. An individual does not have to elect COBRA continuation coverage or exercise similar continuation rights in order to preserve the right to special enrollment. However, an individual does not have a special enrollment right if the individual loses the other coverage as a result of the individual's

failure to pay premiums or for cause (such as making a fraudulent claim). Coverage under special enrollment must be effective no later than the first day of the month after an employee request the enrollment for himself or herself or on behalf of a dependent.

Special Enrollment for New Dependents. A special enrollment period also occurs if a person has a new dependent by birth, marriage, adoption, or placement for adoption. The election to enroll can be made within 30 days following the birth, marriage, adoption, or placement for adoption. In the case of a plan that does not offer any coverage for dependents and is then modified to offer dependent coverage, the election to enroll can instead be made during the 30 days beginning on the date dependent coverage is made available.

The special enrollment rules allow an eligible employee to enroll when he or she marries or has a new child (as a result of marriage, birth, adoption, or placement for adoption). A spouse of a participant can be enrolled separately at the time of marriage or when a child is born, adopted or placed for adoption. The spouse can be enrolled together with the employee when they marry or when a child is born, adopted, or placed for adoption. A child who becomes a dependent of a participant as a result of marriage, birth, adoption, or placement for adoption can be enrolled when the child becomes a dependent. Similarly, a child who becomes a dependent of an eligible employee as a result of marriage, birth, adoption, or placement for adoption can be enrolled if the employee enrolls at the same time.

In the case of a dependent special enrollment period, HIPAA provides that coverage with respect to a marriage is effective no later than the first day of the month after the date the request for enrollment is received and coverage with respect to a birth, adoption, or placement for adoption is effective on the date of the birth, adoption, or placement for adoption.

HMO Affiliation Period as Alternative to Preexisting Condition Exclusion—29 CFR 2590.701-7 and 45 CFR 146.119

This section of the regulations permits a group health plan offering health insurance through an HMO, or an HMO that offers health insurance coverage in connection with a group health plan, to impose an affiliation period, but only if certain other requirements are met. An "affiliation period" is defined in the regulations as a period of time that must expire before health insurance coverage provided by the HMO becomes

effective, and during which the HMO is not required to provide benefits.

The regulations specify the following requirements for imposing an affiliation period:

- No preexisting condition exclusion may be imposed with respect to coverage through the HMO;
- No premium may be charged to a participant or beneficiary for the affiliation period;
- The affiliation period must be applied uniformly without regard to any health status-related factors; and
- The affiliation period must begin on the enrollment date, cannot exceed two months (three months for a late enrollee), and must run concurrently with any waiting period under the plan. The regulations provide for the affiliation period to begin on the enrollment date in the plan, not when coverage with the HMO begins. Accordingly, if a plan offers multiple coverage options simultaneously, the HMO cannot impose an affiliation period on plan participants who change to the HMO option. Comments are requested on this rule.

The regulations permit an HMO to use alternatives in lieu of an affiliation period to address adverse selection, as approved by the State insurance commissioner or other official designated to regulate HMOs. Because an affiliation period may be imposed only if no preexisting condition exclusion is used, an alternative to an affiliation period may not encompass an arrangement that is in the nature of such an exclusion.¹³

While HMOs usually do not impose preexisting condition exclusions, they could choose to apply a preexisting condition exclusion period for all enrollees based on the alternative method of counting creditable coverage if the regulations were to add a category relating to deductibles. However, as described above under the heading "Alternative Method," the regulations currently do not include such a category.

Nondiscrimination in Eligibility and Premiums in the Group Market—26 CFR 54.9802-1, 29 CFR 2590.702, 45 CFR 146.121

The regulations include provisions implementing the nondiscrimination provisions in HIPAA. Comments are welcomed on these provisions, and, in particular, comments are requested on whether guidance is needed concerning:

- The extent to which the statute prohibits discrimination against individuals in eligibility for particular benefits;
- The extent to which the statute may permit benefit limitations based on the source of an injury;
- The permissible standards for defining groups of similarly situated individuals;
- Application of the prohibitions on discrimination between groups of similarly situated individuals; and
- The permissible standards for determining bona fide wellness programs.

The Departments intend to issue further regulations on the nondiscrimination rules in the near future. In no event will the period for good faith compliance (specified in HIPAA sections 102(c)(5), 101(g)(5), and 401(c)(5)) with respect to section 2702 of the PHS Act, section 702 of ERISA, and section 9802 of the Code end before the additional guidance is provided.

A plan or issuer may not establish rules for eligibility (including continued eligibility) of an individual to enroll under the terms of the plan based on a health status-related factor. HIPAA and the regulations provide a list of health status-related factors. The Departments are considering interpreting the statutory language relating to eligibility to enroll so that a plan or issuer would be prohibited from providing lower benefits to certain individuals based on health status-related factors. Comments are welcomed on this interpretation.

Among the health status-related factors listed in the statute is "evidence of insurability (including conditions arising out of acts of domestic violence)." The Conference Report states that the inclusion of evidence of insurability in the list of health status-related factors "is intended to ensure, among other things, that individuals are not excluded from health care coverage due to their participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing and other similar activities." However, HIPAA also provides that a plan or issuer is not required to provide particular benefits other than those provided under the terms of the plan. Moreover, HIPAA provides that a plan or issuer may establish limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan. Comments have been received indicating that some plans contain provisions that exclude coverage for benefits based on the source of injury (such as benefits for injuries sustained

¹³ These alternative that may be used in lieu of an affiliation period to address adverse selection should not be confused with the use of the alternative method for counting creditable coverage discussed in the next paragraph.

in a motorcycle accident, injuries sustained in a motorcycle accident as the result of not wearing a helmet, or injuries sustained in the commission of a felony). Accordingly, comments are requested on how future guidance should treat benefit limitations based on the source of an injury.

The Conference Report also states that "[t]he term 'similarly situated' means that a plan or coverage would be permitted to vary benefits available to different groups of employees, such as full-time versus part-time employees or employees in different geographic locations. In addition, a plan or coverage could have different benefit schedules for different collective bargaining units." Accordingly, comments are requested concerning the appropriate standards for determining "similarly situated individuals," including whether a plan is permitted to vary benefits based on an employee's occupation. Because these standards could impact on the small group market, the Department of Health and Human Services is particularly interested in receiving comments from States with respect to how varying benefits based on occupation could affect rate setting.

The Departments also request comments regarding how the prohibitions on discrimination should be applied between groups of similarly situated individuals. For example, is guidance needed on whether a plan covering employees in two different locations could have a longer waiting period for employees at one location because the health status of those employees results in higher health costs?

A plan or issuer may not require any individual (as a condition of enrollment or continued enrollment) to pay a premium or contribution, that is greater than that for a similarly situated individual enrolled in the plan, based on a health status-related factor. However, this limitation does not restrict the amount that an issuer can charge an employer for the coverage. In addition, this limitation does not prevent a plan or issuer from establishing premium discounts or rebates or otherwise modifying applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention (bona fide wellness programs). Comments are requested regarding the standards for determining bona fide wellness programs, including whether such a program may provide a discount for non-smokers.

Special Rules—Excepted Plans and Excepted Benefits—26 CFR 54.9804-1, 29 CFR 2590.732, 45 CFR 146.145

This section of the regulations provides special rules for certain plans and certain benefits.

Very Small Plans. The group market requirements of HIPAA do not apply to a group health plan, or to 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. However, a State may apply the group market provisions in the PHS Act to plans with fewer than two participants who are current employees. In this case, the State would apply its group market insurance law requirements to such small group plans (and such plans would not be subject to the individual market requirements).

Excepted Benefits. The group market provisions and the related regulations also do not apply to any group health plan or group health insurance issuer in relation to its provision of excepted benefits. The benefits identified in paragraph (b)(2) are generally not health insurance coverage and are excepted in all circumstances. In contrast, the benefits identified in paragraphs (b) (3), (4), and (5) are generally health insurance coverage but are excepted if certain conditions are met.

Limited-scope dental benefits, limited-scope vision benefits, and 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. For this purpose, limited-scope dental coverage typically provides benefits for non-medical services such as routine dental cleanings, x-rays, and other preventive procedures. Such coverage may also provide discounts on the cost of common dental procedures such as fillings, root canals, crowns, full or partial plates, or orthodontic services. Limited-scope dental coverage typically does not provide benefits for medical services, such as those procedures associated with oral cancer or with a mouth injury that results in broken, displaced, or lost teeth.

Similarly, limited-scope vision coverage provides benefits for routine eye examinations or the fitting of eyeglasses or contact lenses. This coverage does not include benefits for such ophthalmological services as treatment of an eye disease (e.g., glaucoma or a bacterial eye infection) or an eye injury.

Noncoordinated benefits may be excepted benefits. The term

"noncoordinated benefits" refers to coverage for a specified disease or illness (such as cancer-only coverage) or hospital indemnity or other fixed dollar indemnity insurance (such as insurance that pays \$100/day for a hospital stay as its only insurance benefit) if three conditions are met. First, the benefits are provided under a separate policy, certificate, or contract for insurance. Second, there is no coordination between the provision of these benefits and another exclusion of benefits under a plan maintained by the same plan sponsor. Third, benefits are paid without regard to whether benefits are provided with respect to the same event under a group health plan maintained by the same plan sponsor.

Certain supplemental benefits are excepted only if they are provided under a separate policy, certificate, or contract of insurance. This category of excepted benefits includes Medicare supplemental (commonly called "Medigap" or "MedSupp") policies, CHAMPUS supplements, and supplements to certain employer group health plans. Such supplemental coverage cannot duplicate primary coverage and must be specifically designed to fill gaps in primary coverage, coinsurance, or deductibles.¹⁴

The regulations do not address section 2721(e) of the PHS Act or section 705(d) of ERISA relating to the treatment of partnerships (or the application of the Code's group market rules to partnerships). Comments are requested on these provisions, including how these provisions coordinate with other provisions relating to self-employed individuals and partnerships.

F. Other Group Market Provisions¹⁵

Guaranteed Renewability in Multiemployer Plans and Multiple Employer Welfare Arrangements—Section 703 of ERISA and Section 9803 of the Code

Requirements relating to guaranteed renewability in multiemployer plans

¹⁴ Note that a group health plan, which provides primary coverage while an individual is an active employee, is often extended to retirees. When the retiree becomes eligible for Medicare, the group health plan commonly coordinates with Medicare and may serve a supplemental function similar to that of a Medigap policy. However, such employer-provided retiree "wrap around" benefits are not excepted benefits (because they are expressly excluded from the definition of a Medicare supplement policy in section 1882(g)(1) of the Social Security Act).

¹⁵ In this section ("Other Group Market Provisions"), references conform to usage in 45 CFR Part 146, which uses "HCFA" in place of "Department of Health and Human Services" or "Secretary of Health and Human Services" and

and multiple employer welfare arrangements are set forth in section 703 of ERISA and section 9803 of the Code (but not in the PHS Act). These provisions state that a group health plan that is a multiemployer plan or that is a multiple employer welfare arrangement may not deny an employer whose employees are covered under such a plan continued access to the same or different coverage under the terms of such plan, other than for certain specified reasons. The Departments are not issuing regulations under section 703 of ERISA or section 9803 of the Code at this time, but anticipate issuing regulations under these sections and solicit comments regarding these sections.

In these provisions, the terms "continued access" and "same or different coverage" are not defined. Comments are requested on how rules under these provisions might address variations and changes in a plan's benefit packages and contribution rates, differences in the characteristics of multiemployer plans and multiple employer welfare arrangements, and any possible implications for the financial integrity of affected plans.

Preemption of State Laws; State Flexibility—29 CFR 2590.731 and 45 CFR 146.190

The McCarran-Ferguson Act of 1945 (Pub. L. 79-15) exempts the business of insurance from federal antitrust regulation to the extent that it is regulated by the States and indicates that no federal law should be interpreted as overriding State insurance regulation unless it does so explicitly. Section 514(a) of ERISA preempts State laws relating to employee benefit plans (including group health plans). However, section 514(b)(2) of the ERISA saves from preemption any State law that regulates insurance. Section 2723 of the PHS Act and section 731 of ERISA make clear that Part A of Title XXVII of the PHS Act and Part 7 of Subtitle B of Title I of ERISA do not in any way affect or modify section 514 of ERISA.

In addition, section 2723 of the PHS Act and section 731(a) of ERISA preempt State insurance laws to the extent such laws "prevent the application of" Part A of Title XXVII of the PHS Act and Part 7 of Subtitle B of Title I of ERISA. (There is no corresponding provision in the Code.) In this regard, the Conference Report states that the conferees intended the narrowest preemption of State laws with

regard to health insurance issuers (not group health plans) with respect to all the provisions of Part A of Title XXVII of the PHS Act and Part 7 of Subtitle B of Title I of ERISA (except for preemption with respect to the provisions of section 2701 of the PHS Act and section 701 of ERISA.) Consequently, the Conference Report states that State laws with regard to health insurance issuers that are broader than federal requirements in certain areas would not "prevent the application of" the provisions of Part A of Title XXVII of the PHS Act or Part 7 of Subtitle B of Title I of ERISA.

However, the preemption is broader for the statutory requirements of section 2701 of the PHS Act and 701 of ERISA that limit the application of preexisting condition exclusions. State laws cannot "differ" from the preexisting condition exclusion requirements of section 2701 of the PHS Act or section 701 of ERISA, except as specifically permitted under section 2723(b)(2) of the PHS Act and section 731(b)(2) of ERISA. These specific exceptions permit a State to impose on health insurance issuers certain stricter limitations relating to preexisting condition exclusions.

Comments are also solicited on issues relating to the coordination of the new requirements under HIPAA and State requirements for associations that may be multiple employer welfare arrangements as defined in section 3(40) of ERISA.

Guaranteed Availability of Coverage for Small Employers Under the PHS Act Group Market Provisions—45 CFR 146.150

Rules relating to guaranteed availability of coverage for employers in the small group market appear only in the PHS Act (at section 2711). In general, this section requires health insurance issuers that offer coverage in the small group market to offer to any small employer all of the products they actively market in that market. This is generally referred to as an all-products guarantee. However, as allowed under applicable State law, the issuer can require that the employer make a minimum contribution toward the premium charged and have a minimum level of participation by eligible individuals. The issuer must also accept for enrollment every eligible individual without regard to health status. For purposes of this section, an eligible individual is one who meets the applicable requirements of the group health plan, the issuer, and State law for coverage under the plan.

Some States have, in recent years, made reforms in their small group

markets that only require guaranteed issue of a basic and a standard policy, rather than an all-products guarantee. They have urged that an all-products guarantee not be adopted, arguing that the law does not specifically require it. However, sections 2711 and 2741 of the PHS Act, as added by HIPAA, contain virtually identical requirements requiring issuers that offer health insurance coverage in either the small group or individual market to make "such coverage" available to, respectively, small employers or eligible individuals. While section 2741 explicitly permits issuers to limit to two policies the offerings they are required to make in the individual market, the small group market provisions contain no similar exception. In fact, section 2713(b)(1)(D) requires that an issuer that offers health insurance to any small employer must provide information concerning "the benefits and premiums available under *all* health insurance coverage for which the employer is qualified." (Emphasis added.) This indicates that Congress intended to require an all-products guarantee in the small group market. (However, a State that implements an "alternative mechanism" in the individual market under section 2744 of the PHS Act has the flexibility either to impose an all-products guarantee or to use a completely different mechanism for making insurance available to individuals guaranteed coverage under the statute.)

Various industry groups and persons responding to the notice that the three Departments published on December 30, 1996 asked that the term "offer" be interpreted to mean "actively marketed," so that issuers would not be required to reopen closed blocks of business. The regulations make this clear.

Section 2711 also requires issuers to accept for enrollment any individuals who are eligible to enroll under the terms of the plan, and who satisfy the requirements of the issuer and applicable State law, during the period in which the individual "first becomes eligible" to enroll under the terms of the group health plan. Thus, the issuer is not required to accept late enrollees. The regulations make it clear that this protection extends to individuals if they "first become eligible" to enroll during a special enrollment period. The special enrollment provisions of the statute evidence the intent that individuals who qualify for special enrollment be given the same protections given to newly-hired employees and their dependents.

"HCFA regulations" in place of "PHS Act regulations."

An issue has also been raised as to whether the statutory definitions of premium contributions and group participation rules, which are repeated in the regulations, related only to percentages of employees or premium dollars or to absolute numbers of employees or premium amounts. If the latter interpretation were permitted, the effect would be to undermine the all-products guarantee by allowing, for example, some products to be available to "larger" small employers, but not to the smallest employers. The regulations currently leave interpretation of this language to the States, but comments are welcomed on this issue.

Section 146.150 also includes rules regarding the circumstances under which issuers are permitted to deny coverage to employers. If the product is a network plan, under which services are furnished by a defined set of providers, the issuer can deny coverage to an employer whose eligible individuals do not live, work, or reside in the network plan's service area. It can also deny coverage if it has demonstrated to the State that its network does not have the capacity to deliver services to additional groups, but is then barred for 180 days from offering coverage in that service area. An issuer may also deny coverage if it demonstrates that it lacks sufficient financial reserves to underwrite additional coverage, but is barred for 180 days from offering coverage in the small group market in the State. Both of these exceptions must be applied to all employers uniformly without consideration of the health status or claims experience of an employer's employees or dependents. Neither of these exceptions relieves a network plan of its responsibility to continue servicing its in-force business under the guaranteed renewability requirements of the regulations.

Finally, § 146.150 provides that if the coverage is only made available to members of "bona fide associations" as that term is defined in the regulations, it is not subject to the guaranteed availability requirements. (Accordingly, the coverage does not have to be offered to non-members.) However, employers that obtain coverage through a bona fide association are assured of guaranteed access to the association's coverage options as long as they remain members of the association. This is because a bona fide association cannot condition membership in the association on health status-related factors. Moreover, it must offer coverage to all employers who are members without regard to health status-related factors relating to their employees or dependents. Therefore, an

association cannot legally refuse enrollment to members on a selective basis so long as they meet the association's membership criteria.

Guaranteed Renewability of Coverage for Employers Under the PHS Act Group Market Provisions—45 CFR 146.152

Section 146.152 of the Health Care Financing Administration (HCFA) regulations implements section 2712 of the PHS Act, which requires issuers to renew or continue in force any coverage in the large or small group market at the option of the plan sponsor. The exceptions to this requirement include nonpayment of premiums, fraud, and violation of minimum participation or contribution rules, as permitted under applicable State law. Also, the issuer can cease to offer either a particular product or all coverage it offers in the particular market, and can refuse to renew if the group health plan's participants all leave the service area of a network plan, or if the coverage is provided through a bona fide association and the employer's membership ends.

Issuers that decide to discontinue offering a particular product or all coverage in the small or large group market are subject to certain requirements outlined in paragraphs (c) and (d) of this section of the regulations. Issuers discontinuing only a particular product must give 90 days' notice, must offer the plan sponsor the option to purchase other coverage the issuer offers in that market, and must discontinue the product uniformly, without regard to claims experience or health status of participants or dependents under a particular group health plan. If the issuer terminates all coverage in a market or markets, it must provide 180 days' notice to each plan sponsor, and it is prohibited from issuing coverage in the market(s) or State involved for five years following the date of discontinuation. Plans or issuers may modify the health insurance coverage at the time of coverage renewal, provided the modification is consistent with State law and, for the small group market, is effective uniformly among group health plans with coverage under that product.

Some States have asked whether an issuer that chooses to stop selling comprehensive products, such as a basic or standard policy, in a particular State's group market, must also cease selling policies consisting of excepted benefits. Because Congress permitted these types of supplemental policies and limited benefit plans to be excepted from the requirements of HIPAA in both the group and individual markets, HCFA intends to defer to the States'

judgment on this issue, and solicit comments.

State law may limit the extent to which an issuer can abandon a product or market, and under what circumstances. For example, a State may choose to require an issuer vacating the market to transfer its business to another issuer through assumption reinsurance, or some other means permitted under State law.

Paragraph (g) of this section of the regulations provides that, with respect to group coverage offered only through associations, the option of guaranteed renewability extends to include employer members of an association. This provision means that all employers covered by an issuer through an association have the right to renew the coverage they received if the association ceases to serve its members, regardless of the reason.

Disclosure of Information by Issuers to Employers Seeking Coverage in the Small Group Market—45 CFR 146.160

Section 146.160 of the HCFA regulations implements section 2713 of the PHS Act by setting forth rules relating to disclosure of information by issuers to employers seeking coverage in the small group market. In its solicitation and sales materials, the issuer must make a reasonable disclosure that the specified information is available on request. The information that must be provided includes the issuer's right to change premium rates and the factors that may affect changes in premium rates, renewability of coverage, any preexisting condition exclusion (including use of the alternative method of counting creditable coverage), any affiliation periods applied by HMOs, the geographic areas served by HMOs, and the benefits and premiums available under all health insurance coverage for which the employer is qualified under minimum contribution and participation rules, as permitted by State law. The issuer is exempted from disclosing proprietary or trade secret information under applicable law.

"Factors that may affect changes in premium rates" and "proprietary and trade secret information under applicable law" have not been defined. Comments are requested regarding whether they should be defined.

The information described in this section must be provided in language that is understandable by the average small employer and sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage. This requirement can be satisfied by using as

a model the outlines of coverage provided under Medicare Supplement insurance. (These outlines are required to provide easy comparison of the coverage and cost of all available products.) Reasonable information includes rating schedules for each product to which more than one rate applies, and, with respect to network plans, maps of service areas or lists of counties served.

Exclusion of Certain Plans From the PHS Act Group Market Requirements—45 CFR 146.180

Section 146.180 of the HCFA regulations implements section 2721 of the PHS Act, which permits certain nonfederal governmental plans to elect to be exempted from some or all of the group market requirements of the HCFA regulations, although they are subject to the certification and disclosure requirements of § 146.115. With respect to nonfederal governmental plans that are collectively bargained, this section does not preempt State and local collective bargaining laws. The regulation establishes the form and manner of the election, and requires a nonfederal governmental plan making this election to notify plan participants, at the time of enrollment and on an annual basis, that it has made the election and what effect the election has. The participant notice and certification and disclosure obligations are integral parts of the election. Failure to comply with these obligations invalidates an election and subjects the nonfederal governmental plan to the requirements the election would have permitted the plan to avoid.

Only nonfederal governmental plans that are self-funded (in whole or in part) can make the election, and the election only applies to the self-funded portion. A health insurance issuer that sells insurance coverage to a nonfederal plan must comply with all the group market requirements.

Enforcement of PHS Act Requirements—45 CFR 146.184

Part 146 imposes requirements on health insurance issuers that offer coverage in the group market in a State, and on nonfederal governmental (i.e., State and local) group health plans. With respect to issuers, the statute makes it clear that it is solely within the discretion of the States, in the first instance, whether to take on the responsibility for enforcing those requirements or whether to leave enforcement to the federal government. HCFA anticipates that the States will choose to enforce the requirements. However, the statute also makes clear

that if a State does not substantially enforce the requirements, HCFA must enforce them. The statute also requires HCFA to enforce the requirements applicable to nonfederal governmental plans.

Section 146.184(b)(2) sets forth the procedures that HCFA will follow if a question is raised about the State's enforcement with respect to issuers. Under the procedures, States are given every opportunity to demonstrate why federal enforcement is not required. The regulations also make it clear that the procedures will not be triggered unless HCFA is satisfied that there has first been a reasonable effort to exhaust any State remedies. However, if, after giving the State a reasonable opportunity to enforce, HCFA makes a final determination that a State is not substantially enforcing these requirements, HCFA will enforce the requirements using the civil money penalties provided for under the statute.

Paragraph (d) describes the process for imposing civil money penalties against issuers or nonfederal plans that fail to comply with the group market requirements in the PHS Act. If HCFA receives a complaint or other information that indicates that a right guaranteed by the group market rules is being denied, HCFA will first determine which entity is potentially responsible for any penalty. If the failure is by an issuer, the issuer will be responsible. If a nonfederal governmental plan is sponsored by a single employer, the employer will be liable, but if the plan is sponsored by two or more employers, the plan will be liable. If, after giving the entity or entities an opportunity to respond, HCFA assesses a penalty, the regulation provides appeal rights. The penalty can consist of up to \$100 for each day, for each individual whose rights are violated.

Effective Dates—26 CFR 54.9806-1, 29 CFR 2590.736, 45 CFR 146.125

The group market provisions are generally effective for plan years beginning after June 30, 1997.¹⁶ In many cases, no preexisting condition exclusion may be imposed with respect to an individual on the effective date because any permitted preexisting condition exclusion period is measured

¹⁶ 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, the group market provision (other than the requirements to provide certifications) 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 agreed to after August 21, 1996).

from the individual's enrollment date in the plan (even if the enrollment date is before the statutory effective date). An individual who has not completed the maximum permitted exclusion period under HIPAA before the effective date for his or her plan may use creditable coverage to reduce the remaining preexisting condition exclusion period. The regulations contain examples illustrating the effect of these rules.

The requirement that a plan or issuer provide certificates to show creditable coverage applies to events occurring on or after July 1, 1996, except that in no case is a certificate required to be provided before June 1, 1997 or to reflect coverage before July 1, 1996.

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. 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, if later, any date that would otherwise apply under the standard rules).

The regulations include an optional transition rule for events before June 1, 1997. (The transition rule applies to automatic certificate events; it does not apply where a certificate is requested.) A group health plan or health insurance issuer offering group health coverage is deemed to satisfy the automatic certificate requirements if a special notice is provided no later than June 1, 1997. The notice must be in writing and must include information substantially similar to the information included in a model notice authorized by the Secretaries. For this purpose, the following model notice is authorized:

IMPORTANT NOTICE OF YOUR RIGHT TO DOCUMENTATION OF HEALTH COVERAGE

Recent changes in Federal law may affect your health coverage if you are enrolled or become eligible to enroll in health coverage that excludes coverage for preexisting medical conditions.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) limits the circumstances under which coverage may be excluded for medical conditions present before you enroll. Under the law, a preexisting condition exclusion generally may not be imposed for more than 12 months (18 months for a late enrollee). The 12-month (or 18-month) exclusion period is reduced by your prior health coverage. You are entitled to a certificate that will show evidence of your prior health coverage. If you buy health insurance other than through an employer group health plan, a certificate of prior coverage may help you obtain coverage without a preexisting condition exclusion. Contact your State insurance department for further information.

For employer group health plans, these changes generally take effect at the beginning of the first plan year starting after June 30, 1997. For example, if your employer's plan year begins on January 1, 1998, the plan is not required to give you credit for your prior coverage until January 1, 1998.

You have the right to receive a certificate or prior health coverage since July 1, 1996. You may need to provide other documentation for earlier periods of health care coverage. Check with your new plan administrator to see if your new plan excludes coverage for preexisting conditions and if you need to provide a certificate or other documentation of your previous coverage.

To get a certificate, complete the attached form and return it to:

[Insert Name of Entity:]

[Insert Address:]

For additional information contact: [Insert Telephone Number]

The certificate must be provided to you promptly. Keep a copy of this completed form. You may also request certificates for any of your dependents (including your spouse) who were enrolled under your health coverage.

REQUEST FOR CERTIFICATE OF HEALTH COVERAGE

Name of Participant: _____

Date: _____

Address: _____

Telephone Number: _____

Name and relationship of any dependents for whom certificates are requested (and their address if different from above): _____

The provisions in the regulations relating to method of delivery and entities required to provide a certificate apply with respect to the provision of the notice. 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 the regulations relating to certificates provided upon request.

HIPAA provides that no enforcement action is to be taken against a group health plan or health insurance issuer with respect to a violation of the group market rules before January 1, 1998 if the plan or issuer has sought to comply in good faith with such requirements. Compliance with the regulations is deemed to be good faith compliance with the group market rules.

G. Interim Rules and Request for Comments

Section 707 of ERISA (redesignated as section 734 by section 603(a)(3) of the NMHPA), Section 2707 of the PHS Act, and Section 9806 of the Code added by HIPAA, provide, in part, that the Secretaries of Labor, Treasury and HHS may promulgate any interim final rules

as they determine are appropriate to carry out the portability provisions of HIPAA.

Under Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when the agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary or contrary to the public interest.

These rules are being adopted on an interim basis because the Secretaries have determined that without prompt guidance, some members of the regulated community will have difficulty complying with the HIPAA's certification requirements, and will be in violation of the statute. Congress expressly intended that the certification and prior creditable coverage provisions serve as the mechanism for increasing the portability of health coverage for plan participants and their beneficiaries. Without the Departments' guidance, plans would likely be unable to produce the necessary amendments to plan documents reflecting HIPAA's new requirements, as well as the appropriate certifications of prior coverage that would help participants and beneficiaries reduce any applicable preexisting condition exclusion periods imposed by a new health plan. Thus, without the Departments' prompt guidance, participants and beneficiaries will not have the benefit of a convenient certificate of prior coverage to present upon changing health coverage, and will likely have greater difficulty proving that they are entitled to health coverage immediately, or soon after joining a new health plan.

Moreover, HIPAA's portability requirements will affect the regulated community in the immediate future. HIPAA's certification requirements are effective for all group health plans on June 1, 1997. HIPAA's underlying requirements concerning establishing periods of prior creditable coverage, pre-existing condition exclusion provisions, and the special enrollment requirements, are generally applicable for group health plans for plan years beginning on or after July 1, 1997. Plan administrators and sponsors, and participants and beneficiaries will need guidance on how to comply with the new statutory provisions before these effective dates. These rules have been written in order to ensure that plan sponsors and administrators of group health plans, as well as participants and beneficiaries, are provided timely guidance concerning compliance with these recently enacted amendments to ERISA, the PHS Act and the Code. These rules provide guidance on these

statutory changes, and are being adopted on an interim basis because the Departments find that issuance of such regulations in interim final form with a request for comments is appropriate to carry out the new regulatory structure imposed by HIPAA on group health plans and health insurance issuers. In addition, these rules are necessary to ensure that plan sponsors and administrators of group health plans, as well as participants and beneficiaries, are provided timely guidance concerning compliance with new and important disclosure obligations imposed by HIPAA.

Sections 101(g)(4), 102(c)(4), and 401(c)(4) of HIPAA also mandate that the Secretaries issue regulations necessary to carry out the portability amendments by April 1, 1997. Issuance of a notice of proposed rule making with public comment thereon prior to issuing a final rule could delay significantly the issuance of essential guidance and prevent the Departments from complying with their statutory rule making deadline. Furthermore, these rules are being adopted on an interim basis and the Departments are inviting interested persons to submit written comments on the rules for consideration in the development of the final rules relating to HIPAA. Such final rules may be issued in advance of January 1, 1998, after affording the public an opportunity to review and comment.

For the foregoing reasons, the Departments find that the publication of a proposed regulation, for the purpose of notice and public comment thereon, would be impracticable, unnecessary, and contrary to the public interest.

H. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to rules which would have significant economic impact on a substantial number of small entities. Section 603 of the RFA requires an agency publishing a general notice of proposed rulemaking (NPRM) under section 553 of the APA to present at the time of the publication of its NPRM an initial regulatory flexibility analysis, describing the impact of the rule on small entities, and seeking public comment on such impact.

Small entities include small business, non-profit organizations, and governmental agencies. A "rule" under the Regulatory Flexibility Act is one for which a general notice of proposed rulemaking is required under section 553(b) of the APA.

Since these rules are issued as interim rules, and not as a general notice of

proposed rulemaking, for the reasons stated above, an Initial Regulatory Flexibility analysis has not been prepared.

While these rules are being promulgated as interim final rules, the Departments nevertheless invite interested persons to submit comments for consideration in the development of the final rules regulating to HIPAA. Consistent with the policy of the Regulatory Flexibility Act, the public is encouraged to submit comments that suggest alternative rules that accomplish the stated purpose of the statute and minimize the impact on small entities. Specifically, the public is encouraged to address:

- What information relating to prior coverage, preexisting condition exclusion, health status, waiting periods and similar issues do employers, plans and issuers currently rely on in maintaining health care coverage systems?
- What are the estimated costs of complying with the statute's requirements on certification of periods of prior creditable coverage?
- How many small issuers offer products that may be subject to the regulations? Is there an anticipated effect on these small companies' competitiveness due to the regulations?
- To what extent do group health plans currently use service providers to fulfill the administrative obligations, including reporting and disclosure, previously imposed by ERISA? To what extent would group health plans also use service providers to comply with this regulation's certification requirements?

I. Executive Order 12866, the Unfunded Mandates Reform Act and the Small Business Regulatory Enforcement Fairness Act of 1995

These rules have been determined to be a significant regulatory action under Section 3(f) of Executive Order 12866. The following analysis is consistent with Section 6(a)(3)(C) of the Order.

These rules are not subject to the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), because they are interim final rules. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, the regulation has been designed to be the least burdensome alternative for state, local and tribal governments and the private sector, while achieving the objectives of HIPAA. In addition, the following analysis provides information concerning the effects of the regulation on state, local, and tribal governments and the private sector.

Throughout the regulatory process, HHS met and consulted with representatives of affected state, local and tribal governments. These groups include the National Association of Insurance Commissioners, the National Governors' Association, the National Council for State Legislatures, the Indian Health Service, and the American Public Welfare Association. HHS also provided technical advice regarding its interpretation of the statute to state insurance commissioners and state legislatures at their request. Generally, these groups have concerns regarding:

- The statute's preemption of state laws that would prevent the implementation of statutory provisions;
- The burden on issuers and plans to implement the statutory provisions, especially with regard to certification of prior creditable coverage; and
- State's desires to have considerable flexibility in complying with the statute, and continuing their traditional role as regulators of insurance.

After serious consideration of these concerns, HHS narrowly interpreted the preemption of state law, taking the least burdensome alternatives provided states considerable flexibility in complying with the statute, and recognized the limited authority of federal agencies in the regulation of health insurance.

The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this is a major rule for purposes of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. Section 801 *et seq.*).

Set forth below is a discussion regarding the impact of the statute and a discussion of the costs and benefits of the regulations implementing the statute.

J. Extensions of Coverage Under the Statute

These regulations implement certain provisions of HIPAA. The statute was enacted to, among other things, "improve portability and continuity of health care coverage in the group and individual markets," as stated in the Conference Report. The statute accomplishes these goals by instituting reforms in the group and individual insurance markets, including provisions limiting the use of pre-existing condition exclusions, and requiring guaranteed access to health care coverage and guaranteed renewability for certain groups and individuals. There are also non-discrimination provisions and special enrollment rights in the statute.

The pre-existing condition exclusion periods that HIPAA restricts are widespread. According to the Bureau of Labor Statistics (BLS), 46 percent of participants in private-sector, employer-sponsored health plans are in plans with pre-existing condition exclusions (1993-1994 data). The same is true of 41 percent of participants in state and local government employer-sponsored plans (1994 data.)

The duration of exclusion periods varies from plan to plan. Based on Peat Marwick's 1995 employer survey, an estimated 57 percent of participants in plans with exclusions are in plans with exclusions that last 12 months. The remainder are distributed as follows: 13 percent in plans with 3-month exclusions, 22 percent in plans with 6-month exclusions, 7 percent in plans with 9-month exclusions, and 1 percent in plans with exclusions that last more than 12 months.

HIPAA's portability provisions resemble provisions of many current state laws. Importantly, however, HIPAA extends these provisions of self-insured ERISA plans which federal law shields from state regulation. In addition, it sets a minimum uniform threshold for insured group plans and individual markets across all states.

HIPAA's portability provisions will result in both direct and social costs and benefits.

In general, direct costs and benefits arise directly from the application of HIPAA's insurance portability and access provisions. Direct costs and benefits are often best understood as transfers of resources among economic agents, which do not necessarily represent changes in overall social welfare. Stated differently, they represent changes in how the economic pie is divided (in this case, mainly with respect to health care), and not changes in the size of the pie. Direct costs and benefits are often easier to quantify than social costs, as they are often directly observable as transactions in the marketplace.

With respect to HIPAA's portability and access provisions, direct costs and benefits arise from the extension of insurance coverage to individuals and conditions not otherwise covered. Direct benefits to individuals include the payment of individuals' claims for those services and conditions. Direct costs of individuals include the premiums associated with that coverage. Some available estimates of these direct costs and benefits are presented below.

Social costs and benefits, in contrast, do result in net changes in overall social welfare. Social benefits generally reflect social welfare gains that arise in

connection with statutory or regulatory interventions that remedy market failure. Likewise, social costs generally reflect welfare losses arising from interventions in otherwise efficient markets. Social welfare changes often play out through a complex set of behavioral responses to interventions. They are more difficult to quantify than direct costs and benefits.

With respect to HIPAA, social welfare changes generally arise indirectly from HIPAA's portability and access provisions. They reflect dynamic behavioral responses to HIPAA's portability and access provisions. Expected social benefits, primarily improved access to health insurance and also improved job mobility, cannot be meaningfully quantified. Expected social costs, which could include erosions in coverage arising from direct premium costs, are expected to be small. Since no measures of HIPAA's many social welfare effects are available, a mostly qualitative discussion of major effects is offered below. A more quantitative discussion of direct costs and benefits follows later.

1. Social Welfare Effects of HIPAA's Portability and Access Provisions

The primary direct benefits of the law are improved access to insurance coverage, and more comprehensive coverage, through employers and in the individual insurance market. Increased access and comprehensiveness helps protect individuals from catastrophic expenses.

There are a number of social benefits associated with improved access:

- It reduces individual's risk of incurring large out-of-pocket costs;
- It is often more cost effective to provide timely preventive and remedial care than to delay care until conditions worsen. Therefore, to the extent that individuals receive more timely and appropriate care as a result of HIPAA, over time, the long-term, cumulative cost of their care may be lower. This has the potential to reduce premiums for all individuals within a risk pool, not just the individuals directly affected by HIPAA. Similarly, the Medicare program may benefit from reduced expenditures because more individuals who become newly entitled to Medicare will have had insurance coverage during the course of their working life or through the individual insurance market.

- To the extent that more timely care results in improved health, worker attendance and productivity might improve.

- HIPAA's portability provisions likewise help individuals transitioning

from state and federal welfare programs to paid work. Individuals with health conditions can offset their new health plan's preexisting condition exclusions against prior coverage from any source, including Medicaid.

- Reductions in job benefit both individuals and the economy at large. Increased mobility can boost individual workers' career opportunities. Increased mobility also strengthens U.S. economic efficiency and competitiveness;

- HIPAA's federal minimum standards for small group and individual access to insurance coverage may improve the functioning of small group and individual markets. The standards will alleviate disruptions that might otherwise arise when "riskier" groups and individuals are denied or dropped from coverage.

- To the extent that HIPAA results, on net, in more insurance payment for otherwise uncompensated care, cost-shifting and associated inefficiencies in health care markets could be reduced.

HIPAA's group-to-individual portability provisions may provide a benefit for employees who move to jobs without health coverage. Some small employers that do not currently offer health care coverage may be able to do so more easily under HIPAA's guaranteed issue provisions. This may help level the playing for small employers to compete with larger ones in recruiting employees. While premium increases resulting from HIPAA may reduce the affordability of coverage for some employers, this effect is expected to be small, as noted below.

HIPAA also requires that issuers offering health insurance coverage in the individual market renew coverage for all individuals purchasing health insurance coverage in the individual market, not only eligible individuals. However, when an eligible individual elects family coverage, the issuer may apply a pre-existing condition exclusion, under applicable State law, to any of the individual's family members who are not eligible individuals under the statute.

The group-to-group portability regulation is likely to benefit individuals who maintain employer-sponsored health benefit coverage and change jobs or health plans, the dependents of such individuals, and workers who face "job lock" due to health coverage concerns.

Under HIPAA, health insurance coverage provided under a COBRA continuation policy qualifies as group health coverage. This distinction is particularly important for individuals moving from the group to the individual market, or from one group health plan

to another, since electing this coverage would enable these individuals to maintain continuous creditable coverage. In addition, individuals seeking coverage in the individual market must elect and exhaust COBRA continuation coverage in order to qualify as an "eligible individual" in the individual market.

Thus, the statute provide an additional incentive for those individuals who lose coverage when they change jobs to elect COBRA continuation coverage in order to avoid a break in coverage. The statute also provides an incentive for those individuals who are seeking coverage in the individual market without a preexisting condition exclusion. Consequently, we expect more individuals to elect COBRA continuation coverage.

Absent HIPAA's group-to-group portability standards, individuals with employer-sponsored health coverage who have preexisting medical conditions and who change health plans could be denied coverage for their conditions. In that case, individuals would have to pay out of pocket for necessary medical services, or forgo some services, thereby risking adverse health consequences and higher future costs. Other individuals with preexisting medical conditions who change health plans and face preexisting condition exclusions may pay for COBRA continuation coverage in addition to paying for their new health plan to ensure coverage for the preexisting condition. Other workers who are concerned about losing health care coverage would stay in their jobs or turn down job offers.

According to the U.S. General Accounting Office, over 20 million individuals changed jobs in 1993 (General Accounting Office, Report HEHS-95-257, "Health Insurance Portability: Reform Could Ensure Continued Coverage for up to 25 Million Americans," September 1995, pg. 7). Approximately 12 million of these workers had employer-sponsored health care coverage. Additionally, nearly 7 million non-working dependents received employer-sponsored health care coverage through these job changers. According to GAO, many of these 20 million could benefit from the regulation's requirement that prior health care coverage be credited against a new health plan's preexisting condition exclusion period. GAO concludes that the statute will allow approximately 9 million job changers (who have at least 12 months of prior creditable coverage), with 5 million dependents, to change jobs without the

risk of facing any preexisting condition exclusions. Another 3 million workers who change jobs (who have some smaller amount of prior coverage), with 2 million dependents, would face reduced waiting periods before receiving full coverage.

The number of workers and dependents actually gaining coverage for a preexisting condition due to credit for prior coverage following a job change under HIPAA will be smaller than this, however. GAO's estimates of people who could benefit include all job changers with prior coverage and their dependents, irrespective of whether their new employer offers a plan, whether their new plan imposed a preexisting condition exclusion period, and whether they actually suffer from a preexisting condition. Accounting for these narrower criteria, as discussed below, CBO estimates that 100,000 will actually receive additional coverage under HIPAA's credit for prior coverage at any point in time.

In addition, employers, especially smaller employers, that offer health care benefits to their employees often change health insurance issuers, exposing workers or their dependents with preexisting medical conditions to gaps in coverage. Small employers generally change insurance issuers every 3 to 4 years (Senate Committee on Labor and Human Resources, Report 104-156, Oct. 12, 1995, pg. 4). The provisions of the statute that allow crediting of prior coverage should reduce the likelihood of gaps in coverage.

One of the benefits of HIPAA to individuals is that it alleviates "job lock." That is, employees who have stayed in a particular job in order to continue health care coverage can now change to a job that the person might not otherwise have taken because he or she (or a dependent) would have been subject to a pre-existing condition exclusion; or the person can seek coverage in the individual insurance market as a result of HIPAA's provisions requiring guaranteed issue for individuals coming from the group market. According to the GAO, there are one to four million Americans "who at some time have been unwilling to leave their jobs because of concerns about losing their health care coverage" (*Health Insurance Portability: Reform Could Ensure Continued Coverage for Up to 25 Million Americans*, HEHS-95-257, September 1995). The GAO notes that "surveys have found that between 11 and 30 percent of individuals report that they or a family member have remained in a job at some time because they did not want to lose health care coverage." Among those individuals,

twenty percent stated that pre-existing conditions exclusions constituted the basis for their reluctance to change jobs.

These figures, reflecting individuals stated intentions, may not accurately predict their behavior under different circumstances, however. Moreover, HIPAA's portability provisions will alleviate only some causes of "job lock"—for example, employees might still be somewhat impeded from taking jobs where no coverage is offered. Eligible individuals might benefit in this case from HIPAA's group-to-individual portability provisions, but would have to pay the premium themselves. Therefore, many individuals who report job lock will not necessarily change jobs as a result of HIPAA.

There also appears to be a difference by age categories of the extent of job lock. The Health and Retirement Study (HRS), conducted by the University of Michigan's Institute for Social Research, which provides an emerging portrait of Americans age 51 through 61 and their spouses, found that job flexibility is a key issue for this age group. "Almost three-quarters of HRS respondents would prefer to phase down from full-time work to part-time work when they retire, in sharp contrast to actual behavior, where most people who retire leave the workforce entirely. About one-third of the people who would not look for another job are victims of 'job lock,' unable to leave because they might give up valuable pensions or health insurance benefits if they switched employers" (HRS National Institute on Aging Press Release, June 17, 1993).

Empirical evidence for job lock is mixed. Buchmueller and Valletta found strong evidence of job lock among women but weak evidence among men ("The Effects of Employer-provided Health Insurance on Worker Mobility," *Industrial and Labor Relations Review*, volume 49, number 3, April 1996). Monheit and Cooper conclude that the magnitude and importance of job lock, which some studies report as causing a 20 to 40 percent reduction in mobility, is not as great as generally thought ("Health Insurance and Job Mobility: Theory and Evidence," *Industrial and Labor Relations Review*, volume 48, number 1, October 1994). Kapur found that job lock does not have a significant effect on job mobility ("The Impact of Pre-existing Health Conditions on Job Mobility: A Measure of Job Lock," WP-95-25, Institute for Policy Research), while Gruber and Madrian found that COBRA continuation provisions, and similar state laws (allowing individuals to continue coverage through their employer group health plan for a specified period), have led to a

significant increase in job mobility ("Health Insurance and Job Mobility: the Effects of Public Policy on Job-lock," *Industrial and Labor Relations Review*, volume 48, number 1, October 1994).

CBO does not quantify potential relief from "job lock," which is a social, rather than a direct, benefit of HIPAA. Because people freed from job lock are going from one type of insurance to another (moving to a different group health plan or to an individual insurance policy under HIPAA portability), CBO also views freedom from job lock as consisting of "insured expenses * * * transferred among different insurers * * * [that] * * * are not * * * direct costs."

The majority of evidence indicates that job lock is a concern for many workers. HIPAA will address this concern, though the number of workers who will gain an advantage is unclear and how the value of the benefit can be measured is also unclear.

As the forgoing discussion illustrates, HIPAA's social benefits are expected to be far ranging, but they cannot be meaningfully quantified.

HIPAA might also pose social costs. In particular, increases in premiums under HIPAA's portability and access provisions could erode coverage. These costs are expected to be small, however, particularly in the group market where premium increases are estimated to be very small relative to the overall market.

In summary, HIPAA's portability and access provisions are expected to result in a number of largely unquantifiable social benefits. These include greater continuity of coverage, improved access to health care and possible corollary improvements in health and productivity, improved stability and efficiency in insurance health care markets, eased movement from public assistance to work, and gains in job mobility that are favorable to individual careers and to U.S. competitiveness.

2. Direct Costs and Benefits of HIPAA's Portability and Access Provisions

HIPAA's portability and access provisions impose direct costs and provide direct benefits to a broad range of entities, as well as to individual citizens. Costs will be incurred by employers, group plans, insurance companies and managed care plans ("issuers"); states, in their capacity as regulators, and states and localities as entities providing health care coverage for their employees, retirees and dependents; the federal government as regulator and as the source of health care coverage for employees, annuitants and dependents, and for others through programs such as Medicaid and

Medicare. Benefits will accrue to individuals and to small employers whose access to comprehensive insurance is improved.

A number of studies have evaluated the direct economic impact of the law. The CBO found that "to the extent that states have not already implemented similar rules, these changes would clarify the insurance situation and possibly reduce gaps in coverage for many people."

The CBO notes that because HIPAA does not impose limits on premiums issuers may charge, insurance coverage, though available, may be expensive. Consequently, CBO observes that the law would "make insurance more

portable for some people, [but] it would not dramatically increase the availability of insurance in general."

The controversial question of the extent to which there will be increases in issuer premiums is discussed more extensively below.

CBO prepared estimates of the direct effects of the provisions of the legislation included in these regulations (Letter to the Honorable Bill Archer, August 1, 1996; notes are also from earlier CBO cost estimates; see table below). The direct cost estimates can reasonably be read as representing direct benefits as well, since they generally reflect transfers from a pre-HIPAA payer to a post-HIPAA payer.

Certain medical expenses that individuals would pay out of pocket absent HIPAA will be paid by insurance programs under HIPAA. In CBO's estimates, this is reflected as a similar transfer in responsibility for payment from individuals to insurance programs. However, the actual transfer would be more complex. For example, to pay the additional claims, insurers must collect additional premiums, which in turn will be paid by the individuals gaining greater coverage and (in most cases) by other covered individuals, or by their employers. CBO's estimates represent gross costs to plans and gross benefits to individuals, and do not account for these complexities.

CBO COST ESTIMATES AND NUMBER OF PEOPLE AFFECTED

Provision	Yearly cost (direct cost to private sector)	Number of people affected	Other effects; comments
Group: Limiting Length of Pre-Existing Condition Exclusions to 12 Months.	\$50 million in first year (1997); \$200 million per year in subsequent years.	300,000 people "would gain coverage" at any point in time, or 0.3% of people with private employment-based coverage.	Assumes "surge" in claims costs; state laws taken into account.
Group: Creditable Coverage Reducing Pre-Ex.	\$25 million in first year; \$100 million per year thereafter.	100,000 people "would receive added coverage" at any point in time.	Small No. of people affected reflects "restrictive eligibility criteria".
Group: Above two combined	\$300 million	Comments: about .2% of total premiums in group and employer-sponsored market; but may be overstated because HMOs, now the dominant option, often do not use pre-ex exclusions.	
Individual (group-to-individual portability, no pre-existing condition exclusion, no denial because of health condition, guaranteed renewal). First year estimates.	\$50 million	45,000 people covered by end of first year.	Provisions would apply in states that currently have 5.4 million of estimated 13.4 million people in indiv. market (but see analyses below).
Individual: Subsequent years	\$200 million by fifth year	"In about four years, the number of people covered; would plateau at around 150,000".	Level of premiums to be charged is unknown; states may limit allowable premiums, but such limits may impose indirect costs.

Virtually all of the insurance market reform provisions of HIPAA that are implemented through these regulations have the potential to increase premiums in the group market. Group plans may have to bear higher costs because of the statutory limits on pre-existing condition exclusions and the creditable coverage provisions reducing the application of permissible pre-existing condition exclusions. CBO has estimated the total costs of these two provisions at \$300 million annually after full implementation, or 0.2% of total premiums in the group market. This reflects coverage for services which would have been excluded under current law due to pre-existing condition exclusions in insurance contracts, but which would be covered under HIPAA due to HIPAA's 12-months cap on exclusions and its provisions requiring credit for prior coverage.

CBO's \$300 million cost figure reflects only the costs of the statute's limits on pre-existing conditions exclusion, and its prior creditable coverage provisions. It does not include the administrative costs to plans and issuers of the HIPAA's certification requirement, which the Department of Labor has measured in its Paperwork Reduction Act analysis below. Similarly, CBO's \$300 million figure does not include any other increased premium costs that might be associated with the statute's health status nondiscrimination or guaranteed renewability provisions. CBO's figure does try to estimate (a) how many people would benefit from the statute's limits on preexisting condition exclusions, and its prior creditable coverage provision, and (b) the average cost to insurers of the extension of coverage to those individuals.

Preexisting condition exclusion limitation: CBO derived its \$300 million

figure by estimating that approximately 300,000 people with private employment-based coverage would gain coverage under the statute's preexisting condition exclusion limitation provision, at a direct private sector cost of \$200 million per year. CBO adjusted this estimate to exclude people who reported being limited by a preexisting condition restriction, but who also had secondary health coverage to pick up the cost of their preexisting condition. CBO reasoned that under these circumstances, the preexisting condition exclusion limitation would not raise the aggregate costs imposed on employment-based plans. CBO likewise adjusted its estimate to reflect the existence of state laws which limited preexisting condition exclusion limitations to one year or less and require that previous coverage be credited against those exclusions. These state laws generally apply to group plans of 50 or fewer employees, and do

not include self-funded health benefit plans subject to ERISA rather than state laws. Since plans covered by such state laws would not have to change their provisions as a result of HIPAA, CBO lowered its initial estimate of the people affected by the bill.

Crediting Prior Coverage: CBO's \$300 million figure also includes an estimate that 100,000 people, at a private sector cost of about \$100 million per year, would receive some added coverage as a result of HIPAA's prior creditable coverage provision.

CBO reports that these estimates are subject to considerable uncertainty for several reasons. First, they are based on individuals' responses to surveys, which should be treated with caution. Likewise, unforeseen changes in the health insurance market, such as changes in medical costs or the growth of managed care plans, could raise or lower the direct costs of the law. Increases in medical costs would obviously raise the costs, while the expansion of HMO penetration in the market would tend to reduce the law's effect, since HMOs generally do not use preexisting condition exclusions.

CBO also reports that in particular, distribution of the costs these provisions would be uneven across health plans. CBO notes that "[o]nly plans that currently use pre-existing condition exclusions of more than 12 months would face the \$200 million direct costs of the statute's exclusion limitation." Data from a Peat Marwick survey used by CBO indicate that 2.5% of employees are in such plans. Consequently, "the costs to health plans that use long preexisting condition exclusions would be about 4.5% of their premium costs." Likewise, only those plans that use preexisting condition exclusions would face the \$100 million direct cost of the mandate to credit prior coverage against the preexisting conditions exclusion. CBO reports that "almost half of employees are in such plans—implying that the plans directly affected by this mandate would have direct costs equal to about one-tenth of one percent of their premiums" absent the statute.

The increased costs may be shared by insurers, plans, and insured individuals. Additionally, costs also may be borne directly by plans that an issuer "experience rates," i.e. the insurer determines rates according to the utilization of the group being insured. Costs may also be borne by others insured through an issuer that uses some form of community rating, which spreads risk over a greater number of "insured lives" beyond the particular group that is the source of the additional costs. To a certain extent, a group may

have a choice in the degree of burden: if the group knows that its members incur lower costs than the average of the issuer's pool, the group can avoid a community-rated pool by becoming self-insured.

There is also the possibility that group market premiums may increase as a result of the HIPAA reforms in the individual market if insurers spread the costs of claims in the individual market across a pool that includes group members. HIPAA expressly provides for this possibility as one of the elements of an acceptable state alternative mechanism. (Such issues relating to the individual market are discussed in more detail below.)

Assuming that the CBO is correct in projecting that the premium effect translates into 0.2 percent of total premiums in the group market, a minimal premium effect is likely.

CBO did not quantify the cost of nondiscrimination or special enrollment provisions.

With respect to nondiscrimination, approximately 135,000 workers reported in 1993 that they were excluded from their employer's health plan because of their health, according to DOL tabulations of the April 1993 Current Population Survey. In general, HIPAA would require plans to offer benefits to such individuals.

With respect to special enrollments, HIPAA provides that individuals, under certain conditions, are permitted to enroll for health coverage on the same terms as new participants, rather than as late enrollees. The conditions triggering eligibility for special enrollment generally include events in which an individual loses coverage (such as when a spouse changes jobs when couples legally separate or divorce) or joins a family that is eligible for coverage (through marriage, birth, or adoption).

Special enrollment requirements benefit individuals. Absent this provision, eligible individuals could be subject to pre-existing conditions exclusion periods of up to 18 months, and therefore would might need 18 months of prior creditable coverage to fully offset a preexisting condition exclusion period. Under the provision, eligible individuals' exclusion periods are limited to 12 months. This special enrollment provision also permits eligible individuals to enroll immediately in plans which otherwise prohibit late enrollment, or which allow late enrollments only during annual open enrollment periods.

Considering some of the major groups that could benefit, the Departments estimate that 734,000 families would gain eligibility for special enrollments

due to marriage, as would 701,000 due to births, and 292,000 due to job changes in the family. These estimates, based on the Survey of Income and Program Participation, reflect an annual count of such events following which the relevant spouse or new born was uninsured, or covered under an individual policy or Medicaid.

Special enrollments may result in a marginal increase in aggregate premiums and claims paid, but no change in average premium levels for any one individual, since eligible individuals are not likely to have any higher health care costs than the average new health plan participant.

In summary, HIPAA's portability and access provisions will result in a number of direct costs and benefits. These direct costs represent transfers among parties and not changes in overall social welfare. CBO estimates that HIPAA's group portability provisions will result in \$300 million of additional annual direct costs to insurance programs, which in turn represents a direct benefit of \$300 million in added coverage for individuals. Additional direct costs and benefits will arise from similar extensions of coverage under HIPAA's group-to-individual portability, special enrollment, and nondiscrimination provisions. Various estimates of the costs and benefits of the group-to-individual provisions are offered below. Costs and benefits of the special enrollment and nondiscrimination provisions have not been quantified.

3. Affected Market Segments

(1). Impact on State, Local and Tribal Governments

The statute establishes federal standards and allows for federal enforcement in an area that has traditionally been the domain of the states, the regulation of insurance. However, the statute also permits states to use alternative, state-specific mechanisms to achieve greater portability and continuity in a manner similar to the federal standards. Many states have undertaken insurance reforms similar to the HIPAA provisions and are likely to seek approval for the continuation of these alternative mechanisms. The statute provides that enforcement of the requirements of the law will be the responsibility of the states (for those states implementing alternative mechanisms as well as for those states implementing the federal standards), unless a state is unwilling or unable to enforce the law. Only in the latter case of unwillingness or inability to enforce the law will the federal

government implement and enforce the law in a given state. It is highly unlikely that there will be any instance of the federal government assuming such a role, with the exception perhaps of the territories. There is no federal financial assistance or resources to implement these provisions.

The CBO has generally determined that there will be a negligible impact on these governmental entities, even in the event that, in their capacity as sponsor of employee health care coverage, they choose not to "opt out" of having certain provisions of the statute apply to them. HIPAA provides that states and localities that self-insure their health care coverage for employees, are permitted, under the statute, to "opt out" of the provisions of the law affecting them with respect to rules governing pre-existing condition limitations. Some entities that have the option available will "opt out." However, this does not relieve them of the responsibility of providing certifications of creditable coverage for their covered individuals. HIPAA does not preempt state and local government collective bargaining laws. If there were no opt-out entities, CBO projects that state and local governments would see an increase in health care costs of less than \$50 million, or 0.1% of the \$40 billion annually in state and local total health insurance expenditures.

Those who would benefit from the imposition of HIPAA requirements on state and local governments are individuals who are subject to a pre-existing condition exclusion that would have been shortened in length by HIPAA either under the 12-month limit or the crediting or prior creditable coverage provision. As the CBO points out, this benefit (for some) is coupled with a cost to (all covered) individuals because it is assumed that states and localities would pass the cost off to their employees through reduced compensation or benefits.

According to CBO, the impact of the law on the states in their capacity as regulators enforcing new insurance provision is marginal. For states that have been enacting insurance reform measures in the small group and individual markets, it could be argued that HIPAA provides a benefit to the extent that the introduction of federal standards facilitates the states' ability to continue insurance reforms in these markets. According to the Intergovernmental Health Policy Project (IHPP), in a report dated June of 1996, all but two states had enacted some type of small group market reform, and 35 states had enacted some type of individual insurance market reform.

The presence of a federal standard that may be viewed as constituting a "floor" of requirements imposed on issuers in these two markets may also benefit the states.

The individual insurance market has traditionally been regulated by the states, and Congress intended that, to the maximum extent possible, the states should continue this regulatory role. To this end, the law provides states with these options: (1) implement an alternative, state-specific mechanism to ensure access to individual health care coverage; (2) adopt and administer the federal standards of HIPAA; or (3) allow the federal government to administer the law.

In devising the first option, the implementation of an alternative mechanism, Congress afforded states a good deal of flexibility in establishing an alternative mechanism. At least 30 states are expected to implement alternative mechanism, each unique to the state's demographics and market conditions. States are encouraged to explore innovative options and intend to afford states as much flexibility as possible in the design of their alternative mechanisms. Throughout the process of reviewing proposed alternative mechanisms, the states' need for flexibility must be balanced with the rights of the individuals afforded protection under the law.

Our main concern is that the primary goal of HIPAA be achieved: that eligible individuals are guaranteed coverage in the individual market, to the extent that policies are available, without a preexisting condition exclusion period. HHS intends to review states' mechanisms with this goal in mind; so the information presented should present a clear picture of the mechanism's impact on eligible individuals. The information requested in these regulations (section 148.126(h)) closely parallels the statutory provisions. While such information collection requirements may impose a burden on each state that chooses to implement an alternative mechanism, such information is necessary in order to effectively evaluate the mechanism and ensure that the mechanism will provide eligible individuals the protection guaranteed by the law.

The states are unlikely to choose the option whereby the Secretary (HCFA) implements and enforces HIPAA in the states. Eight states, however, may choose the "federal fall-back" option of incorporating the HIPAA standards into state law rather than developing an alternative mechanism.

The statutes provides that a state is presumed to be implementing an

acceptable alternative mechanism as of January 1, 1998, unless the Secretary of HHS notifies a state of her disapproval of the mechanism by July 1, 1997. In states where the legislature does not meet in a regular session between August 21, 1996 and August 20, 1997, the state is presumed to be implementing an acceptable alternative mechanism as of July 1, 1998. To our knowledge, only Kentucky qualifies for this exception. The statute also provides an extension. Before making an initial determination, HHS intend to make every effort to consult with the appropriate state officials. After consultation with appropriate state officials, should there still be cause for disapproval, HHS will allow the state a reasonable opportunity to revise the mechanism or submit a new mechanism. Throughout this process, HHS may require further information from state officials regarding particular aspects of their insurance market reform. While such requests for information may also impose an additional burden on the state, this information will be necessary to insure that the mechanism will provide the protections guaranteed to eligible individuals under the law.

As required by law, the Secretary of HHS will review each alternative mechanism every three years. In this respect, the regulation adheres closely to the statutory burden and merely clarified that resubmission is required on every three-year anniversary of the last submission date. HHS has also provided a process for review of future mechanisms, should a state may wish to revise an existing mechanism or propose a new mechanism.

In addition to implementing an alternative mechanism, a state may choose to adopt and administer the federal statutory provisions. Our regulations in this regard do not differ from the statutory provisions. As noted above, it is likely that up to eight states would choose this option.

Finally, a state may choose to allow the federal government to administer the federal statutory provisions in the state. Although this is a possibility contemplated in the statute, it is unlikely that any state would choose this option. However, the impact of the regulations that implement this option is discussed below.

In states that have an acceptable alternative mechanism for ensuring access to individual insurance or health care coverage, the implementation of laws and determination of compliance with those laws is exclusively a state matter. For other states, HIPAA gives the Secretary authority to issue

regulations to carry out the implementation and enforcement of HIPAA provisions for the states that choose the "federal fallback" option (using federal standards), and for states in which the federal government will directly administer the HIPAA provisions. These regulations specify the following:

- Documentation that must be submitted to the state (federal default) or to HCFA (direct regulation by the federal government) demonstrating compliance with the statute;
- The manner in which an insurer markets individual policies;
- The procedure and time frames the issuer follows in determining whether someone is an eligible individual, and the effective date of the individual's coverage;
- The procedure to follow for a request to limit enrollment in the case of an HMO's or insurer's capacity limitations (network capacity or financial capacity); and
- The procedure for determining whether the benefit packages offered in the individual market are consistent with statutory requirements.

In states electing the federal fall-back approach, the state determines the level of documentation required to establish compliance with the HIPAA provisions. The Departments do not know the extent of burden states will impose on plans as a result of HIPAA. Although there is not likely to be direct federal enforcement in any state, in those states in which HCFA does administer the law, issuers have 90 days after July 1, 1997, to provide documentation concerning individual policy forms the issuer already markets; and 90 days prior to the beginning of the calendar year prior to marketing a new policy form. With regard to these time frames, the 90-day period should not be burdensome. Much of the information required to be submitted regarding the policy forms in the individual market is material the issuer will generally have filed with a state insurance commissioner ("information on all products offered in the individual market"; marketing material, often submitted to states on a "file and use," or informational basis). For such information the submission to the federal government is burdensome only in that it is duplicative of material given to the state. The HIPAA-specific materials are generally not duplicative and constitute a burden on issuers to provide HCFA with the following information:

- An explanation of how the issuer is complying with the provisions of HIPAA, including how the issuer will

inform eligible individuals of available policy forms;

- Premium volumes or actuarial values (depending on which election is made regarding compliance with rules on the type of policy to be offered); and
- A description of the risk spreading/financial subsidization mechanism to be used for individual policy forms.

The last two items represent requirements of the statute, while the first item is necessary to ensure that there is effective implementation of the statute. For the first item, issuers will have to become familiar with the provisions of HIPAA in order to comply with the documentation requirement, which can be a considerable burden, but the other information requirements should not be burdensome. One way in which these regulations lessen the burden for plans electing to offer "representative coverage" rather than the most popular policy forms is by not prescribing the method of determining the actuarial value of representative coverage. Issuers may make their own determinations of actuarial value and present them to HCFA for verification.

(2). Impact of the Law in Different States

The impact of the law on individuals, employers, group plans, and issuers may vary somewhat from state to state. Many state reforms resemble HIPAA's portability provisions, often meeting or exceeding particular HIPAA standards. The CBO notes that it "lowered its initial estimate of the number of people affected by the bill" in recognition of such state reforms. Where state laws resembling HIPAA exist, the marginal impact of HIPAA is reduced.

The degree to which a state's reforms lessen the impact of HIPAA's portability provisions depends on the degree to which the state's requirements exceed these provisions, and on what proportion of insured individuals in the state are covered by the state's reforms. In general, individuals not covered by state reforms are those enrolled in programs for which such state reforms are preempted by federal law. These include individuals enrolled in federal programs such as Medicare and the Federal Employees Health Benefits Program or in self-insured ERISA plans. Individuals enrolled in ERISA plans that are not self insured are covered by such state reforms that are specifically saved from preemption by HIPAA.

According to a study by Jacob Klerman of RAND, *New Estimates of the Effect of Kassebaum-Kennedy's Group-to-Individual Conversion Provision on Premiums for Individual Health Insurance* (1996), 42 states have guaranteed issue rules in the individual

market or a high-risk pool that could qualify the states as meeting the alternative mechanism requirements of HIPAA. This is consistent with other information the Departments have received to the effect that only eight states may adopt the federal HIPAA standards (to be administered by the states). (The individual market issues are discussed in greater detail below.)

An analysis prepared by staff of the Pension and Welfare Benefits Administration (PWBA) of the Department of Labor found, for the group market, that 41 states have small group guaranteed issue; of that number five do not conform with (or are not more generous than) HIPAA rules on guaranteed issue, and 21 define a small group differently from HIPAA by starting the small group category at three individuals (rather than HIPAA's two)—the situation in 11 states—or by extending the provisions to groups not reaching HIPAA's 50 (4 states define a small group as up to 49; one as 40; and ten as either 24 or 25). These states are likely to make relatively small changes as necessary to conform their laws to HIPAA standards. The National Association of Insurance Commissioners has also engaged in extensive efforts to help the states conform their laws.

Thirty-one states already have provisions which require that group health plans offer additional enrollment opportunities to employees under circumstances similar to HIPAA's special enrollment opportunities. The statute expands the state baseline by adding legal separation as a grounds for special enrollment eligibility, and expressly includes COBRA as prior group health coverage. The statute further requires retroactive coverage for newborns and adopted children if special enrollment is requested within 30 days of birth, placement for adoption, or adoption. Current state requirements reduce the overall economic impact of the special enrollment requirements on the group health market.

For pre-existing conditions limitations in group health plans, HIPAA provides that the maximum allowable period is 12 months ("look-forward"), or 18 months for a late enrollee (someone enrolling outside of an initial or special enrollment period) for conditions arising within the six months ("look-back") preceding the enrollment date in a group health plan. HIPAA also provides that prior coverage for which there was not a break in coverage of 63 days or more would be credited against the pre-existing condition exclusion. Using the PWBA analysis and information from the IHPP,

as of mid-1996, 30 states had time limits on pre-existing condition exclusion periods that are the same as, or more favorable to individuals, than the HIPAA provisions for the group market; and 14 other states have limits on pre-existing condition time limits. Among these 44 states, ten states allow crediting or prior coverage for which the duration of the break in coverage equals or exceeds 63 days (more generous than HIPAA); eight states allowed breaks in coverage of 60 days; 18 states allowed 30 or 31 days of a break in coverage; and four states had no crediting of prior coverage. State laws which exceed HIPAA standards will not be preempted by HIPAA.

(3). Group Plans

HIPAA sets minimum standards for all group health plans, including self-funded plans that are shielded by ERISA from states' HIPAA-like requirements. The General Accounting Office has estimated that about 27% of the Nation's population received health care coverage through ERISA self-funded plans (17%).

Although the GAO report indicated that the number of people covered by self-insured plans is increasing, other data indicate that there has been a decline in such coverage because of the increasing number of individuals covered by HMOs that operate as insured plans. However, an HMO network may constitute an exclusive provider organization for a self-insured plan. Liston and Patterson (*Analysis of the Number of Workers Covered by Self-Insured Health Plans Under the Employee Retirement Income Security Act of 1974—1993 and 1995*, prepared for the Henry J. Kaiser Family Foundation, August 1996) found that from 1993 to 1995 the number of Americans covered by fully or partly self-insured plans declined from 37.6 million to 32.5 million (a 14% decline). The rate of decline was greatest in smaller firms: for firms with fewer than 100 workers, the number of workers covered under fully or partially self-insured plans declined from 8.2 million to 5.4 million (a 34% decline). For firms with 25 or fewer employees, the numbers declined from 2.9 million to 2.2 million from 1993 to 1995 (a 24% decline).

The relevance of these numbers to an analysis of HIPAA has to do both with the number of people that can potentially benefit from the HIPAA provisions (if the employees moving to ERISA-insured plans are in states that already have provisions similar to HIPAA, effects will be smaller), as well as the related issue (partially a

consequence of the former) of the extent to which the small group market in a given state may be "disrupted" because of the effects of HIPAA. (For example, will the HIPAA provisions create a situation in which either insurers will abandon markets or employers will discontinue health care coverage?) Although the Departments' economic impact analysis does not contain a state-by-state analysis of the relationship between employees covered under self-insured plans (and any changes in those numbers) and the states that have reforms similar to HIPAA, Liston and Patterson found that the South was the only region of the country in which there was an increase in the number of employees covered by self-insured or partially self-insured (reflecting the lower penetration of HMOs in Southern states). Data about individual states do not appear to be available. A recent GAO report notes that "no analysis exists on the number of individuals affected by these state [insurance] reforms" (*Health Insurance Portability: Reform Could Ensure Continued Coverage for Up to 25 Million Americans*, HEHS-95-257, September 1995).

For 1995, the South (stretching, under the Liston-Patterson definition, from the South Atlantic states to the West South Central states of Arkansas, Louisiana, Oklahoma and Texas) had 35% of all employees covered by self-insured or partially self-insured plans, while those same states had 30% of the private-sector employees with health care coverage. Three of the seven states that had no pre-existing condition limitations regulations in the PWBA analysis were Southern states; of the 11 states that had no guaranteed renewal provisions for group health plans, four were in Southern states. It would appear then, that to the extent that practices in the ERISA small group market in Southern states diverge significantly from HIPAA provisions employers will have to adhere to, there are possible major impacts of HIPAA in those markets.

(4). The Individual Insurance Market

In the individual insurance market the statute provides for guaranteed issue of a policy to "eligible individuals" (individuals coming from the group market, who have 18 months of aggregate creditable coverage, from any of various types of health care coverage). In addition to this guaranteed issue requirement, insurers are not permitted to apply any pre-existing condition exclusions to this group. Individual policies are guaranteed renewable except under certain circumstances. The

statute does not place any limits on the premiums insurers may charge for the policies made available to eligible individuals. States are permitted to have alternative mechanisms that achieve the same ends as the HIPAA requirements, though any alternative is required to have no pre-existing condition exclusions.

The individual insurance market reforms are of greatest benefit to individuals who voluntarily or involuntarily leave their jobs and wish to maintain some level of health insurance. As discussed above, the availability of individual insurance may decrease "job lock" by allowing people to maintain continuous protection as they move between jobs. Individuals who enter the individual market from the group market may choose to do so because their new employer may not offer insurance or the employer's coverage is limited; or they may expect to be without a job for a period of time (for example, because they are "early retirees" who do not yet have Medicare entitlement and do not have employment-based retiree health care coverage). The CBO projects, in data cited above, that the number of people benefiting from the HIPAA (getting coverage when it would have been denied absent HIPAA) individual market reforms would "plateau" at the 150,000 range by the fourth year of the law. The GAO (HEHS-95-257, cited above) determined that about two million people each year could convert to individual insurance from group coverage, based on turnover rates among small employers and rates of COBRA continuation of coverage.

Individual market premium effects vary by state. In state regulatory activity, fewer states have provisions similar to HIPAA's in the individual market as compared to state reforms in the small group market. HIPAA will affect the individual insurance markets in many states. The RAND and IHPP data indicate that only eleven states have guaranteed issue laws for the individual market. Eight additional states have an insurer (Blue Cross-Blue Shield) offering open enrollment in the individual market. Twenty-three states have laws limiting the period of pre-existing condition exclusions, but only one state allows no such exclusion period, with most states allowing a 12-month exclusion period with a 6- or 12-month "look back."

One of the most contentious issues in discussions of HIPAA's effect on the individual insurance market has been the issue of premiums in that market. HIPAA does not impose any rating requirements on insurers in the

individual market, meaning that the insurers are free to price their individual products in any manner that is consistent with state law. IHPP data show that for the individual market, seven states have rating bands (premiums must be within certain upper and lower bounds in relation to a "standard" premium), and eight states require community rating of some form (a form of rating that can be roughly described as rating across a larger pool of insured individuals, for example, across all of an issuer's insured individuals, across defined age categories, etc.). Rating bands and community rating requirements have the same intended effect as HIPAA, to increase the availability of insurance, but they additionally seek to assure affordable coverage. There will be interactions between the HIPAA approach to increased availability (guaranteed issue and elimination of pre-existing condition exclusions for certain individuals with prior coverage) and the rating approach in those states in which guaranteed issue rules and pre-existing condition exclusion rules differ from HIPAA's provisions.

Affordability of individual coverage is a significant issue with HIPAA. The Health Insurance Association of America (HIAA) has projected that the individual market reform provisions of HIPAA will cause an eventual 22% increase in premiums in that market ("The Cost of Ending 'Job Lock' or How Much Would Health Insurance Costs Go Up If 'Portability' of Health Insurance Were Guaranteed?", February 20, 1996). HIAA projects, on that basis, that eventually 500,000 to one million people would leave the individual insurance market because of rate increases necessitated by the HIPAA reforms. HIAA bases this estimate on the current number of people insured in the individual market, the number of new entrants in the market, their costs, and the price-sensitivity of purchasers of insurance.

Other studies have arrived at conclusions that are very different from the HIAA conclusions. The main difference with other studies is that HIAA assumes that HIPAA will cause states to impose restrictions on the level of premiums insurers may charge in the individual market. There are no such requirements in HIPAA. The HIAA assumes that people currently covered in the individual market will be included in the rating pool that includes individuals who are newly insured under HIPAA provisions. The American Academy of Actuaries (AAA), for example, found that the premium increases in the individual market

would be in the range of two to five percent, and the increases would take effect over a longer time span than one year. The AAA took into account current state laws, including state laws related rate restrictions in the small group market.

Jacob Klerman, or RAND, examined HIAA's assumptions and methodology and found that (a) using HIAA's assumptions, but employing more up-to-date or otherwise improved data ("better estimates of the underlying figures"), the increase in individual premiums would be 5.7%; and (b) using different assumptions, the premium effect would be 2.3% and may be as little as 1% or less (*New Estimates of the Effect of Kassebaum-Kennedy's Group-to-Individual Conversion Provision on Premiums for Individual Health Insurance*, RAND, 1996). For the latter projections, Klerman assumed a different level of claims costs for new entrants (150%, based on studies of the costs for COBRA continuation policies, versus the HIAA's 200%), that the premium pricing for the new policies would not be pooled with others in the individual market, and that state laws would have effects that the HIAA analysis did not consider. Note that, as with the GAO report quoted above, these analyses are based on an earlier version of an insurance reform bill, S. 1028, in which the guaranteed issue was available only to those with 18 months of group coverage. This analysis does not measure how many more people are encompassed in the larger HIPAA "eligible individual" group comprising individuals whose last type of coverage was group coverage but who had prior coverage during the 18-month period from a different source; this will slightly increase the cost.

Another study, done for HHS, by Actuarial Research Corporation (ARC), had results that were similar to the RAND results. ARC projects possible increases in individual premiums ranging from 1.4 percent to 2.8 percent.

K. Statutory Provisions Affecting Administrative Processes

While these rules implement the statute's goal of expanding coverage and portability of coverage by reducing the use of pre-existing condition exclusions, for purposes of performing this economic impact analysis, it is appropriate to break the regulations down into the following components: certifications and notices informing individuals of their right to request a certification; notification of the application of a pre-existing condition exclusion period; alternative methods of crediting coverage; and guidelines for

implementing the statute's special enrollment requirements. The notice and notification requirements are largely a result of this rulemaking. The certification requirements are largely prescribed by HIPAA, with certain aspects that mitigate the impact of the statute resulting from this rulemaking. While the alternative method of counting compliance is authorized by HIPAA, the classes and categories of coverage to be measured were created at the discretion of the three Departments.

1. Staggered Effective Dates

In general, the effective dates of HIPAA's group health plan provisions are tied to plans' fiscal years and to the expiration of collective bargaining agreements under which some plans are maintained. Provisions whose effective dates are so tied included those pertaining to pre-existing condition exclusions, crediting prior coverage, and special enrollments. (The effective dates of HIPAA's certification provisions are not so tied.) Non-collectively bargained plans become subject to these provisions of HIPAA in the first plan year beginning on or after the July 1, 1997. Collectively bargained plans become subject the first plan year beginning on or after the later of July 1, 1997 or the expiration of a collective bargaining agreement that was in place prior to HIPAA's date of enactment, August 21, 1996.

More than one-half of plans begin their fiscal years on January 1. Therefore, there is a large concentration of plans and participants that become subject to HIPAA in January 1998. Overall, the proportions of participants and plans (respectively) that become subject to HIPAA in 1997 are 15 percent and 24 percent; in 1998, 68 percent and 69 percent; in 1999, 11 percent and 4 percent; and in 2000, 5 percent and 2 percent.

The compliance costs of these regulations regarding certification and notice, pre-existing condition exclusion notification, and notice of enrollment rights was estimated based upon information in the public domain and data available to the Departments on industry practices. To derive data on health coverage and employment shifts of individuals, for the purposes of this analysis the Departments referred to data collected from the Census Bureau's Current Population Survey and Survey of Income and Program Participation, as well as the National Health Interview Survey and the Department of Labor's database of 1993 Form 5500 information, the most current available. Supplemental data on employer-sponsored health care was obtained

from the Peat Marwick Benefits Survey and the BLS Employee Benefits Survey.

2. Initial vs. Ongoing Costs

Costs may be separated into initial costs and ongoing costs. Initial costs of the new certification, notice, pre-existing condition exclusion notification, and special enrollment requirements have several components, including capital costs of preparations for collecting information such as purchasing or upgrading computers and software, and record storage facilities. Initial costs may also be expected to include programming or reprogramming automated systems to track periods of prior creditable coverage, and to track plan participants and the type of coverage they hold, e.g. individual or family coverage. Initial costs also include up-front expenditures for revisions of plan documents to comply with the new statutory and regulatory requirements. These costs were annualized over the estimated "life" of the regulation, 10 years, in order to show such costs on an annual basis. It is estimated that the 15,604 plans that will process certifications internally (rather than use a service provider) will incur an average cost of \$5,000 per plan to revise their automated records systems to accommodate this information for a total cost of \$78 million over 10 years beginning in 1997. Presented here as direct costs, initial costs are a component of overall social costs.

Ongoing expenditures incurred annually include the costs to group health plans, health insurance issuers and self-funded plans of performing the continuing administrative tasks of calculating periods of creditable coverage, printing forms for notices, preparing an original and a copy of notices and certifications for participants with dependants having identical coverage, and mailing these documents to individuals. Also included in ongoing expenditures is the cost to plans which use pre-existing condition exclusions to notify participants of the plans' provisions, and calculating periods of pre-existing condition exclusions for new participants, and issuing an individualized notification, as necessary, to each individual who would be subject to a pre-existing condition exclusion of any duration. Total annualized initial costs and ongoing costs were aggregated to estimate total annual costs.

3. The Certification Process

The statute specifies that every individual leaving a group health plan,

ending COBRA coverage, ending individual insurance coverage, or leaving other types of health coverage must receive a written certification of creditable coverage containing specific information about the individual and his or her coverage, including information on the coverage of dependents. This requirement constitutes a burden in information collection and processing.

Despite recent incremental state reforms in the laws affecting the group health insurance market, no states have required group health plans or health insurance issuers to provide participants and their dependents with certifications or notices regarding prior health coverage. Therefore, the statute imposes discrete new burdens on all group health plans and health insurance issuers in connection with providing certifications, and issuing to individuals of their right to receive a certification.

Respondents preparing certification forms must collect the appropriate information about a person, prepare a certification form, and, in most cases, mail the information. One certification can serve to provide information about dependents covered under the same policy. The respondent may have to prepare multiple certification forms for an individual, or for dependents, in the event that the certificate is lost or misplaced. The process may require the development of new information systems or, more likely, modifications to existing information systems, to collect and process the necessary information.

The statute makes the certification requirement a key implementation component of the portability provision in both the group and individual markets.

The cost of providing certifications for private group plans (absent the regulatory relief described below) is estimated to be at least \$98 million for 69 million certifications in 1997 and \$84 million for 59 million in each subsequent year. Absent transition relief provided under the regulations, early year costs could be far higher. The direct cost of certifications contributes to the overall social cost of the statute.

L. Impact of Regulatory Discretion

These regulations mitigate the impact of the statutory requirements on the regulated public, while preserving protections, in several ways. These regulations will reduce implementation costs.

The Departments exercised discretion in connection with group plan provisions, as follows:

First, intermediate issuers will not have to issue a certification when an

individual changes options under the same health plan. In lieu of the certification, they could simply transfer the start and stop dates of coverage to the plan. An individual would retain the right to get a certification upon request if they leave the plan.

Second, telephonic certification will fulfill the requirement to send a certification if the receiving plan and the prior plan mutually agree to that arrangement. The individual can always get a written certification upon request.

Third, the requirement to send certifications on June 1, 1997 to those who have left plans between October 1, 1996 and May 31, 1997 can be satisfied by sending a notice; the Departments have offered a model notice in these regulations for that purpose.

Fourth, until July 1, 1998, plans and issuers that do not collect individual information on dependants can comply with the requirement to send each dependant a separate certification by simply listing the category of coverage (e.g., individual, spouse or family).

Fifth, in situations where the issuer and the plan contract for the issuer to complete the certifications, the plan would not remain liable if the issuer failed to send the certifications.

Thus, plans would not need to keep data and files on this information.

Sixth, the period of coverage listed on automatic certifications will only be the last continuous period of coverage without any break. This is the most efficient and simplest method of record keeping for plans and issuers.

Seventh, the period of coverage contained in the on-request certification will be all periods of coverage ending within 24 months before the date of the request. Essentially, a plan may simply look back two years and send copies of any automatic certifications issued during that period.

The above reductions in burdens on plans and issuers may cause more frequent circumstances in which participants are required to prove creditable coverage and the status of their dependants. In order to help offset some of the additional burdens that will be shifted to the participants, the regulations provide the following protections:

First, if 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.

Second, a plan shall treat an individual as having furnished a certificate if the individual attests to the period of creditable coverage, and the individual also presents relevant corroborating evidence of some creditable coverage during the period and the individual cooperates with the plan's efforts to verify the individual's coverage.

Third, plans and issuers that impose preexisting condition exclusions periods must notify participants of this fact. They must also explain that prior creditable coverage can reduce the length of a preexisting condition exclusion period and offer to request a certification on the participant's behalf. An exclusion may not be imposed until this notice is given. This is beneficial to participants insofar as it forewarns them of potential claim denials and enables them to more easily exercise their right to protection from such denials under HIPAA's portability provisions.

Fourth, a plan that imposes a preexisting condition exclusion must notify a participant if the individual's creditable coverage is not enough to completely offset the exclusion period, and give the individual the option to provide additional information. An exclusion may not be imposed until this notice is given. This provides participants an opportunity to correct any failure to establish credit for prior coverage before a claim is denied.

Under the regulation, in the group health plan enrollment materials ordinarily provided to most new participants, plans that contain pre-existing condition exclusion provisions must also provide notice that the plan contains these provisions, that the participant has the right to prove prior creditable coverage, including the right to secure a certificate from a prior plan or issuer, and that the new plan will assist in obtaining the certificate. Those plans using the alternative method of crediting coverage also must disclose their methods to the participant, including an identification of the categories of coverage used.

In addition, a plan seeking to impose a pre-existing condition exclusion on a participant or dependant must inform them in writing of the determination that they lack adequate prior coverage, and provide an opportunity for the individual to submit additional materials regarding prior creditable coverage, and provide an explanation of any appeals procedure.

The annual cost of these disclosure procedures to private group plans is estimated to be \$280,000 in 1997, \$2.1 million in 1998, and \$1.9 million in 1999 (about 20 cents per notice). The

same costs for state group plans would be \$25,500, \$51,000, and \$51,000, respectively. For local plans, they would be \$42,000, \$84,000, and \$84,000. The Departments believe the marginal burden of the notice will be modest because, irrespective of the notice requirement, under the statute plans must make this determination before imposing a preexisting condition exclusion. Comments are encouraged as to whether this assumption is appropriate. These costs do not include any burdens attributable to the use of the alternative method of crediting coverage, since it is assumed that any plans incorporating this method will do so only if the net cost is less than using the standard method. Under the alternative method of crediting coverage, the regulation allows the prior plan to charge the receiving plan using the alternative method for the reasonable costs of providing evidence of classes and categories of prior health coverage.

On balance, to the extent that the Departments have exercised regulatory discretion, they have acted to reduce compliance costs. This is particularly true with respect to the certification process.

These regulations attempt to reduce the burden of certifications by limiting the amount of information that needs to be reported and offering a model form that can be used to satisfy the requirement of the law. In the absence of a written certification, the regulations allow for alternative means of establishing creditable coverage, which includes having the individual present documentation of coverage or conducting telephone verification with the entity that previously covered the individual.

During a transition period, respondents may provide individuals with a notice that they have the right to receive a certificate of creditable coverage, a requirement that can be met by including the information in an evidence of coverage or other generic document individuals receive that contains information about their policy. This notice may be provided in lieu of a certificate for events that occur on or after October 1, 1996 but before June 1, 1997.

The cost to issuers of the certification requirement is primarily in the paperwork production of the certification form. All health insurance issuers are likely to have the kinds of systems in place to be able to produce the information necessary for a certification, although there will be moderate systems start-up costs, and some systems modifications for insurers

and HMOs. Systems modifications may also be necessary to retain the data for the certificates for several years, but, like the other requirements, this burden should also be limited. The model certification form of the Preamble contains the kind of information that is routinely used as the basis for claims processing by a health insurance issuer or by an HMO (for example, in adjudicating an out-of-network claim).

For example, in order to deny a claim dating from a period prior to the beginning date of coverage of a particular individual, the issuer's information system could determine that (1) a particular individual was covered by the issuer; (2) the issuer identification number submitted with the claim is correct; (3) the individual was insured on the date the health care service was provided; (4) the service was provided during a waiting period or affiliation period before coverage was available; and (5) coverage may have ended prior to the date of service. The issuer's information system would also determine the limitations of coverage (e.g. high or low option coverage, with or without specific riders). The remaining information of the certification form could also be available to the issuer, especially for COBRA-eligible individuals: whether COBRA continuation coverage is involved (given that the premium is charged directly to the individual at a specified rate); the beginning and ending dates of coverage and waiting periods; and the name, address, phone number and contact person (or Department) for information.

Respondents may need to modify their systems to determine whether, for a given insurer's coverage of a particular individual, there was a 63-day period of interrupted coverage for purposes of specifying this information on a certification form. As noted above, the Departments have taken into consideration the difficulties insurers have in identifying dependents under family coverage, and the regulations make appropriate accommodations, in recognition of the need for a transition period during which information about dependent coverage information may be unavailable from issuers.

The cost of producing and issuing certifications (or notices in lieu of certifications where permitted) for private group plans is estimated to be \$57 million for 53 million certifications in 1997, \$64 million for 44 million in 1998, and \$66 million for 44 million in each subsequent year. Medicaid programs would provide 10 million certifications annually at an annual cost of \$600,000. Medicare would issue

92,000 annually at a cost of \$115,000. (Should HHS decide to allow the Medicare award and termination letters to suffice as certifications, then there would be no cost to the Medicare program for the HIPAA certification requirements.) By 1999, the annual cost and volume would total \$500,000 and 200,000 for OPM, \$2.9 million and 1.9 million for state plans, and \$6.1 million and 4.1 million for local plans, and \$4.7 million and 2.9 million for individual market issuers.

Relative to the cost implied by the statute alone, regulatory provisions directed at the certification process reduce private group plans' cost of compliance by a minimum of \$41 million (or 42 percent) in 1997, \$20 million (or 24 percent) in 1998, and \$18 million (or 21 percent) in 1999 and later years, through the creation of transitional rules, safe harbors and good faith compliance periods. The regulation acts to reduce parallel burdens on issuers and state and local government group plans in similar proportion.

In another discretionary provision, these regulations require group plans to notify eligible new employees of their special enrollment rights. This provision is necessary to make sure employees are sufficiently informed to exercise their rights within the 30-day window provided in the statute. The cost of this disclosure is expected to be small, since it is a uniform disclosure that can accompany ordinary materials provided to new participants. In order to minimize the burden, the preamble to these regulations provides model language for the notice adequate for meeting the statutory obligation. The cost, which would reach \$1.72 million in 1999 for private group plans, is described in the PRA analysis. In 1999, the cost for State plans would reach \$167,000; the cost for local plans would reach \$290,000.

The direct cost of certifications and notices contribute to the overall social cost of the statute and regulations.

HHS has exercised regulatory discretion regarding two specific provisions that will be enforced exclusively by HHS (also referred to as the "non-shared group market" provisions).

These two areas are as follows:

Guaranteed Availability of Coverage for Employers in the PHS Act Group Health Market Provisions

The group market provisions include rules relating to guaranteed availability of coverage for employers in the small group market that are only in the PHS Act (not in ERISA or the Code). Section

146.150 of the HHS regulations implements section 2711 of the PHS Act. In general, this section requires health insurance issuers that offer coverage in the small group market to offer all policy forms to any eligible small employer and to accept for enrollment every eligible individual without regard to health status. HHS has interpreted this guaranteed availability requirement to apply to all products offered in the small group market. Some States and issuers argue that the statute would permit guaranteed availability of an issuer's basic and standard plan, as opposed to all products offered by the issuer in the small group market. HHS does not agree with this interpretation and have proposed our interpretation in the regulation. Depending upon State law, this decision may provide the benefit of additional choices to small employers purchasing coverage in the small group market, while adding some potential costs for issuers offering coverage in the small group market.

Exclusion of Certain Plans From the PHS Act Group Market Requirements

The group market provisions also include rules under which certain plans are excluded from the group market provisions that are only in the PHS Act (not in ERISA or the Code). Section 146.180 of the HHS regulations implements section 2721 of the PHS Act. Section 146.180(b) includes rules pertaining to non-federal governmental plans, which are permitted under HIPAA to elect to be exempted from some or all of HIPAA's requirements in the PHS Act. HHS has exercised regulatory discretion by prescribing the form and manner of the election and the contents of the notice. HHS has also required a non-federal governmental plan making this election to notify plan participants, at the time of enrollment and on an annual basis, of the fact and consequences of the election. HHS has exercised this regulatory authority in order to ensure adequate documentation of a non-federal governmental plan's proper and appropriate election without placing an undue burden on the plan. In addition, HHS has provided a non-federal governmental plan the flexibility to elect to opt out of specific provisions of the statute and have allowed for this flexibility in the contents of the notice. The cost of providing these notices for non-federal governmental would range from \$79,000 to \$158,000 in 1997 and from \$158,000 to \$315,000 in 1999.

HHS has also exercised regulatory discretion in connection with individual market provisions by specifying that college health plans are treated as bona fide associations. Since,

under HIPAA, coverage offered through a bona fide association is creditable coverage, individuals covered under a college plan would receive credit for this coverage. However, because this coverage is offered through a bona fide association (as defined in Part 144 of the group market rules), the issuer benefits because it does not have to make the coverage available in the individual market to eligible individuals, and does not have to renew coverage for a student who leaves the association. This regulatory provision is expected to minimally disrupt business practices for those college plans.

HHS also exercised regulatory discretion in connection with individual market provisions. When an eligible individual applies for coverage in the individual market, the effective date of such coverage is deemed, in the regulations, to be the date on which the individual applies for such coverage, and assuming the individual's application for coverage was accepted.

The impact of this regulatory provision is that an individual who wishes to maintain creditable coverage may delay, for up to 63 days, an application for coverage in the individual insurance market, especially if he or she is assured of being covered by an issuer (e.g., if the person is guaranteed issuance of an individual product as an individual coming from group coverage, under the Act's guaranteed availability provisions). The individual may forego medical treatment during the 63-day period of non-coverage, resulting in a deterioration of health on entering the new health plan, with a potential for greater costs incurred by the insurer or health plan.

The regulation could have required that the individual apply for coverage within a reasonable time period in advance of the 63-day period, such as 30 days after the end of prior coverage (which is similar to the statutory requirement for a request for enrollment in a group health plan following exhaustion of COBRA coverage or other exhaustion of coverage); or, the insurer could have been required to begin coverage within some specified time period after application. However, the approach taken in the regulation is consistent with statutory provisions regarding the treatment of waiting periods or HMO affiliation periods, which the statute specifically excludes from being considered breaks in coverage. The regulatory provision also accords the same status to all individuals in any circumstance by making a 63-day period the maximum during which an individual can be

without coverage and still receive credit for creditable coverage.

**M. Paperwork Reduction Act—
Department of Labor and Department of
the Treasury**

The Department of Labor and the Department of the Treasury have submitted this emergency processing public information collection request (ICR), consisting of three distinct ICRs, to the OBM for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). The Departments have asked for OMB clearance as soon as possible, and OMB approval is anticipated by or before June 1, 1997.

These regulations contain three distinct ICRs. Two of them (Establishing Prior Creditable Coverage and Notice of Enrollment Rights) are prescribed by the statute.

The first ICR implements statutorily prescribed requirements necessary to establish prior creditable coverage. This is accomplished primarily through the issuance of certificates of prior coverage by group health plans or by service providers that the group health plans contract with in order to provide these documents. In addition, this ICR permits the use of a notice that may be used by the plans to meet their obligations in connection with periods of coverage ending during the transition period, October 1, 1996 through May 31, 1997, saving the respondents both hours and cost during that period. This ICR also covers the requests that certain plans will make regarding additional information they require because they are using the Alternative Method of Crediting Coverage. Finally, this ICR also includes the occasional circumstances where a participant is unable to secure a certificate and needs to provide some supplemental form of documentation in order to establish prior creditable coverage.

The second ICR, Notice of Special Enrollment Rights, implements the statutorily prescribed disclosure obligation of the plans to inform a participant, at the time of enrollment, of the plan's special enrollment rules.

The third ICR, Notice of Pre-Existing Condition Exclusion, concerns the disclosure requirements on those plans that contain pre-existing condition exclusion provisions. This ICR has two components: a notice to all participants at the time of enrollment stating the terms of the plan's pre-existing condition provisions, the participant's right to demonstrate creditable coverage, and that the plan or issuer will assist in securing a certificate if necessary; and notice by the plan of its determination

that an exclusion period applies to an individual.

**1. Establishing Prior Creditable
Coverage**

i. Department of Labor

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed information collection requests (ICR) in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (Pub. L. 104-13, 44 U.S.C. chapter 35) and 5 CFR 1320.11. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Pension and Welfare Benefits Administration is soliciting comments concerning the proposed new collection of Establishing Prior Creditable Coverage.

Dates: Written comments must be submitted to the office listed in the addressee section below on or before May 31, 1997. In light of the request for OMB clearance by June 1, 1997, submission of comments within the first 30 days is encouraged to ensure their consideration.

The Department of Labor is particularly interested in comments which:

- evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- enhance the quality, utility, and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Addressee: Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue, Room N-5647, Washington, DC

20210. Telephone: 202-219-4782 (this is not a toll-free number). Fax: 202-219-4745.

ii. Department of the Treasury

The collection of information is in Section 54.9801-5T. This information is required by the statute so that participants will be informed about their rights under HIPAA and about the amount of creditable coverage that they have accrued under a group health plan. The likely respondents are business or other for-profit institutions, non-profit institutions, small businesses or organizations, and Taft-Hartley trusts. Responses to this collection of information are mandatory.

Books or records relating to a collection of information must be retained as long as their contents may be come material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224. Comments on the collection of information should be received by May 31, 1997. In light of the request for OMB clearance by June 1, 1997, submission of comments within the first 30 days is encouraged to ensure their consideration. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How to enhance the quality, utility, and clarity of the information to be collected;

How to minimize the burden of complying with the proposed collection of information, including the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Additional PRA 95 Information:

I. Background: In order to meet HIPAA's goal of improving access to and portability of health care benefits,

the statute provides that, after the submission of evidence establishing prior creditable coverage, a subsequent health insurance provider would be limited in the extent to which it could use pre-existing condition exclusions to limit coverage. This ICR covers the submission of materials sufficient to establish prior creditable coverage.

II. *Current Actions:* Under 29 CFR 2590.701-5 and 26 CFR 54.9801-5T of the interim rule, a group health plan offering group health insurance coverage is obligated to provide a written certificate of information suitable for establishing the prior creditable coverage of a participant or beneficiary. To the extent that a certification is not available or inadequate to prove prior creditable coverage, paragraph (c) provides other methods for establishing creditable

coverage. During the transition period for certification (29 CFR 2590.710(e) and 26 CFR 54.9806-1T(e)), plans have the option of providing notices regarding participant's rights to certification rather than the certification itself; plans then provide certificates only to those participants who request them. 29 CFR 2590.701-5(a)(7) and 26 CFR 54.9801-5T(a)(7) provides special rules for establishing prior coverage of defendants, and 29 CFR 2590.701-5(b) and 26 CFR 54.9801-5T(b) provides guidance on providing evidence of coverage to those plans that use the alternative method of crediting coverage.

These regulations offer model certification and notice forms to be used by group health plans and health insurance issuers, containing the minimum information mandated by the

statute. Based on past experience, the staff believes that most of the materials required to be exchanged under the certification procedure will be prepared by contract service providers such as insurance companies and third-party administrators.

Type of Review: New

Agencies: U.S. Department of Labor, Pension and Welfare Benefits Administration; U.S. Department of the Treasury, Internal Revenue Service.

Title: Establishing Prior Creditable Coverage

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions; Group Health Plans.

Frequency: On occasion

Burden:

Year	Total respondents	Total responses	Average time per response (range) (minutes)	Burden hours (range)	Cost (range)
1997	2,600,000	51,799,410	3.23	502,080	\$57,180,000
			6.12	950,710	84,590,000
1998	2,600,000	44,431,970	5.04	672,120	64,480,000
			11.77	1,569,390	119,310,000
1999	2,600,000	44,399,150	5.27	702,360	66,310,000
			12.01	1,599,630	121,140,000
Totals					

Start up costs: It is estimated that the 15,604 plans that will perform these functions internally (rather than use a service provider) will incur an average cost of \$5,000 per plan to revise their automated records systems to accommodate this information for a total cost of \$78 million over 10 years beginning in 1997.

Estimated total cost:

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

2. Notice of Enrollment Rights

i. Department of Labor

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed information collection requests (ICR) in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (Pub. L. 104-13, 44 U.S.C. Chapter 35) and 5 CFR 1320.11. This program helps to ensure that

requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Pension and Welfare Benefits Administration is soliciting comments concerning the proposed new collection of Notice of Enrollment Rights.

Dates: Written comments must be submitted to the office listed in the addressee section below on or before May 31, 1997. In light of the request for OMB clearance by June 1, 1997, submission of comments within the first 30 days is encouraged to ensure their consideration.

The Department of Labor is particularly interested in comments which:

- evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

- enhance the quality, utility, and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Addressee: Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue, Room N-5647, Washington, D.C. 20210. Telephone: 202-219-4782 (this is not a toll-free number). Fax: 202-219-4745.

ii. Department of the Treasury

The collection of information is in Section 54.9801-6T. This information is required by the statute so that participants will be informed about their rights under HIPAA and about the amount of creditable coverage that they have accrued under a group health plan.

The likely respondents are business or other for-profit institutions, non-profit institutions, small businesses or organizations, and Taft-Hartly trusts. Responses to this collection of information are mandatory.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224. Comments on the collection of information should be received by May 31, 1997. In light of the request for OMB clearance by June 1, 1997, submission of comments within the first 30 days is encouraged to ensure their consideration. Comments are specially requested concerning:

Whether the proposed collection of information is necessary for the proper

performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How to enhance the quality, utility, and clarity of the information to be collected;

How to minimize the burden of complying with the proposed collection of information, including the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Additional PRA 95 Information:

I. *Background:* In order to improve participants' understanding of their rights under an employer's welfare benefits plan, the statute provides that, a participant be provided with a description of a plan's special enrollment rules on or before the time when a participant is offered the opportunity to enroll in a group health plan.

II. *Current Actions:* Under 29 CFR 2590.701-6 and 26 CFR 54.9801-6T of

the interim rule, a group health plan offering group health insurance coverage is obligated to provide a description of the plans' special enrollment rules. The special enrollment rules generally apply in circumstances when the participant initially declined to enroll in the plan, and subsequently would like to have coverage.

These regulations offer a model form to be used by group health plans and health insurance issuers, containing the minimum information mandated by the statute. Based on past experience, the staff believes that most of the materials required to be supplied under this ICR will be prepared by contract service providers such as insurance companies and third-party administrators.

Type of Review: New.

Agencies: U.S. Department of Labor, Pension and Welfare Benefits Administration; U.S. Department of the Treasury, Internal Revenue Service.

Title: Notice of Enrollment Rights.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions; Group Health Plans.

Frequency: On occasion.

Burden:

Year	Total respondents (000)	Total responses	Average time per response (minutes)	Burden hours	Cost
1997	2,600,000	499,080	.50	750	100,000
1998	2,600,000	7,622,010	.50	11,430	1,460,000
1999	2,000,000	8,959,380	.50	13,440	1,720,000
Totals

3. Notice of Pre-Existing Condition Exclusion

i. Department of Labor

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed information collection requests (ICR) in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (Pub. L. 104-13, 44 U.S.C. Chapter 35) and 5 CFR 1320.11. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Pension and Welfare Benefits

Administration is soliciting comments concerning the proposed new collection of Notice of Pre-Existing Condition Exclusion.

Dates: Written comments must be submitted to the office listed in the addressee section below on or before May 31, 1997. In light of the request for OMB clearance by June 1, 1997, submission of comments within the first 30 days is encouraged to ensure their consideration.

The Department of Labor is particularly interested in comments which:

- evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

- enhance, the quality, utility, and clarity of the information to be collected; and

- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Addressee: Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue, Room N-5647, Washington, D.C. 20210. Telephone: 202-219-4782 (this is not a toll-free number) Fax: 202-219-4745.

ii. Department of the Treasury

The collection of information is in Sections 54.9801-3T, 54.9801-4T, and 54.9801-5T. This information is required by the statute so that participants will be informed about their rights under HIPAA and about the amount of creditable coverage that they have accrued under a group health plan. The likely respondents are business or other for-profit institutions, non-profit institutions, small businesses or organizations, and Taft-Hartley trusts. Responses to this collection of information are mandatory.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Officer of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224. Comments on the collection of information should be received by May 31, 1997. In light of the request for OMB clearance by June 1, 1997, submission of comments within the first 30 days is encouraged to ensure their consideration. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the

Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How to enhance the quality, utility, and clarity of the information to be collected;

How to minimize the burden of complying with the proposed collection of information, including the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Additional PRA 95 Information:

I. *Background:* In order to meet HIPAA's goal of improving portability of health care coverage, participants need to understand their rights to show prior creditable coverage when entering a group health plan that contain pre-existing condition exclusion provisions. In addition, participants entering plans that use the alternative method of crediting coverage also need to be informed of the plan's provisions. Therefore, the Department has determined that plans that contain these provisions must disclose that fact to new participants, as well as inform individual participants of the extent to which a pre-existing condition exclusion applies to them.

II. *Current Actions:* 29 CFR 2590.701-3(c) and 26 CFR 54.9801-3T(c) requires that a group health plan or health insurance issuer offering group health insurance under the plan may not impose any pre-existing condition

exclusions on a participant unless the participant has been notified in writing that the plan contains pre-existing condition exclusions, that a participant has the right to demonstrate any period of prior creditable coverage, and that the plan or issuer will assist the participant in obtaining a certificate of prior coverage from any prior plan or issuer, if necessary. 29 CFR 2590.701-4(c)(4) and 26 CFR 54.9801-4T(c)(4) requires that plans that use the alternative method of crediting coverage disclose their method at the time of enrollment in the plan. No additional cost of preparing or distributing this information has been included in this analysis because plans would only pursue this option if it were, on net, less costly than the standard method.

In addition, 29 CFR 2590.701-5(d)(2) and 26 CFR 54.9801-5T(d)(2) requires that before a plan or issuer imposes a pre-existing condition exclusion on a particular participant, it must first disclose that determination in writing, including the basis for the decision, and an explanation of any appeal procedure established by the plan or issuer.

Type of Review: New.

Agencies: U.S. Department of Labor, Pension and Welfare Benefits Administration; U.S. Department of the Treasury, Internal Revenue Service.

Title: Notice of Pre-Existing Exclusion Provisions.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions; Group Health Plans.

Frequency: On occasion.

Burden:

Cite/reference	Total respondents	Total responses	Average time per responses (minutes)	Burden hours	Cost
Notice at time of enrollment:					
1997	1,261,450	500,800	0.70	2,470	\$180,000
1998	1,261,450	7,626,880	0.54	16,300	1,700,000
1999	1,261,450	8,959,700	0.50	13,750	1,730,000
Notice of pre-existing condition causing lack of coverage:					
1997	1,261,450	57,900	2.27	1,800	100,000
1998	1,261,450	862,830	0.84	6,160	410,000
1999	1,261,450	1,008,810	0.52	1,830	210,000
Totals

*Estimated Total Burden Cost:***N. Paperwork Reduction Act—Department of Health and Human Services**

Under the Paperwork Reduction Act of 1995, HHS is required to provide 60-day notice in the **Federal Register** and

solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are, however, requesting an emergency review of this notice. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirement for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, to ensure compliance with section 111 of the HIPAA necessary to implement congressional intent with respect to guaranteeing availability of individual health insurance coverage to certain individuals with prior group coverage. We cannot reasonably comply with the normal clearance procedures because public harm is likely to result because eligible individuals will not receive the health insurance protections under the statute.

We are requesting that OMB provide a 30-day public comment period from the date of the publication, with OMB review and approval by June 1, 1997, and a 180-day approval. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: New collection.

Title of Information Collection: Information Requirements Referenced in HIPAA for Group Health Plans.

Form Number: HCFA-R-206.

Use: This regulation and related information collection requirements will ensure that group health plans provide individuals with documentation necessary to demonstrate prior creditable coverage, and that group health plans notify individuals of their special enrollment rights in the group health insurance market.

Frequency: On occasion.

Affected Public: State and local governments, Business or other for profit, not-for-profit institutions, individuals or households, Federal government.

Number of Respondents: 1,430.

Total Annual Responses: Due to the rolling effective dates in the statute, the number of annual responses is estimated to be 32.5 million in 1997, but will increase to 41 million in 1998 and 42.5 million in 1999.

Total Annual Hours Requested: 1.8 million to 3.6 million hours in 1997; 2.3 million to 5.8 million hours in 1998; and 2.6 million to 5.9 million hours in 1999.

Total Annual Costs: \$36.8 million to \$53.9 million in 1997; \$42.4 million to \$76.3 million in 1998; and \$43.5 million to \$77.3 million in 1999. 45 CFR §§ 146.120, 146.122, 146.150, 146.152, 146.160, and 146.180 of this document contain information collection requirements.

45 CFR 146.120 Certificates and Disclosure of Previous Coverage

Certificates and Disclosure of Prior Coverage. This section sets forth guidance regarding the certification and other disclosure of information requirements relating to prior creditable coverage of an individual. In general, the certificate must be provided in writing and must include the following information: (1) The date any waiting or affiliation period began, (2) the date coverage began, and (3) the date

coverage ended (or indicate if coverage is continuing). The regulations also allow a plan or issuer in an appropriate case to simply state in the certificate that the individual has at least 18 months of creditable coverage that is not interrupted by a significant break and indicate the date coverage ended. In general, individuals have the right to receive a certificate automatically (an automatic certificate) when they lose coverage under a plan and when they have a right to elect COBRA continuation coverage.

We anticipate that approximately 1,400 issuers will be required to produce 30 million certifications per year based on the model certificate provided. Our estimate of issuers (1,400) includes commercial insurers and HMOs, but does not include some types of issuers, such as Preferred Provider Organizations (PPOs); however, these types of issuers are small in number. The time estimate includes the time required to gather the pertinent information, create a certificate, and mail the certificate to the plan participant. This time estimate is based on discussions with industry individuals. We believe that, as a routine business practice, the issuers' administrative staff have the necessary information readily available to generate the required certificates. In addition, we have determined that the majority of issuers have or will have the capability to automatically computer generate and disseminate the necessary certification when appropriate.

These estimates include the certificates required by issuers acting as service providers on behalf of group health plans and state and local government health plans. We anticipate that most, if not all, state and local government health plans will contract with an issuer to develop the certificate.

ESTIMATES FOR CERTIFICATIONS

Year	Total respondents	Total responses	Average time per response (range)	Burden hours (range)	Cost (range)
1997	1,400	32,698,845	3.32 min	1,809,119 hrs ...	\$36,366,106
		6.34min	3,456,036 hrs ...	53,434,628.	
1998	1,400	28,072,131	5.19 min	2,242,866 hrs ...	40,928,939
			12.23 min	5,720,198 hrs ...	74,859,759
1999	1,400	28,055,984	5.37 min	2,510,461 hrs ...	42,124,907
			12.41 min	5,804,408 hrs ...	75,760,119

NOTE: The costs above include the costs associated with issuers acting as service providers for group health plans. The costs are also included in the Department of Labor's estimates.

Notice to all participants: Under this section, issuers are required to notify all participants at the time of enrollment

stating the terms of the issuer's pre-existing condition exclusion provisions, the participant's right to demonstrate

creditable coverage, and that the issuer will assist in securing a certificate if necessary.

We have estimated the burden associated with this information collection requirement to be the time required for issuers to develop standardized language outlining the existence and terms of any preexisting condition exclusion under the plan and the rights of individuals to demonstrate creditable coverage. In specific, we anticipate that issuers will be required to develop approximately 660,000

notices in 1997; 5.6 million notices in 1998; and 6.2 million notices in 1999. At 30 seconds for each notice, we estimate the total hour burden to be 4,400 hours in 1997; 30,000 hours in 1998; and 34,000 hours in 1999. The respective costs will be \$49,000 in 1997; \$330,000 in 1998; and \$377,000 in 1999. These estimates and subsequent estimates are based on an hourly wage of \$11 for issuers and \$15 for State and

local government employees. These estimates include the notices required by issuers on behalf of state and local government health plans, since we anticipate that most, if not all state and local government health plans will contract with an issuer to develop the notice. The estimates have been disaggregated below:

Year	Issuers	State health plans	Local health plans	Total notices
Total notices:				
1997	320,000	129,826	214,880	664,706
1998	4,878,200	259,653	429,761	5,567,614
1999	5,734,300	259,653	429,761	6,189,714
Total burden hours:				
1997	1,592	1,078	1,784	4,454
1998	24,293	2,155	3,567	30,015
1999	28,557	2,155	3,567	34,279

Notice to individual of period of preexisting condition exclusion. Within a reasonable time following the receipt of the certificate, information relating to the alternative method, or other evidence of coverage, a plan or issuer is required to make a determination regarding the length of any preexisting condition exclusion period that applies to the individual and notify the individual of its determination. Whether a determination and notification is made within a reasonable period of time will depend upon the relevant facts and circumstances including whether the application of the preexisting condition exclusion period would prevent access

to urgent medical services. The individual need only be notified, however, if, after considering the evidence, a preexisting condition exclusion period will be imposed on the individual. The basis of the determination, including the source and substance of any information on which the plan or issuer relied, must be included in the notice. The plan's appeals procedures and the opportunity of the individual to present additional evidence must also be explained in the notification.

We estimate that issuers will be required to develop approximately 29,000 notices in 1997; 425,000 notices

in 1998; and 498,000 notices in 1999. At 2 minutes for each notice, we estimate the total hour burden to be 960 hours in 1997; 14,000 hours in 1998; and 16,600 hours in 1999. We estimate the respective costs associated with these burdens to be \$10,600 in 1997; \$156,000 in 1998; and \$183,000 in 1999. These estimates include the notices required by issuers on behalf of state and local government health plans, since we anticipate that most, if not all state and local government health plans will contract with an issuer to develop the notice. The estimates have been disaggregated below:

Year	Issuers	State health plans	Local health plans	Total notices
Total notices:				
1997	27,650	588	766	29,004
1998	422,136	1,176	1,531	425,143
1999	496,182	1,176	1,531	498,889
Total burden hours:				
1997	921	20	25	966
1998	14,057	40	51	14,148
1999	16,553	40	51	16,644

45 CFR 146.122 Special Enrollment Periods

This section in the regulation provides guidance regarding new enrollment rights that employees and dependents have under HIPAA. A health insurance issuer offering group health insurance coverage is required to provide a description of the special enrollment rights to anyone who declines coverage at the time of enrollment. The regulations provide a model of such a description containing

the minimum information mandated by the statute.

The first burden associated with this requirement is the time required for health insurance issuers and state and local government health plans to incorporate the model notice into the plan's standard policy information. We estimate the burden to be 2 hours annually per issuer, for a total burden of 2,800 hours. The cost associated with this hour burden is estimated to be \$30,800 annually.

The second burden associated with this requirement is the time required to disseminate the notice to new enrollees. We estimate that issuers will be required to develop approximately 1 million notices in 1997; 5.3 million notices in 1998; and 5.9 million notices in 1999. At 30 seconds for each notice, we estimate the total hour burden to be 8,300 hours in 1997; 43,000 hours in 1998; and 48,000 hours in 1999. We have estimated the costs associated with these hour burdens to be \$91,000 in 1997; \$469,000 in 1998; and \$527,000 in

1999. These estimates include the notices required by issuers on behalf of state and local government health plans,

since we anticipate that most, if not all state and local government health plans will contract with an issuer to develop

the notice. The estimates have been disaggregated below:

Year	Issuers	State health plans	Local health plans	Total notices
Total notices:				
1997	245,508	287,938	500,750	1,034,196
1998	3,750,024	575,875	1,001,500	5,327,399
1999	4,407,828	575,875	1,001,500	5,985,203
Total burden hours:				
1997	1,964	2,304	4,006	8,273
1998	30,000	4,607	8,012	42,619
1999	35,263	4,607	8,012	47,881

45 CFR 146.150 Guaranteed Availability of Coverage for Employers in the PHS Act Group Market Provisions

This section allows a health insurance issuer to 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 does not have the financial reserves necessary to underwrite additional coverage and that it is applying this denial 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. Thus, issuers are only required to report to the applicable State authority if they are discontinuing coverage in the small group market.

This requirement exists in the absence of this regulation because under current insurance practices, State insurance departments oversee discontinuance of insurance products in their State as a normal business practice. Therefore, these information collection requirements are exempt from the PRA under 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(b)(3). However, under HIPAA, States must review policies during their oversight process to make sure there is a guaranteed availability clause in each policy. For the 37 States that currently require guaranteed availability, it is our understanding that this is normal business practice. For the other 18 States, however, we see this State burden to be about 10 minutes per policy, since States already review policies for other requirements and this process does not prescribe a timetable for reviewing the policies. We see this as a total burden of 10,850 hours. We have estimated the cost associated with this hour burden to be \$163,000. If the State identifies a violation and a State has to take some action, we believe that each State will be required to initiate

fewer than 10 administrative actions on an annual basis against specific individuals or entities who failed to implement the Federal guarantee availability requirements.

45 CFR 146.152 Guaranteed Renewability of Coverage for Employers in the PHS Act Group Market Provisions

In this section issuers are only required to report if they are discontinuing a particular type of coverage or discontinuing all coverage. This requirement exists in the absence of this regulation because under current insurance practices, State insurance departments oversee discontinuance of insurance products in their State as a normal business practice. Therefore, these information collection requirements are exempt from the PRA under 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(b)(3). However, under HIPAA, States must review policies during their oversight process to make sure there is a guaranteed availability clause in each policy. For the 43 States that currently require guaranteed renewability, it is our understanding that this is normal business practice. For the other 12 States, however, we see this State burden to be about 10 minutes per policy, since States already review policies for other requirements and this process does not prescribe a timetable for reviewing the policies. We see this as a total burden of 6,700 hours. We have estimated the cost associated with this hour burden to be \$100,500. If the State identifies a violation and a State has to take some action, we believe that each State will be required to initiate fewer than 10 administrative actions on an annual basis against specific individuals or entities who failed to implement the Federal guarantee renewability requirements.

45 CFR 146.160 Disclosure of Information by Issuers to Employers Seeking Coverage in the Small Group Market in the PHS Act Provisions

This section requires issuers to disclose information to employers seeking coverage in the small group market. This section requires information to be provided by a health insurance issuer offering any health insurance coverage to a small employer. This information includes the issuer's right to change premium rates and the factors that may affect changes in premium rates, renewability of coverage, any preexisting condition exclusion, any affiliation periods applied by HMOs, the geographic areas served by HMOs, and the benefits and premiums available under all health insurance coverage for which the employer is qualified. The issuer is exempted from disclosing information that is proprietary or trade secret information under applicable law.

The information described in this section must be language that is understandable by the average small employer and sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage. This requirement is satisfied if the issuer provides an outline of coverage, the minimum contribution and group participation rules that apply to any particular type of coverage, and any other information required by the State. An outline of coverage is defined as a general description of benefits and premiums. This would include an outline of coverage similar to the manner in which Medigap policies are presented, allowing the employer to easily compare one policy form to another to determine what is covered and how much the coverage will cost.

We have estimated the total burden associated with this activity to be 2,400 hours. We anticipate that 1,200 issuers will be required to provide disclosure to small employers on an annual basis. We

estimate this time to be approximately 2 hours for each issuer to develop and update the standard information related to the general description of benefits and premiums on an annual basis and include this information in their policy information. We have estimated the cost associated with this hour burden to be \$36,000.

45 CFR 146.180 Exclusion of Certain Plans From the PHS Act Group Market Requirements

Section 145.180(b) includes rules pertaining to nonfederal governmental plans, which are permitted under HIPAA to elect to be exempted from some or all of HIPAA's requirements in the PHS Act. The regulation establishes the form and manner of the election. In particular, a nonfederal governmental plan making this election is required to notify plan participants, at the time of enrollment and on an annual basis, of the fact and consequences of the election. The burden imposed by this is the requirement for plans to disseminate standard notification language describing the plans' election and the consequences of this election. We anticipate that between 3,500 and 5,000 nonfederal governmental plans will make this election and will therefore be required to disseminate notifications to their participants on an annual basis. Since this is standard language that will be incorporated into plans' existing policy documents, we see the burden as approximately 2 hours per plan to develop and update this standardized disclosure statement on an annual basis. Thus, we estimate the total burden for this activity to range from 7,000 to 10,000 hours. We estimate the cost associated with these hourly burdens to range from \$77,000 to \$110,000 per year.

The above estimate does not include the cost of disseminating the notices to all plan participants on an annual basis and to new enrollees at the time of enrollment. Although we do not have an accurate estimate of the number of nonfederal governmental plans will choose to opt out of these provisions, we have provided for a range of 50 to 100 percent. Using these ranges, we estimated 400,000 to 800,000 of these notices would need to be produced in 1997 and 800,000 to 1.6 million in 1998 and 1999. At 30 seconds per notice, we estimate the total burden hours to range from 3,400 to 6,800 in 1997; and 6,800 to 13,600 in 1998 and 1999. We have estimated the costs associated with these hour burdens to range from \$37,400 to \$74,800 in 1997; and from \$74,800 to \$149,600 in 1998 and 1999.

We have submitted a copy of this rule to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained. Interested persons are invited to send comments regarding this burden or any other aspect of these collections of information. If you comment on these information collection and record keeping requirements, please mail copies directly to the following addresses:

Health Care Financing Administration,
Office of Financial and Human
Resources, Management Planning and
Analysis Staff, Room C2-26-17, 7500
Security Boulevard, Baltimore, MD
21244-1850. Attn: John Burke
Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Attn: Allison Herron Eydt,
HCFA Desk Officer.

Statutory Authorities

The Department of Labor interim final rule is adopted pursuant to the authority contained in Section 707 of ERISA (Pub. L. 93-406, 88 Stat. 894; 29 U.S.C. 1135) as amended by HIPAA, (Pub. L. 104-91; 101 Stat. 1936; 29 U.S.C. 1181).

The Department of Health and Human Services interim final rule is adopted pursuant to the authority contained in Sections 2701, 2702, 2711, 2712, 2713, and 2792 of the PHS Act, as established by HIPAA, (Pub. L. 104-191, 42 U.S.C. 300gg-1 through 300gg-13, and 300gg-92).

The Department of the Treasury temporary rule is adopted pursuant to the authority contained in Section.

List of Subjects

26 CFR Part 54

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

29 CFR Part 2590

Employee benefit plans, Employee Retirement Income Security Act, Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Parts 144 and 146

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

Amendments to the Regulations

Internal Revenue Service

26 CFR Chapter 1

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 is amended by adding entries in numerical order to read as follows:

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

Section 54.9801-1T also issued under 26 U.S.C. 9806.

Section 54.9801-2T also issued under 26 U.S.C. 9806.

Section 54.9801-3T also issued under 26 U.S.C. 9806.

Section 54.9801-4T also issued under 26 U.S.C. 9806.

Section 54.9801-5T also issued under 26 U.S.C. 9801(c)(4), 9801(e)(3), and 9806

Section 54.9801-6T also issued under 26 U.S.C. 9806.

Section 54.9802-1T also issued under 26 U.S.C. 9806.

Section 54.9804-1T also issued under 26 U.S.C. 9806.

Section 54.9806-1T also issued under 26 U.S.C. 9806.

Par. 2. Sections 54.9801-1T, 54.9801-2T, 54.9801-3T, 54.9801-4T, 54.9801-5T, 54.9801-6T, 54.9802-1T, 54.9804-1T, and 54.9806-1T are added to read as follows:

§ 54.9801-1T Basis and scope (temporary).

(a) *Statutory basis.* Sections 54.9801-1T through 54.9801-6T, 54.9802-1T, 54.9804-1T, and 54.9806-1T (portability sections) implement Chapter 100 of Subtitle K of the Internal Revenue Code of 1986.

(b) *Scope.* A group health plan may provide greater rights to participants and beneficiaries than those set forth in these portability sections. These portability sections set forth minimum requirements for group health plans concerning:

(1) Limitations on a preexisting condition exclusion period.

(2) Certificates and disclosure of previous coverage.

(3) Rules relating to creditable coverage.

(4) Special enrollment periods.

(c) *Similar Requirements Under the Public Health Service Act and Employee Retirement Income Security Act.*

Sections 2701, 2702, 2721, and 2791 of the Public Health Service Act and sections 701, 702, 703, 705, and 706 of the Employee Retirement Income Security Act of 1974 impose requirements similar to those imposed under Chapter 100 of Subtitle K of the Code with respect to health insurance issuers offering group health insurance coverage. See 45 CFR parts 144, 146 and 148 and 29 CFR part 2590. See also Part B of Title XXVII of the Public Health Service Act and 45 CFR part 148 for other rules applicable to health insurance offered in the individual market (defined in § 54.9801-2T).

§ 54.9801-2T Definitions (temporary).

Unless otherwise provided, the definitions in this section govern in applying the provisions of §§ 54.9801-1T through 54.9801-6T, 54.9802-1T, 54.9804-1T, and 54.9806-1T.

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.

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 601-608 of the ERISA, section 4980B of the Code (other than paragraph (f)(1) of such section 4980B insofar as it relates to pediatric vaccines), and Title XXII of the PHSA.

(4) *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.

Condition means a medical condition.

Creditable coverage means *creditable coverage* within the meaning of § 54.9801-4T(a).

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

Enroll means to become covered for benefits under a group health plan (i.e., 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 § 54.9801-3T(a)(2) (i) and (ii).

Excepted benefits means the benefits described as excepted in § 54.9804-1T(b).

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.

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

Group health plan means a plan (including a self-insured plan) of, or contributed to by, an employer (including a self-employed person) or employee organization to provide health care (directly or otherwise) to the employees, former employees, the employer, others associated or formerly associated with the employer in a business relationship, or their families.

Group market means the market for health insurance coverage offered in connection with a group health plan. (However, 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.)

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. However, benefits described in § 54.9804-1T(b)(2) are not treated as benefits consisting of medical care.

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). Such 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 PHSA);

(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.

Individual health insurance coverage means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited duration insurance. For this purpose, short-term, limited duration insurance means health insurance coverage provided pursuant to 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 such contract becomes effective. 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 PHSA, 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.

Issuer means a health insurance issuer.

Late enrollment definitions (*late enrollee* and *late enrollment*) are set forth in § 54.9801-3T(a)(2) (iii) and (iv).

Medical care has the meaning given such term by section 213(d) of the Internal Revenue Code, determined without regard to section 213(d)(1)(C) and so much of section 213(d)(1)(D) as relates to qualified long-term care insurance.

Medical condition on 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.

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 such person terminates upon the termination of such legal obligation.

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, then 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, then the plan year is the employer's taxable year; or

(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 preenrollment period.

Public health plan means *public health plan* within the meaning of § 54.9801-4T(a)(1)(ix).

Public Health Service Act (PHSA) means the Public Health Service Act (42 U.S.C. 201, *et seq.*).

Significant break in coverage means a *significant break in coverage* within the meaning of § 54.9801-4T(b)(2)(iii).

Special enrollment date means a *special enrollment date* within the meaning of § 54.9801-6T(d).

State health benefits risk pool means a *State health benefits risk pool* within the meaning of § 54.9801-4T(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.

§ 54.9801-3T Limitations on preexisting condition exclusion period (temporary).

(a) **Preexisting condition exclusion—**
(1) *In general.* Subject to paragraph (b)

of this section, a group health plan may impose, with respect to a participant or beneficiary, a preexisting condition exclusion only if the requirements of this paragraph (a) are satisfied. (See PHSA section 2701 and ERISA section 701 under which this prohibition is also imposed on a health insurance issuer offering group health insurance coverage.)

(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 rules of this paragraph (a)(1)(i) are illustrated by the following examples:

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 1*, 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 2*, 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. Two months later, B is hospitalized for asthma.

(ii) In this *Example 3*, 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 attributed to diabetes). After enrolling in the plan, D stumbles and breaks a leg.

(ii) In this *Example 4*, 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.

(i) **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 § 54.9801-4T. For purposes of § 54.9801-1T through § 54.9801-6T, the phrase "days of creditable coverage" has the same meaning as the phrase

"aggregate of the periods of creditable coverage" as such term is used in section 9801(a)(3) of the Internal Revenue Code.

(iv) *Other standards.* See § 54.9802-1T 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) The following example illustrates the rule 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) (A) *Late enrollment* means enrollment under a group health plan other than on—

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

(2) A special enrollment date for the individual.

(B) If an individual ceases to be eligible for coverage under the plan by

terminating employment, and then 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 following a suspension of coverage that applied generally under the plan.

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

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 1*, 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 2*, F would not be a late enrollee with respect to F's coverage that became effective on January 1, 2000.

(b) *Exceptions pertaining to preexisting condition exclusions*—(1) *Newborns*—

(i) *In general.* Subject to paragraph (b)(3) of this section, a group health plan 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 rule of this paragraph (b)(1) is illustrated by the following example:

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 45 days after 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 2 months 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 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 (2) of this section no longer apply to a child after a significant break in coverage.

(4) *Pregnancy.* A group health plan 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 § 54.9801-6T(b).

(c) *Notice of plan's preexisting condition exclusion.* A group health 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 § 54.9801-5T. The description of the rights of individuals to demonstrate 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.

§ 54.9801-4T Rules relating to creditable coverage (temporary).

(a) *General rules*—(1) *Creditable coverage.* For purposes of this section,

except as provided in paragraph (a)(2) of this section, the term *creditable coverage* means coverage of an individual under any of the following:

(i) A group health plan as defined in § 54.9801-2T.

(ii) Health insurance coverage as defined in § 54.9801-2T (whether or not the entity offering the coverage is subject to chapter 100 of Subtitle K, and without regard to whether the coverage is offered in the group market, the individual market, or otherwise).

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

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

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

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

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

(A) An organization qualifying under section 501(c)(26);

(B) A qualified high risk pool described in section 2744(c)(2) of the PHSA; 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 expected benefits (described in § 54.9804-1T).

(3) *Methods of counting creditable coverage.* For purposes of reducing any preexisting condition exclusion period, as provided under § 54.9801-3T(a)(1)(iii), a group health plan determines the amount of an individual's creditable coverage by using the standard method described in paragraph (b) of this section, except that the plan may use the alternative method under paragraph (c) of this section with respect to any or all of the categories of benefits described under paragraph (c)(3) of this section or may provide that a health insurance issuer offering health insurance coverage under the plan may use the alternative method of counting creditable coverage.

(b) *Standard method*—(1) *Specific benefits not considered.* Under the standard method, a group health plan 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 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 PHSA 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 under this paragraph (b)(2):

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 Q, and enrolls in Employer Q's group health plan, 64 days after the last date of coverage under Employer P's plan. Employer Q's plan has a 12-month preexisting condition exclusion period.

(ii) In this *Example 1*, because A had a break in coverage of 63 days, Employer Q's plan may disregard A's prior coverage and A may be subject to a 12-month preexisting condition exclusions period.

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

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

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

(ii) In this *Example 3*, the issuer that provides group health insurance to Employer Q'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 Q's plan is a self-insured plan, and, thus is not subject to State insurance laws.

(ii) In this *Example 4*, 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 plan has a 30-day waiting period before coverage begins. B enrolls in Employer R's plan when first eligible.

(ii) In this *Example 5*, 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 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 6*, *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-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 7*, because *D* applied for the policy before the end of the 63rd day, 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 8*, 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) Rule.* Notwithstanding any other provision of this paragraph (b)(2), for purposes of reducing a preexisting condition exclusion period (but not for purposes of issuing a certificate under § 54.9801–5T), a group health plan may determine the amount of creditable coverage in any other manner that is at least as favorable to the individual as the method set forth in this paragraph (b)(2), subject to the requirements of other applicable law.

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

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 her 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 determines the amount of creditable coverage based on coverage within any category of benefits described in paragraph (c)(3) of this section and not based on coverage for any other benefits. The plan may use the alternative method for any or all 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 using the alternative method is required to apply it uniformly to all participants and beneficiaries under the plan. A plan that provides benefits through one or more insurance policies (or in part through one or more insurance policies) will not fail the uniform application requirement of this paragraph (c)(2) if the alternative method is used (or not used) separately with respect to participants and beneficiaries under any policy, provided that the alternative method is applied uniformly with respect to all coverage under that policy. The use of the alternative method is required to be set forth in the plan.

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

- (i) Mental health;
- (ii) Substance abuse treatment;
- (iii) Prescription drugs;
- (iv) Dental care; or
- (v) Vision care.

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

- (i) State prominently that the plan is using the alternative method of counting creditable coverage in disclosure statements concerning the plan, and state this to each enrollee at the time of enrollment under the plan; and
- (ii) Include in these statements a description of the effect of using the alternative method, including an identification of the categories used.

(5) *Disclosure of information on previous benefits.* See § 54.9801–5T(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).

(6) *Counting creditable coverage—(i) In general.* Under the alternative method, the group health plan 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 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 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 may determine the amount of creditable coverage in any other reasonable manner, uniformly applied, this is at least as favorable to the individual.

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

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, 2002 (*D's* enrollment date). Employer *Y's* plan uses the alternative method of counting creditable coverage and imposes a 12-month preexisting condition exclusion on prescription drug benefits.

(ii) 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.

§ 54.9801–5T Certification and disclosure of previous coverage (temporary).

(a) *Certificate of creditable coverage—(1) Entities required to provide certificate—(i) In general.* A group

health plan is required to furnish certificates of creditable coverage in accordance with this paragraph (a) of this section. (See PHSA section 2701(e) and ERISA section 701(e) under which this obligation is also imposed on a health insurance issuer offering group health insurance coverage.)

(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, a group health plan is deemed to have satisfied the certification requirement with respect to a participant or beneficiary if any other entity 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 employer sponsoring the plan 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 plan does not violate the certification requirements of this paragraph (a) (though the issuer would have violated the certification requirements pursuant to section 2701(e) of the PHSA and section 701(e) of ERISA).

(iv) *Special rules relating to issuers providing coverage under a plan—(A)(1) Responsibility of issuer for coverage period.* See 29 CFR 2590.701-5 and 45 CFR 146.115, under which an issuer is not required to provide information regarding coverage provided to an individual by another party.

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

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) (1) *Cessation of issuer coverage prior to cessation of coverage under a plan.* If an individual's coverage under an issuer's policy ceases before the individual's coverage under the plan ceases, the issuer is required (under section 2701(e) of the PHSA and section 701(e) of ERISA) 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 paragraph (a)(2)(ii) and (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)(2) 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 rule of this paragraph (a)(1)(iv)(B) is illustrated by the following example:

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 automatic certificates as permitted under paragraph (a)(2)(ii) 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 certificate must be provided; timing of issuance—(i) Individuals.* A certificate must be

provided, without charge, for participants or dependents who are or were covered under a group health plan upon the occurrence of any of the events described in paragraph (a)(2)(ii) or (iii) of this section.

(ii) *Issuance of automatic certificates.*

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

(A) *Qualified beneficiaries upon a qualifying event.* In the case of an individual who is a qualified beneficiary (as defined in section 4980B(g)(1)) entitled to elect COBRA continuation coverage, an automatic certificate is required to be provided at the time the individual would lose coverage under the plan in the absence of COBRA continuation coverage or alternative coverage elected instead of COBRA continuation coverage. A plan 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 4980B(f)(6) (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 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 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, acting in a reasonable and prompt fashion, can provide the certificate. A certificate is required to be provided under this paragraph (a)(2)(iii) even if the individual has previously received an automatic certificate under paragraph (a)(2)(ii) of this section.

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

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

(ii) In this *Example 1*, 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 2*, 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 3*, 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, 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 4*, the plan must provide an updated automatic certificate to C within a reasonable time after the end of the grace period.

Example 5. (i) Individual D is currently covered under the group health plan of

Employer T. D requests a certificate, as permitted under paragraph (a)(2)(iii). 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 5*, the plan's procedure satisfies paragraph (a)(2)(iii) of this section.

(3) *Form and content of certificate—*(i) *Written certificate—(A) In general.*

Except as provided in paragraph (a)(3)(i)(B) of this section, the certificate must be provided in writing (including any form approved by the Secretary as a writing).

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

(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 (e.g., by telephone); and

(4) The receiving plan or issuer receives such 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 the following—

(A) The date the certificate is issued;

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

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

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

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

(F) Either—

(1) A statement that an individual has at least 18 months (for this purpose, 546 days is deemed to be 18 months) of creditable coverage, disregarding days of

creditable coverage before a significant break in coverage, or

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

(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 pursuant to paragraph (a)(2)(ii) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate pursuant to paragraph (a)(2)(iii) of this section, 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 provides a certificate in accordance with a model certificate authorized by the Secretary.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in § 54.9804-1T. In addition, the information in the certificate regarding coverage is not required to specify categories of benefits described in § 54.9801-4T(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 pursuant to 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)(A) Reasonable efforts.* A plan is required to use reasonable efforts to determine any information needed for a certificate relating to the 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 knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the plan.

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

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) of this

section that it make reasonable efforts to determine the cessation of dependents' coverage and the related dependent coverage information.

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by a plan or issuer does not provide the name of any dependent 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 § 54.9801-3T(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) In general.* A group health plan 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 and specifying that the type of coverage described in the certificate is for dependent coverage (e.g., 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 pursuant to paragraph (a)(2)(iii) of this section, a plan 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 credible coverage in the certificate applies to the dependent.

(C) *Demonstrating a dependent's credible 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 specification rules for entities not subject to Chapter 100 of Subtitle K of the Internal Revenue Code—(i) Issuers.* For rules requiring that issuers in the group and individual markets provide certificates consistent with the rules in this section, see section 701(e) of ERISA and sections

2701(e), 2721(b)(1)(B), and 2743 of the PHSA.

(ii) *Other entities.* For special rules requiring that certain other entities, not subject to Chapter 100 of Subtitle K of the Internal Revenue Code, provide certificates consistent with the rules in the section, see section 2791(a)(3) of the PHSA applicable to entities described in sections 2701(c)(1) (C), (D), (E), and (F) (relating to Medicare, Medicaid, CHAMPUS, and Indian Health Service), section 2721(b)(1)(A) of the PHSA applicable to nonfederal governmental plans generally, and section 2721(b)(2)(C)(ii) of the PHSA applicable to nonfederal governmental plans that elect to be excluded from the requirements of Subparts 1 and 3 of Part A of Title XXVII of the PHSA.

(b) *Disclosure of coverage to a plan, or issuer, using the alternative method of counting creditable coverage—(1) In 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 § 54.9801-4T(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 to 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) In general.* The rules in this paragraph (c) implement section 9801(c)(4), which permits individuals to establish creditable coverage through means other than certificates, and section 9801(e)(3), 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 pursuant to 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 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 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 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 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 may refuse to credit coverage where the individual fails to cooperate with the plan's or issuer's efforts to verify coverage, the plan 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 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 rules of this paragraph (c)(2) are illustrated by the following example:

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's *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 receives information under paragraph (a) of this section (certifications), paragraph (b) of this section (disclosure of information relating to the alternative method), or paragraph (c) of this section (other evidence of creditable coverage), the plan 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 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 relied. In addition, the plan is required to provide the individual with a written explanation of any appeal procedures established by the plan, 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 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 such reconsideration, as described in this paragraph (d), is provided to the individual; and

(ii) Until the final determination is made, the plan, 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 *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 1*, 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 2*, 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 3*, 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) of this section).

§ 54.9801-6T Special enrollment periods (temporary).

(a) *Special enrollment for certain individuals who lose coverage*—(1) *In general.* A group health plan is required to permit employees and dependents described in paragraph (a)(2), (3) or (4) of this section to enroll for coverage under the terms of the plan if the conditions in paragraph (a)(5) of this section are satisfied and the enrollment is requested within the period described in paragraph (a)(6) of this section. The enrollment is effective at the time described in paragraph (a)(7) of this section. 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. (See PHSA section 2701(f)(1) and ERISA section 701(f)(1) under which this obligation is also imposed on a health insurance issuer offering group health insurance coverage.)

(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 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 this 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 CORRA 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 paragraph (a) (2), (3), or (4) of this section) not later than 30 days after the exhaustion of the other coverage described in paragraph (a)(5)(ii)(A) of this section 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) of this section 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 (e.g., 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) *In 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 paragraph (b) (2), (3), (4), (5), or (6) of this section 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) of this section. The enrollment is effective at the time described in paragraph (b)(8) of this section. 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, in 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 individual 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 and 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, in 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 rules of this paragraph (b) are illustrated by the following example:

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) of this section are satisfied, the conditions for special enrollment of an employee and a spouse with a new dependent under paragraph (b)(4) of this section are satisfied, and the conditions for special enrollment of an employee and a new dependent under paragraph (b)(6) of this section 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) (1) *Special enrollment date definition.* A special enrollment date for an individual means any date in paragraph (a)(7) or (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 rules of this section are illustrated by the following examples:

Example 1. (i)(A) Employer Y maintains a group health plan that allows employees to enroll in the plan either—

(1) Effective on the first day of employment by an election filed within three days thereafter;

(2) Effective on any subsequent January 1 by an election made during the preceding months of November or December; or

(3) Effective as of any special enrollment date described in this section.

(B) 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) of this section.

(ii) In this *Example 1*, B has enrolled on a special enrollment date because the enrollment is effective at a date described in paragraph (a)(7) of this section.

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) of this section.

(ii) In this *Example 2*, B has enrolled on a special enrollment date because the enrollment is effective at a date described in paragraph (a)(7) of this section (even though this date is also a regular enrollment date under the plan).

§ 54.9802-1T Prohibiting discrimination against participants and beneficiaries based on a health status-related factor (temporary).

(a) *In eligibility to enroll—*(1) *In general.* Subject to paragraph (a)(2) of this section, a group health plan may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following

health status-related factors in relation to the individual or a dependent of the individual:

- (i) Health status.
- (ii) Medical condition (including both physical and mental illnesses), as defined in § 54.9801-2T.
- (iii) Claims experience.
- (iv) Receipt of health care.
- (v) Medical history.
- (vi) Genetic information, as defined in § 54.9801-2T.
- (vii) Evidence of insurability (including conditions arising out of acts of domestic violence).
- (viii) Disability.

(2) *No application to benefits or exclusions.* To the extent consistent with section 9801 and § 54.9801-3T, paragraph (a)(1) of this section shall not be construed—

- (i) To require a group health plan to provide particular benefits other than those provided under the terms of such plan; or
- (ii) To prevent such a plan from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

(3) *Construction.* For purposes of paragraph (a)(1) of this section, rules for eligibility to enroll include rules defining any applicable waiting (or affiliation) periods for such enrollment and rules relating to late and special enrollment.

(4) *Example.* The following example illustrates the rules of this paragraph (a):

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

(ii) In this *Example*, the plan discriminates on the basis of one or more health status-related factors.

(b) *In premiums or contributions—(1) In general.* A group health plan may not require an individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual enrolled in the plan based on any health status-related factor, in relation to the individual or a dependent of the individual.

(2) *Construction.* Nothing in paragraph (b)(1) of this section shall be construed—

- (i) To restrict the amount that an employer may be charged by an issuer for coverage under a group health plan; or
- (ii) To prevent a group health plan from establishing premium discounts or

rebates or modifying otherwise applicable copayments or deductibles in return for adherence to a bona fide wellness program. For purposes of this section, a bona fide wellness program is a program of health promotion and disease prevention.

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

Example. (i) Plan X offers a premium discount to participants who adhere to a cholesterol-reduction wellness program. Enrollees are expected to keep a diary of their food intake over 6 weeks. They periodically submit the diary to the plan physician who responds with suggested diet modifications. Enrollees are to modify their diets in accordance with the physician's recommendations. At the end of the 6 weeks, enrollees are given a cholesterol test and those who achieve a count under 200 receive a premium discount.

(ii) In this *Example*, because enrollees who otherwise comply with the program may be unable to achieve a cholesterol count under 200 due to a health status-related factor, this is not a bona fide wellness program and such discounts would discriminate impermissibly based on one or more health status-related factors. However, if, instead, individuals covered by the plan were entitled to receive the discount for complying with the diary and dietary requirements and were not required to pass a cholesterol test, the program would be a bona fide wellness program.

§ 54.9804-1T Special rules relating to group health plans (temporary).

(a) *General exception small group health plans.* The requirements of Chapter 100 of Subtitle K of the Internal Revenue Code do not apply to any 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) In general.* The requirements of §§ 54.9801-1T through 54.9801-6T and 54.9802-1T do not apply to any 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); and

(viii) Coverage for on-site medical clinics.

(3) *Limited excepted benefits—*

(i) *In general.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of 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 in a narrow range or type of benefits that are generally excluded from hospital/medical/surgical benefit 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); 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.* Covered 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 not coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and

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

event under any group health plan maintained by the same plan sponsor.

(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.

(c) *Treatment of partnerships.*
[Reserved]

§ 54.9806–1T Effective dates (temporary).

(a) *General effective dates—(1) Non-collectively-bargained plans.* Except as otherwise provided in this section, Chapter 100 of Subtitle K of the Internal Revenue Code and §§ 54.9801–1T through 54.9804–1T apply with respect to group health plans for plan years beginning after June 30, 1997.

(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, Chapter 100 of Subtitle K of the Internal Revenue Code and §§ 54.9801–1T through 54.9804–1T 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 pursuant to 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)(i) *Preexisting condition exclusion periods for current employees.* Any preexisting condition exclusion period permitted under § 54.9801–3T is measured from the individual's enrollment date in the plan. Such exclusion period, as limited under § 54.9801–3T, may be completed prior to 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 Chapter 100 of Subtitle K of the Internal Revenue Code, no preexisting condition exclusion may be imposed with respect to an individual beyond the limitation in § 54.9801–3T. 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 individual had prior to the enrollment date to reduce the remaining preexisting condition exclusion period applicable to the individual.

(ii) *Examples.* The following examples illustrate the rules 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.

(ii) In this *Example 1*, 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 2*, 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 of A received before January 1, 1998.

(b) *Effective date for certification requirement—(1) In general.* Subject to the transitional rule in § 54.9801–5T(a)(5)(iii), the certification rules of § 54.9801–5T 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 § 54.9801–5T, 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, pursuant to Chapter 100 of Subtitle K of the Internal Revenue Code, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by Chapter 100 of Subtitle K of the Internal Revenue Code before January 1, 1998 if the plan or issuer has sought to comply in good faith with such requirements. Compliance with these regulations is

deemed to be good faith compliance with the requirements of Chapter 100 of Subtitle K.

(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 § 54.9801–5T(c). For coverage relating to an event occurring before July 1, 1996, a group health plan and a health insurance issuer is 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 § 54.9801–5T(c).

(e) *Transition rules for certificates 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 § 54.9801–5T(a)(2) (ii) and (iii).

(3) *Optional notice—(i) In general.* This paragraph (e)(3) applies with respect to events described in § 54.9801–5T(a)(5)(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 § 54.9801–5T(a)(2) and (3) if a notice is provided in accordance with the provisions of paragraphs (e)(3) (i) through (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 pursuant to this paragraph (e)(3) must be in writing and must include information substantially similar to the information included in a model notice authorized by the Secretary. Copies of the model notice are available at the following website—<http://www.irs.ustreas.gov> (or call (202) 622–4695).

(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 § 54.9801–5T(a)(5)(iii).

(v) *Other certification rules apply.* The rules set forth in § 54.9801–5T(a)(4)(i) (method of delivery) and

54.9801–5T(a)(1) (entities required to provide a certificate) apply with respect to the provision of the notice.

Dated: March 24, 1997.

Margaret Milner Richardson,
Commissioner of Internal Revenue.

Approved:

Donald C. Lubick,
Assistant Secretary of the Treasury.

Pension and Welfare Benefits Administration

29 CFR Chapter XXV

For the reasons set forth above, Chapter XXV of Title 29 of the Code of Federal Regulations is amended as set forth below:

1. A new Subchapter L, consisting of Part 2590, is added to read as follows:

Subchapter L—Health Insurance Portability and Renewability for Group Health Plans

PART 2590—RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

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

Sec.

- 2590.701–1 Basis and scope.
 - 2590.701–2 Definitions.
 - 2590.701–3 Limitations on preexisting condition exclusion period.
 - 2590.701–4 Rules relating to creditable coverage.
 - 2590.701–5 Certification and disclosure of previous coverage.
 - 2590.701–6 Special enrollment periods.
 - 2590.701–7 HMO affiliation period as alternative to preexisting condition exclusion.
 - 2590.702 Prohibiting discrimination against participants and beneficiaries based on a health status-related factor.
 - 2590.703 Guaranteed renewability in multiemployer plans and multiple employer welfare arrangements.
- [Reserved]

Subpart B—Other Requirements

- 2590.711 Standards relating to benefits for mothers and newborns. [Reserved]
 - 2590.712 Parity in the application of certain limits to mental health benefits.
- [Reserved]

Subpart C—General Provisions

- 2590.731 Preemption; State flexibility; construction.
- 2590.732 Special rules relating to group health plans.
- 2590.734 Enforcement. [Reserved]
- 2590.736 Effective dates.

Authority: Sec. 29 U.S.C. 1027, 1059, 1135, 1171, 1194; Sec. 101, Pub. L. 104–191, 101 Stat. 1936 (29 U.S.C. 1181); Secretary of labor's Order No. 1–87, 52 FR 13139, April 21, 1987.

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

§ 2590.701–1 Basis and scope.

(a) *Statutory basis.* This subpart implements Part 7 of Subtitle B of Title I of the Employee Retirement Income Security Act of 1974, as amended (hereinafter ERISA or the Act).

(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 subpart. This subpart A sets forth minimum requirements for group health plans and health insurance issuers offering group health insurance coverage concerning:

- (1) Limitations on a preexisting condition exclusion period.
- (2) Certificates and disclosure of previous coverage.
- (3) Rules relating to counting creditable coverage.
- (4) Special enrollment periods.
- (5) Use of an affiliation period by an HMO as an alternative to a preexisting condition exclusion.

§ 2590.701–2 Definitions.

Unless otherwise provided, the definitions in this section govern in applying the provisions of §§ 2590.701 through 2590.734.

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.

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 601–608 of the Act, section 4980B of the Code (other than paragraph (f)(1) of such section 4980B insofar as it relates to pediatric vaccines), and Title XXII of the PHSA.

(4) *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.

Condition means a medical condition.

Creditable coverage means creditable coverage within the meaning of § 2590.701–4(a).

Enroll means to become covered for benefits under a group health plan (i.e., 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 § 2590.701–3(a)(2) (i) and (ii).

Excepted benefits means the benefits described as excepted in § 2590.732(b).

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.

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 to the extent that the plan provides medical care (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, 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.)

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 the Act). Such 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 PHSA);

(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.

Individual health insurance coverage means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited duration insurance. For this purpose, short-term, limited-duration insurance means health insurance coverage provided pursuant to 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 such contract becomes effective. 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 PHSA, 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.

Late enrollment definitions (late enrollee) and late enrollment) are set forth in § 2590.701-3(a)(2) (iii) and (iv).

Medical care means amounts paid for—

(1) The diagnosis, cure, mitigation, treatment, 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; and

(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.

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 such person terminates upon the termination of such legal obligation.

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, then 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, then the plan year is the employer's taxable year; or

(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 means *public health plan* within the meaning of § 2590.701-4(a)(1)(ix).

Public Health Service Act (PHSA) means the Public Health Service Act (42 U.S.C. 201, *et seq.*).

Significant break in coverage means a significant break in coverage within the meaning of § 2590.701-4(b)(2)(iii).

Special enrollment date means a special enrollment date within the meaning of § 2590.701-6(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 means a State health benefits risk pool within the meaning of § 2590.701-4(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.

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) **Preexisting condition exclusion—**
(1) *In 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.

(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 rules of this paragraph (a)(1)(i) are illustrated by the following examples:

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 1*, 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 2*, The rider is 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. Two months later, B is hospitalized with asthma.

(ii) In this *Example 3*, 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 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 attributed to diabetes). After enrolling in the plan, D stumbles and breaks a leg.

(ii) In this *Example 4*, the leg is 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 § 2590.701-4. For purposes of this subpart the phrase "days of creditable coverage" has the same meaning as the phrase "aggregate of the periods of creditable coverage" as such term is used in section 701(a)(3) of the Act.

(iv) *Other Standards.* See § 2590.702 for other standards that may apply with respect to certain benefits 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) The following example illustrates the rule 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's 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 in 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) (A) *Late enrollment* means enrollment under a group health plan other than on—

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

(2) A special enrollment date for the individual.

(B) If an individual ceases to be eligible for coverage under the plan by terminating employment, and then 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 following a suspension of coverage that applied generally under the plan.

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

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 1*, 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 2*, F would not be a late enrollee with respect to F's coverage that became effective on January 1, 2000.

(b) *Exceptions pertaining to preexisting condition exclusions—(1) Newborns—(i) In general.* Subject to

paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion 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 rule of this paragraph (b)(1) is illustrated by the following example:

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 45 days after 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 2 months 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 (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 § 2590.701-6(b).

(c) *Notice of plan's preexisting condition exclusion.* A group health plan, and 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 § 2590.701-5. The description of the rights of individuals to demonstrate 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.

§ 2590.701-4 Rules relating to creditable coverage.

(a) *General rules—*

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

(i) A group health plan as defined in § 2590.701-2.

(ii) Health insurance coverage as defined in § 2590.701-2 (whether or not the entity offering the coverage is subject to Part 7 of Subtitle B of Title I of the Act, and without regard to whether the coverage is offered in the group market, the individual market, or otherwise).

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

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

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

Administration and of the Public Health Service).

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

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

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

(B) A qualified high risk pool described in section 2744(c)(2) of the PHSA; 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 § 2590.732).

(3) *Methods of counting creditable coverage.* For purposes of reducing any preexisting condition exclusion period, as provided under § 2590.701-3(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) of this section, except that the plan, or issuer, may use the alternative method under paragraph (c) of this section with respect to any or all of the categories of benefits described under paragraph (c)(3) of this section.

(b) *Standard method—*(1) *Specific benefits not considered.* Under the standard method, 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 the Act and section 2723(b)(2)(iii) of the PHSA 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 under this paragraph (b)(2):

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 Q, and enrolls in Employer Q's group health plan, 64 days after the last date of coverage under Employer P's plan. Employer Q's plan has a 12-month preexisting condition exclusion period.

(ii) In this *Example 1*, because A had a break in coverage of 63 days, Employer Q'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 Q, and enrolls in Employer Q's plan, on the 63rd day after the last date of coverage under Employer P's plan.

(ii) In this *Example 2*, A has a break in coverage of 62 days. Because A's break in coverage is not a significant break in coverage, Employer Q'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 Q's plan provides benefits through an insurance policy that, as required by applicable State insurance laws, defines a significant break in coverage as 90 days.

(ii) In this *Example 3*, the issuer that provides group health insurance to Employer Q'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 Q's plan is a self-insured plan, and, thus, is not subject to State insurance laws.

(ii) In this *Example 4*, 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 plan has a 30-day waiting period before coverage begins. B enrolls in Employer R's plan when first eligible.

(ii) In this *Example 5*, 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 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 6*, 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 7*, 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 8*, 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) *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 § 2590.701-5), a group health plan, and a health insurance issuer offering group health insurance coverage, may determine the amount of creditable coverage in any other manner that is at least as favorable to the individual as the method set forth in this paragraph (b)(2), subject to the requirements of other applicable law.

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

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) of this section, that F has 82 days of creditable coverage (29 days in January, 28 days in February, and 25 days in March). Thus, the preexisting condition exclusion 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) of this section and not based on coverage for any other benefits. The plan or issuer may use the alternative method for any or all of the categories. The plan 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 required to be set forth in the plan.

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

- (i) Mental health;
- (ii) Substance abuse treatment;
- (iii) Prescription drugs;
- (iv) Dental care; or
- (v) Vision care.

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

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

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

(5) *Disclosure of information on previous benefits.* See § 2590.701–5(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).

(6) *Counting creditable coverage—(i) In general.* Under the alternative method, the group health plan or issuer counts creditable coverage within a category if any level of benefits is provided within the category. Coverage under a reimbursement account or arrangement, such as a flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code), does not constitute coverage within any category.

(ii) *Special rules.* In counting an individual's creditable coverage under the alternative method, the group health plan, or issuer, first determines the amount of the individual's creditable coverage that may be counted under paragraph (b) of this section, up to a total of 365 days of the most recent creditable coverage (546 days for a late enrollee). The period over which this creditable coverage is determined is referred to as the determination period. Then, for the category specified under the alternative method, the plan or issuer counts within the category all days of coverage that occurred during the determination period (whether or not a significant break in coverage for

that category occurs), and reduces the individual's preexisting condition exclusion period for that category by that number of days. The plan or issuer may determine the amount of creditable coverage in any other reasonable manner, uniformly applied, that is at least as favorable to the individual.

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

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, 2002 (*D*'s enrollment date). Employer *Y*'s plan uses the alternative method of counting creditable coverage and imposes a 12-month preexisting condition exclusion on prescription drug benefits.

(ii) 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.

§ 2590.701–5 Certification and disclosure of previous coverage.

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

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

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

Example. (i) 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)(1) *Cessation of issuer coverage prior to cessation of coverage under a plan.* 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 paragraph (a) (2)(ii) and (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)(2) 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 rule of this paragraph (a)(1)(iv)(B) is illustrated by the following example.

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 automatic certificates as permitted under paragraph (a)(2)(ii) 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 certificate must be provided; timing of issuance—*

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

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

(A) *Qualified beneficiaries upon a qualifying event.* In the case of an individual who is a qualified beneficiary (as defined in section 607(3) of the Act) entitled to elect COBRA continuation coverage, an automatic certificate is required to be provided at the time the individual would lose coverage under the plan in the absence of COBRA continuation coverage or alternative coverage elected instead of COBRA continuation coverage. A plan or issuer satisfies this requirement if it provides the automatic certificate no later than the time a notice is required to be furnished for a qualifying event under section 606 of the 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 required to be provided under this paragraph (a)(2)(iii) even if the individual has previously received a certificate under this paragraph (a)(2)(iii) or an automatic certificate under paragraph (a)(2)(ii) of this section.

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

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

(ii) In this *Example 1*, 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 2*, 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 3*, 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, 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 4*, the plan must provide an updated automatic certificate to C within a reasonable time after the end of the grace period.

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

(3) *Form and content of certificate—*

(i) *Written certificate—*(A) *In general.* Except as provided in paragraph (a)(3)(i)(B) of this section, the certificate must be provided in writing (including any form approved by the Secretary 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 paragraph (a)(2) (ii) or (iii) of this section, if—

(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 (e.g., by telephone); and

(4) The receiving plan or issuer receives such 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 the following—
 (A) The date the certificate is issued;
 (B) The name of the group health plan that provided the coverage described in the certificate;

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

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

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

(F) Either—

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

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

(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 pursuant to paragraph (a)(2)(ii) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate pursuant to paragraph (a)(2)(iii) of this section, 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 the Secretary.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in § 2590.732. In addition, the information in the certificate regarding coverage is not required to specify categories of benefits described in § 2590.701–4(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 pursuant to 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)(A) Reasonable efforts.* A plan or issuer is required to use reasonable efforts to determine any information needed for a certificate relating to the dependent coverage. In any case in which an automatic certificate is required to be furnished with respect to a dependent under paragraph (a)(2)(ii) of this section, no individual certificate is required to be furnished until the plan or issuer knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the plan.

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

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) of this section that it make reasonable efforts to determine the cessation of dependents' coverage and the related dependent coverage information.

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by a plan or issuer does not provide the name of any dependent 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 § 2590.701–3(b), under which such a child would not be subject to a preexisting condition exclusion.

(iii) *Transaction rule for dependent coverage through June 30, 1998—(A) In 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 (e.g., 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 pursuant to 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 certificates provided with respect to events occurring through June 30, 1998.

(6) *Special certification rules for entities not subject to Part 7 of Subtitle B of Title I of the Act—*(i) *Issuers.* For special rules requiring that issuers, not subject to part 7 of subtitle B of title I of the Act, provide certificates consistent with the rules in this section, including issuers offering coverage with respect to creditable coverage described in sections 701(c)(1)(G) through (c)(1)(J) of the 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), see section 2721(b)(1)(B) of the PHSA (requiring certificates by issuers offering health insurance covering in connection with a group health plan, including a church plan or a governmental plan (including the Federal Employees Health Benefits Program (FEHBP)). In addition, see section 2743 of the PHSA 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, as described in the definition of *individual health insurance coverage* in § 2590.701-2, that is not provided by a group health plan or issuer offering health insurance in connection with a group health plan.)

(ii) *Other entities.* For special rules requiring that certain other entities, not subject to part 7 of subtitle B of title I of the Act, provide certificates consistent with the rules in this section, see section 2791(a)(3) of the PHSA applicable to entities described in sections 2701(c)(1)(C), (D), (E), and (F) of PHSA (relating to Medicare, Medicaid, CHAMPUS, and Indian Health Service), section 2721(b)(1)(A) of the PHSA applicable to nonfederal governmental plans generally, section 2721(b)(2)(C)(ii) of the PHSA applicable

to nonfederal governmental plans that elect to be excluded from the requirements of subparts 1 and 3 of part A of Title XXVII of the PHSA, and section 9805(a) of the Internal Revenue Code applicable to group health plans, which includes church plans (as defined in section 414(e) of the Internal Revenue Code).

(b) *Disclosure of coverage to a plan, or issuer, using the alternative method of counting creditable coverage—*(1) *In general.* 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 § 2590.701-4(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.* 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) *In general.* The rules in this paragraph (c) implement section 701(c)(4) of the Act, which permits individuals to establish creditable coverage through means other than certificates, and section 701(e)(3) of the 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 pursuant to 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 (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 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 rules of this paragraph (c)(2) are illustrated by the following example:

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 under paragraph (a) of this section (certifications), paragraph (b) of this section (disclosure of information relating to the alternative method), or paragraph (c) of this section (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 or 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 such reconsideration, as described in this paragraph (d), 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 *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 1*, 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 2*, 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 3*, 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) of this section).

§ 2590.701–6 Special enrollment periods.

(a) *Special enrollment for certain individuals who lose coverage—(1) In general.* A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, is required to permit employees and dependents described in paragraph (a) (2), (3), or (4) of this section to enroll for coverage under the terms of the plan if the conditions in paragraph (a)(5) of this section are satisfied and the enrollment is requested within the period described in paragraph (a)(6) of this section. The enrollment is effective at the time described in paragraph (a)(7) of this section. 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 this 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 has 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 paragraph (a) (2), (3), or (4) of this section) not later than 30 days after the exhaustion of the other coverage described in paragraph (a)(5)(ii)(A) of this section 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) of this section 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 (e.g., 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) *In 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 paragraph (b) (2), (3), (4), (5), or (6) of this section 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) of this section. The enrollment is effective at the time described in paragraph (b)(8) of this section. 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, in 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 individual 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 and 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, in 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 rules of this paragraph (b) are illustrated by the following example:

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) of this section are satisfied, the conditions for special enrollment of an employee and a spouse with a new dependent under paragraph (b)(4) of this section are satisfied, and the conditions for special enrollment of an employee and a new dependent under paragraph (b)(6) of this section 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)(1) *Special enrollment date definition.* A special enrollment date for an individual means any date in paragraph (a)(7) or (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 rules of this section are illustrated by the following examples:

Example 1. (i)(A) Employer Y maintains a group health plan that allows employees to enroll in the plan either—

(1) Effective on the first day of employment by an election filed within three days thereafter;

(2) Effective on any subsequent January 1 by an election made during the preceding months of November or December; or

(3) Effective as of any special enrollment date described in this section.

(B) 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) of this section.

(ii) In this *Example 1*, B has enrolled on a special enrollment date because the enrollment is effective at a date described in paragraph (a)(7) of this section.

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) of this section.

(ii) In this *Example 2*, B has enrolled on a special enrollment date because the enrollment is effective at a date described in paragraph (a)(7) of this section (even though this date is also a regular enrollment date under the plan).

§ 2590.701–7 HMO affiliation period as alternative to preexisting condition exclusion.

(a) *In general.* A group health plan offering health insurance coverage through an HMO, or an HMO that offers health insurance coverage in connection with a group health plan, may impose an affiliation period only if each of the 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 the part requires a State to receive proposals for or approve alternatives to affiliation periods.

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

(a) *In eligibility to enroll—*(1) *In general.* Subject to paragraph (a)(2) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual.

(i) Health status.

(ii) Medical condition (including both physical and mental illnesses), as defined in § 2590.701–2.

(iii) Claims experience.

(iv) Receipt of health care.

(v) Medical history.

(vi) Genetic information, as defined in § 2590.701–2.

(vii) Evidence of insurability (including conditions arising out of acts of domestic violence).

(viii) Disability.

(2) *No application to benefits or exclusions.* To the extent consistent with section 701 of the Act and § 2590.701–3, paragraph (a)(1) of this section shall not be construed—

(i) To require a group health plan, or a health insurance issuer offering group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage; or

(ii) To prevent such a plan or issuer from establishing limitation or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

(3) *Construction.* For purposes of paragraph (a)(1) of this section, rules for eligibility to enroll include rule defining any applicable waiting (or affiliation) periods for such enrollment and rules relating to late and special enrollment.

(4) *Example.* The following example illustrates the rules of this paragraph (a):

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

(ii) In this *Example*, the plan discriminates on the basis of one or more health status-related factors.

(b) *In premiums or contributions—(1) In general.* 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) to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual enrolled in the plan based on any health status-related factor, in relation to the individual or a dependent of the individual.

(2) *Construction.* Nothing in paragraph (b)(1) of this section shall be construed—

(i) To restrict the amount that an employer may be charged by an issuer for coverage under a group health plan; or

(ii) To prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to a bona fide wellness program. For purposes of this section, a bona fide wellness program is a program of health promotion and disease prevention.

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

Example. (i) Plan X offers a premium discount to participants who adhere to a cholesterol-reduction wellness program. Enrollees are expected to keep a diary of their food intake over 6 weeks. They periodically submit the diary to the plan physician who responds with suggested diet modifications. Enrollees are to modify their diets in accordance with the physician's recommendations. At the end of the 6 weeks, enrollees are given a cholesterol test and those who achieve a count under 200 receive a premium discount.

(ii) In this *Example*, because enrollees who otherwise comply with the program may be unable to achieve a cholesterol count under 200 due to a health status-related factor, this

is not a bona fide wellness program and such discounts would discriminate impermissibly based on one or more health status-related factors. However, if, instead, individuals covered by the plan were entitled to receive the discount for complying with the diary and dietary requirements and were not required to pass a cholesterol test, the program would be a bona fide wellness program.

§ 2590.703 Guaranteed renewability in multiemployer plans and multiple employer welfare arrangements. [Reserved]

Subpart B—Other Requirements

§ 2590.711 Standard relating to benefits for mothers and newborns. [Reserved]

§ 2590.712 Parity in the application of certain limits to mental health benefits. [Reserved]

Subpart C—General Provisions

§ 2590.731 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 7 of subtitle B of title I of the 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 requirements of this part.

(b) *Continued preemption with respect to group health plans.* Nothing in part 7 of subtitle B of title I of the Act affects or modifies the provisions of section 514 of the Act with respect to group health plans.

(c) *Special rules—(1) In general.* Subject to paragraph (c)(2) of this section, the provisions of part 7 of subtitle B of title I of the 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 701 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 701(a)(1) of the Act and § 2590.701–3(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 701(a)(2) of the Act and § 2590.701–3(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 701(c)(2)(A) and (d)(4)(A) of the Act and §§ 2590.701–3(a)(1)(iii) and 2590.701–4 (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 701 (b)(2) and (d)(1) of the Act and § 2590.701–3(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 701(d) of the Act or expands the exceptions described therein;

(vi) Requires special enrollment periods in addition to those required under section 701(f) of the Act; or

(vii) Reduces the maximum period permitted in an affiliation period under section 701(g)(1)(B) of the Act.

(d) *Definitions—(1) State law.* For purposes of this § 2590.736 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 Island, or any agency or instrumentality of either.

§ 2590.732 Special rule relating to group health plans.

(a) *General exception for certain small group health plans.* The requirements of this part 7 of subtitle B of title I of the Act 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) In general.* The requirements of subparts A and C 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)(92), (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); and
- (viii) Coverage for on-site medical clinics.

(3) *Limited excepted benefits*—(i) *In general.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of 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 benefit 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 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

(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.

(c) *Treatment of partnerships.*

[Reserved]

§ 2590.734 Enforcement. [Reserved]

§ 2590.736 Effective dates.

(a) *General effective dates*—(1) *Non-collectively-bargained plans.* Except as otherwise provided in this section, part 7 of subtitle B of title I of the Act and subparts A and C of this part apply with respect to group health plans, including health insurance issuers offering health insurance coverage in connection with group health plans, for plan years beginning after June 30, 1997.

(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 7 of subtitle B of title I of the Act and subparts A and C of this part 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 pursuant to 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)(i) *Preexisting condition exclusion periods for current employees.* Any preexisting condition exclusion period permitted under § 2590.701–3 is measured from the individual's enrollment date in the plan. Such exclusion period, as limited under § 2590.701–3, may be completed prior to 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 7 of subtitle B of title I of the Act, no preexisting condition exclusion may be imposed with respect to an individual beyond the limitation of § 2590.701–3. 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 individual had prior to the enrollment date to reduce the remaining preexisting condition exclusion period applicable to the individual.

(ii) *Examples.* The following examples illustrate the rules 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.

(ii) In this *Example 1*, 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 2*, 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 of A received before January 1, 1998.

(b) *Effective date for certification requirement*—(1) *In general.* Subject to the transitional rule in § 2590.701–5(a)(5)(iii), the certification rules of

§ 2590.701–5 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 subpart A or C 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, pursuant to part 7 of subtitle B of title I of the Act, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by part 7 of subtitle B of title I of the 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 7 of subtitle B of title I of the 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 § 2590.701–5(c). For coverage relating to an event occurring before July 1, 1996, a group health plan and a health insurance issuer is 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 § 2590.701–5(c).

(e) *Transition rules for certificates 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 § 2590.701–5(a)(2) (ii) and (iii).

(3) *Optional notice—(i) In general.* This paragraph (e)(3) applies with respect to events described in § 2590.701–5(a)(5)(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 § 2590.701–5(a) (2) and (3) if a notice is provided in accordance with the provisions of paragraphs (e)(3) (i) through (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 pursuant to this paragraph (e)(3) must be in writing and must include information substantially similar to the information included in a model notice authorized by the Secretary. Copies of the model notice are available on the following website—<http://www.dol.gov/dol/pwba/> (or call 1–800–998–7542).

(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 § 2590.701–5(a)(5)(iii).

(v) *Other certification rules apply.* The rules set forth in § 2590.701–5(a)(4)(i) (method of delivery) and § 2590.701–5(a)(1) (entities required to provide a certificate) apply with respect to the provision of the notice.

Signed at Washington, D.C., this 27 day of March, 1997.

Olena Berg,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

Department of Health and Human Services

45 CFR Subtitle A

45 CFR is amended as set forth below:

1. The heading for subtitle A is revised to read as follows:

SUBTITLE A—DEPARTMENT OF HEALTH AND HUMAN SERVICES

2. Existing parts 1 through 100 are designated as subchapter A of subtitle A and a new subchapter heading is added to read as follows:

SUBCHAPTER A—GENERAL ADMINISTRATION

3. New subchapter B, consisting of parts 140 through 199, is added to read as follows:

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.

144.101 Basis and purpose.

144.102 Scope and applicability.

144.103 Definitions applicable to both group (45 CFR Part 146) and individual (45 CFR Part 148) markets.

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.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

Subpart A—General Provisions

§ 144.101 Basis and purpose.

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 and to guarantee the renewability of all coverage in the group market. 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 eligible individuals who previously had group coverage, and to guarantee the renewability of all coverage in the individual market. 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.

§ 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.

(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.

§ 144.103 Definitions applicable to both group (45 CFR part 146) and individual (45 CFR part 148) markets.

Unless otherwise provided, the following definitions apply:

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, 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 of 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 146.11(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) The individual market provisions in 45 CFR part 148, the term is defined in 45 CFR 148.220.

Federal government 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.)

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

Medical care or condition 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 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 that is not a Federal government plan.

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.

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 inclusion 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 means "public health plan" within the meaning of 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 means a "State health benefits risk pool" within the meaning of 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.

Subpart B—[Reserved]

PART 145—[RESERVED]

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

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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.

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

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 and to guarantee the renewability of all coverage in the group market. 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 D.* Subpart D of this part sets forth exceptions to the requirements of Subpart B for certain plans and certain types of benefits.

(3) *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.

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

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

§ 146.111 Limitations on preexisting condition exclusion period.

(a) *Preexisting condition exclusion—*(1) *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) *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 of 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 attributed 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 term 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 following 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 2 months 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 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 demonstrate 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.

§ 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;

(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 work 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 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: (1) 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).

(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 include 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), 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 the equivalent of 90-days of creditable coverage relating to prescription drug benefits within *D*'s determination period.

§ 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 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) with respect to the participant or beneficiary.

(iii) *Special rule for group health plan*. 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)(2) 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 automatic certificates as permitted under paragraph (a)(2)(ii) 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) and (a)(2)(iii) of this section.

(ii) *Issuance of automatic certificates.* The certificates described in this paragraph (a)(2)(ii) of this section 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 elected instead of COBRA continuation coverage. A plan or issuer satisfies this requirement if it provides the automatic certificate no later than the time a notice is required to be furnished for a qualifying event under section 606 of the Act, 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 or 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, *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). 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 HCFA 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 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.

(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 HCFA.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits 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 the 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. It 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 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 and 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 (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 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) 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 or 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: (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)).

§ 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, in 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 individual 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 and 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, in 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).

§ 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 status-related factor.

(a) *In eligibility to enroll*—(1) *General.* Subject to paragraph (a)(2) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

- (i) Health status.
- (ii) Medical condition (including both physical and mental illnesses), as defined in § 146.102.
- (iii) Claims experience.
- (iv) Receipt of health care.
- (v) Medical history.
- (vi) Genetic information, as defined in § 146.102.
- (vii) Evidence of insurability (including conditions arising out of acts of domestic violence).
- (viii) Disability.

(2) *No application to benefits or exclusions.* To the extent consistent with section 2701 of the Act and § 146.111, paragraph (a)(1) of this section shall not be construed—

(i) To require a group health plan, or a health insurance issuer offering group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage; or

(ii) To prevent such a plan or issuer from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

(3) *Construction.* For purposes of paragraph (a)(1) of this section, rules for eligibility to enroll include rules defining any applicable waiting (or

affiliation) periods for such enrollment and rules relating to late and special enrollment.

4. *Example.* The following example illustrates the requirements of this paragraph (a):

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

(ii) In this *Example*, the plan discriminates on the basis of one or more health status-related factors.

(b) *In premiums or contributions*—(1) *General.* 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) to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual enrolled in the plan based on any health status-related factor, in relation to the individual or a dependent of the individual.

(2) *Construction.* Nothing in paragraph (b)(1) of this section can be construed—

(i) To restrict the amount that an employer may be charged by an issuer for coverage under a group health plan; or

(ii) To prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to a bona fide wellness program. For purposes of this section, a bona fide wellness program is a program of health promotion and disease prevention.

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

Example. (i) Plan X offers a premium discount to participants who adhere to a cholesterol-reduction wellness program. Enrollees are expected to keep a diary of their food intake over 6 weeks. They periodically submit the diary to the plan physician who responds with suggested diet modifications. Enrollees are to modify their diets in accordance with the physician's recommendations. At the end of the 6 weeks, enrollees are given a cholesterol test and those who achieve a count under 200 receive a premium discount.

(ii) In this *Example*, because enrollees who otherwise comply with the program may be unable to achieve a cholesterol count under 200 due to a health status-related factor, this is not a bona fide wellness program and such discounts would discriminate impermissibly

based on one or more health status-related factors. However, if, instead, individuals covered by the plan were entitled to receive the discount for complying with the diary and dietary requirements and were not required to pass a cholesterol test, the program would be a bona fide wellness program.

§ 146.125 Effective dates.

(a) *General effective dates*—(1) *Non-collectively-bargained plans.* Except as otherwise provided in this section, part A of title XXVII of the PHS Act and this part applies with respect to group health plans, including health insurance issuers offering health insurance coverage in connection with group health plans, for plan years beginning after June 30, 1997.

(2) *Collectively bargained plans.* Except as otherwise provided in this section (other than paragraph (a)(1)), in the case of a group health plan maintained under 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 this part does 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 credible 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 credible coverage before this date.

(ii) In this *Example*, Employer X may continue to impose the preexisting conditions 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 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 is 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)(5)(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 HCFA. Copies of the model notice are available at the following website—www.hcfa.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)(5)(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.

Subpart C—[Reserved]

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 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 expected 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

(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.

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, which is inconsistent with the nondiscrimination provisions of § 146.121 on an eligible individual being a participant or beneficiary.

(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 in accordance with paragraph (d)(1) of this section may not offer coverage in connection with group health plans in the small group market in the State 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.

(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) of this section 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).

§ 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 as failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* The plan sponsor has failed to comply with a material plan provision relating to any employer contribution or group participation rules permitted under § 146.150(e) in the case of the small group market or under applicable State law in the case of the large group market.

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

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the group health plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 146.150(c).

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

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the small or large group market, that product may be discontinued by the issuer in accordance with applicable State law in the particular market only if—

(1) The issuer provides notice in writing to each plan sponsor provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 days before the date the coverage will be discontinued;

(2) The issuer offers to each plan sponsor provided that particular product the option, on a guaranteed issue basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in that market; and

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* An issuer may elect to discontinue offering all health insurance coverage in the small or large group market or both markets in a State in accordance with applicable State law only if—

(1) The issuer provides notice in writing to the applicable State authority and to each plan sponsor (and all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 days prior to the date the coverage will be discontinued; and

(2) All health insurance policies issued or delivered for issuance in the State in the market (or markets) are discontinued and not renewed.

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

(f) *Exception for uniform modification of coverage.* Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan in the—

(1) Large group market; and

(2) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(g) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to “plan sponsor” is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

§ 146.160 Disclosure of information.

(a) *General rule.* In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer is required to—

(1) Make a reasonable disclosure to the employer, as part of its solicitation and sales materials, of the availability of information described in paragraph (b) of this section; and

(2) Upon request of the employer, provide that information to the employer.

(b) *Information described.* Subject to paragraph (d) of this section, information that must be provided

under paragraph (a)(2) of this section is information concerning the following:

(1) Provisions of coverage relating to the following:

(i) The issuer's right to change premium rates and the factors that may affect changes in premium rates.

(ii) Renewability of coverage.

(iii) Any preexisting condition exclusion, including use of the alternative method of counting creditable coverage.

(iv) Any affiliation periods applied by HMOs.

(v) The geographic areas served by HMOs.

(2) The benefits and premiums available under all health insurance coverage for which the employer is qualified, under applicable State law. See § 146.150(b) through (f) for allowable limitations on product availability.

(c) *Form of information.* The information must be described in language that is understandable by the average small employer, with a level of detail that is sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage. This requirement is satisfied if the issuer provides each of the following with respect to each product offered:

(1) An outline of coverage. For purposes of this section, outline of coverage means a description of benefits in summary form.

(2) The rate or rating schedule that applies to the product (with and without the preexisting condition exclusion or affiliation period).

(3) The minimum employer contribution and group participation rules that apply to any particular type of coverage.

(4) In the case of a network plan, a map or listing of counties served.

(5) Any other information required by the State.

(d) *Exception.* An issuer is not required to disclose any information that is proprietary and trade secret information under applicable law.

Subpart F—Exclusion of Plans and Enforcement

§ 146.180 Treatment on non-Federal governmental plans.

The plan sponsor of a non-Federal governmental plan may elect to be exempted from any or all of the requirements identified in paragraph (a) of this section with respect to any portion of its plan that is not provided through health insurance coverage, if the election complies with the requirements of paragraphs (b) and (c) of

this section. The election remains in effect for the period described in paragraph (d) of this section.

(a) *Exemption from requirements.* The election described in this paragraph (a) exempts a non-Federal governmental plan from the following requirements:

(1) Limitations on preexisting condition exclusion periods (§ 146.111).

(2) Special enrollment periods for individuals (and dependents) losing other coverage (§ 146.117).

(3) Prohibitions against discriminating against individual participants and beneficiaries based on health status (§ 146.121).

(4) Standards relating to benefits for mothers and newborns (section 2704 of the PHS Act).

(5) Parity in the application of certain limits to mental health benefits (section 2705 of the PHS Act).

(b) *Form and manner of election.* (1) The election must be in writing.

(2) The election document must include as an attachment a copy of the notice described in paragraphs (f) and (g) of this section.

(3) The election document must state the name of the plan and the name and address of the plan administrator.

(4) The election document must either state that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through insurance.

(5) The election must be made in conformity with all the plan sponsor's rules, including any public hearing, if required, and the election document must 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.

(6) The election document must be signed by the person described in paragraph (b)(5) of this section.

(c) *Timing of election.* (1) For plans not subject to collective bargaining agreements, the election must be received by HCFA by the day preceding the beginning date of the plan year.

(2) For plans provided under a collective bargaining agreement, the election must be received by HCFA no later than 30 days after—

(i) The date of the agreement between the governmental entity and union officials; or

(ii) If applicable, ratification of the agreement.

(3) HCFA may extend the deadlines specified under paragraphs (c)(1) and (c)(2) of this section for good cause.

(4) If the plan sponsor fails to file a timely election in accordance with paragraphs (c)(1) through (c)(3) of this section, the plan is subject to the

requirements described in paragraph (a) for the entire plan year, or, in the case of a plan provided under a collective bargaining agreement, for the term of the agreement.

(d) *Period of election.* An election under paragraph (a) of this section applies—

(1) For a single specified plan year; or

(2) In the case of a plan provided under a collective bargaining agreement, for the term of the agreement. (For purposes of this section, if a collective bargaining agreement expires during the bargaining process for a new agreement, and the parties agree that the prior bargaining agreement continues in effect until the new agreement takes effect, the “term of the agreement” is deemed to continue until the new agreement takes effect.)

(e) *Subsequent elections.* An election under this section may be extended through subsequent elections.

(f) *Notice to participants.* (1) A plan that makes the election described in this section notifies the participant of the election, and explains the consequences of the election. This notice must be provided—

(i) to each participant at the time of enrollment under the plan; and

(ii) To all participants on an annual basis.

(2) The notice shall be in writing, and must include the information specified in paragraph (g) of this section.

(3) The notice shall be provided to each participant individually.

(4) Subject to paragraph (g) of this section, the requirements of paragraphs (f)(1) through (f)(3) of this section are considered to have been met if the notice is prominently printed in the summary plan document, or equivalent document, and each participant receives a copy of that document at the time of enrollment and annually thereafter.

(g) *Notice content.* The notice must contain at least the following information:

(1) A statement that, in general, Federal law imposes upon group health plans the requirements described in paragraph (a) of this section (which must be individually described in the notice).

(2) A statement that Federal law gives the plan sponsor of a non-Federal governmental plan the right to exempt the plan in whole or in part from the requirements described in paragraph (a) of this section, and that the plan sponsor has elected to do so.

(3) A statement identifying which parts of the plan are subject to the election, and each of the requirements of paragraph (a) of this section from

which the plan sponsor has elected to be exempted.

(4) If the plan chooses to provide any of the protections of paragraph (a) of this section voluntarily, or is required to under State law, a statement identifying which protections apply.

(h) *Certification and disclosure of creditable coverage.* Notwithstanding 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 in accordance with § 146.115.

(i) *Effect of failure to comply with election requirements.* (1) Subject to paragraph (i)(2) of this section, a plan's failure to comply with the requirements of paragraphs (f) through (h) of this section invalidates an election made under this section.

(2) Upon a finding by HCFA that a non-Federal governmental plan has failed to comply with the requirements of paragraphs (f) through (h), and has failed to correct the noncompliance within 30 days (as provided in § 146.184(d) (7)(iii)(B)), HCFA notifies the plan that its election has been invalidated and that it is subject to the requirements of this part.

(3) A non-Federal governmental plan described in paragraph (i)(2) of this section that fails to comply with the requirements of this part is subject to Federal enforcement by HCFA under § 146.184, including appropriate civil money penalties.

§ 146.184 Enforcement.

(a) *Enforcement with respect to group health plans—*(1) *Scope.* In general, the requirements of the Health Insurance Portability and Accountability Act that apply to group health plans are contained in part 7 of subtitle B of title I of ERISA, and in subtitle K of the Internal Revenue Code. They are enforced by the Secretary of Labor under part 5 of subtitle B of title I of ERISA, and the Secretary of the Treasury under 26 U.S.C. 4980D.

However, the provisions that apply to group health plans that are non-Federal governmental plans are contained in title XXVII of the PHS Act, and enforced by HCFA. The provisions of title XXVII that apply to health insurance issuers that offer coverage in connection with any group health plan are enforced in the first instance by the States. If HCFA determines under paragraph (b) of this section that a State is not substantially enforcing the provisions, HCFA enforces them under paragraph (d) of this section.

(2) *Non-Federal governmental plans.* Requirements of this part that apply to group health plans that are non-Federal governmental plans (sponsored by a State or local governmental entity) are enforced by HCFA, as provided in paragraph (d) of this section.

(b) *Enforcement with respect to health insurance issuers—*(1) *General rule—enforcement by State.* Except as provided in paragraph (b)(2) of this section, each State enforces the requirements of this part with respect to health insurance issuers that issue, sell, renew or offer health insurance coverage in the small or large group markets in the State.

(2) *Enforcement by HCFA.* HCFA enforces the provisions of this part with respect to health insurance issuers, using the procedures described in paragraph (d) of this section, only in the following circumstances:

(i) *State election.* If the State chooses not to enforce the Federal requirements.

(ii) *State failure to enforce.* If HCFA makes a determination under paragraph (c) of this section that a State has failed to substantially enforce one or more provisions of this part.

(c) *Determination by Administrator.* If HCFA receives information, through a complaint or any other means, that raises a question whether a State is substantially enforcing one or more provisions of this part, HCFA follows the procedures set forth in this section.

(1) *Verification of exhaustion.* HCFA makes a threshold determination of whether the individuals affected by the alleged failure to enforce have made a reasonable effort to exhaust any State remedies. This may involve informal contact with State officials about the questions raised.

(2) *Notice to the State.* If HCFA is satisfied that there is a reasonable question whether there has been a failure to substantially enforce, HCFA provides notice as specified in paragraph (c)(3) of this section, to the following State officials:

(i) The Governor or chief executive officer of the State.

(ii) The insurance commissioner or chief insurance regulatory official.

(iii) The official responsible for regulating HMOs, if different than paragraph (c)(2)(ii) of this section, but only if the alleged failure involves HMOs.

(3) *Form and content of notice.* The notice described in paragraph (c)(2) is in writing, and does the following:

(i) Identifies the provision or provisions of the statute and regulations that have allegedly been violated;

(ii) Describes the facts of the specific violations.

(iii) Explains that the consequence of a failure to substantially enforce any provisions(s) is that HCFA enforces the provision(s) in accordance with paragraph (d) of this section.

(iv) Advises the State that it has 45 days to respond to the notice, unless the time is extended as described in paragraph (c)(3) of this section, and that the response should include any information that the State wishes HCFA to consider in making the preliminary determination described in paragraph (c)(5) of this section.

(4) *Good cause.* The time for responding can be extended for good cause. Examples of good cause include an agreement between HCFA 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.

(5) *Preliminary determination.* If at the end of the 45-day period, and any extension, the State has not established to HCFA's satisfaction that it is substantially enforcing the provision or provisions described in the notice, HCFA takes the following actions:

(i) Consults with the officials described in paragraph (c)(1) of this section.

(ii) Notifies the State of HCFA's preliminary determination that the State has failed to enforce the provisions, and that the failure is continuing.

(iii) Permits the State a reasonable opportunity to show evidence of substantial enforcement.

(6) *Final determination.* If, after providing notice and the opportunity to enforce under paragraph (c)(5) of this section, HCFA finds that the failure to enforce has not been corrected, HCFA sends the State a written notice of that final determination. The notice—

(i) Identifies the provisions with respect to which HCFA is taking over enforcement;

(ii) States the effective date of HCFA's enforcement;

(iii) Informs the State of the mechanism for establishing in the future that it has corrected the failure, and has begun enforcement. This mechanism will include transition procedures for ending HCFA's enforcement.

(d) *Civil money penalties*—(1) *General rule.* If any health insurance issuer that is subject to HCFA's enforcement authority under paragraph (b)(2) of this section, or any non-Federal governmental plan (or employer that sponsors a non-Federal governmental plan) that is subject to HCFA's enforcement authority under paragraph (a)(2) of this section, fails to comply with any applicable requirement of this part, it may be subject to a civil money

penalty as described in this paragraph (d).

(2) *Complaint.* Any person who is entitled to any right under this part, and who believes that the right is being denied as a result of any failure described in paragraph (d)(1) of this section, may file a complaint with HCFA. Based on the complaint, HCFA identifies which entities are potentially responsible for the violation, in accordance with paragraph (d)(3) of this section.

(3) *Determination of responsible entity.* If a failure to comply is established under this section, the responsible entity, as determined under this paragraph, is liable for the penalty. If the violation is due to a failure by—

(i) A health insurance issuer, the issuer is the responsible entity;

(ii) A group health plan that is a non-Federal governmental plan sponsored by a single employer, the employer is the responsible entity;

(iii) A group health plan that is a non-Federal governmental plan sponsored by two or more employers, the plan is the responsible entity.

(4) *Notice to responsible entities.* HCFA provides notice to the appropriate entity or entities identified under paragraph (d)(3) of this section that a complaint or other information has been received alleging a violation of this part. The notice—

(i) Describes the substance of any complaint or other allegation;

(ii) Provides 30 days for the responsible entity or entities to respond with additional information. This can include—

(A) Information refuting that there has been a violation;

(B) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation;

(C) Evidence of a previous record of compliance.

(5) *Notice to other regulators.* HCFA notifies the State if the alleged violation involves a health insurance issuer under its jurisdiction.

(6) *Notice of assessment.* If, based on the information provided in the complaint, as well as any information submitted by the entity or any other parties, HCFA proposes to assess a civil money penalty, HCFA sends written notice of assessment to the responsible entity or entities by certified mail, return receipt requested. The notice contains the following information:

(i) A reference to the provision that was violated.

(ii) The name or names of the individuals with respect to whom a violation occurred, with relevant identification numbers.

(iii) The facts that support the finding of a violation, and the initial date of the violation.

(iv) The amount of the proposed penalty as of the date of the notice.

(v) The basis for calculating the penalty, including consideration of prior compliance.

(vi) Instructions for responding to the notice, including—

(A) A specific statement of the respondent's right to a hearing; and

(B) A statement that failure to request a hearing within 30 days permits the imposition of the proposed penalty, without right of appeal.

(7) *Amount of penalty*—(i) *Maximum daily penalty.* The penalty cannot exceed \$100 for each day, for each responsible entity, for each individual with respect to whom such a failure occurs.

(ii) *Standard for calculating daily penalty.* In calculating the amount of the penalty HCFA takes into account the responsible entity's previous record of compliance and the gravity of the violation.

(iii) *Limitations on penalties.* No civil money penalty is imposed:

(A) With respect to a period during which a failure existed, but none of the responsible entities knew, or exercising reasonable diligence would have known, that the failure existed.

(B) With respect to the period occurring immediately after the period described in paragraph (d)(7)(iii)(A) of this section, if the failure—

(1) Was due to reasonable cause and was not due to willful neglect; and

(2) 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.

(C) The burden is on the responsible entity or entities to establish to the satisfaction of HCFA that none of the entities knew, or exercising reasonable diligence could have known that the failure existed.

(8) *Hearings*—(i) *Right to a hearing.* Any entity against which a penalty is assessed may request a hearing by HCFA. The request must be in writing, and must be postmarked within 30 days after the date the notice of assessment is issued.

(ii) *Failure to request a hearing.* If no hearing is requested under this paragraph, the notice of assessment constitutes a final order that is not subject to appeal.

(iii) *Parties to the hearing.* Parties to the hearing include any responsible entities, as well as the party who filed the complaint. An informational notice

is also sent to the State, or to the Secretaries of Labor and the Treasury, as appropriate.

(iv) *Initial agency decision.* The initial agency decision is made by an administrative law judge. The decision is made on the record according to section 554 of title 5, United States Code. The decision becomes a final, appealable order after 30 days, unless it is modified in accordance with paragraph (d)(8)(v) of this section.

(v) *Review by HCFA.* HCFA may modify or vacate the initial agency decision. Notice of intent to modify or vacate the decision is issued to the parties within 30 days after the date of the decision of the administrative law judge.

(9) *Judicial review—(i) Filing of action for review.* Any entity against whom a final order imposing a civil money penalty is entered in accordance with paragraph (d)(8) of this section may obtain review in the United States District Court for any district in which the entity is located or the United States District Court for the District of Columbia by—

(A) Filing a notice of appeal in that court within 30 days from the date of a final order; and

(B) Simultaneously sending a copy of the notice of appeal by registered mail to HCFA.

(ii) *Certification of administrative record.* HCFA will promptly certify and file with the court the record upon which the penalty was imposed.

(iii) *Standard of review.* The findings of HCFA may not be set aside unless they are found to be unsupported by substantial evidence, as provided by Section 706(2) (E) of title 5, United States Code.

(iv) *Appeal.* Any final decision, order or judgement of the district court concerning the Administrator's review is subject to appeal as provided in Chapter 83 of Title 28, United States Code.

(10) *Failure to pay assessment, maintenance of action—(i) Failure to pay assessment.* If any entity fails to pay an assessment after it becomes a final order under paragraphs (d)(7)(i)(A) or (d)(7)(iii) of this section, or after the court has entered final judgment in favor of HCFA, HCFA refers the matter to the Attorney General, who brings an action in the appropriate United States district court to recover the amount assessed.

(ii) *Final order not subject to review.* In an action brought under paragraph

(d)(10)(i) of this section, the validity and appropriateness of the final order described in paragraphs (d)(7)(i)(A) or (d)(7)(iii) of this section is not subject to review.

(11) *Use of penalty funds.* (i) Any funds collected under this section will be paid to HCFA or other office imposing the penalty.

(ii) The funds will be available without appropriation and until expended.

(iii) The funds may only be used for the purpose of enforcing the provisions with respect to which the penalty was imposed.

PARTS 147—199 [RESERVED]

Authority: Secs. 2701 through 2723, 2791, and 2792 of the PHS Act, 42 U.S.C. 300gg-41 through 300gg-63, 300gg-91, and 300gg-92.

Dated: March 25, 1997.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

Dated: March 25, 1997.

Donna E. Shalala,
Secretary.

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