

"Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software." A premarket notification (510(k)) is an application submitted to FDA under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)), to demonstrate that the medical device to be marketed is substantially equivalent to a legally marketed device that was or is currently on the U.S. market.

In a March 31, 1994, letter sent to manufacturers of blood establishment computer software, FDA stated that software products used in the manufacture or maintenance of data for blood and blood components are devices under section 201(h) of the act (21 U.S.C. 321(h)) because these products aid in the prevention of disease by identifying unsuitable donors and by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing use. The original date for submissions was March 31, 1995, but after careful evaluation of the needs expressed by the software manufacturers and the impact of the initiative on blood establishments, FDA concluded that a 1-year extension to March 31, 1996, was warranted. FDA notified known manufacturers of blood establishment computer software of the extension, by letter, the text of which was published in the Federal Register of October 3, 1995 (60 FR 51802). The reviewer guidance was presented and discussed at the Blood Products Advisory Committee meeting held on June 20, 1996.

The content and format required for a 510(k) submission may be found in 21 CFR part 807. FDA intends that the guidance document will be used as a supplement to the "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review," issued by the Center for Devices and Radiological Health on August 29, 1991. The reviewer guidance announced in this notice contains a description of the content and format that a reviewer should expect in a 510(k) submission for blood establishment computer software.

As with other guidance documents, FDA does not intend this document to be all-inclusive. Moreover, not all information may be applicable to all situations. The reviewer guidance document is intended to provide information and does not set forth requirements. Although this guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, it does represent the agency's current thinking on the review of premarket

notification submissions for blood establishment computer software.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the reviewer guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and information are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA anticipates revising the reviewer guidance document periodically, in response to comments received or to reflect advancements in blood establishment computer software.

Dated: December 31, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-715 Filed 1-10-97; 8:45 am]

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Health Care Financing Administration

[BPD-882-N]

Notification Procedures for States Implementing "Alternative Mechanisms" in the Individual Health Insurance Market

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

ACTION: Notice.

SUMMARY: This notice generally describes the statutory provisions under section 111 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that guarantee availability of individual health insurance coverage to certain individuals with prior group coverage. It also provides procedural guidance for States that intend to implement an alternative mechanism under section 111 of HIPAA. Finally, this notice describes the statutory provisions that will apply in a State that does not implement an acceptable alternative mechanism.

This notice does not establish new policy or requirements.

FOR FURTHER INFORMATION CONTACT: Gertrude Saunders of the Insurance Reform Implementation Task Force (IRITF), (410) 786-5888 or e-mail (iritf@hcfa.gov).

ADDRESSES: All correspondence regarding this notice should be submitted to the following address: HCFA, Bureau of Policy Development, Office of Chronic Care and Insurance

Policy, Insurance Reform Implementation Task Force, S-LL-17, Attention: Marc Thomas, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

SUPPLEMENTARY INFORMATION:

I. Background—Summary of Recent Legislation

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, Pub. L. 104-191) was enacted on August 21, 1996. HIPAA amended the Public Health Service (PHS) Act to provide for, among other things, improved access, portability, and renewability of health insurance in both the group and individual health insurance markets. Group health plans are regulated, in part, by the Federal government under the Employee Retirement Income Security Act of 1974 (ERISA) and the Internal Revenue Code and, to the extent they purchase insurance, in part, by the States under State insurance law. Policies sold in the individual health insurance market are regulated by the States. This notice pertains to only the individual market changes made by section 111 of HIPAA.

Section 2741 of the PHS Act, as added by section 111 of HIPAA, essentially gives a State two options to ensure that "eligible individuals" have access to the individual health insurance market. Under the first option, assuming there is appropriate authority in State law, the State may simply enforce the Federal statutory provisions that require all issuers who offer coverage in the individual market to make all their individual policies available to all eligible individuals on a guaranteed basis, without preexisting condition exclusions. (These provisions are commonly referred to as the "Federal default" provisions.) If the State chooses this option, individual issuers may elect to impose certain limitations on the policies that they are required to offer under the Federal default provisions. (For additional information on these limitations see section VIII of this notice.)

Under the second option, States may choose to implement an "alternative mechanism" to ensure that eligible individuals have access to the individual health insurance market or comparable coverage. States that choose this option must submit to us a timely notice with sufficient documentation to enable us to determine whether it is an acceptable alternative mechanism. (This process is discussed in more detail under section VI of this notice, which includes the address for written submissions.)

II. Preemption

Section 2762 of the PHS Act specifies that the Federal statutory provisions pertaining to health insurance issuers in the individual market generally do not preempt State regulation of individual insurance. Nevertheless, if the State standards and requirements prevent the application of a Federal requirement, the statute preempts the State standards and requirements and the Federal requirements prevail.

Accordingly, the State standards and requirements must ensure at a minimum that every eligible individual in the State is provided access to coverage that comports with Federal requirements. The State standards may not depart from the Federal requirements in a way that diminishes this minimum coverage. The State, however, is permitted to adopt standards that expand the number of individuals who are protected. For example, as discussed below, an eligible individual must have an aggregate of at least 18 months of "creditable coverage," with no breaks in coverage that exceed 62 days. The same concept of creditable coverage is used in section 2701 of the PHS Act, which limits the use of preexisting condition exclusions in the group market. Under section 2723(b)(2)(iii) of the PHS Act, States may permit breaks in coverage that exceed 62 days. If the State adopts this provision in the group market, it would not be precluded from applying the same rule in the individual market, since it would potentially extend coverage to people whose breaks in coverage would otherwise exclude them from the definition of an eligible individual.

Section 2762 of the PHS Act also specifies that nothing in the individual market provisions of HIPAA shall be construed to affect or modify the provisions of section 514 of ERISA, which preempts State regulation of employee welfare benefit plans, including group health plans, except through the regulation of insurance.

III. Federal Definitions

The individual market rules of HIPAA provide health insurance protection to an "eligible individual." This term is defined in section 2741(b) of the PHS Act. It includes an individual who meets all of the following criteria:

- The individual has aggregate periods of "creditable coverage" (as defined in section 2701(c) of the PHS Act) totaling 18 or more months at the time the individual seeks individual market coverage. In general, under section 2701(c) of the PHS Act, multiple periods of coverage are aggregated only

if there has been no more than a 62-day break between periods of creditable coverage.

- The individual's most recent creditable coverage must have been provided under a group health plan (including a governmental plan or church plan), as defined under section 2791 of the PHS Act, or health insurance offered in connection with that plan.

- The individual is not eligible for coverage under a group health plan, is not eligible for Medicare or Medicaid coverage, and does not have other health insurance coverage.

- The termination of the individual's most recent health plan coverage is not related to nonpayment of premiums or fraud, as described in sections 2712(b)(1) or (b)(2) of the PHS Act.

- The individual must have elected any continuation coverage offered by an employer plan under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA, Pub. L. 99-272) or under a similar State requirement, and must have exhausted that coverage. (Federal COBRA provisions only apply to plans of an employer that normally employed at least 20 employees on a typical business day in the preceding calendar year. In some cases, there are State requirements similar to COBRA that require continuation coverage for insurance policies not subject to the Federal COBRA provisions.)

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

"Health insurance coverage" is defined in section 2791(b)(1) of the PHS Act to mean benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital, or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

"Health insurance issuer" is defined in section 2791(b)(2) of the PHS Act as an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in section 2791(b)(3) of the PHS Act) which is licensed to engage in the business of insurance in the State and which is

subject to State laws that regulate insurance. The term "health insurance issuer" does not include a group health plan.

"Individual health insurance coverage" is defined in section 2791(b)(5) of the PHS Act to mean health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance.

Section 2791(a)(2) of the PHS Act defines "medical care" as amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body; including transportation primarily for and essential to the medical care and insurance covering the medical care.

IV. Alternative Mechanisms; Minimum Requirements

Although the law recognizes diversity among the States by allowing for alternative mechanisms, there are minimum requirements for alternative mechanisms. Under section 2744(a)(1) of the PHS Act, 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 on eligible individuals.

- 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 in 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, or the Individual Health Insurance Portability Model Act, as adopted on June 3, 1996.
- + 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 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.
- + Another mechanism—
- That provides for risk adjustment, risk spreading, or a risk-spreading mechanism (among issuers or policies of issuers) 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

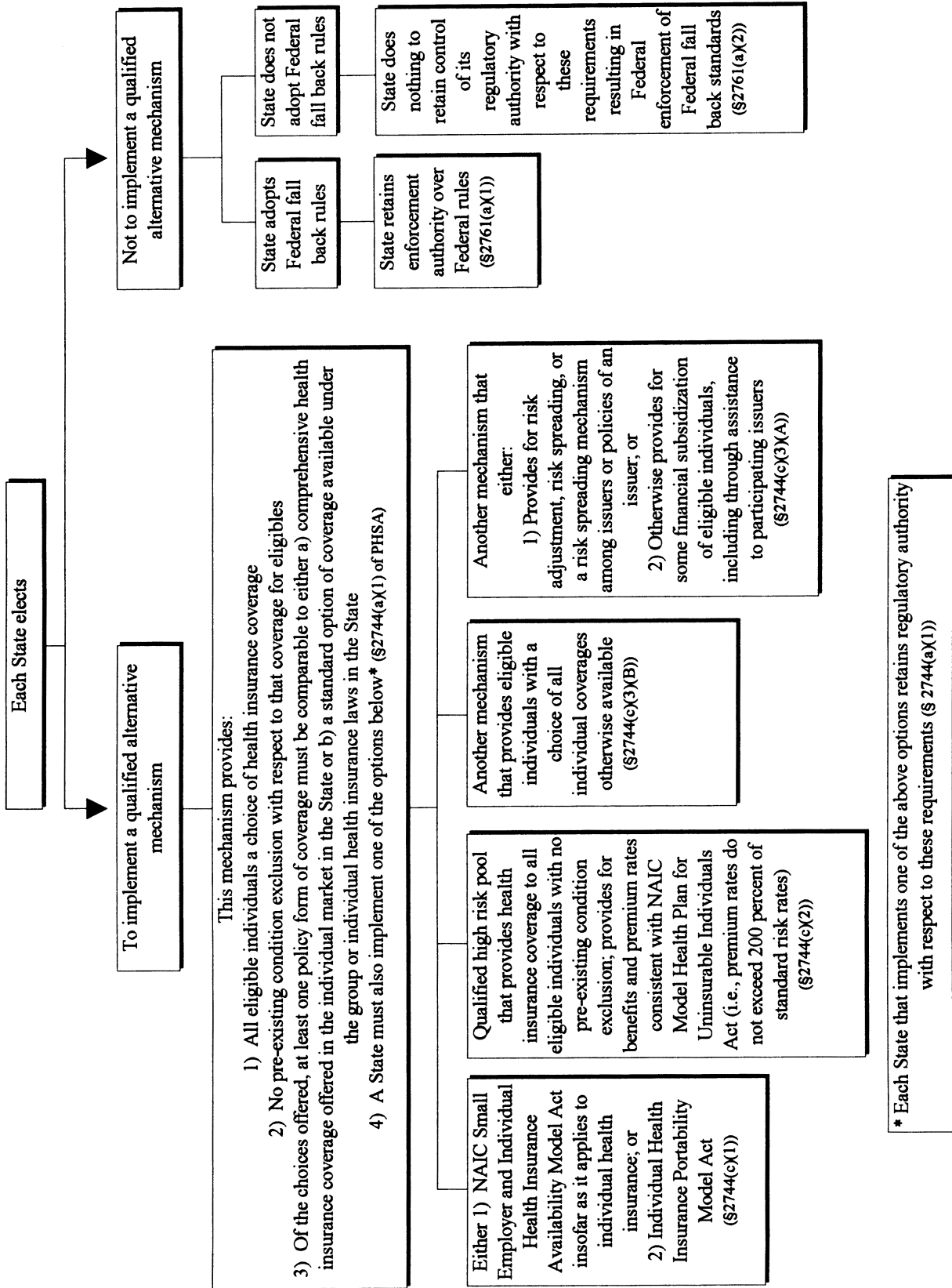
health insurance coverage otherwise available.

If a State adopts into law or regulation any provisions from the NAIC Model Acts cited in section 2744 of the PHS Act, it must verify that none of the Model Acts would prevent the application of a requirement of the PHS Act, and therefore be preempted. Since those Model Acts predate the enactment of HIPAA, they do not fully conform with HIPAA requirements that apply to

eligible individuals. The NAIC is currently analyzing these Model Acts to provide guidance to States in identifying revisions that would conform with the provisions of the PHS Act. (See later discussion in section VI.C.3. of this notice.)

State options for ensuring that eligible individuals have access to the individual health insurance market are illustrated in the chart below.

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* Each State that implements one of the above options retains regulatory authority with respect to these requirements (§ 2744(a)(1))

V. Presumption of an Acceptable Alternative Mechanism

An acceptable alternative mechanism includes a private or public individual health insurance mechanism that is designed to provide access to health benefits for individuals in the individual market in the State in accordance with section 2744 of the PHS Act. Examples of an acceptable alternative mechanism may include a health insurance coverage pool or program, a mandatory group conversion policy, guaranteed issue of one or more plans of individual health insurance coverage, open enrollment by one or more health insurance issuers, or a combination of these mechanisms that meet at least the minimum standards under section 2744.

A. State Submission by April 1, 1997

A State is presumed to be implementing an acceptable alternative mechanism as of July 1, 1997, if, by not later than April 1, 1997, the Chief Executive Officer (generally the Governor) of the State notifies us that the State has enacted or intends to enact any necessary legislation as of January 1, 1998, and provides us with the information necessary to review the mechanism and its implementation (or proposed implementation), and, if, within 90 days after receiving the State's submission, we do not disapprove it as described in section VII.B. of this notice. (If we notify the State of our need for additional information or further discussions on its submission, we will suspend the review period until the State provides the necessary information or participates in the necessary discussions. If the State chooses not to provide the necessary information or our discussions with the State cannot be concluded satisfactorily, we may disapprove the State's submission.) The State must provide information necessary for us to review the mechanism's implementation every 3 years to continue to be presumed to have an acceptable alternative mechanism.

B. State Submission After April 1, 1997

A State may presume that we have accepted its proposed alternative mechanism if—

- After April 1, 1997, the State submits notice and sufficient documentation (see section VI of this notice) for either an initial proposed alternative mechanism or revisions to an already submitted proposed alternative mechanism, and
- We make no determination disapproving the mechanism within 90

days (or a longer period if we suspended the 90-day review period awaiting additional information or to conduct further discussion with the State).

After an additional 90 days, the State may presume its alternative mechanism to be an acceptable alternative mechanism. (For further information on future adoptions and revisions see section VI.D.5. of this notice.)

VI. Notification, Documentation, and Review

A. Notification

Under section 2744(b) of the PHS Act, except as described below in section VII.B., a State is presumed to be implementing an acceptable alternative mechanism as of July 1, 1997, if, by not later than April 1, 1997, the Chief Executive Officer (generally the Governor) of the State takes the following two actions:

- Notifies us that the State has enacted, or intends to enact, by January 1, 1998 (or July 1, 1998 if the State legislature cannot meet before August 21, 1997) any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998 (or July 1, 1998 if the State legislature cannot meet before August 21, 1997).
- Provides us with the information necessary for us to review the mechanism and its implementation (or its proposed implementation).

B. Documentation

Since the law gives States substantial flexibility in devising alternative mechanisms, we do not intend that this notice set forth a checklist of criteria. If a State chooses to submit a proposed alternative mechanism, the State must determine what to submit. We must, however, be able to determine whether the mechanism will be both designed and enforced in a way that will 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.

Since time will be of the essence in reviewing a large volume of submissions and responding to the States timely, we recommend that a State provide summaries and full text of any critical supporting information (such as the text (or proposed text) of legislation or

regulations) in its initial State submission. If we notify the State of our need for additional information or further discussions on its submission, we will suspend the review period until the State provides the necessary information or participates in the necessary discussions. If the State chooses not to provide the necessary information or our discussions with the State cannot be concluded satisfactorily, we may disapprove the State's submission. We discuss disapproval and the consequences of disapproval in sections VII.B. and C. of this notice.

The submission must include sufficient information to provide us with a reasonable basis for concluding that the proposed alternative mechanism meets the requirements described in section VI.C. of this notice. Along with a detailed description of the alternative mechanism and how it will be implemented and function, we recommend the State include the following information:

- *Contact Person*—The name, position title, address, and telephone number of the person to whom we should address all questions and contacts concerning the proposed alternative mechanism.
- *State Legislative Calendar*—Clear and prominent identification of needed State legislative action and the State legislature's sessions. We need to know of any legislative issues affecting a State's ability to implement an alternative mechanism so that we can determine priorities for reviewing State submissions. Also, the State should submit a description of the authority and procedures it follows for calling a special or emergency legislative session, if these exist.
- *State Laws and Regulations*—A summary and copies of the full text of existing State laws and regulations pertaining to the individual health insurance market. Laws and regulations that could be critical to an adequate analysis include the following:
 - + Medical underwriting and rating restrictions.
 - + Restrictions on preexisting condition exclusions.
 - + Guaranteed issue requirements.
 - + Solvency requirements.

If a State chooses to implement an "other mechanism" described in section 2744(c)(3) of the Act, we recommend that the State submit a more detailed description of the mechanism than it would if it planned to implement a mechanism that relies on one of the three NAIC Model Acts referenced in section 2744 of the PHS Act. In particular, unless the State chooses to

provide a choice to eligible individuals of all individual policies sold in the State, the State should describe in detail how the risk associated with serving all anticipated eligible individuals would be spread under the mechanism and how the additional cost associated with serving this new population would be subsidized.

The following examples illustrate the differences in documentation that a State may submit, based on differences in the State's legislation and proposed alternative mechanism.

- *Example 1*—State A has already adopted a comprehensive reform for its individual health insurance market. The State now prohibits preexisting condition limitations on coverage, provides for guaranteed issue and guaranteed renewability, and has taken active steps to ensure the participation of insurers in the State individual health insurance market. State A submits, in addition to its recent law (which was adopted before August 21, 1996, the enactment date of HIPAA), two analyses: the first identifies technical amendments to make its recent law consistent with HIPAA; the second shows that any eligible individual under HIPAA also would be eligible for the individual market under the State law. The State's submission also shows that the State's residency requirements would not prevent any HIPAA-eligible individual from entering the individual market without causing a break in coverage.

- *Example 2*—State B has a State high-risk pool, but that pool has a significant waiting list or appears to be entering a "premium death spiral." State B offers an improved risk pool legislative and funding package. Because the financial stability of the existing risk pool is known to be in question, State B includes, in considerable detail, analyses of the projected revenue, subsidies, and financial condition of the pool under the proposed law. State B also specifies how HIPAA-eligible individuals will be able to enter the risk pool without causing a break in coverage.

A State may wish to submit other information, depending on the extent of the changes the State is planning and its relevance to the State's proposed alternative mechanism. Some examples follow:

- *Characteristics of the Existing Individual Market*—Analysis of information relating to the existing availability and sale of individual health insurance to the current population of the State. Examples of this information might be a description of the policy forms currently available in the

individual market in the State; numbers of policies held under each form; current population of the State; estimated percentage of that population currently covered under group plans or coverage other than individual coverage; and estimated uninsured population.

- *Projected Market Impact of the Alternative Mechanism*—The State's best estimate of the number of eligible individuals who will need to be served under the proposed alternative mechanism, including a description of the factors the State considered in determining the size of the affected population, how the mechanism will serve the needs of the affected population, how much the mechanism serving this population will cost, and how those costs will be borne. In describing its population of eligible individuals or potentially eligible individuals in the individual health insurance market, the State may want to consider the relative prevalence of certain groups of individuals in the State and how the alternative mechanism will affect the likely number of individuals eligible for coverage under the mechanism. For a mechanism that will rely on State-supported operations such as risk pools and other risk-spreading mechanisms, the State should show the level and source of funding needed to provide for the needs of the eligible or potentially-eligible individuals.

Groups whose relative size may be large enough to have substantial impact on the number of eligible, as well as ineligible, individuals include the following:

- + Individuals eligible for Medicaid (especially if the State has a waiver under section 1115 of the Social Security Act that expands eligibility for Medicaid and would thus make these people ineligible under HIPAA for transition to the individual market).
- + Individuals eligible for Medicare.
- + Individuals who are receiving medical coverage under special programs such as the Indian Health Service. These individuals may meet the definition of an "eligible individual," but their eligibility for coverage under the Indian Health Service program may make it unlikely that they would purchase private health insurance.
- + Individuals who elect and exhaust their continued group health plan coverage under COBRA or coverage under a similar State requirement.
- + Individuals who do not have the COBRA protection (or similar protection under a State requirement)

and will be entering the alternative mechanism directly as an eligible individual. For example, an individual whose employer stops offering health insurance coverage may be eligible for coverage under the alternative mechanism without waiting for the COBRA continuation period to end.

C. Standard of Review

1. General

We will base our review on certain principles set forth in the statute and legislative history. The statute clearly requires us to make a substantive determination whether a mechanism is an "acceptable alternative mechanism" that meets all of the requirements set forth in the statute. However, while, as noted in section II of this notice, no State requirement can prevent the application of a requirement of HIPAA, the Conference Report that accompanied that legislation states that the conferees intended the narrowest preemption. This notice describes how we intend to apply these principles.

2. Statutory Requirements

We will review each State's submission to determine whether it addresses *each* of the following requirements:

- Is the mechanism reasonably designed to provide all eligible individuals with a choice of health insurance coverage?
 - Does the choice offered to eligible individuals include at least one policy form that meets the following requirements?
 - + Is comparable to comprehensive health insurance coverage offered in the individual market in the State.
 - + Is comparable to a standard option of coverage available under the group or individual health insurance laws of the State.
 - Does the mechanism provide access to coverage for all eligible individuals within Federal time frames?
 - Does the mechanism prohibit preexisting condition exclusions for all eligible individuals?
 - Is the State implementing one of the following?
 - + The NAIC Small Employer and Individual Health Insurance Availability Model Act (Availability Model), adopted on June 3, 1996.
 - + The Individual Health Insurance Portability Model Act (Portability Model), adopted on June 3, 1996.
 - + 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).

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

- Has the State enacted all legislation necessary for implementing the alternative mechanism?

+ If not, will the necessary legislation be enacted by January 1, 1998?

+ If not, is the State legislature meeting during the 12-month period beginning August 21, 1996 and ending August 20, 1997?

3. Concern About Using NAIC Models

As discussed previously, while the statute recommends the use of certain NAIC Model Acts and references them by specific adoption dates, these Model Acts contain certain provisions that are inconsistent with HIPAA requirements. If inconsistencies exist, a State must alter these provisions as they apply to eligible individuals under HIPAA so that its mechanism conforms with the Federal requirements. For example, if a State uses the Portability Model (which permits the use of preexisting condition exclusions and affiliation periods), it must distinguish between Federally-eligible individuals and all others served under the State's rules. As long as it exempts all Federally-eligible individuals from any preexisting condition exclusions or affiliation periods, the State may still use (with respect to non-Federally-eligible individuals in the individual market) the preexisting condition and affiliation rules of the Portability Model.

Although the following is not an all-inclusive list, we note the following additional discrepancies between the NAIC Model Acts and HIPAA requirements:

- The Portability Model permits only a 31-day break in coverage for individuals rather than the 62-day break permitted by section 2701(c)(2) of the PHS Act. Federally-eligible individuals must be given at least the 62-day break required under section 2701(c)(2).

- The Availability Model contains a definition of "qualifying coverage" that excludes coverage under a group health plan that is regulated under ERISA. Under HIPAA, however, the definition of "creditable coverage" clearly includes coverage under a "group health plan," which is defined to include self-insured plans regulated under ERISA.

- Certain key concepts (for example, "eligible person," "preexisting

condition," and "qualifying coverage") are defined in both the Availability and Portability Models somewhat differently than in HIPAA. To the extent that State law incorporates or plans to incorporate portions of the Models that use those terms, the State must ensure that use of these terms does not prevent the application of HIPAA protections to eligible individuals. This may be done simply by applying special provisions to those eligible individuals.

- The Availability and Portability Models also contain residency requirements that cannot be applied to HIPAA-eligible individuals.

- If a State uses the NAIC Model Health Plan for Uninsurable Individuals Act, certain otherwise acceptable high-risk pool practices such as "wait-listing" individuals or applying preexisting condition exclusions are not permitted with respect to HIPAA-eligible individuals.

4. Interim Response to Frequently Asked Questions

We recognize that States would like to have answers now to questions such as whether a difference in deductibles constitutes enough choice or how comprehensive a policy must be to be an acceptable offering. However, this document is a procedural notice and not a regulation. Until we issue regulations dealing with these and other issues, States must make a good faith effort to interpret the statute as best they can when proposing an alternative mechanism before April 1, 1997. Should any discrepancies later emerge between a State's interpretation of the statute and our interpretation, as expressed in the interim final rule that we expect to publish by April 1, 1997, we plan that the Federal rules will apply prospectively and will afford a transition period that will give a State an adequate opportunity to amend its mechanism to conform with any new regulation requirements. We will include rules on the transition period in the interim final rule.

D. Notification Procedure

1. Advance Notification Requested

We request that a State notify us in writing or by e-mail (irif@hcfa.gov) of its intent to submit or not to submit an alternative mechanism. If we do not hear from a State by February 14, 1997, we will contact the State to find out its intention regarding the submission of an alternative State mechanism. The law does not create a requirement that States notify us of their intentions, but notification will help us plan our work to meet the statutory deadlines.

If a State does not plan to offer an alternative mechanism, we request that the State advise us of its plans to implement the Federal requirements.

If a State does not plan to offer either an alternative mechanism, or to implement the Federal requirements, we request that the State advise us as soon as possible so that we may begin action to implement Federal enforcement of the Federal requirements in the State.

2. Contents of Notification Package

We request that a State's submission be submitted in duplicate and be accompanied by a cover letter, signed by the Chief Executive Officer (generally the Governor) of the State. In addition, States should include a brief summary of their legislative calendars and note any deadlines that are significant to this review process. We are requesting that States submit two copies of their proposed alternative mechanisms to assist us in timely review of their submissions. Our regional offices may assist us in reviewing the States' submissions and we wish to avoid any delays that may occur in reproducing these submissions.

3. Deadline

We must receive all submissions from the States no later than April 1, 1997 in order for the State to qualify for the presumption that it is implementing an acceptable alternative mechanism as of July 1, 1997. For official confirmation of our receipt date, we suggest that States use the postal certification services of the United States Post Office.

No later than 90 days after we receive a State's proposed alternative mechanism, we will take at least one of the following actions:

- Notify the State that we have accepted its proposed alternative mechanism. (This notification may be before the 90-day review period ends.)

- Make no determination concerning the State's alternative mechanism; therefore, the State may presume we have accepted its alternative mechanism.

- Forward to the State a request for additional information or a notification that we need to discuss further with the CEO (or his or her designee) the proposed alternative mechanism. We expect to make requests for additional information or initiate discussions as soon as possible after receiving the State's proposed alternative mechanism. If we notify the State of our need for additional information or further discussions on its submission, we will suspend the review period until the State provides the necessary information or participates in the

necessary discussions. If the State chooses not to provide the necessary information or our discussions with the State cannot be concluded satisfactorily, we may disapprove the State's submission. We discuss disapproval and the consequences of disapproval in sections VII.B. and C. of this notice. The State may contact us for information on implementing the Federal default requirements.

4. Where To Submit a Package

We request each State submit its proposed alternative mechanism, in duplicate, to the following address: HCFA, Bureau of Policy Development, Office of Chronic Care and Insurance Policy, Insurance Reform Implementation Task Force, S-LL-17, Attention: Marc Thomas, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

5. Future Adoptions and Revisions

A State with an approved alternative mechanism may request approval of revisions to its alternative mechanism. Similarly, a State operating under the Federal default provisions may, at any time, submit a proposed alternative mechanism. The State should mail its submission to the above address. We request that future revisions to already approved mechanisms be submitted no earlier than July 1, 1997.

E. Continued Presumption for States Entitled to Statutory Delay

In accordance with section 2744(b) of the PHS Act, States whose legislatures do not meet within the 12-month period beginning August 21, 1996 and ending August 20, 1997, and that need legislative authority in order to enact an acceptable alternative mechanism may qualify for extended deadlines for implementing an acceptable alternative mechanism. To qualify for an extension, the State must comply with the following deadlines:

- In order for the State to be entitled to the presumption that it has an acceptable alternative mechanism in effect as of July 1, 1997, the Chief Executive Officer (generally the Governor) must notify us by April 1, 1997 about the following:

- + The State legislature has not and will not meet during the 12-month period beginning August 21, 1996 and ending August 20, 1997.

- + The State intends to implement an alternative mechanism by July 1, 1998.

- In order for the presumption to continue on and after July 1, 1998, the State must—

- + Notify us by April 1, 1998 that the State has enacted any necessary legislation to provide for implementation of an acceptable alternative mechanism as of July 1, 1998, and

- + Provide us with the information described in this section to enable us to review the mechanism and its implementation.

VII. Notification to the State

A. Time Frames

For State submissions received by April 1, 1997, we will do a preliminary review to determine whether the package appears to be complete enough for us to make a determination. If not, we will notify the State by telephone and in writing, and provide the State the opportunity to submit supplemental information. We will issue a written response to each State's request as soon as possible, and no later than 90 days after receipt of the State's submission.

B. Disapproval

In accordance with section 2744(b)(2) of the PHS Act, we will review the information submitted and make a preliminary determination whether the State has or has not submitted an acceptable alternative mechanism.

If our preliminary determination is that the mechanism is not acceptable, we will consult with the Chief Executive Officer (generally the Governor) of the State, or his or her designee, and the State Insurance Commissioner or the Chief Insurance Regulatory Official of the State. If after these consultations, we still conclude that the State's alternative mechanism is not acceptable, we will—

- Notify the State of that determination; and
- Inform the State that if the State fails to implement an acceptable alternative mechanism, the Federal default provisions will take effect.

If we disapprove a State's proposed alternative mechanism, we will give the State a reasonable opportunity to modify the mechanism (or to adopt another mechanism).

C. Consequences of Disapproval and Enforcement Action

If we make a final determination that (1) the design of a State's alternative mechanism is not acceptable or (2) the State is not substantially enforcing an otherwise acceptable alternative mechanism, we will notify the State in writing of our determination. We will provide the State with notice that the requirements of section 2741 of the PHS Act apply to health insurance coverage

offered in the individual market in the State, effective as of a date specified in our notice.

VIII. Alternative Coverage Where There Is No State Mechanism

In accordance with section 2741(c) of the PHS Act, if a State is not implementing an acceptable alternative mechanism, a health insurance issuer may elect to limit coverage offered through the individual market within prescribed parameters. The issuer may limit the individual market coverage offered as long as there are two different policy forms of coverage offered. 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 section 2741(c)(2) or (c)(3) of the PHS Act.

Under section 2741(c)(2), the health insurance issuer must offer the policy forms for individual health insurance coverage with the largest, and next to largest, premium volume of all similar policy forms offered by the issuer in the State or applicable marketing or service area by the issuer in the individual market for the period involved. Under section 2741(c)(3), the health insurance issuer must offer a lower-level coverage policy form that meets the requirements of section 2741(c)(3)(B) and a higher-level coverage policy form that meets the requirements of section 2741(c)(3)(C). Each of these policy forms must include benefits substantially similar to other individual health insurance coverage offered by the issuer in the State and each must be covered under a method described in section 2744(c)(3)(A) pertaining to risk adjustment, risk spreading, or financial subsidization.

IX. Information Collection Requirements

Under the Paperwork Reduction Act of 1995, agencies 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. This notice contains information collections that are subject to review by OMB under the Paperwork Reduction Act of 1995. The title, description, and respondent description of the information collections are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and

collecting and reviewing the collection of information.

We are, however, requesting an emergency review of this notice. In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the OMB the following information collection 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. So that a State does not have to incur the burden of temporarily implementing the Federal default requirements or live under Federal enforcement of those requirements, HIPAA requires a State to submit to us its proposed alternative mechanisms by April 1, 1997. A State may voluntarily submit the suggested information collection referenced in this notice when it submits its proposed alternative mechanisms. The description of the information collection will assist a State in submitting sufficient information for our review of its proposed alternative mechanisms.

We are requesting that OMB provide a 2-day public comment period with a 2-day OMB review period 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: Notification Procedures for States Implementing "Alternative Mechanisms" in the Individual Health Insurance Market and Supporting Notice (BPD-882-N).

Form Number: HCFA-R-202.

Use: To outline the documentation for States to obtain Federal approval of a State's alternative mechanism under section 111 of HIPAA.

Frequency: On occasion.

Affected Public: States.

Number of Respondents: 55.

Total Annual Responses: 55.

Total Annual Hours Requested: 66,000.

In summary, the information collection referenced in section VI. "Notification, Documentation, and Review" provides that each State electing to implement an alternative mechanism notify us that the State has enacted, or intends to enact, any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable

alternative mechanism and provides us with the information to review the mechanism and its implementation (or proposed implementation).

If a State chooses to submit a proposed alternative mechanism, the State must submit sufficient information to provide us with a reasonable basis for concluding that the proposed alternative mechanism meets the criteria described in section VI.C.2. of this notice. Along with a detailed description of the alternative mechanism and how it will function, we recommend the State include the name of a contact person, State Legislative Calendar, and text of existing State laws and regulations pertaining to the individual health insurance market.

If a State chooses to implement an "other mechanism" described in section 2744(c)(3) of the Act, we recommend that the State submit a more detailed description of the mechanism than it would if it planned to implement a mechanism that relies on one of the three NAIC Model Acts referenced in section 2744 of the PHS Act.

To request copies of the proposed information collections referenced above, call the Reports Clearance Office on (410) 786-1325.

The information collections of this notice are not effective until they have been approved by the OMB. We have submitted a copy of this notice to the OMB for its review of these information collections. A notice will be published in the Federal Register when approval is obtained. Interested persons are invited to send comments regarding this burden or any other aspect of these collections of information, including any of the following subjects: (1) The necessity and utility of the information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Comments on these information collections may be faxed to Allison Herron Eydt at 202-395-6974 or mailed directly to the following address: 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. A copy of the comments may be mailed to the following address: Health Care Financing Administration, Office of Financial and Human Resources, Management Analysis and Planning

Staff, Room C2-26-17, 7500 Security Boulevard, Baltimore, MD 21244-1850.

X. Waiver of Solicitation of Comments

This notice announces the options a State has under section 111 of HIPAA to ensure that eligible individuals have access to the individual health insurance market. As has been our custom, we use general notices, rather than formal notice and comment rulemaking procedures, to make these announcements. In doing so, we acknowledge that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure or practice are excepted from the requirements of notice and comment rulemaking.

This notice does not establish new policy or requirements beyond those found in the statute. We are publishing this notice to assist a State that chooses to submit a proposed alternative mechanism under section 111 of HIPAA. We intend that the information we have identified in this notice provide guidance to a State and assist it in submitting sufficient information to enable us to approve the State's proposed alternative mechanism. We intend that this information assist a State to implement timely HIPAA provisions under its own State requirements. This would prevent the need for a State to comply with Federal requirements and subsequently transition to the State's requirements after we approve a State's proposed alternative mechanism. We wish to avoid an unnecessary burden on the State.

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

Authority: Section 2741 of the Public Health Service Act.

Dated: December 17, 1996.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

Approved: December 20, 1996.

Donna E. Shalala,
Secretary, Health and Human Services.
[FR Doc. 97-672 Filed 1-10-97; 8:45 am]

BILLING CODE 4120-01-P

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National