5. Section 2520.104b–3 is amended by revising the second sentence of paragraph (a), redesignating paragraphs (d) and (e) as paragraphs (f) and (g), respectively, and adding new paragraphs (d) and (e) to read as follows:

§ 2520.104b–3 Summary of material modifications to the plan and changes in the information required to be included in the summary plan description.

(a) * * * Except as provided in paragraph (d) of this section, the plan administrator shall furnish this summary, written in a manner calculated to be understood by the average plan participant, not later than 210 days after the close of the plan year in which the modification or change was adopted. * * *

* * * * *

(d) *Special rule for group health plans.* (1) *General.* Except as provided in paragraph (d)(2) of this section, the administrator of a group health plan, as defined in section 733(a)(1) of the Act, shall furnish to each participant covered under the plan and each beneficiary receiving benefits under the plan a summary, written in a manner calculated to be understood by the average plan participant, of any modification to the plan or change in the information required to be included in the summary plan description, within the meaning of paragraph (a) of this section, that is a material reduction in covered services or benefits not later than 60 days after the date of adoption of the modification or change.

(2) *90-day alternative rule.* The administrator of a group health plan shall not be required to furnish a summary of any material reduction in covered services or benefits within the 60-day period described in paragraph (d)(1) of this section to any participant covered under the plan or any beneficiary receiving benefits who would reasonably be expected to be furnished such summary in connection with a system of communication maintained by the plan sponsor or administrator, with respect to which plan participants and beneficiaries are provided information concerning their plan, including modifications and changes thereto, at regular intervals of not more than 90 days and such communication otherwise meets the disclosure requirements of 29 CFR 2520.104b–1.

(3) *''Material reduction''.* (i) For purposes of this paragraph (d), a ''material reduction in covered services or benefits'' means any modification to the plan or change in the information required to be included in the summary plan description that, independently or in conjunction with other contemporaneous modifications or changes, would be considered by the average plan participant to be an important reduction in covered services or benefits under the plan.

(ii) A ''reduction in covered services or benefits'' generally would include any plan modification or change that: eliminates benefits payable under the plan; reduces benefits payable under the plan, including a reduction that occurs as a result of a change in formulas, methodologies or schedules that serve as the basis for making benefit determinations; increases deductibles, co-payments, or other amounts to be paid by a participant or beneficiary; reduces the service area covered by a health maintenance organization; establishes new conditions or requirements (e.g., preauthorization requirements) to obtaining services or benefits under the plan.

(e) *Applicability date.* Paragraph (d) of this section is applicable as of the first day of the first plan year beginning after June 30, 1997.

* * * * *

6. Section 2520.104b–1 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) to read as follows:

§ 2520.104b–1 Disclosure.

* * * * *

(c) *Disclosure through electronic media.* (1) The administrator of a group health plan furnishing documents described in section 104(b)(1) of the Act through electronic media will be deemed to satisfy the requirements of paragraph (b)(1) of this section with respect to participants described in paragraph (c)(2) of this section if:

(i) The administrator takes appropriate and necessary measures to ensure that the system for furnishing documents results in actual receipt by participants of transmitted information and documents (e.g., uses return-receipt electronic mail feature or conducts periodic reviews or surveys to confirm receipt of transmitted information);

(ii) Electronically delivered documents are prepared and furnished in a manner consistent with the applicable style, format and content requirements (See 29 CFR 2520.102–2 through 2520.102–5);

(iii) Each participant is provided notice, through electronic means or in writing, apprising the participant of the document(s) to be furnished electronically, the significance of the document (e.g., the document describes changes in the benefits provided by your plan) and the participant's right to request and receive, free of charge, a paper copy of each such document; and

(iv) Upon request of any participant, the administrator furnishes, free of charge, a paper copy of any document delivered to the participant through electronic media.

(2) For purposes of paragraph (c)(1) of this section, the furnishing of documents through electronic media satisfies the requirements of paragraph (b)(1) of this section only with respect to participants:

(i) Who have the ability to effectively access at their worksite documents furnished in electronic form; and

(ii) Who have the opportunity at their worksite location to readily convert furnished documents from electronic form to paper form free of charge.

(3) This paragraph (c) applies on or after June 1, 1997.

* * * * *

Signed at Washington, D.C., this 27th day of March, 1997.

Olena Berg,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 97–8173 Filed 4–1–97; 12:52 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 148

[BPD–882–IFC]

RIN 0938–AH75

Individual Market Health Insurance Reform: Portability From Group to Individual Coverage; Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules

AGENCY: Department of Health and Human Services.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements section 111 of the Health Insurance Portability and Accountability Act of 1996, which sets forth Federal requirements designed to improve access to the individual health insurance market. Certain ''eligible individuals'' who lose group health insurance coverage are assured availability of coverage in the individual market, on a guaranteed issue basis, without preexisting condition exclusions. In addition, all individual health insurance coverage must be guaranteed renewable. This rule also sets forth procedures that apply to States that choose to implement a

mechanism under State law, as an alternative to the Federal requirements, with respect to guaranteed availability for eligible individuals. It also sets forth the rules that apply if a State does not substantially enforce the statutory requirements.

DATES: *Effective date:* These regulations are effective April 8, 1997.

However, affected parties do not have to comply with the information collection requirements in §§ 148.120, 148.122, 148.124, 148.126, 148.200, and 148.202 until the Department has published in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB) to these information collection requirements. Section 148.128 is currently approved under emergency OMB approval number 0938–0699, which will expire on July 31, 1997, but will be reapproved with the sections referenced above. Publication of the control numbers notifies the public that OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on July 7, 1997.

Applicability dates: The various dates that these regulations are applicable are set forth in the Supplementary Information section of the preamble.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–882–IFC, P.O. Box 26676, Baltimore, MD 21207–0488.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) or E-mail transmission. In commenting, please refer to file code BPD–882–IFC. Comments received timely will be available for pubic inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Gertrude Saunders of the Insurance Reform Implementation Task Force (IRITF), (410) 786–5888.

SUPPLEMENTARY INFORMATION:

I. Summary of Recent Legislation

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, Pub. L. 104–191) was enacted on August 21, 1996. Title I of the statute enacted reforms in both the group and individual health insurance markets, in part, to help many individuals maintain insurance coverage if they lose or leave their jobs. Sections 101 through 103 of HIPAA amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), and the Internal Revenue Code of 1986 (Code) to provide for improved access and renewability with respect to employment-related group health plans (GHPs), and health insurance coverage sold in connection with GHPs. Section 111 of HIPAA amends the PHS Act to improve availability and renewability in the individual market.

Group health plans are generally regulated by the Department of Labor under ERISA, and by the Internal Revenue Service under the Code. For health insurance coverage sold to group health plans, and sold in the individual market, the insurance issuers are regulated by the States under State law.

We believe that the individual health insurance market provisions of HIPAA recognize that States play the primary role in the regulation of insurance, and afford the States great flexibility in implementing the reforms required by the statute. While the statute provides enforcement authority to HHS in the event that a State substantially fails to enforce Federal requirements, the primary authority clearly rests with the States.

This rule only pertains to the individual market changes made to sections 2741 through 2763 and 2791 of the PHS Act by section 111 of HIPAA. For rules implementing the group market provisions of HIPAA, see the ''Interim Rules for Health Insurance Portability for Group Health Plans'' (BPD–890–IFC), which is published elsewhere in this **Federal Register**.

II. Provisions of This Interim Final Rule

A. Guaranteed Availability—General

The statue requires all health insurance issuers offering coverage in the individual market to accept any ''eligible individuals'' who apply for coverage, without imposing a preexisting condition exclusion.

A health insurance issuer means an insurance company, insurance service, or insurance organization (including an HMO) that is 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 ERISA. The term does not include a group health plan. For purposes of this rule, we will use the term ''issuer'' to mean a health insurance issuer.

1. Definition of an Eligible Individual (§ 148.103)

An eligible individual must met several criteria:

- *The individual must have at least 18 months of creditable coverage without a significant break in coverage.*

The rules for determining creditable coverage are set forth in the group market regulations at § 146.113 and explained in the preamble to that regulation. In general, creditable coverage includes almost any type of health care coverage. A significant break in coverage is 63 days without any creditable coverage. This requirement is related to the group market rules, since an individual in the group market is protected against preexisting condition exclusions under any circumstances if the individual has 18 months of creditable coverage without a significant break. As with the group market rules, States may have requirements that are more generous to individuals. For instance, a State may require less than 18 months of creditable coverage in order to be considered an eligible individual in the individual market. It may also lengthen the significant break in coverage period from 63 days to some longer period.

We are also including a provision in § 148.120(f)(2) that deems certain

children to be eligible individuals, even if they do not have a full 18 months of creditable coverage. These are children who were covered under any creditable coverage within 30 days of birth, adoption, or placement for adoption, and have not had a significant break in coverage. Under §§ 146.111(b) and 146.117(b)(5), these children are entitled to a special enrollment period under a group health plan or group health insurance coverage, and are fully protected from the imposition of preexisting condition exclusions under the group coverage. We believe that deeming these children to be eligible individuals is necessary in order to carry out clear congressional intent to provide special protection for them.

- *The individual's most recent coverage must have been under a group health plan.*

There is no limit on the amount of time that must have been spent under group coverage—one day is sufficient. The coverage must, however, be under a group health plan as defined in Part 146, which means it must be employment-related. However, it does not have to be a group health plan that is regulated under ERISA. It may be under governmental or church plans (or under health insurance coverage offered in connection with either type of group health plan). Governmental plans are plans for employees of government entities, not public welfare or other benefit plans such as Medicare, Medicaid, or IHS.

- *The individual cannot currently be eligible for Medicare or Medicaid or covered under any other health insurance.*

This requires that the individual actually be covered under the health insurance. Except for COBRA or similar continuation coverage, the individual who has the option of purchasing some sort of health insurance and does not do so may still meet the definition of an eligible individual.

This interpretation of the law permits an individual to choose among options. In addition to the products that are available to him or her as an eligible individual, the individual may have available a conversion policy, other coverage sold in the individual market on an underwritten basis, or coverage through any associations to which the individual may be eligible to join. Eligible individuals cannot be required to obtain denials of other coverage (a common requirement of many risk pools) because the only disqualifying circumstance is ''having'' other coverage, not having other options available. Nevertheless, individuals will want to explore other options to ensure that they obtain the best coverage for the lowest cost.

- *The individual has both elected and exhausted any continuation coverage available under COBRA or a similar State program.*

This requirement means that if an individual's qualifying event entitles him or her to more than 18 months of COBRA coverage, the individual must exhaust all the COBRA coverage that is available to him or her before becoming eligible under HIPAA's individual market rules. Many State laws, by contrast, require less than 18 months. Therefore, an individual would need to aggregate prior group coverage with the coverage under the mini-COBRA to reach the minimum of 18 months of creditable coverage required to be an eligible individual. Note, however, that the exhaustion requirement refers only to the continuation coverage that is mandated under Federal law (COBRA) or a similar program under State law (sometimes referred to as ''mini-COBRA''). An individual, however, is not required to accept a ''conversion'' policy that may be available when continuation coverage ends, and should be careful about doing so. Continuation coverage meets the criterion of coverage for both the individual and group markets. An individual who accepts a conversion policy, however, maintains eligibility only for the group market and forfeits the right to be an ''eligible individual,'' for the individual market. This is so because the statute provides no portability from one individual policy to another. A conversion policy is an individual policy, not a group policy, even though prior group coverage is a prerequisite to qualifying for the conversion policy.

- *Residency requirements.* We wish to clarify that States may not require a specific period of residency for HIPAA protected eligible individuals, however, States may require that an HIPAA eligible individual be a State resident to be eligible for protection under applicable State law.

2. State Flexibility

States are given the flexibility either to enforce the Federal requirements set forth in § 148.120, or to implement an alternative mechanism, under State law, that achieves the statutory mandate of providing eligible individuals with access to individual health insurance, or comparable coverage, without preexisting condition exclusions. The statute provides that if States notify the Secretary no later than April 1, 1997, with supporting information, that they intend to implement an alternative mechanism by January 1, 1998, they will be presumed to be implementing a mechanism as of July 1, 1997 (the effective date of the statute). Alternative mechanisms are discussed in section II.F. of this preamble.

If a State chooses to enforce the Federal guaranteed availability requirements (sometimes referred to as the ''Federal fallback'' requirements), the provisions of § 148.120 apply, and must be enforced by the State under State law. If the State implements neither an alternative mechanism, nor the Federal fallback requirements, we will implement the Federal fallback provisions in that State and will enforce those requirements using the penalty provisions specified in §§ 148.200 and 148.202.

B. Alternative Coverage Under the Federal Fallback Provisions

In accordance with § 148.120(c), if the Federal fallback provisions are in effect in a State, an issuer that offers health insurance coverage in the individual market in that State may elect to limit coverage by making only two policies available to eligible individuals.

1. Limitation of Policy Forms—General

The issuer may limit the individual market coverage it offers as long as it offers two different policy forms. Both policy forms must be designed for, made generally available to, actively marketed to, and enroll both eligible and other individuals, and meet one of two requirements regarding policy forms described in § 148.120(c)(2) and (c)(3).

The statute creates an ambiguity when it indicates that policy forms that have different cost-sharing arrangements or different riders must be considered different policy forms. It is our understanding that this is inconsistent with State law definitions of a policy form, which refer to a contract form that is filed with the State, which has a number assigned to it, and which may have more than one cost-sharing arrangement. Since the statute does not define ''policy form,'' we believe the statutory intent was to leave the definition to State law.

However, we also believe the intent of the statutory requirement of two different policy forms was to ensure that eligible individuals would have some choice of coverage and/or cost for that coverage. Because differences in levels of cost sharing in out-of-pocket spending are among the most important determinants of price, for Federal enforcement purposes, we would interpret this statutory provision to mean that significant differences in deductibles or other significantly

different cost-sharing arrangements provide sufficient choice.

2. Most Popular Policies

Under § 148.120(c)(2), the health insurance issuer may choose to offer the policy forms for individual health insurance coverage with the largest, and the second largest, premium volume of all similar policy forms offered by the issuer in the State, or applicable marketing or service area, for the period involved. In the absence of applicable State standards, ''premium volume'' means earned premiums for the last reporting year. In the absence of applicable State standards, the last reporting year is the period from October 1 through September 30 of the preceding year. Blocks of business closed under applicable State law are not included in calculating premium volume.

3. Representative Policy Forms

Under § 148.120(c)(3), the health insurance issuer may choose, instead, to offer a lower-level and higher-level coverage policy form. Each of these policy forms must meet the requirements of § 148.120(c)(3)(ii), which state that issuers must include benefits substantially similar to other individual health insurance coverage offered by the issuer in the State; and must be covered under a method described in § 148.120(c)(3)(ii)(D) pertaining to risk adjustment, risk spreading, risk spreading mechanism, or financial subsidization; and must meet all applicable State requirements.

In a State that chooses to enforce the Federal fallback provisions instead of an alternative mechanism, the issuer must provide the appropriate state authorities with any documentation required by the State (§ 148.120(c)(5)(i)). In a State where we enforce the individual market provisions, the issuer must provide us with documentation that we determine to be necessary (§ 148,120(c)(5)(ii)). The following is an example of what we would expect to be a minimum level of documentation:

(A) Issuer name, address, and explanation of corporate and company structure.

(B) Information on all products offered by the issuer in the individual market.

(C) If the issuer elects the option for—

(i) The most popular policies, data on premium volumes of all policy forms offered by the issuer in the individual market; or

(ii) Representative coverage, data, assumptions, and methods used to calculate the actuarial values of the two representative policy forms.

(D) Explanation of how the issuer is complying with the provisions of HIPAA.

(E) List of all products the issuer is making or will make available to eligible individuals and an explanation of how the issuer will inform eligible individuals of these policy forms, with copies of all marketing material.

(F) Description of risk spreading and financial subsidization mechanism.

For policy forms already being marketed as of July 1, 1997 (the effective date of the Federal fallback provisions), the issuer must submit the information to HCFA no later than September 1, 1997. For other policy forms, the issuer must submit the information 90 days before the beginning of the calendar year in which the issuer wants to market the policy form.

4. Special Rules for Network Plans

An issuer that offers coverage in the individual market through a network plan may require that eligible individuals live, reside, or work within the service area for the plan (§ 148.120(d)). An issuer may also deny coverage if it has demonstrated the following, if required, to the appropriate State authority:

- It does not have the capacity to deliver services adequately to additional individual enrollees because of the volume of current group contract holders and enrollees, and to current individual enrollees. In addition, the issuer must not offer any coverage in the individual market within that service area for a period of 180 days after the coverage is denied.
- It uniformly denies coverage to an individual without regard to any health status-related factor or whether the individual is an eligible individual.

5. Application of Financial Capacity Limits

A health insurance issuer may deny coverage in the individual market to an eligible individual if the issuer has demonstrated the following, if required, to the applicable State authority (§ 148.120(e)(1)):

- It does not have the financial reserves necessary to underwrite additional coverage.
- It uniformly denies coverage to an individual without regard to any health status-related factor or whether the individual is an eligible individual.

In those States under Federal enforcement of the individual market provisions, the demonstration of a lack of capacity to provide services, or a lack of financial capacity, must be made to us rather than the State (§ 148.120(e)(2)). The issuer must not deny coverage to any eligible individual until 30 days after we receive and do not reject the required information. We are currently developing reporting requirements for this information and we request comments regarding criteria that would be fair to all issuers, and at the same time promote the intent of the law to guarantee access to health insurance coverage for all eligible individuals.

An issuer that denies coverage in any service area is provided in § 148.120(e)(1), as prohibited from offering that coverage in the individual market for a period of 180 days after the later of the date coverage is denied or 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. A State may apply the 180 day suspension described in § 148.120(e)(3) on a service-area-specific basis.

6. Dependent Coverage

In general, if an issuer offers policies in the individual market that provide dependent coverage, the issuer may apply a preexisting condition exclusion, as allowed under applicable State law, to dependents who are not eligible individuals (§ 148.120(f)). However, the issuer may not apply a preexisting condition exclusion on certain children who have less than 18 months creditable coverage but are protected from an exclusion under the group market rules of Part 146.

These children are dependents who were enrolled as a dependent under a group health plan within 30 days of birth, adoption, or placement for adoption and have not had a significant break in coverage. We believe that the statute did not intend to eliminate this protection for children who could not have been enrolled any earlier (that is, before birth, adoption, or placement for adoption), and thus could not possibly have aggregated 18 months of creditable coverage.

7. Construction of Provisions

The regulation clarifies several areas that are not affected by this regulation (§ 148.120(g)). A health insurance issuer offering health insurance coverage only in connection with group health plans, or only through one or more bona fide associations, or both, is not required to offer that type of coverage in the individual market. Similarly, an issuer that only offers a conversion policy in connection with a group health plan is not considered to be an issuer offering individual health insurance coverage. The premium amount that an issuer charges for coverage in the individual

market is only restricted by applicable State law. An issuer offering coverage in the individual market is not prohibited from establishing premium discounts or rebates, or modifying applicable copayments or deductibles, in return for adherence to programs of health promotion and disease prevention. Also, issuers are not required to reopen blocks of business that have been closed under applicable State law, and an issuer in the individual market is not required to offer a family coverage option with any policy form unless State law requires the issuer to do so.

In addition, if an issuer elects to sell coverage to an individual who is not an eligible individual, the issuer may apply a preexisting condition exclusion period as permitted under State law. The HIPAA group rules relating to reduction of preexisting condition exclusion periods do not apply in the individual market unless a State chooses to apply them.

8. Broad Preclusion of Preexisting Condition Exclusions for Eligible Individuals

The individual market provisions (§ 148.120(a)(2)) preclude an issuer from imposing on an eligible individual a preexisting condition exclusion as defined under section 2701(b)(1)(A) of the PHS Act. That definition is very broad, including any limitation relating to a condition based on the fact that the condition was present before the date of enrollment under the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date.

9. Treatment of Coverage Under the Federal Employee Health Benefit Plan (FEHBP)

Federal employees are not subject to COBRA, but they may elect Federal Employee Temporary Continuation Coverage (TCC). This continuation coverage, like COBRA, is considered group coverage. While the individual is under the continuation coverage, the individual is still eligible for group coverage until that coverage has been exhausted. Therefore, the individual does not qualify as an eligible individual in the individual market by simply failing to exhaust TCC.

C. Guaranteed Renewability

Section 148.122 requires that a health insurance issuer providing individual health insurance coverage to an individual, renew or ''continue in force'' the coverage at the option of the individual. ''Continue in force'' means that the issuer maintains the same policy form that the individual purchased. The requirements in this section apply to all individuals purchasing health insurance coverage in the individual market, not only eligible individuals.

A health insurance issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market only for the following reasons: nonpayment of premiums, fraud, termination of plan, movement outside service area, and cessation of association membership. If coverage is terminated based on movement outside the service area and cessation of association membership, coverage must be terminated uniformly without regard to the health status-related factor of any covered individuals. Health status-related factor is defined in § 144.103 (definitions for the group and individual health insurance markets.)

Becoming eligible for Medicare by reason of age or otherwise is not a basis for nonrenewal or termination of an individual's health insurance coverage in the individual market, because it is not included in the statute's specifically defined list of permissible reasons for nonrenewal. If permitted by State law, however, policies that are sold to individuals before they attain Medicare eligibility may contain coordination of benefit clauses that exclude payment under the policy to the extent that Medicare pays.

Issuers who decide to discontinue offering a particular type or all coverage in the individual market are subject to certain requirements outlined in § 148.122 (d) and (e). Issuers discontinuing all coverage in the individual market are prohibited from issuing coverage in the market and State involved for 5 years following the date of discontinuation of the last coverage policy not renewed (§ 148.122(f)).

Issuers may modify the health insurance coverage for a policy form only at the time of coverage renewal, if the modification is consistent with State law and effective uniformly for all individuals with that policy form (§ 148.122(g)).

In the case of health insurance coverage made available by a health insurance issuer in the individual market to individuals only through one or more associations, the reference to an ''individual'' is deemed to include a reference to the association (§ 148.122(h)).

D. Certification of Coverage

Section 148.124 specifies that an issuer in the individual market must provide a certificate of creditable coverage, and, if required, make certain other disclosures regarding an individual's coverage under an individual policy. In general, the certificates and disclosure requirements are substantially identical to the relevant provisions of § 146.115 that apply to health insurance coverage offered by issuers in the group market. The preamble accompanying the group market regulation published elsewhere in this **Federal Register** explains these procedures in detail. The certificates and other disclosure of information are intended to enable individuals to avoid or reduce preexisting condition exclusions included under subsequent group health insurance coverage the individual may obtain.

The following model is different from the model certificate in the group market regulation. The individual market model certificate provides for the date that the substantially completed application was received from the policyholder. This date tolls the significant break period.

Certificate of Individual Health Insurance Coverage

* IMPORTANT—This certificate provides evidence of your health coverage. You may need to furnish this certificate if you become eligible under a group health plan that excludes coverage for medical conditions you have before you enroll, if medical advice, diagnosis, care, or treatment is recommended or received for the condition during the 6 months before you enroll 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 establish your right to buy coverage for yourself or your family, with no exclusion for previous medical conditions, if you are not covered under a group health plan.

1. Date of this certificate: _____
2. Name of policyholder: _____
3. Identification number of policyholder: _____
4. Name of any dependents to whom this certificate applies: _____
5. Name, address, and telephone number of issuer responsible for providing this certificate:

_____
_____
_____

6. For further information, call: _____
7. If all individual(s) identified in items 2 and 4 have at least 18 months of creditable coverage (disregarding periods of coverage before a 63-day break), check here _____ and skip items 8 and 9.
8. Date coverage began: _____
9. Date that a substantially completed application was received from the policyholder: _____
10. Date coverage ended: _____ (or check here if coverage is continuing as of the date of this certificate:_____)

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

Individuals have the right to receive a certificate automatically (an automatic certificate) when they lose coverage under an individual policy. A certificate must also be provided upon a request by, or on behalf of, an individual no later than 24 months after coverage ceases. The certificate must be provided at the earliest time that an issuer, acting in a reasonable and prompt fashion, can provide the certificate. The certificate must also be provided consistent with State law.

An issuer of an individual policy is required, to the same extent as an issuer of insurance in the group market, to prepare certificates with respect to the coverage of any of the individual's dependents that are covered under the individual policy. During a transitional period until July 1, 1998, an issuer may satisfy its obligation to provide a written certificate regarding the coverage of a dependent of a policyholder by providing the name of the policyholder covered by the policy and specifying the type of coverage as family coverage. If requested to provide a certificate related to a dependent, however, the issuer must make reasonable efforts to obtain and provide the name of the dependent.

For certain types of creditable coverage, including under a State health benefits risk pool, a public health plan, and section 5(e) of the Peace Corps Act, the statute does not identify a particular entity that is responsible for providing a certificate. However, any issuer that provides coverage in connection with those programs must provide certificates.

E. Determination of an Eligible Individual

An issuer is potentially subject to civil money penalties if it denies coverage, or applies a preexisting condition exclusion to, an eligible individual, unless it can show that it did not know, or exercising reasonable diligence could not have known, of the violation. Section 148.126 specifies that the issuer is responsible for determining whether an applicant is an eligible individual, and must exercise reasonable diligence in making this determination. An issuer could, for example, include questions on the application form that would be designed to elicit information that would indicate that the applicant may be an eligible individual.

An individual seeking to establish that he or she is an eligible individual may not have a certificate of creditable coverage that establishes 18 months of creditable coverage, and that the most recent period of creditable coverage is in a group health plan. The individual has the same right to demonstrate periods of creditable coverage as in the group market. Thus the issuer must take into account all information that the individual presents, and must treat the individual as having furnished a certificate if the individual attests to the period of creditable coverage, the individual presents relevant corroborating evidence of some creditable coverage during the period, and the individual cooperates with the issuer's efforts to verify the individual's coverage.

F. State Flexibility

1. Alternative Mechanism

If a State implements an alternative mechanism as described in § 148.128, the State does not have to enforce the ''Federal fallback'' provisions for guaranteed availability, although it must still enforce the guaranteed renewability provisions set forth in § 148.122. Although the law recognizes diversity among the States by allowing for an alternative mechanism, there are minimum requirements for an alternative mechanism. Under § 148.128, an alternative mechanism must meet the following requirements:

- Provide a choice of health insurance coverage to all eligible individuals.
- Not impose any preexisting condition exclusions and affiliation periods for coverage of an eligible individual.
- Include at least one policy form of coverage that is comparable to either one of the following:

+ Comprehensive health insurance coverage offered in the individual market in the State.
+ A standard option of coverage available under the group or individual health insurance laws of the State.

- Implement one of the following:

+ The National Association of Insurance Commissioners (NAIC) Small Employer and Individual Health Insurance Availability Model Act, as it applies to individual health insurance coverage, and as revised in State regulations to meet all the requirements of Part 148 of this rule and Part 144 published elsewhere in this **Federal Register** with the group market rules.
+ The Individual Health Insurance Portability Model Act, as adopted on June 3, 1996, and revised in State regulations to meet all the requirements of Part 148 of this rule and Part 144 published elsewhere in this **Federal Register** with the group market rules.
+ A qualified high-risk pool that provides for the following:
  —Health insurance coverage (or comparable coverage) to all eligible individuals that does not impose any preexisting condition exclusion or affiliation periods with respect to this coverage for all eligible individuals.
  —Premium rates and covered benefits for that coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act in effect on August 21, 1996, and revised in State regulations to meet all the requirements of Part 148 of this rule and Part 144 published elsewhere in this **Federal Register** with the group market rules.
+ Another mechanism—
  —That provides for risk adjustment, risk spreading, or a risk-spreading mechanism (among issuers or policies of an issuer) or otherwise provides for some financial subsidization for eligible individuals, including through assistance to participating issuers, or
  —Under which each eligible individual is provided a choice of all individual health insurance coverage otherwise available.

2. Permissible Forms of Mechanisms

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

3. Transition Rules for Establishing an Acceptable Alternative Mechanism

We presume a State to be implementing an acceptable alternative mechanism as of July 1, 1997, if the State submits a notice and required information that meets the notice and information requirements for an acceptable alternative mechanism described in § 148.128(c), no later than April 1, 1997, and we do not make a determination within 90 days (except as provided in § 148.128(e)(3)(ii) for suspensions of the review period) that the State will not be implementing a

mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998. To assist States in meeting the April 1, 1997, statutory deadline for notifying HCFA and submitting the necessary information, HCFA will consider postmark dates, special delivery service dates or other such dates as the date of receipt.

4. Delay Permitted for Certain States

If a State notifies us that its legislature is not meeting in a regular session between August 21, 1996, and August 20, 1997, our presumption that the State is implementing an acceptable alternative mechanism will continue until July 1, 1998, if the State meets the notice and information requirements in § 148.128(d).

5. General Rules for Establishing an Alternative Mechanism

A State that chooses to implement an acceptable alternative mechanism must submit the notice and supporting information specified in § 148.128(e). After receiving the information, if we do not make a preliminary determination as described in § 148.128(e)(2), within 90 days of receiving the State's information (except as provided in § 148.128(e)(3)(ii), that the mechanism is not accepted, the (proposed) alternative mechanism is presumed to be an acceptable alternative mechanism. If we do make a preliminary determination, after consultation with the chief executive officer of the State, that an alternative mechanism is not acceptable, we will notify the State, in writing, of the consequences of failing to implement an acceptable alternative mechanism and permit the State a reasonable opportunity to modify the mechanism or adopt another mechanism. In determining a reasonable opportunity, we will take into consideration a State's legislative calendar and process. If after taking all of these actions, our final determination is that a State's alternative mechanism is not an acceptable mechanism or the State is not substantially enforcing an acceptable mechanism, we will notify the State, in writing, as provided in § 148.128(e)(4)(ii).

A State may request that we notify it, after reviewing the material submitted, if we did not make a preliminary determination that the mechanism is not an acceptable alternative mechanism (§ 148.128(e)(4)).

6. Suspension of Review Period

If we notify a State of our need for additional information or further discussions on its submission, we will suspend the review period, as described in § 148.128(e)(3)(ii) until the State provides the necessary information. If the State chooses not to provide the necessary information or our discussions with the State cannot be concluded satisfactorily, we may make a preliminary determination that the mechanism is not an acceptable alternative mechanism.

7. Review Criteria

The law gives States substantial flexibility in devising alternative mechanisms. If a State chooses to submit a proposed alternative mechanism, the State determines what to submit. We must, however, be able to determine whether the mechanism is designed to ensure that eligible individuals are given the required access to insurance coverage. Our review will focus on results for eligible individuals. Our main concern is that the State submission show the analysis and the reasoning behind the design of the proposed alternative mechanism, and a reasonable assessment of the likelihood that the mechanism will achieve the legislative objectives. These requirements are described in § 148.128(g).

8. Continued Application and Effective Dates

A State must provide information necessary for us to review its mechanism's implementation every 3 years, or before implementing any significant change, to continue to be presumed to have an acceptable alternative mechanism (§ 148.128(f)). We suggest that a State inform us of any significant change to its alternative mechanism 120 days before implementing the change.

For alternative mechanisms submitted after April 1, 1997, if we do not make a preliminary determination within the review period, the alternative mechanism is effective 90 days after the end of the 90-day review period (except as provided in § 148.128(e)(3)(ii).

9. Limitation on HCFA's Authority

We do not make a preliminary or final determination on any basis other than that a mechanism is not considered an acceptable alternative mechanism or is not being implemented by the State (§ 148.128(h)).

G. Enforcement

Sections 2741 through 2763 and 2791 of the PHS Act, as implemented by Part 148 of these regulations, impose requirements on health insurance issuers that offer coverage in the individual market in a State. The statute makes 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. We anticipate 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, we must enforce them. Section 148.200 sets forth the procedures that we will follow in the event that a question is raised about the State's enforcement. The procedures are designed to give the State every opportunity to show why Federal enforcement is not required. The regulation also makes clear that the process will not be triggered unless we are satisfied that there has been a reasonable effort to exhaust any State remedies. However, if, after giving the State a reasonable opportunity to enforce, we make a final determination that a State is not substantially enforcing these requirements, we will enforce the requirements using the civil money penalties provided for under § 148.202.

Section 148.202 describes the process for imposing civil money penalties against issuers that fail to comply with the requirements of Part 148 requiring them to make coverage available to eligible individuals, to renew all individual coverage, and to provide certificates of creditable coverage. If we receive a complaint or other information that indicates that the issuer is not in compliance with these requirements, we will give the issuer an opportunity to respond. If we assess the penalty, which can consist of up to $100 for each day, for each individual whose rights are violated, the regulation provides appeal rights.

H. Preemption

Section 2762 of the PHS Act specifies that, in general, State laws regarding health insurance issuers are not preempted unless they ''prevent the application of'' a requirement of the individual market rules in Part 148 of this rule or Part 144 published elsewhere in this **Federal Register** with the group market rules. Within these restrictions, however, the conference report makes clear that the conferees intended ''the narrowest preemption'' of State law, and indicates that State laws that are ''broader'' than Federal requirements would not ''prevent the application of'' the HIPAA requirements.

The statute, however, makes clear that nothing in sections 2741 through 2763 and 2791 of the PHS Act can be construed to affect or modify the

provisions of section 514 of ERISA, which limits State regulation of group health plans.

I. Excepted Benefits

Section 146.145 specifies that certain benefits are excluded from certain requirements of the group market only if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of the plan. Under § 148.220, for purposes of the individual market, these benefits are excluded if provided under a separate policy certificate, or contract of insurance. The term ''integral to a plan'' does not apply in the individual market.

In addition, in the group market, coverage for only a specified disease or illness or hospital indemnity or other fixed dollar indemnity insurance is excepted only if the following applies:

- It is provided under a separate policy, certificate, or contract of insurance.
- 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. (This does not apply in the individual market.)
- 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. (This does not apply in the individual market.)

The requirements of Part 148 do not apply to ''excepted benefits,'' which are benefits under one or more (or any combination) of the following:

- Fully excepted benefits—

—Coverage only for accident (including accidental death and dismemberment);
—Disability income insurance;
—Liability insurance, including general liability insurance and automobile liability insurance;
—Coverage issued as a supplement to liability insurance;
—Workers' compensation or similar insurance;
—Automobile medical payment insurance;
—Credit-only insurance (for example, mortgage insurance); and
—Coverage for onsite medical clinics.

- Other excepted benefits, which are excepted only if they are provided under a separate policy, certificate, or contract of insurance—

—Limited scope dental or vision benefits;
—Benefits for long-term care;
—Coverage only for a specified disease or illness (for example, cancer policies) as long as the policy does not coordinate benefits;
—Hospital indemnity or other fixed indemnity insurance (for example, $100 per day) as long as the policy does not coordinate benefits;
—Medicare supplemental health insurance, also known as Medigap or MedSup insurance (as defined in section 1882(g)(1) of the Social Security Act);
—Supplemental coverage provided under Chapter 55 Title 10 of the United States Code (also known as CHAMPUS supplemental programs); and
—Similar supplemental coverage provided under a group health plan.

J. Associations in the Individual Market

As we discuss in the preamble to the interim final rules for the group market rules published elsewhere in this **Federal Register**, an association policy that is not offered in connection with an employment-related group health plan falls under the individual market provisions of HIPAA, even if a State otherwise regulates it as ''association group'' coverage. In response to the notice published in the **Federal Register** on December 30, 1996 (61 FR 68697), we received a large number of comments relating to coverage under ''college plans,'' which provide association group coverage for students (as distinguished from employees of a college or university).

The following discussion of college plans, which generally applies to any association coverage in the individual market, addresses the commenters' concerns.

- College plans are clearly creditable coverage under § 146.113(a)(1) because they meet the definition of ''health insurance coverage'' under part 144 of the group market rules.
- If an issuer offers student coverage through a ''bona fide association,'' that meets all six requirements set forth in the definition of these entities 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. The student also benefits because a bona fide association must make the coverage available to all association members regardless of any health status-related factors. If the college plan is not a bona fide association, however, it does have to guarantee coverage to all eligible individuals in the individual market and must renew the coverage indefinitely at the option of former students. In addition, State laws may be more stringent than the Federal definition of bona fide association.
- The commenters were concerned that students should be able to move from coverage under an employment-related group health plan (through their own or their parents' employment) to a college plan, between college plans, and from a college plan to individual coverage, with guaranteed availability and without preexisting condition exclusions. These concerns cannot be fully addressed under the current law. Because HIPAA provides for full portability from individual products to group market coverage, moving from a college plan to a employer plan presents no problem, since the coverage under the college plan constitutes creditable coverage that reduces any preexisting condition exclusion under the group health plan. However, a student moving from a group health plan to college or other individual coverage will not qualify for these protections unless he or she qualifies as an ''eligible individual'' as defined in § 148.103. To gain this status, a student must exhaust any COBRA or State ''mini-COBRA'' continuation coverage available. A child aging out of a parent's coverage generally qualifies for 36 months of COBRA. This puts the student in the position of either paying the higher cost of continuation coverage for the duration of the continuation coverage, or taking the lower-cost student coverage subject to a preexisting condition exclusion of any length permitted under State law. HIPAA places no limits on preexisting condition exclusion in the individual market for noneligible individuals.

Moreover, HIPPA does not provide any guaranteed availability or protection against preexisting condition exclusions for students moving from one individual policy to another. This is true even if the student originally enrolled in a student plan as an eligible individual, since that status is applicable only when the student's most recent coverage is under a group health plan.

III. Regulatory Impact Analysis

Ordinarily, we would include a Regulatory Impact Statement in this section of the document. We have chosen, however, to address the economic impact analysis of this regulation in a combined impact statement contained in the interim final rule for the group market provisions (BPD–890–IFC). A combined impact analysis has been prepared because of the close connection between the effects of HIPAA's group market reforms and the reforms in the individual insurance

market, and because of the overlap of issuers participating in both the group and individual market. The regulatory burdens placed on entities in the group and individual markets are virtually identical in many respects, notably in the certification process. There are also economic effects that crossover from one market segment to the other because of HIPPA provisions, such as the group-to-individual portability provision, which may have an effect on premiums in either or both market segments. We believe a single discussion of the economic impact is the most appropriate means of highlighting the similarities and discussing the interactions between the two market segments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are 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 requirements 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. This is necessary to ensure compliance with section 111 of 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 publication, with OMB 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: Individual Health Insurance.

Reform: Portability from Group to Individual Coverage; Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules BPD–882–IFC.

Form Number: HCFA–R–205.

Use: These rules ensure access to the individual insurance market for certain individuals and allows the States to implement their own program to meet the HIPAA requirements for access to the individual market. The information collection requirements outlined in this rule document the record keeping necessary for issuers and States to ensure individuals receive protection under section 111 of HIPAA.

Frequency: On occasion.

Affected Public: States, businesses or other for profit, not-for-profit institutions, Federal Government, individuals or households.

Number of Respondents: 1,035.

Total Annual Responses: 3.5 million in 1997; 3 million each in 1998 and 1999;

Total Annual Hours Requested: 335,000 to 586,000 hours in 1997; 384,000 to 882,000 in 1998; and 377,000 to 882,000 in 1999.

Total Annual Cost: $4.9 million to $6.8 million in 1997; $5.1 million to $8.7 million in 1998; and $5.4 million to $8.7 million in 1999.

Sections 148.120, 148.122, 148.124, 148.126, 148.128, 148.200, and 148.202 of this document contain information collection requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to OMB for its review of these information collection requirements.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

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

States are given the flexibility either to enforce the Federal requirements set forth in § 148.120, or to implement an alternative mechanism, under State law, that achieves the statutory mandate of providing eligible individuals with access to individual health insurance, or comparable coverage, without preexisting condition exclusions. However, a State could choose to do nothing, resulting in Federal enforcement of the individual market regulations under HIPAA. Thirty States have indicated to us an intent to implement an alternative mechanism under § 148.128. The information collection requirements associated with implementing and enforcing the alternative mechanism are discussed below for § 148.128.

If a State chooses to enforce the Federal guaranteed availability requirements (sometimes referred to as the ''Federal fall back'' requirements), the provisions of § 148.120 apply, and must be enforced by the State under State law. Since many of these requirements are enforced under existing State law, for these instances, they are exempt from the Paperwork Reduction Act (PRA) as described under 5 CFR 1320.3(b)(3). Although applicable PRA burden will vary by State and issuer, we anticipate that ten States will be required to review materials submitted by at most 325 issuers per State on an annual basis to ensure compliance with the requirements of all products guaranteed or alternative coverage, which are not currently required under State laws and regulations. Therefore, the PRA burden imposed under this option is the time required by the ten States to review the materials submitted by the issuers. This burden is 1,625 hours based on each of the ten States reviewing the material for 30 minutes for each issuer on an annual basis. We estimate the cost associated with this burden to be $24,375.

If a State implements neither an alternative mechanism, nor the Federal fall back requirements, we will implement the Federal fall back provisions in that State and will enforce those requirements using the penalty provisions specified in §§ 148.200 and 148.202. We anticipate that fewer than ten States will rely on Federal enforcement of the statute. In particular, the only jurisdictions that we believe

will choose this option are the five U.S. territories.

This section also requires an issuer who elects the alternative coverage option to document any actuarial calculations necessary to satisfy State and/or Federal oversight provisions referenced in § 148.120. Since the majority of issuers rely on automated means of storing their calculations, we estimate the annual burden for this record keeping activity to be 25 hours. This is based on the assumption that it will take approximately 10 issuers per State, in 15 States, on an annual basis, 10 minutes per issuer, to electronically store and verify the storage of their calculations. We estimate the cost associated with this burden to be $375.

Section 148.122 Guaranteed renewability of individual health insurance coverage.

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 oversite process to make sure there is a guarantee renewability clause in each policy. For the 21 States that currently require guaranteed renewability, it is our understanding that this is normal business practice. For the other 34 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 annual burden of 20,000 hours. We estimate the cost associated with this burden to be $300,000. 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 renewability requirements.

Section 148.124 Certification and disclosure of coverage.

Section 148.124 specifies that an issuer in the individual market must provide a written certificate of creditable coverage, and, if required, make other certain disclosures regarding an individual's coverage under an individual policy. In general, the certification and disclosure requirements are substantially identical to the relevant provisions of § 146.115 that apply to health insurance coverage offered by issuers in the group market. The preamble accompanying the group market regulation explains these procedures in detail. In general, the certificates from issuers in the individual market and other disclosure of information are intended to enable individuals to avoid or reduce preexisting condition exclusions included under subsequent group health insurance coverage the individual may obtain.

Individuals have the right to receive a certificate automatically (an automatic certificate) when they lose coverage under an individual policy. A certificate must also be provided upon a request by, or on behalf of, an individual for the period not later than 24 months after coverage ceases. The certificate must be provided at the earliest time that an issuer, acting in a reasonable and prompt fashion, can provide the certificate. The certificate must also be provided consistent with State law.

An issuer of an individual policy is required, to the same extent as an issuer of insurance in the group market, to prepare certificates with respect to the coverage of any of the individual's dependents that are covered under the individual policy.

We anticipate that 3 million individual market-based certificates will be generated on an annual basis. We are assuming that the majority of certificates issued in the individual market will require issuers to find out the application date since many individuals will have less than 18 months of credible coverage with that issuer.

The range of time estimates, shown in the table below, are 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.

Year	Total respondents	Total responses	Average time (in minutes) per response (range)	Burden hours (range)	Cost (range)
1997	1,000	3,418,052	4.63	263,548	$3,897,932
			8.95	509,665	5,716,826
1998	1,000	2,929,759	6.94	338,781	4,542,924
			17.11	835,517	8,035,131
1999	1,000	2,929,759	6.81	332,480	4,746,736
			17.11	835,517	8,035,131

Section 148.126 Determination of an eligible individual.

In this section, issuers may maintain records for those individuals who they determine are not HIPAA eligible individuals. We estimate this to be on average less than 50 individuals per the 1,000 issuers nationwide each year. At 20 minutes per record, this represents an annual burden of 16,667 hours. We estimate the cost associated with this burden to be $183,000.

Section 148.128 State flexibility in individual market reforms—alternative mechanisms.

As explained above, 30 or more States may implement acceptable alternative mechanisms as allowed under this section. It is estimated that this reporting burden will range from 33,000 to 38,500 hours depending on the number of States that choose to submit the required information. We estimate the cost associated with this burden to be $495,000 to $577,500.

The information collection requirements associated with submitting the required documentation outlining a State's alternative mechanism is currently approved under emergency OMB approval number 0938–0699 which expires on 07/31/97. The information collection requirements

currently approved in this section will be re-approved with the remaining information collection requirements referenced in the HHS PRA section.

Section 148.200 Enforcement and Section 148.202 Civil money penalties.

We anticipate identifying violations through individual nonstandardized consumer complaints. Therefore, the complaints submitted and our enforcement activities do not fall within the requirements of the PRA, as outlined in 5 CFR 1320.3(c) and 5 CFR 1320.4(a).

We have submitted a copy of this notice 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 the burden or any other aspect of these collections of information requirements.

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.

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.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Interim Rules and Request for Comments

Section 2792 of the PHS Act, provides in part, that HHS may promulgate any interim final rules as they determine are appropriate to carry out the provisions of the new Part B of the PHS Act. 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, rather than as proposed rules, because the Department has determined that, without prompt guidance, some members of the regulated community will have difficulty complying with the HIPAA's certification requirements and could be in violation of the statute. The Congress expressly intended that the certification and prior creditable coverage provisions serve as the mechanism for increasing the portability of health coverage for individuals. Without the Department's guidance, issuers will likely be unable to produce the necessary amendments to policy documents reflecting HIPAA's new requirements, as well as the appropriate certifications of prior coverage that would eliminate preexisting condition exclusion periods for eligible individuals. Moreover, without the Department's prompt guidance, insured individuals will not understand the benefit to them of having a certificate of prior coverage to present upon entering the individual health insurance market and will likely have greater difficulty proving that they are entitled to health coverage.

HIPAA's portability requirements will affect the regulated community in the immediate future. HIPAA's certification requirements are effective for all issuers on June 1, 1997. HIPAA's underlying requirements concerning establishing periods of prior creditable coverage and eliminating pre-existing condition exclusions in the individual market are generally applicable July 1, 1997. Issuers and individuals will need guidance on how to comply with the new statutory provisions before this effective date. The rules have been written in order to ensure that issuers of individual health insurance, as well as individuals, are provided timely guidance concerning compliance with these recently enacted amendments to the PHS Act. The rules provide guidance on these statutory changes, and are being adopted on an interim basis because the Department finds 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 health insurance issuers. In addition, the rules are necessary to ensure that issuers, as well as individuals, are provided timely guidance concerning compliance with new and important disclosure obligations imposed by HIPAA.

Section 2792 of the PHS Act authorizes the Department to issue regulations necessary to carry out the amendments made by section 111 of HIPAA by April 1, 1997. Issuance of a notice of proposed rule making with public comment prior to issuing a final rule could delay significantly the issuance of essential guidance and prevent the Department from complying with its statutory rulemaking deadline. Furthermore, although these rules are being adopted on an interim basis, the Department is inviting interested persons to submit written comments on the rules for consideration in the development of the final rules relating to HIPAA. Development of subsequent rules may be issued in advance of January 1, 1998.

For the foregoing reasons, the Department finds that the publication of a proposed regulation, for the purpose of notice and public comment, would be impracticable, unnecessary, and contrary to the public interest. However, we are providing a 90-day period for public comment, as indicated at the beginning of this rule.

List of Subjects in 45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 45 CFR Subtitle A is amended as set forth below: A new Part 148, consisting of §§ 148.101 through 148.220, is added to Subchapter B to read as follows:

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

Subpart A—General Provisions

Sec.

Subpart B—Requirements Relating to Access and Renewability of Coverage

Subpart C—[Reserved]

Subpart D—Enforcement; Penalties; Preemption

Sec.

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

Subpart A—General Provisions

§ 148.101 Basis and purpose.

This part implements sections 2741 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to improve access to individual health insurance coverage for certain eligible individuals who previously had group coverage, and to guarantee the renewability of all coverage in the individual market.

§ 148.102 Scope, applicability, and effective dates.

(a) *Scope and applicability.* (1) Individual health insurance coverage includes all health insurance coverage (as defined in 45 CFR 144.103) that is neither health insurance coverage sold in connection with an employment-related group health plan, nor short-term, limited duration coverage as defined in 45 CFR 144.103. In some cases, coverage that may be considered group coverage under State law (such as coverage sold through certain associations) is considered individual coverage.

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

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

§ 148.103 Definitions.

Unless otherwise provided, the following definition applies:

Eligible individual means an individual who meets the following conditions:

(1) The individual has at least 18 months of creditable coverage (as determined under 45 CFR 146.113) as of the date on which the individual seeks coverage under this part.

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

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

(i) A group health plan.

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

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

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

(5) The individual's most recent coverage was not terminated because of nonpayment of premiums or fraud. (For more information about nonpayment of premiums or fraud, see 45 CFR 146.152(b)(1) and (b)(2).)

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

Subpart B—Requirements Relating to Access and Renewability of Coverage

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

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

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

(i) Provide information about all available coverage options.

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

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

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

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

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

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

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

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

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

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

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

(A) Include a lower-level coverage policy form under which the actuarial value of benefits under the coverage is at least 85 percent but not greater than 100 percent of the weighted average.

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

(C) Include benefits substantially similar to other individual health

insurance coverage offered by the issuer in the State.

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

(E) Meet all applicable State requirements.

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

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

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

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

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

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

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

(d) *Special rules for network plans.* (1) An issuer that offers coverage in the individual market through a network plan may take the following actions:

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

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

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

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

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

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

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

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

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

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

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

(1) The coverage is denied; or

(ii) The issuer demonstrates to the applicable State authority (if required under applicable State law) that the issuer has sufficient financial reserves to underwrite additional coverage.

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

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

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

(i) The child was covered under any creditable coverage within 30 days of birth, adoption, or placement for adoption (or longer if the State provides for a longer special enrollment period than required under 45 CFR 146.117).

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

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

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

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

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

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

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

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

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

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

§ 148.122 Guaranteed renewability of individual health insurance coverage.

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

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

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

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

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

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

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

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

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

(d) *Discontinuing a particular type of coverage.* An issuer may discontinue offering a particular type of health insurance coverage offered in the individual market only if it meets the following requirements:

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

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

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

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

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

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

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

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

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

(h) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the individual market only through one or more associations, any reference in this section to an ''individual'' is deemed to include a reference to the association of which the individual is a member.

§ 148.124 Certification and disclosure of coverage.

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

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

(i) Health insurance coverage furnished in connection with a group health plan defined in 45 CFR 144.103. (These issuers are regulated under 45 CFR 146.115 to provide a certificate of coverage.)

(ii) Excepted benefits described in § 148.220.

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

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

(ii) *Any individual upon request.* A request for a certificate may be made by, or on behalf of, an individual within 24 months after coverage ends. For example, an entity that provides coverage to an individual in the future may, if authorized by the individual, request a certificate of the individual's creditable coverage on behalf of the individual from the issuer of the individual's prior coverage. After the request is received, an issuer must provide the certificate promptly. A certificate must be provided under this paragraph even if the individual has previously received an automatic certificate under paragraph (a)(l)(i) of this section.

(2) *Form and content of certificate*—(i) *Written certificate*—(A) *General rule.* Except as provided in paragraph (b)(2)(i)(B) of this section, the issuer must provide the certificate in writing (including any form approved by the HCFA) (B) *Other permissible forms.* No written certificate must be provided if the following occurs:

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

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

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

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

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

(A) The date the certificate is issued.

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

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

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

(E) Either one of the following:

(*1*) A statement that the individual has at least 18 months (for this purpose, 546 days is deemed to be 18 months) of creditable coverage, disregarding days of creditable coverage before a significant break in coverage as defined in 45 CFR 146.113(b)(2)(iii).

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

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

(iii) *Periods of coverage under a certificate.* If any automatic certificate is provided under paragraph (b)(1)(i) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate under paragraph (b)(1)(ii) of this section, a certificate must be provided for each period of continuous coverage ending within the 24-month period ending on the date of the request (or continuing on the date of the request). A separate certificate may be provided for each period of continuous coverage.

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

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

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in § 148.220. If excepted benefits are provided concurrently with other creditable coverage (so that the coverage does not consist solely of excepted benefits), information concerning the benefits may be required to be disclosed under paragraph (c) of this section.

(3) *Procedures*—(i) *Method of delivery.* The certificate is required to be provided, without charge, to each individual described in paragraph (b)(1) of this section or an entity requesting the certificate on behalf of the individual. The certificate may be provided by first-class mail. If the certificate or certificates are provided to the individual and the individual's spouse at the individual's last known address, the requirements of this paragraph (b)(3) are satisfied with respect to all individuals and dependents residing at that address. If a dependent does not reside at the individual's last known address, a separate certificate must be provided to the dependent at the dependent's last known address. If separate certificates are provided by mail to individuals and dependents who reside at the same address, separate mailings of each certificate are not required.

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

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

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

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by an issuer does not provide the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (d)(3) of this section for demonstrating dependent status. An individual may, if necessary, use these procedures to demonstrate that a child was enrolled within 30 days of birth, adoption, or placement for adoption, in which case the child would not be subject to a preexisting condition exclusion under § 148.120(f)(2).

(iii) *Transition rule for dependent coverage before July 1, 1998*—(A) *General rule.* An issuer that cannot provide the names of dependents (or related coverage information) for purposes of providing a certificate of coverage for a dependent may satisfy the requirements of paragraph (b)(2)(ii)(C) of this section by providing the name of the policyholder and specifying that the type of coverage provided in the certificate is for dependent coverage (for example, family coverage or individual-plus-spouse coverage).

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

(C) *Timing.* An issuer providing an automatic certificate that does not contain the name of a dependent must furnish a certificate within 21 days after the individual ceases to be covered under the policy.

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

(E) *Optional notice.* This paragraph applies to events described in § 148.124 (b)(4)(ii), that occur on or after October 1, 1996, but before June 1, 1997. An issuer offering individual health insurance coverage is deemed to satisfy § 148.124 (b)(1) and (b)(2) if a notice is

provided in accordance with the provisions of § 148.124(b)(4)(iii).

(c) *Disclosure of coverage to a plan, or issuer, electing the alternative method of creating coverage*—(1) *General rule.* If an individual enrolls in a group health plan and the plan or issuer uses the alternative method of determining creditable coverage described in 45 CFR 146.113(c), the individual provides a certificate of coverage under paragraph (b) of this section or demonstrates creditable coverage under paragraph (d) of this section, and the plan or coverage in which the individual enrolls requests from the prior entity, the prior entity must disclose promptly to the requesting plan or issuer (''requesting entity'') the information set forth in paragraph (c)(2) of this section.

(2) *Information to be disclosed.* The prior entity must promptly identify for the requesting entity the categories of benefits and services used by the individual for which the requesting entity uses the alternative method of crediting coverage, and any specific information that the requesting entity requests to determine the individual's creditable coverage. The prior entity must promptly disclose to the requesting entity the creditable coverage information.

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

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

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

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

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

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

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

(2) *Evidence of creditable coverage*—(i) *Consideration of evidence.* An issuer must take into account all information that it obtains or that is presented on behalf of an individual to make a determination, based on the relevant facts and circumstances, whether or not an individual has 18 months of creditable coverage. An issuer must treat the individual as having furnished a certificate if the individual attests to the period of creditable coverage, the individual presents relevant corroborating evidence of some creditable coverage during the period, and the individual cooperates with the issuer's efforts to verify the individual's coverage. For this purpose, cooperation includes providing (upon the issuer's request) a written authorization for the issuer to request a certificate on behalf of the individual, and cooperating in efforts to determine the validity of the corroborating evidence and the dates of creditable coverage. While an issuer may refuse to credit coverage if the individual fails to cooperate with the issuer's efforts to verify coverage, the issuer may not consider an individual's inability to obtain a certificate to be evidence of the absence of creditable coverage.

(ii) *Documents.* Documents that may establish creditable coverage (and waiting periods or affiliation periods) in the absence of a certificate include explanations of benefit claims (EOB) or other correspondence from a plan or issuer indicating coverage, pay stubs showing a payroll deduction for health coverage, a health insurance identification card, a certificate of coverage under a group health policy, records from medical care providers indicating health coverage, third party 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 be established through means other than documentation, such as by a telephone call from the issuer to a third party verifying creditable coverage.

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

§ 148.126 Determination of an eligible individual.

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

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

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

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

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

(2) *Failure to provide a certification of creditable coverage.* If an entity fails to provide the certificate that is required under this part or 45 CFR part 146 to the applicant, the issuer is subject to the procedures set forth in § 148.124(d)(1) concerning an individual's right to demonstrate creditable coverage.

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

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

(1) The alternative mechanism meets the following conditions:

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

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

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

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

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

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

(i) One of the following model acts, as adopted by the NAIC on June 3, 1996, but only if the model has been revised in State regulations to meet all of the requirements of this part and part 144:

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

(B) The Individual Health Insurance Portability Model Act.

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

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

(B) Provides for premium rates and covered benefits for the coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect as of August 21, 1996), but only if the model has been revised in State regulations to meet all of the requirements of this part and part 144.

(iii) One of the following mechanisms:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Provide HCFA with the information necessary for HCFA to review the mechanism and its implementation (or proposed implementation).

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

(3) *Review period*—(1) *General.* The review period begins on the date the State's notice and information are received by HCFA, and ends 90 days later, not counting any days during which the review period is suspended under paragraph (e)(3)(ii) of this section.

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

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

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

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

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

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

(A) HCFA's final determination.

(B) That the requirements of § 148.120 concerning guaranteed availability apply to health insurance coverage offered in the individual market in the State are effective as of a date specified in the notice from HCFA.

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

(5) *Effective date.* If HCFA does not make a preliminary determination within the review period, the acceptable alternative mechanism is effective 90 days after the end of the 90-day review

period described in paragraph (e)(3)(i) of this section.

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

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

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

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

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

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

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

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

(3) Does the mechanism prohibit preexisting condition exclusions for all eligible individuals?

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

(i) The NAIC Small Employer and Individual Health Insurance Availability Model Act (Availability Model), adopted on June 3, 1996, revised to reflect HIPAA requirements.

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

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

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

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

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

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

Subpart C—[Reserved]

Subpart D—Enforcement; Penalties; Preemption

§ 148.200 Enforcement by State; determination regarding failure to enforce.

(a) *General rule—enforcement by State.* Except as provided in paragraph (b) 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 individual market in the State.

(b) *Exception—enforcement by HCFA.* HCFA enforces the provisions of this part with respect to health insurance issuers, using the procedures described in § 148.202, only in the following circumstances:

(1) *State election.* The State chooses not to enforce the Federal requirements.

(2) *State failure to enforce.* HCFA determines under paragraph (c) of this section that a State has failed to substantially enforce the requirements of this part.

(c) *HCFA determination.* If HCFA receives information, through a complaint or any other means, that raises a question about whether a State is substantially enforcing the requirements of this part, HCFA follows the following procedures:

(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 about whether there has been a failure to substantially enforce the requirements of this part, HCFA sends, in writing, the notice described 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) If the alleged failure involves HMOs, the official responsible for regulating HMOs, if different than the official listed in paragraph (c)(2)(ii) of this section.

(3) *Form and content of notice.* HCFA's written notice to the State sets forth the following information:

(i) Describes the facts of the specific violations.

(ii) Explains that the consequence of a failure to substantially enforce the requirements of this part is that HCFA enforces the requirements in accordance with paragraph (d) of this section.

(iii) Advises the State that it has 45 days to respond to the notice, unless the time is extended as described in paragraph (c)(4) 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) *Extension.* HCFA may, for good cause, grant the State an extension of the time period described in paragraph (c)(3)(iii) of this section. 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 for a State to respond to HCFA's notice (and any extension), the State has not established to HCFA's satisfaction that it is substantially enforcing the requirements of this part, 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 requirements, 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 the requirements of this part, HCFA finds that the failure to enforce has not been corrected, HCFA sends the State a written notice of that final determination. The notice sets forth the following:

(i) The effective date of HCFA enforcement.

(ii) The mechanism for establishing in the future that it has corrected the failure, and has begun enforcement. This mechanism includes transition procedures for ending HCFA's enforcement period.

§ 148.202 Civil money penalties.

(a) *General rule.* If any health insurance issuer that is subject to HCFA's enforcement authority under § 148.200 fails to comply with any

applicable requirement of this part, it may be subject to a civil money penalty.

(b) *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 an issuer's failure to comply with the requirements of this part may file a complaint with HCFA.

(c) *Notice to issuer.* HCFA sends a written notice to the issuer that a complaint or other information has been received alleging a violation of this part. The notice sets forth the following:

(1) A description of the substance of any complaint or other allegation.

(2) A time frame of 30 days for the issuer to respond with additional information, which can include the following:

(i) Information refuting that there has been a violation.

(ii) Evidence that the issuer did not know, and exercising reasonable diligence could not have known, of the violation.

(iii) Evidence of a previous record of compliance.

(d) *Notice of assessment.* If, based on the information provided in the complaint, as well as any information submitted by the issuer or any other parties, HCFA proposes to assess a civil money penalty, HCFA sends written notice of the assessment to the issuer by certified mail, return receipt requested. The notice contains the following information:

(1) The name or names of the individuals with respect to whom a violation occurred, with relevant identification numbers.

(2) The facts that support the finding of a violation, and the initial date of the violation.

(3) The amount of the proposed penalty as of the date of the notice.

(4) The basis for calculating the penalty, including consideration of prior compliance.

(5) Instructions for responding to the notice, including the following information:

(i) A specific statement of the issuer's right to a hearing.

(ii) A statement that failure to request a hearing within 30 days permits the imposition of the proposed penalty, without right of appeal.

(e) *Amount of penalty*—(1) *Maximum daily penalty*. The penalty cannot exceed $100 for each day, for each individual with respect to whom a failure occurs.

(2) *Standard for calculating daily penalty*. In calculating the amount of the penalty, HCFA takes into account the issuer's previous record of compliance and the seriousness of the violation.

(3) *Limitations on penalties.* No civil money penalty is imposed for the following periods:

(i) A period during which a failure existed, but the issuer did not know, and exercising reasonable diligence would not have known, that the failure existed.

(ii) A period occurring immediately after the period during which a failure existed, but the issuer did not know, and exercising reasonable diligence would not have known, that the failure existed if the failure—

(A) Was due to reasonable cause and was not due to willful neglect; and

(B) Was corrected within 30 days of the first day that the issuer knew, or exercising reasonable diligence would have known, that the failure existed.

(iii) The burden is on the issuer to establish to the satisfaction of HCFA that it did not know, and exercising reasonable diligence could not have known that the failure existed.

(f) *Hearings*—(1) *Right to a hearing.* Any issuer 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 HCFA issues the notice of assessment.

(2) *Failure to request a hearing.* If no hearing is requested in accordance with this paragraph (f), the notice of assessment constitutes a final order that is not subject to appeal.

(3) *Parties to the hearing.* Parties to the hearing include the issuer and the party who filed the complaint. HCFA sends an informational notice to the State.

(4) *Initial agency decision*. The initial agency decision is made by an administrative law judge. The decision is made on the record under section 554 of Title 5, United States Code. The decision becomes a final and appealable order after 30 days, unless it is modified in accordance with paragraph (g) of this section.

(5) *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 by the administrative law judge.

(g) *Judicial review*—(1) *Filing of action for review*. Any issuer against whom a final order imposing a civil money penalty is entered may obtain review in the United States District Court for any district in which the entity is located or the United States District Court for the District of Columbia by—

(i) Filing a notice of appeal in that court within 30 days from the date of a final order; and

(ii) Simultaneously sending a copy of the notice of appeal by registered mail to HCFA.

(2) *Certification of administrative record*. HCFA promptly certifies and files with the court the record upon which the penalty was imposed.

(3) *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.

(4) *Appeal*. Any final decision, order, or judgment of the district court concerning HCFA's review is subject to appeal as provided in Chapter 83 of Title 28, United States Code.

(h) *Failure to pay assessment, maintenance of action*—(1) *Failure to pay assessment*. If an issuer fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of HCFA, HCFA refers the matter to the Attorney General, who brings an action against the issuer in the appropriate United States district court to recover the amount assessed.

(2) *Final order not subject to review*. In an action brought under paragraph (h)(1) of this section, the validity and appropriateness of the final order described in paragraph (g)(1)(i) of paragraph (g)(3) of this section is not subject to review.

(i) *Use of penalty funds*. (1) Any funds collected under this section are paid to the Administrator or other office imposing the penalty.

(2) The funds are available without appropriation and until expended.

(3) The funds may only be used for the purpose of enforcing the provisions for which the penalty was imposed.

§ 148.210 Preemption.

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

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

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

§ 148.220 Excepted benefits.

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

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

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

(2) Disability income insurance.

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

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

(5) Workers' compensation or similar insurance.

(6) Automobile medical payment insurance.

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

(8) Coverage for on-site medical clinics.

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

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

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

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

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

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

(3) Coverage only for a specified disease or illness (for example, cancer policies), or hospital indemnity or other fixed indemnity insurance (for example, $100/day) if the policies meet the requirements of 45 CFR 146.145(b)(4)(ii)(B) and (b)(4)(ii)(C) regarding noncoordination of benefits.

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

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

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

Authority: Secs. 2741 through 2763, 2791, and 2792 of the PHS Act, 42 U.S.C. 300gg–41 through 300gg–63, 300gg–91, and 300gg–91.

Dated: March 25, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: March 25, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–8217 Filed 4–1–97; 12:58 pm]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 8716]

RIN 1545–AV05

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2590

RIN 1210–AA54

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.

ACTION: Interim rules: Correction.

SUMMARY: This document contains a correction regarding the preamble to the 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 that were published elsewhere in this issue of the **Federal Register**. A sentence in the preamble to the interim rules was inadvertently dropped. This document adds this sentence.

EFFECTIVE DATE: June 1, 1997.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION: The last sentence of the first paragraph of the preamble to the interim rules entitled section ''M. Paperwork Reduction Act—Department of Labor and Department of the Treasury'' is inadvertently missing. This document adds this sentence to the preamble to the interim rules. The sentence reads ''An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget''.

Signed at Washington, DC, this 3rd day of April, 1997.

Olena Berg,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

Dale D. Goode,

Federal Register Liaison, Assistant Chief Counsel (Corporate), U.S. Department of the Treasury.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

45 CFR Subtitle A

[BPD–882–CN]
[BPD–890–CN]

Interim Rules for Health Insurance Portability for Group Health Plans and Individual Market Health Insurance Reform: Portability from Group to Individual Coverage; and Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim rule; correction.

SUMMARY: **Federal Register** documents 97–8217 and 97–8275 in this issue include provisions that implement the health insurance portability, availability, and renewability provisions of the Health Insurance Portability and Accountability Act of 1996.

Those documents contain a technical error in amendments because of differing effective dates. The rule with the earlier effective date establishes a new part in a subchapter established by the rule with the later date. This document corrects that error.

EFFECTIVE DATE: This correction is effective on April 8, 1997.