and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395(g), 13951(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

§ 413.30 [Corrected]

2. In paragraph (d) the word ''as'' is added after the phrase ''has operated'' in the third sentence.

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance)

Dated: April 25, 2002.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 02–17620 Filed 7–25–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 146

[CMS–2033–IFC]

RIN 0938–AK00

Technical Change to Requirements for the Group Health Insurance Market; Non-Federal Governmental Plans Exempt From HIPAA Title I Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period amends the exemption election requirements that apply to self-funded non-Federal governmental plans. In it, we clarify the circumstances under which plan sponsors may exempt these plans from most of the requirements of title XXVII of the Public Health Service (PHS) Act and provide guidance on the procedures, limitations, and documentation associated with exemption elections.

In this interim final rule with comment period, we provide that a sponsor of a self-funded, non-Federal governmental plan may elect to exempt its plan from the Women's Health and Cancer Rights Act of 1998. Additionally, we revise a number of procedural requirements affecting the exemption election process and establish certain enrollee protections with respect to exemption elections.

In response to public comments on an interim final rule published in the **Federal Register** on April 8, 1997 (62 FR 16894), we amend our regulation to clarify that nothing in the statute or regulation affects a State's right to limit the extent to which its non-Federal governmental employers may exempt their self-funded plans from title XXVII of the PHS Act.

Finally, we include a technical correction to our regulation on guaranteed availability of health insurance coverage for employers in the small group market.

DATES: *Effective date:* These regulations are effective on September 24, 2002.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 4 p.m. on September 24, 2002.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2033–IFC, P.O. Box 8010, Baltimore, MD 21244–8010.

To ensure that mailed comments are received in time for us to consider, please allow for possible delays in delivery.

If you prefer, you may deliver (by hand or courier) your written comments (1 original and 3 copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–2033–IFC. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: David Holstein, (410) 786–1565.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

Comments received timely will be available for public inspection in Room C5–16–03, 7500 Security Blvd., Baltimore, Maryland 21244–1850, generally beginning approximately 3 weeks after the document has been published. Members of the public who are interested in reviewing timely public comments are asked to schedule an appointment by calling (410) 786–9994 Monday through Friday from 8:30 a.m. to 5 p.m.

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I. Background

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the PHS Act to establish various reforms to the group and individual health insurance markets. The group market reforms are contained under Part A of title XXVII, which includes, among other things, guaranteed availability of coverage to small group market employers and renewability of coverage in the small and large group markets; limitations on pre-existing condition exclusion periods; special enrollment periods under certain circumstances; and prohibition of discrimination against individual participants and beneficiaries based on health status.

Part A of title XXVII was amended by the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA), the Mental Health Parity Act of 1996 (MHPA), and the Women's Health and Cancer Rights Act of 1998 (WHCRA), which added new sections 2704, 2705 and 2706 (subpart 2 of Part A of title XXVII), respectively. NMHPA provides protections for mothers and newborn children for hospital stays following childbirth. MHPA, which applies to group health plans sponsored by employers with more than 50 employees, provides for parity between annual and lifetime dollar limits applicable to mental health benefits, and annual and lifetime dollar limits applicable to medical and surgical benefits. WHCRA requires group health plans that provide medical and surgical benefits for mastectomies to cover, among other things, reconstructive

surgery and prostheses following a mastectomy.

Section 2721(b)(2) of the PHS Act, as added by HIPAA and implemented at 45 CFR 146.180, permits non-Federal governmental employers to elect to exempt self-funded portions of their group health plans (that is, benefits not provided through health insurance coverage) from most of the requirements of title XXVII of the PHS Act. (This practice is sometimes referred to in this preamble as ''opting out of HIPAA.'') However, health plans cannot be exempted from certification and disclosure of creditable coverage requirements under section 2701(e) of the PHS Act.

We received numerous inquiries as to whether non-Federal governmental entities may ''opt out'' of various requirements added by NMHPA, MHPA and WHCRA, which were enacted after the initial HIPAA legislation. Section 2721(b)(2) of the PHS Act permits a plan sponsor of a self-funded non-Federal governmental plan to elect to exempt its group health plan from the requirements of ''subparts 1 through 3'' of Part A of title XXVII (except with respect to section 2701(e) of subpart 1). Therefore, the requirements of sections 2704, 2705 and 2706, which comprise subpart 2 of Part A of title XXVII, fall within the scope of section 2721(b)(2).

II. Technical Correction to § 146.150 Guaranteed Availability of Coverage for employers in the small group Market

The regulation at § 146.150(d)(2), which was intended to track the statute (section 2711(d)(2) of the PHS Act), misstates a statutory requirement. Under section 2711(d)(2), an issuer that denies group health insurance coverage to any small employer in a State on the basis that the issuer does not have financial reserves necessary to underwrite additional coverage, is prohibited from offering additional coverage in the small group market in the State for a period of 180 days after the date coverage is denied, or until the issuer demonstrates to the applicable State authority, if required under State law, that the issuer has sufficient financial reserves to underwrite additional coverage, ''whichever is later.'' However, § 146.150(d)(2) is worded in a way that the issuer is required to wait 180 days after it demonstrates renewed financial capacity before it may offer additional coverage in the small group market.

Section 146.150(d)(2), which was simply intended to track the statute, is revised to correctly reflect section 2711(d)(2) of the PHS Act. Because the revision is a technical correction that is required by statute, the effective date of this revision is as if it was included in the regulations published on April 8, 1997 in the **Federal Register** at 62 FR 16894; that is, on June 7, 1997.

III. Analysis of and Response to Public Comments Received on the April 8, 1997 Interim Final Rule

(For ease of reference, unless otherwise specified, the acronym ''HIPAA,'' as used subsequently in this preamble, refers to title I of HIPAA, as well as to NMHPA, MHPA, and WHCRA, and ''HIPAA requirements'' refers to requirements of all of these statutes.)

We received two letters of comment in response to the April 8, 1997 interim final rule with comment period published in the **Federal Register** (62 FR 16894) that pertained exclusively to 45 CFR 146.180 ''Treatment of non-Federal governmental plans.''

Comment: One commenter noted that there appeared to be an inconsistency in HIPAA between an amendment made to the PHS Act, and another amendment made to the Internal Revenue Code (the Code). The PHS Act, as amended by HIPAA, provides that non-Federal governmental plans are subject to HIPAA (while permitting self-funded non-Federal governmental plans to elect to be exempted); the Internal Revenue Code, as amended by HIPAA, states that HIPAA amendments to the Code do not apply to governmental plans. The commenter requested that we clarify whether the PHS Act or the Code is the appropriate authority.

Response: The group market provisions of HIPAA made parallel amendments to the PHS Act, the Internal Revenue Code, and the Employee Retirement Income Security Act (ERISA). However, the HIPAA provisions of each statute *generally* apply to a different set of entities. In particular, the PHS Act applies to health insurance issuers and non-Federal governmental plans, and the Code applies to employer-sponsored group health plans (including church plans) except governmental plans. The fact that the Code does not reference non-Federal governmental plans simply means that the Code is not the source of HIPAA requirements for those plans. Rather, the PHS Act is the source of those requirements. Thus, non-Federal governmental plans are subject to HIPAA (except to the extent that the plan sponsor has elected to exempt a self-funded plan under section 2721(b)(2) of the PHS Act), and authority for enforcing HIPAA requirements with respect to non-Federal governmental plans rests with HHS in accordance with section 2722(b)(1)(B) of the PHS Act.

Comment: The commenter stated that § 146.180 should be amended to clarify that an election to exempt a plan from HIPAA means that the plan becomes subject to State law, including any applicable provisions that might parallel the requirements of HIPAA. The commenter noted that governmental plans are exempted from ERISA, and, accordingly, some States regulate their State and local plans. The commenter cited section 2723(a) of the PHS Act, presumably as the authority for adopting the suggested change.

Response: We adopt the recommendation, but not on the basis of section 2723(a). Section 2723(a) of the PHS Act addresses the preemption of State laws'' * * * solely relating to health insurance issuers in connection with group health insurance coverage. * * *'' Self-funded plans are not provided through health insurance issuers. Section 2721(b)(2) of the PHS Act permits only plan sponsors of self-funded non-Federal governmental plans to elect to exempt their plans from HIPAA requirements.

There is nothing in section 2721(b)(2) that prevents a State, by law, regulation, or other State action having the effect of law, from establishing State requirements for non-Federal governmental plans that parallel HIPAA requirements, or from simply limiting the extent to which its non-Federal governmental employers may elect to exempt their self-funded plans from HIPAA requirements. States are free to regulate group health plans of non-Federal governmental employers because governmental group health plans, unlike group health plans sponsored by private employers, are exempt from ERISA requirements under section 4(b)(1) of ERISA. (Section 514(a) of ERISA preempts State laws relating to employee benefit plans, including group health plans, that are subject to ERISA.) We amend 45 CFR 146.180 by adding a new paragraph (l) *Construction* to make clear that HIPAA does not interfere with a State's right to regulate non-Federal governmental plans. (This change is referenced in section IV.L. of this preamble.)

IV. Amendments to § 146.180 ''Treatment of non-Federal Governmental Plans''

This regulation amends § 146.180 by redesignating existing paragraphs and adding new text to this section. For reference purposes, a redesignation table is provided at the end of this section for specific citations under § 146.180.

A. Paragraph (a) Requirements Subject to Exemption

We amend § 146.180 by revising paragraph (a) and adding four new paragraphs. New paragraph (a)(1) summarizes the former prefatory text of § 146.180 and adds WHCRA requirements to the list of HIPAA requirements from which a non-Federal governmental plan sponsor may elect to exempt its self-funded plan.

New paragraph (a)(2)(i) clarifies that an exemption election cannot circumvent a HIPAA requirement to the extent the requirement applied to the plan before the effective date of the exemption election. Examples are provided.

New paragraph (a)(2)(ii) clarifies that if a group health plan is co-sponsored by two or more employers, only those participants and dependents enrolled in the plan through the non-Federal governmental employer or employers that have opted out of HIPAA are affected by the opt-out election. This limitation is in accordance with the express language of section 2721(b)(2) of the PHS Act, which permits only ''* * * the plan sponsor of a nonfederal governmental plan'' to opt out of HIPAA with regard to self-funded plans. To the extent a plan is sponsored by an employer that is not a governmental employer, the plan is not a ''non-Federal governmental plan,'' which is defined at § 144.103 to mean ''a governmental plan established or maintained for its employees by the government of any State or political subdivision thereof, or by any agency or instrumentality of either.'' Similarly, to the extent a plan is co-sponsored by governmental employers, not all of which have elected to opt out of HIPAA, HIPAA applies with respect to enrollees of the non-Federal governmental employers that have not opted out.

New paragraph (a)(3) deals with stop-loss or excess risk coverage. In general, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan has no effect on the plan sponsor's ability to opt out of HIPAA. However, if coverage offered by an issuer as stop-loss or excess risk coverage is regulated as group health insurance coverage under State law that has not been preempted by ERISA or otherwise invalidated by any court, then for purposes of § 146.180, the non-Federal governmental plan that purchases the coverage is considered to be fully insured. In that event, the plan is not permitted to opt out of HIPAA.

Accordingly, a sponsor of a non-Federal governmental plan that wishes to opt out of HIPAA should ensure that the stop-loss policy being considered is not regulated as group health insurance coverage by the State. Paragraph (a)(3) applies solely for purposes of § 146.180.

New paragraph (a)(4) clarifies that nothing in part 146 imposes collective bargaining obligations on any party to the collective bargaining process. However, as stated in the preamble to our initial HIPAA regulations published on April 8, 1997 in the **Federal Register** (62 FR 16906), § 146.180 does not preempt State and local collective bargaining laws. While neither title XXVII of the PHS Act nor this regulation mandates that HIPAA protections be collectively bargained, State or local law may do so.

B. Paragraph (b) Form and Manner of Election

(A model election document is provided under section V. of this preamble as an example to assist the reader.) Paragraph (b) is amended to list the requirements pertaining to the form and manner of an opt-out election under a new paragraph (b)(1). Paragraph (b)(1)(iii) incorporates existing paragraphs (d)(1) and (2) (with the exception of the parenthetical statement in the existing (d)(2), which is incorporated in a new paragraph (b)(2)). Paragraph (b)(1)(iii) requires an election document to include a statement specifying the beginning and ending dates of the applicable election period. That period may be a single specified plan year, or, in the case of a collectively bargained plan, the ''term of the agreement'' as defined in paragraph (b)(2) (discussed below). In order to facilitate administrative efficiency, paragraph (b)(1)(iv) requires the election document to include the name and telephone number of a person CMS may contact regarding the election.

New paragraph (b)(2) defines ''term of the agreement,'' and clarifies the extent to which an opt-out election applies to the initial plan year under a collective bargaining agreement and the last plan year governed by the agreement. Except as provided in new paragraphs (b)(2)(i) and (ii), paragraph (b)(2) provides that for purposes of the opt-out provision, ''term of the agreement'' means all plan years governed by a single collective bargaining agreement.

For the last plan year governed by a collective bargaining agreement, it has come to our attention that a collective bargaining agreement may expire before the last plan year governed by the agreement expires. In that event, we interpret the statutory reference to an opt-out election applying ''for the term of such agreement'' to mean that the election applies to the last plan year (in its entirety) governed by a particular collective bargaining agreement. For instance, a collective bargaining agreement may expire on December 31 and the last group health plan year governed by that agreement may expire on June 30 of the following year. If, in this example, the plan sponsor decided not to renew its opt-out election, HIPAA requirements would *not* take effect in the middle of the plan year (that is, on January 1), but rather on July 1, the first day of the plan year following expiration of the last plan year governed by the prior collective bargaining agreement.

For purposes of the opt-out provision, new paragraph (b)(2), which incorporates and revises the parenthetical statement of existing paragraph (d)(2), may effectively extend the last plan year under a prior collective bargaining agreement or shorten the initial plan year under a new agreement. Paragraph (b)(2)(i) provides that if the last plan year governed by a collective bargaining agreement expires during the bargaining process for a new agreement, the term of the prior agreement continues until the latest of the following dates, as applicable: the date agreement is reached for the new agreement, the date of ratification of the agreement, or other closure of the collective bargaining process. Under paragraph (b)(2)(ii), the term of the new agreement begins at that point.

This rule revises the existing rule, which provided that the parties to the collective bargaining process had to ''agree'' that the prior agreement continued until the new agreement took effect. For purposes of the opt-out provision, we are revising the rule by deleting the precondition that the parties must agree to the extension, because the collective bargaining process should not, by default, cause HIPAA requirements that were not previously in effect to take effect, nor, conversely, to effectively permit a plan sponsor, for the period preceding closure of the collective bargaining process for a new agreement, to retroactively opt out of HIPAA requirements that continue to be in effect under a prior agreement.

Under section 2721(b)(2) of the PHS Act, the opt-out decision is vested solely in the plan sponsor (in the absence of applicable State law or regulation). Thus, it is our position that in instances when collective bargaining for a new agreement extends beyond the contract expiration date under which a plan was exempt from HIPAA requirements, those requirements should not take effect by default (merely because the

union does not agree that the prior agreement is extended), and thereby prevent a plan sponsor from electing to opt out of those requirements under the new agreement. This situation could arise in the case of a collectively bargained plan that is exempt from HIPAA requirements under the special effective date rule of section 102(c)(3) of HIPAA and § 146.125(a)(2) of the implementing regulations, and in the case where a plan was exempt from HIPAA requirements under a prior opt-out election.

The special effective date rule provides that for a group health plan that is governed by one or more collective bargaining agreements that were ratified before enactment of HIPAA (that is, before August 21, 1996), the requirements of title I of HIPAA do not take effect until the last of those collective bargaining agreements expires. The last of the collective bargaining agreements ratified before August 21, 1996 may expire before closure is reached for a new agreement. Also, the period of time during which a plan is exempt from HIPAA requirements under a prior opt-out election could expire before closure is reached for a new agreement and the opt-out election is renewed.

We believe that the rule permitting a HIPAA exemption to continue during the collective bargaining process for a new agreement does not unduly affect enrollees because the plan was previously exempt from HIPAA requirements. (Of course, if collective bargaining that continues beyond the beginning of a plan year leads to an agreement that the plan will comply with one or more HIPAA requirements that legitimately did not apply to the plan under the prior agreement, the plan must comply with the requirement(s) retroactively to the first day of the initial plan year governed by the new agreement.) The special rules for the term of the agreement under paragraphs (b)(2)(i) and (ii) apply only for purposes of § 146.180; that is, only for HIPAA requirements from which a plan opts out under the new agreement.

On the other hand, to the extent a plan was subject to HIPAA requirements under a prior agreement, a plan sponsor's decision to opt out of HIPAA for those requirements must have prospective effect in order to ensure that enrollees that have benefited from those HIPAA requirements cannot be disadvantaged retroactively. This situation could arise in the case of a collectively bargained plan that is subject to HIPAA because the plan sponsor had not previously opted out, as well as in the case of a plan that is generally exempt from HIPAA requirements under the special effective date rule discussed above, but that was amended solely to conform the plan to any HIPAA requirement, as permitted under section 102(c)(3) of HIPAA and § 146.125(a)(2) of the implementing regulations.

When a plan has been in compliance with one or more HIPAA requirements, there is a greater need to strike a balance between the interests of the plan and the interests of enrollees. For a collectively bargained plan that is in compliance with HIPAA, we believe that enrollees expect the plan to continue to comply with those requirements unless otherwise notified. The same is true of new enrollees. Permitting a plan in that situation, following closure of the collective bargaining process, to retroactively opt out of HIPAA to the first day of the plan year could seriously disadvantage enrollees.

For instance, under the prior collective bargaining agreement, a plan was in compliance with HIPAA. An enrollee with a serious medical condition enrolls in the plan under the HIPAA special enrollment period rules during ongoing collective bargaining with respect to a new agreement. Two months later, after a collective bargaining agreement has been reached, the plan sponsor opts out of the special enrollment period requirements effective with the beginning of the first plan year governed by the new agreement. Conceivably, in the absence of this rule, the plan could attempt to disenroll the individual retroactively, causing great financial harm to that individual. (This situation would not arise in the case where a plan under the prior agreement was exempt from the special enrollment period rules because, under that exemption, the individual would not have been entitled to a special enrollment period.) Thus, the definition of ''term of the agreement'' in paragraph (b)(2) precludes the possibility that someone who properly benefitted under HIPAA could be retroactively deprived of that benefit.

New paragraph (b)(3) clarifies that we do not arbitrate disputes regarding whether an opt-out election complies with all of a plan sponsor's rules. These disputes must be resolved by the parties to the election or by the courts. Also, paragraph (b)(3) clarifies that if a plan must comply with one or more HIPAA requirements for a given plan year or period of plan coverage, the plan sponsor is free to opt out of those requirements for a subsequent plan year or period of plan coverage. For instance, a plan may comply with HIPAA requirements because the plan sponsor declined to opt out, or decided after opting out to rescind its election in whole or in part. Also, a plan might have to comply with HIPAA requirements because its opt-out election is invalidated in whole or in part by CMS (refer to sections IV.J. & K of this preamble) or by a court order. Such occurrences do not inhibit a plan sponsor's ability to opt out of HIPAA requirements for subsequent plan years.

C. Paragraph (c) Mailing Address

A new paragraph (c) is added to specify the mailing address for a non-Federal governmental employer to mail its opt-out election.

D. Paragraph (d) Filing a Timely Election

Under paragraph (d)(1), which incorporates existing paragraph (c)(1), we made a minor revision to the filing deadline for an opt-out election for a plan that is not governed by a collective bargaining agreement. Since under the existing rule we had to *receive* the election document before the first day of the plan year, new paragraph (d)(1) now provides that, subject to a good cause extension, the election document must be filed (that is, mailed) before the first day of the plan year.

In new paragraph (d)(2), which incorporates existing paragraph (c)(2), we revise the filing deadline for a plan that is governed by a collective bargaining agreement. The existing regulation stipulates that an election must be received by us within 30 days after certain events associated with collective bargaining. New paragraph (d)(2) provides that, subject to an extension based on good cause, an election for a plan governed by a collective bargaining agreement must be filed (that is, mailed) before the first day of the first plan year governed by the agreement, or by the 45th day after the latest of the following dates, as applicable, if the 45th day falls on or after the first day of the plan year: the date of the agreement between the governmental employer and union officials; the date of ratification of the agreement; or the date impasse resolution, arbitration, or other closure of the collective bargaining process is finalized when agreement is not reached. (Paragraph (d)(2) incorporates these dates via cross reference to paragraph (b)(2)(i).) The date of impasse resolution, arbitration or other closure of the collective bargaining process is included to make clear that a non-Federal governmental plan sponsor is not foreclosed under HIPAA from opting out in the event agreement is not

reached with the union through collective bargaining.

Paragraph (d)(3) specifies that we will use the postmark on the envelope in which the election is submitted to verify timely filing.

Paragraph (d)(4), which incorporates existing paragraph (c)(3), clarifies that we may extend the filing deadlines established in paragraphs (d)(1) and (d)(2) by finding good cause if a plan substantially complies with the requirements of paragraph (f) of this regulation to notify enrollees of an opt-out election at the time of enrollment and on an annual basis. For example, we could find that good cause exists for extending an election filing deadline in a case where a plan is not in violation of paragraph (f) and a plan sponsor states that there was a miscommunication between the plan sponsor and another entity that administers the plan regarding which entity was to file the election document with us.

Under certain situations, we may find good cause even if the plan sponsor does not make a specific request. For example, the sponsor of a self-funded non-Federal governmental plan decides to opt out of HIPAA for an upcoming plan year that begins on January 1. During the annual open enrollment period, all employees are given a plan brochure that contains a prominently printed notice that the plan will be exempt from HIPAA requirements for the upcoming plan year. After the plan year begins, all new enrollees are provided notice of the opt-out election at the time of enrollment. Five months into the plan year, the Personnel Department discovers that it did not file an election document with us. It belatedly files the document, which includes a statement that the plan has complied with the enrollee notification requirements of paragraph (f) of this regulation. However, the plan sponsor does not request an extension of the filing deadline for good cause. In this case, we may find that good cause exists to accept the election as being timely filed.

We believe that extending the filing deadlines in situations such as these is appropriate. Enrollees are entitled to the group health plan benefit package offered by the plan sponsor. As long as a plan has complied with the enrollee notification requirements regarding an opt-out election, extending the election filing deadlines does not disadvantage enrollees beyond the extent to which they are disadvantaged directly by the statute, which permits non-Federal governmental employers that sponsor self-funded plans to opt out of HIPAA.

Paragraph (d)(5), which incorporates and revises existing paragraph (c)(4), provides that, absent an extension based on good cause, if an election is not timely filed, the plan becomes subject to HIPAA requirements for the entire plan year to which the election would have applied, or, in the case of a plan governed by collective bargaining, for any plan year under the agreement for which the election is not timely filed.

For a collectively bargained plan, in paragraph (d)(5) we revise the requirement of existing paragraph (c)(4) that provides that failure to file a timely election subjects the plan to HIPAA requirements for the term of the collective bargaining agreement. It is our position that it is inequitable to penalize a plan governed by collective bargaining to a greater extent than other plans, which, in the case of untimely filing, must comply with HIPAA requirements only for the single plan year to which the election would have applied. Therefore, in the case of a collectively bargained plan, the plan must comply with HIPAA requirements only for plan years for which the election is not timely filed.

For instance, a collective bargaining agreement governs a group health plan for a period of 5 years, but the plan sponsor does not submit its opt-out election to us until after the third plan year has begun. The plan complies with the enrollee notification requirements of paragraph (f) of this regulation beginning with the third plan year governed by the agreement. The plan must comply with HIPAA requirements solely with respect to the first 2 plan years governed by the collective bargaining agreement. Under the revised regulation, the election is considered to be filed timely with regard to the remaining 3 plan years.

E. Paragraph (e) Additional Information Required

This paragraph provides that, in response to a notice from us, a plan sponsor, or the entity that filed the election if other than the plan sponsor, must submit additional information by the end of the plan year or 45 days after the date of the written notification, whichever is later. We will use the postmark on the envelope in which the additional information is submitted to verify timely filing. We may invalidate an election in the event of a failure to respond timely.

F. Paragraph (f) Notice to Enrollees

(A model enrollee notice is provided under section V. of this preamble as an example to assist the reader.)

This paragraph consolidates existing paragraphs (f) and (g). Paragraph (f)(1)(i) provides that a plan must notify enrollees of an opt-out election and explain the consequences of the election. If the dependents of a participant reside with the participant, the plan need only provide a notice to the participant.

Paragraph (f)(1)(ii) provides that the opt-out notice must be in writing, and, subject to notice rules associated with the initial plan year under an opt-out election, must be given to enrollees at the time of enrollment, and on an annual basis, which generally means that the notice to plan enrollees must be provided no later than the last day of each plan year for which there is an election. Thus, in general, the annual notice may be provided to plan enrollees prior to the beginning of a plan year—for instance, during an annual open enrollment period—or at any time during a plan year. Also, paragraph (f)(1)(iii) clarifies that a notice provided to an enrollee at the time of enrollment can also serve as the initial annual notice for that enrollee. That is, a plan is not required to give an enrollee more than one notice with respect to a given plan year.

Paragraph (f)(2) sets forth new special rules applicable to notices associated with the initial plan year under an opt-out election. For a plan not governed by a collective bargaining agreement, paragraph (f)(2)(i) states that a plan must provide the annual notice to all enrollees *before* the first day of that plan year, and at the time of enrollment to individuals who enroll during that plan year.

For a collectively bargained plan, paragraph (f)(2)(ii) states that the plan must provide the annual notice for the initial plan year under an election before the first day of that plan year, or within 30 days after the latest of the following dates, as applicable, if the 30th day falls on or after the first day of the plan year: the date of the agreement between the governmental employer and union officials; the date of ratification of the agreement; or the date impasse resolution, arbitration, or other closure of the collective bargaining process is finalized when agreement is not reached. (Paragraph (f)(2)(ii) incorporates these dates via cross reference to paragraph (b)(2)(i)). Also, the plan must provide a notice at the time of enrollment to all individuals who enroll on or after the first day of the plan year when closure of the collective bargaining process is reached prior to the beginning of the plan year, or to individuals who enroll on or after the date of closure of the collective

bargaining process, if that date falls on or after the first day of the plan year.

For the initial plan year that is subject to an opt-out election, this regulation requires that the annual notice be provided ''up front'' to ensure that plan enrollees are informed from the beginning that their rights under HIPAA are limited. This is consistent with the intent of the statute that enrollees have this knowledge from the beginning, that is, from ''the time of enrollment.'' This rule ensures that individuals who are already enrolled in the plan when the initial opt-out election takes effect will not be deprived of important information relevant to their health benefits, and the rule will help to eliminate situations where an enrollee assumes he or she is protected under HIPAA only to discover later that he or she is not.

For instance, if an enrollee who has had a mastectomy would be eligible to switch to other coverage, but declines to do so because she expects to have WHCRA protections under the non-Federal governmental plan, clearly she would be disadvantaged upon learning several months later (after it is too late to switch coverage) that she does not have those protections. Similarly, if someone covered under the plan expects to adopt a child, he or she may be relying on the fact that there are special enrollment rights under HIPAA, perhaps only to discover after the child is adopted that the plan sponsor has opted out of the special enrollment period requirements.

However, for a plan that is governed by collective bargaining, a plan may not be able to provide the initial opt-out notice by the beginning of the plan year because of ongoing collective bargaining. Under section 2721(b)(2) of the PHS Act, a plan must notify enrollees of the ''fact and consequences'' of an opt-out election. When a plan sponsor's intention to opt out of HIPAA is subject to collective bargaining, an (initial) election does not in ''fact'' exist until the collective bargaining process with respect to the election is completed. Therefore, when closure of the collective bargaining process occurs after the beginning of the initial plan year to which the election is to apply, a plan cannot disseminate a notice regarding the ''fact'' of that election prior to the point of closure.

In that event, individuals who enroll in the plan on or after the first day of the initial plan year that is to be subject to an opt-out election, but before closure of the collective bargaining process, are not entitled to an opt-out notice at the time of enrollment because the election in ''fact'' does not exist at that point. However, these individuals are afforded some protection by the rule in paragraph (b)(2) that prohibits an opt-out election from taking effect retroactively. (Refer to the previous discussion under item IV.B of this preamble.) Also, these individuals along with other enrollees will receive the annual notice, which must be provided within 30 days after closure of the collective bargaining process. Individuals who enroll on or after the date of closure of the collective bargaining process must be given a notice at the time of enrollment.

New paragraph (f)(3) incorporates existing paragraph (g) for notice content. A new paragraph (f)(3)(v) requires that the notice to plan enrollees regarding the opt-out election include a statement informing plan enrollees that the plan will provide for certification and disclosure of creditable coverage for covered employees and their dependents who lose coverage under the plan. This requirement is designed to benefit plan enrollees by ensuring that plans inform them of their rights regarding certification and disclosure of creditable coverage, regardless of the plan sponsor's decision to exempt the plan from other HIPAA requirements.

G. Paragraph (g) Subsequent Elections

(A model election renewal document is provided under section V. of this preamble as an example to assist the reader.)

New paragraph (g)(1) incorporates existing paragraph (e), and states that election renewals are subject to the timeliness standards in paragraph (d). Paragraph (g)(2) addresses the form and manner of renewing an election.

Paragraph (g)(3) specifies that if an opt-out election renewal includes a HIPAA requirement from which the plan sponsor did not elect to exempt the plan for the preceding plan year, the advance notification requirements that apply to initial elections (paragraph (f)(2)) also apply for the additional HIPAA requirements from which the plan sponsor is electing to exempt the plan. As in the case of initial elections, this rule requires that the annual notice be provided ''up front'' to ensure that plan enrollees are informed from the beginning that the plan sponsor is electing to exempt the plan from certain HIPAA requirements from which the plan was not exempted under the previous opt-out election.

Paragraph (g)(4) specifies new special rules regarding the renewal of an election under a collective bargaining agreement. Paragraph (g)(4)(i) requires that if protracted negotiations for a new agreement result in an extension of the term of the prior agreement under which an opt-out election was in effect (Refer to the previous discussion in section IV.B of this preamble), the plan sponsor must comply with the enrollee notification requirements of paragraph (f)(1), and file an election renewal with us in accordance with the time frames specified in paragraph (d)(2).

Also, if a non-Federal governmental employer provides coverage to employees and dependents under a single group health plan, but enters into separate collective bargaining agreements of varying lengths with various bargaining units, paragraph (g)(4)(ii) specifies that in the case of an election renewal, the timeliness standards of paragraph (d)(2) apply to the plan as governed by the agreement that results in the earliest filing date.

H. Paragraph (h) Certification and Disclosure of Creditable Coverage

Existing paragraph (h) is retained with minor editorial changes.

I. Paragraph (i) Effect of Failure to Comply With Certification and Notification Requirements

This paragraph revises existing paragraphs (i)(1) and (2). New paragraph (i)(1) generally provides that a substantial failure to comply with the enrollee notification requirements of paragraph (f) or the certification and disclosure requirements of paragraph (h) results in the invalidation of an opt-out election with respect to all plan enrollees for the entire plan year.

We determine whether a non-Federal governmental plan has substantially failed to comply based on a review of all relevant facts and circumstances, including the previous record of compliance, gravity of the violation, and whether the plan takes corrective action, as warranted, within 30 days of learning of the violation. However, in general, a failure to provide the opt-out notice to an enrollee at the time of enrollment or on an annual basis is considered to be a substantial failure to comply. In the case of a substantial failure that is limited to certain individuals, CMS may permit the election to remain in effect if the plan agrees not to apply the election with respect to the affected individuals for the plan year with respect to which the failure has occurred and so informs those individuals in writing.

New paragraph (i)(1) further specifies that in the case of a plan that is sponsored by multiple employers, the invalidation applies only for the employer(s) responsible for the substantial failure, and not for other employers that complied with the

requirements of paragraphs (f) or (h), unless the plan chooses to cancel its election entirely. For example, if 10 non-Federal governmental employers co-sponsor a plan, and one employer substantially fails to comply with the requirements of paragraph (f), the invalidation applies only with respect to enrollees of that one employer (unless the plan chooses to cancel its election entirely).

Examples illustrating the rules of new paragraph (i)(1) are provided in new paragraph (i)(2).

J. Paragraph (j) Election Invalidated

Paragraph (j) specifies the rules that apply if we invalidate an opt-out election.

K. Paragraph (k) Enforcement

Existing paragraph (i) (3) is redesignated and revised as new paragraph (k). Paragraph (k) cross-refers to part 150 of 45 CFR under which we enforce HIPAA requirements that apply to non-Federal governmental plans, including imposing a civil money penalty on a plan or plan sponsor when a non-Federal governmental plan is subject to the requirements of part 146 and fails to comply with one or more of those requirements. All non-Federal governmental plans must comply with requirements pertaining to certification and disclosure of creditable coverage under section 2701(e) of the PHS Act and § 146.115.

Paragraph (k) applies not only to a plan for which an election has not been filed, or for which an election has been invalidated, but also to a plan that has selectively opted out of HIPAA requirements and fails to comply with any requirements that are not subject to the opt-out election. For instance, a plan opts out of the preexisting condition exclusion limitations only, but also fails to comply with requirements pertaining to special enrollment periods. We enforce the special enrollment period rules under part 150.

L. Paragraph (l) Construction

This paragraph clarifies that States are not precluded from restricting the extent to which their non-Federal governmental employers may opt out of HIPAA. (Refer to our response to public comments on the April 8, 1997 interim final rule with comment period published in the **Federal Register** (62 FR 16894) that appears under section III. of this preamble.)

REDESIGNATION TABLE FOR § 146.180

Existing designation	New designation
Prefatory text and paragraph (a)	Paragraph (a)(1).
Paragraph (b)	Paragraph (b)(1).
Paragraph (c)(1) and (2)	Paragraph (d)(1) and paragraph (d)(2).
Paragraph (c)(3)	Paragraph (d)(4).
Paragraph (c)(4)	Paragraph (d)(5).
Paragraph (d)(1) and paragraph (2) (except parenthetical)	Paragraph (b)(1)(iii).
Paragraph (d)(2) (parenthetical)	Paragraph (b)(2)(i) and Paragraph (b)(2)(ii).
Paragraph (e)	Paragraph (g)(1).
Paragraph (f)	Paragraph (f)(1).
Paragraph (g)	Paragraph (f)(3).
Paragraph (h)	Paragraph (h).
Paragraph (i)(1) and paragraph (i)(2) (except invalidation notice)	Paragraph (i)(1).
Paragraph (i)(2) (invalidation notice)	Paragraph (j).
Paragraph (i)(3)	Paragraph (k).

V. Model Election/Election Renewal Document; Model Notice to Plan Enrollees

To assist non-Federal governmental employers that wish to exercise their option to exempt their self-funded plans from requirements of title XXVII of the PHS Act, we have developed a model election/election renewal document, and a model notice to plan enrollees. Use of these model documents, which are presented below, is not required. However, use of these model documents will satisfy applicable requirements of § 146.180(b)(1), (f)(3) and (g)(2). We encourage you to access these model documents at our Web site at *http://www.cms.hhs.gov/hipaa1.*

A. Model HIPAA Exemption Election/Election Renewal Document

The following may be submitted on plan sponsor's or plan administrator's letterhead:

Name of Plan: _____
Plan Sponsor: _____
Address: _____
(Not applicable if election document is on letterhead showing the plan sponsor's address.)
EIN: _____
Plan Number: _____ (if applicable)
Plan Year/Period of Plan coverage:
(beginning date) through (ending date)
(may reflect multiple plan years governed by a collective bargaining agreement.)
Plan Administrator:
Address: (If different from plan sponsor's)

(Name of plan, or portion of plan that is self-funded) is not provided through insurance. (Plan sponsor) elects under authority of section 2721(b)(2) of the Public Health Service (PHS) Act, and 45 CFR 146.180 of Federal regulations, to exempt (name of plan or self-funded portion) from the following requirements of title XXVII of the PHS Act (list any or all of the following requirements):

1. Limitations on preexisting condition exclusion periods.

2. Special enrollment periods.

3. Prohibitions against discriminating against individual participants and beneficiaries based on health status.

4. Standards relating to benefits for mothers and newborns.

5. Parity in the application of certain limits to mental health benefits.

6. Required coverage for reconstructive surgery following mastectomies.

This election has been made in conformity with all rules of the plan sponsor, including any public hearing, if required. I certify that the undersigned is authorized to submit this election on behalf of (name of plan). A copy of the notice to plan enrollees is enclosed. (In the case of an election renewal, in lieu of enclosing a copy of an updated notice to plan enrollees, the plan sponsor may include a statement that the notice has been, or will be, provided to plan enrollees in accordance with 45 CFR 146.180(f).) If CMS has any questions regarding this election, please contact (name) at (phone number).

Signature
Title

B. Model Notice to Enrollees in a Self-Funded Non-Federal Governmental Group Health Plan

Under a Federal law known as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, as amended, group health plans must generally comply with the requirements listed below. However, the law also permits State and local governmental employers that sponsor health plans to elect to exempt a plan from these requirements for any part of the plan that is ''self-funded'' by the employer, rather than provided through a health insurance policy. (Name of plan sponsor) has elected to exempt (name of plan) from (all) (or specify which ones) of the following requirements:

[The description of each listed requirement may be omitted.]

1. *Limitations on preexisting condition exclusion periods.* A preexisting condition exclusion period generally may not exceed 12 months, and generally must be reduced by prior health coverage an individual has had. Also, a plan may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition, nor, under certain conditions, with respect to newborns or children adopted or placed for adoption.

2. *Special enrollment periods.* Group health plans are required to provide special enrollment periods for individuals who do not enroll in the plan because they have other coverage, but subsequently lose that coverage. Also, if a plan provides dependent coverage, the plan must provide a special enrollment period for new dependents (and the employee if not already enrolled) within 30 days after a marriage, birth, adoption or placement for adoption.

3. *Prohibitions against discriminating against individual participants and beneficiaries based on health status.* A group health plan may not discriminate in enrollment rules or in the amount of premiums or contributions it requires an individual to pay based on certain health status-related factors: health status, medical condition (physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability.

4. *Standards relating to benefits for mothers and newborns.* Group health plans offering health coverage for hospital stays in connection with the birth of a child generally may not restrict benefits for the stay to less than 48 hours for a vaginal delivery, and 96 hours for a cesarean section.

5. *Parity in the application of certain limits to mental health benefits.* Group health plans (of employers that employ more than 50 employees) offering mental health benefits may not set annual or lifetime dollar limits on mental health benefits that are lower than limits for medical and surgical benefits. A plan that does not impose an annual or lifetime dollar limit on medical and surgical benefits may not impose that type of limit on mental health benefits. These requirements do not apply to benefits for substance abuse or chemical dependency.

6. *Required coverage for reconstructive surgery following mastectomies.* Group health plans that provide medical and surgical benefits for a mastectomy must provide certain benefits in connection with breast reconstruction as well as certain other related benefits.

The exemption from these Federal requirements will be in effect for the (plan year) (period of plan coverage) beginning (specify date) and ending (specify date). The election may be renewed for subsequent plan years.

(If the Plan provides protections similar to any of the exempted requirements, either voluntarily or in accordance with State law, identify those protections.)

HIPAA also requires the Plan to provide covered employees and dependents with a ''certificate of creditable coverage'' when they cease to be covered under the Plan. There is no exemption from this requirement. The certificate provides evidence that you were covered under this Plan, because if you can establish your prior coverage, you may be entitled to certain rights to reduce or eliminate a preexisting condition exclusion if you join another employer's health plan, or if you wish to purchase an individual health insurance policy. (If someone will be available to answer questions, an appropriate contact, such as a third party administrator, or personnel officer may be identified).

VI. Response to Comments on this Interim Final Rule

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, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Waiver of Proposed Rulemaking

In accordance with the requirements of the Administrative Procedures Act (APA), we ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment before a final rule is made effective. The notice of proposed rulemaking required by the APA incorporates a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We are making various discretionary changes to the prior April 8, 1997 interim final rule (62 FR 16894) at § 146.180 under the broad authority granted by the Congress to the Secretary of Health and Human Services—''The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this title [XXVII of the PHS Act].'' (Section 2792 of the PHS Act, as added by HIPAA, Public Law 104–191.) Because this broad regulatory authority was made a permanent part of title XXVII of the PHS Act, it has continuing effect with respect to any rules the Secretary may promulgate for purposes of carrying out title XXVII of the PHS Act. We believe that it serves the public interest to issue these regulations in accordance with the authority granted by the Congress under section 2792 of the PHS Act.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this rule as an interim final rule with comment period. We are providing a 60-day public comment period and will respond to major comments we receive in any subsequent **Federal Register** document.

VIII. 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.

The reporting and disclosure requirements referenced under § 146.180 are currently approved under OMB number 0938–0702 (HIPAA Group Market Information Collection Requirements), with a current expiration date of December 31, 2002.

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.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, DCES, SSG, Attn: John Burke, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; ATTN: CMS 0047–F

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

IX. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies.

For purposes of the RFA, all political subdivisions of States, and any agency or instrumentality of these political subdivisions, are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This regulation does not have the effect of imposing unfunded mandates on State or local governments.

We have previously estimated that between 3,500 and 5,000 non-Federal governmental plans would be affected by § 146.180 (62 FR 16927, April 8, 1997). (Only non-Federal governmental entities that provide group health plan coverage to employees on a self-funded basis (not through health insurance coverage) are eligible to elect to exempt their plans from the requirements of title XXVII of the PHS Act.) To date, we have received approximately 650 elections covering fewer than 2,000 non-Federal governmental entities, virtually all of which are small entities for purposes of the RFA.

As a group, non-Federal governmental entities that elect to opt out of HIPAA are diverse and difficult to categorize. Depending on the circumstances, elections can vary tremendously, from single plan groups, to those which incorporate multiple political and plan subdivisions. There have also been cases where plan sponsors that initially sought exemption from HIPAA requirements have subsequently elected to bring their plans into HIPAA compliance. Although there is no way to estimate the number of additional non-Federal governmental entities that will elect to exempt their plans from HIPAA requirements, based on our experience to date, we maintain that most of the eligible non-Federal governmental entities that intend to exempt their plans from one or more HIPAA requirements have already done so.

The Women's Health and Cancer Rights Act of 1998 (WHCRA) was effective for plan years beginning on or after October 21, 1998. However, we believe that, in general, non-Federal governmental entities that were eligible, but declined to exempt their plans from the requirements of HIPAA , the Newborns' and Mothers' Health Protection Act of 1996, and the Mental Health Parity Act of 1996 are not likely to elect to exempt their plans from the requirements of WHCRA. Thus, we do not anticipate that the number of opt-out elections will increase substantially as a result of WHCRA. Accordingly, we estimate that fewer than 2,000 non-Federal governmental entities are affected by these regulations, and we expect that number to remain fairly stable.

Non-Federal governmental entities are subject to these regulations *only* if they *elect* to exempt their plans from any requirements of title XXVII of the PHS Act. We did not consider alternatives to these regulations because regulations are necessary to modify existing regulations at § 146.180. Moreover, section 2721(b)(2)(A) of the PHS Act expressly calls for regulations—plan sponsors of non-Federal governmental plans may elect to exempt their self-funded group health plans from the requirements of title XXVII ''in such form and manner as the Secretary may by regulations prescribe.''

These regulations are designed to assist non-Federal governmental employers in exercising their prerogative under section 2721(b)(2) to exempt eligible plans from various requirements of title XXVII of the PHS Act, and to clarify that States are not precluded by section 2721(b)(2) and § 146.180 from limiting the extent to which non-Federal governmental plan sponsors may elect to exempt their self-funded group health plans from HIPAA requirements. The effect of not issuing these regulations would be to deprive non-Federal governmental employers and States of information pertinent to implementing section 2721(b)(2) of the PHS Act. However, not issuing these regulations would have negligible economic consequences for non-Federal governmental employers. The requirement that group health plans must notify enrollees regarding an exemption election at the time of enrollment and on an annual basis is prescribed by the statute. Our initial implementing regulations (62 FR 16894, April 8, 1997) address the consequences of a plan's failure to comply with those statutory enrollee notification requirements—a plan's exemption election is invalidated, and the plan must come into compliance with HIPAA requirements. Thus, the potential for incurring costs associated with bringing a plan into HIPAA compliance as a result of a plan's failure to comply with the enrollee notification requirements already exists and would not accrue to non-Federal governmental employers if these regulations are not issued.

For these reasons, we are not preparing an analysis for the RFA because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities.

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

X. Federalism

We have reviewed this regulation under the threshold criteria of Executive Order 13132. We have determined that this interim final rule with comment period does not significantly affect the rights, roles, and responsibilities of States.

List of Subjects in 45 CFR Part 146

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

For the reasons set forth in the preamble, 45 CFR Part 146 is amended as set forth below:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

A. Part 146 is amended as set forth below.

1. The authority citation for part 146 is corrected to read as follows:

Authority: Secs. 2701 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–23, 300gg–91, and 300gg–92).

2. In § 146.150, paragraph (d)(2) is revised to read as follows:

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

* * * * *

(d) Application of financial capacity limits.

* * * * *

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

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

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

* * * * *

3. Section 146.180 is revised to read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) *Requirements subject to exemption.* (1) *Basic rule.* A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), from any or all of the following requirements:

(i) Limitations on preexisting condition exclusion periods described in § 146.111.

(ii) Special enrollment periods for individuals and dependents described in § 146.117.

(iii) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121.

(iv) Standards relating to benefits for mothers and newborns described in § 146.130.

(v) Parity in the application of certain limits to mental health benefits described in § 146.136.

(vi) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2706 of the PHS Act.

(2) *Limitations.* (i) An election under this section cannot circumvent a requirement of this part to the extent the requirement applied to the plan before the effective date of the election.

(A) *Example 1.* A plan is subject to requirements of section 2706 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2706 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

(B) *Example 2.* An individual is hired by a non-Federal governmental employer and reports to work on August 6. The individual has diabetes. Under the terms of the plan in effect on August 6, if an individual files an enrollment application within the first 30 days of employment, enrollment in the plan is effective as of the first day of employment. The individual timely files an enrollment application. The application is processed on September 10. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from § 146.121, which prohibits enrollment discrimination based on health status-related factors, by requiring new enrollees to pass medical underwriting. The plan cannot decline to enroll the individual effective August 6, even if he would not pass medical underwriting under the terms of the plan in effect on September 1.

(ii) If a group health plan is co-sponsored by two or more employers, then only plan enrollees of the non-Federal governmental employer(s) with a valid election under this section are affected by the election.

(3) *Stop-loss or excess risk coverage.* For purposes of this section—(i) Subject to paragraph (a)(3)(ii), the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

(ii) Regardless of whether coverage offered by an issuer is designated as ''stop-loss'' coverage or ''excess risk'' coverage, if it is regulated as group health insurance under an applicable State law, then for purposes of this section, a non-Federal governmental plan that purchases the coverage is considered to be fully insured. In that event, a plan may not be exempted under this section from the requirements of this part.

(4) *Construction.* Nothing in this part should be construed as imposing collective bargaining obligations on any party to the collective bargaining process.

(b) *Form and manner of election.* (1) *Election requirements.* The election must meet the following requirements:

(i) Be made in writing.

(ii) Be made in conformance with all of the plan sponsor's rules, including any public hearing requirements.

(iii) Specify the beginning and ending dates of the period to which the election is to apply. This period can be either of the following periods:

(A) A single specified plan year, as defined in § 144.103 of this subchapter.

(B) The ''term of the agreement,'' as specified in paragraph (b)(2) of this section, in the case of a plan governed by collective bargaining.

(iv) Specify the name of the plan and the name and address of the plan administrator, and include the name and telephone number of a person CMS may contact regarding the election.

(v) State that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through health insurance coverage.

(vi) Specify each requirement described in paragraph (a) of this section from which the plan sponsor elects to exempt the plan.

(vii) Certify that the person signing the election document, including (if applicable) a third party plan administrator, is legally authorized to do so by the plan sponsor.

(viii) Include, as an attachment, a copy of the notice described in paragraph (f) of this section.

(2) *''Term of the agreement'' defined.* Except as provided in paragraphs (b)(2)(i) and (b)(2)(ii), for purposes of

this section ''term of the agreement'' means all group health plan years governed by a single collective bargaining agreement.

(i) In the case of a group health plan for which the last plan year governed by a prior collective bargaining agreement expires during the bargaining process for a new agreement, the term of the prior agreement includes all plan years governed by the agreement plus the period of time that precedes the latest of the following dates, as applicable, with respect to the new agreement:

(A) The date of an agreement between the governmental employer and union officials.

(B) The date of ratification of an agreement between the governmental employer and the union.

(C) The date impasse resolution, arbitration or other closure of the collective bargaining process is finalized when agreement is not reached.

(ii) In the case of a group health plan governed by a collective bargaining agreement for which closure is not reached before the last plan year under the immediately preceding agreement expires, the term of the new agreement includes all plan years governed by the agreement excluding the period that precedes the latest applicable date specified in paragraph (b)(2)(i) of this section.

(3) *Construction.* (i) *Dispute resolution.* Nothing in paragraph (b)(1)(ii) of this section should be construed to mean that CMS arbitrates disputes between plan sponsors, participants, beneficiaries, or their representatives regarding whether an election complies with all of a plan sponsor's rules.

(ii) *Future elections not preempted.* If a plan must comply with one or more requirements of this part for a given plan year or period of plan coverage, nothing in this section should be construed as preventing a plan sponsor from submitting an election in accordance with this section for a subsequent plan year or period of plan coverage.

(c) *Mailing address.* The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Private Health Insurance Group, CMSO, 7500 Security Boulevard, S3–16–16, Baltimore, MD 21244–1850.

(d) *Filing a timely election.* (1) *Plan not governed by collective bargaining.* Subject to paragraph (d)(4) of this section, if a plan is not governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the plan year.

(2) *Plan governed by a collective bargaining agreement.* Subject to paragraph (d)(4) of this section, if a plan is governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the first plan year governed by a collective bargaining agreement, or by the 45th day after the latest applicable date specified in paragraph (b)(2)(i) of this section, if the 45th day falls on or after the first day of the plan year.

(3) *Verifying timely filing.* CMS uses the postmark on the envelope in which the election is submitted to determine that the election is timely filed as specified under paragraphs (d)(1) or (d)(2) of this section, as applicable. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(4) *Filing extension based on good cause.* CMS may extend the deadlines specified in paragraphs (d)(1) and (d)(2) of this section for good cause if the plan substantially complies with the requirements of paragraph (f) of this section.

(5) *Failure to file a timely election.* Absent an extension under paragraph (d)(4) of this section, a plan sponsor's failure to file a timely election under paragraph (d)(1) or (d)(2) of this section makes the plan subject to all requirements of this part for the entire plan year to which the election would have applied, or, in the case of a plan governed by a collective bargaining agreement, for any plan years under the agreement for which the election is not timely filed.

(e) *Additional information required.* (1) *Written notification.* If an election is timely filed, but CMS determines that the election document (or the notice to plan enrollees) does not meet all of the requirements of this section, CMS may notify the plan sponsor, or other entity that filed the election, that it must submit any additional information that CMS has determined is necessary to meet those requirements. The additional information must be filed with CMS by the later of the following dates:

(i) The last day of the plan year.

(ii) The 45th day after the date of CMS's written notification requesting additional information.

(2) *Timely response.* CMS uses the postmark on the envelope in which the additional information is submitted to determine that the information is timely filed as specified under paragraph (e)(1) of this section. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(3) *Failure to respond timely.* CMS may invalidate an election if the plan sponsor, or other entity that filed the election, fails to timely submit the additional information as specified under paragraph (e)(1) of this section.

(f) *Notice to enrollees.* (1) *Mandatory notification.*

(i) A plan that makes the election described in this section must notify each affected enrollee of the election, and explain the consequences of the election. For purposes of this paragraph (f), if the dependent(s) of a participant reside(s) with the participant, a plan need only provide notice to the participant.

(ii) The notice must be in writing and, except as provided in paragraph (f)(2) of this section with regard to initial notices, must be provided to each enrollee at the time of enrollment under the plan, and on an annual basis no later than the last day of each plan year (as defined in § 144.103 of this subchapter) for which there is an election.

(iii) A plan may meet the notification requirements of this paragraph (f) by prominently printing the notice in a summary plan description, or equivalent description, that it provides to each enrollee at the time of enrollment, and annually. Also, when a plan provides a notice to an enrollee at the time of enrollment, that notice may serve as the initial annual notice for that enrollee.

(2) *Initial notices.* (i) If a plan is not governed by a collective bargaining agreement, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of that plan year, and notice at the time of enrollment to all individuals who enroll during that plan year.

(ii) In the case of a collectively bargained plan (including a self-funded non-Federal governmental plan that has been exempted from requirements of this part under § 146.125(a)(2)), with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of the plan year, or within 30 days after the latest applicable date specified in paragraph (b)(2)(i) of this section if the 30th day falls on or after the first day of the plan year. Also, the plan must provide a notice at the time of enrollment to individuals who—

(A) Enroll on or after the first day of the plan year, when closure of the collective bargaining process is reached before the plan year begins; or

(B) Enroll on or after the latest applicable date specified in paragraph

(b)(2)(i) of this section if that date falls on or after the first day of the plan year.

(3) *Notice content.* The notice must include at least the following information:

(i) The specific requirements described in paragraph (a)(1) of this section from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

(ii) A statement that Federal law gives the plan sponsor of a self-funded non-Federal governmental plan the right to exempt the plan in whole, or in part, from the listed requirements, and that the plan sponsor has elected to do so.

(iii) A statement identifying which parts of the plan are subject to the election.

(iv) A statement identifying which of the listed requirements, if any, apply under the terms of the plan, or as required by State law, without regard to an exemption under this section.

(v) A statement informing plan enrollees that the plan provides for certification and disclosure of creditable coverage for covered employees and their dependents who lose coverage under the plan.

(g) *Subsequent elections.* (1) *Election renewal.* A plan sponsor may renew an election under this section through subsequent elections. The timeliness standards described in paragraph (d) apply to election renewals under this paragraph (g).

(2) *Form and manner of renewal.* Except for the requirement to forward to CMS a copy of the notice to enrollees under paragraph (b)(1)(viii) of this section, the plan sponsor must comply with the election requirements of paragraph (b)(1) of this section. In lieu of providing a copy of the notice under (b)(1)(viii), the plan sponsor may include a statement that the notice has been, or will be, provided to enrollees as specified under paragraph (f) of this section.

(3) *Election renewal includes provisions from which plan not previously exempted.* If an election renewal includes a requirement described in paragraph (a) of this section from which the plan sponsor did not elect to exempt the plan for the preceding plan year, the advance notification requirements of paragraph (f)(2) of this section apply with respect to the additional requirement(s) of paragraph (a) from which the plan sponsor is electing to exempt the plan.

(4) *Special rules regarding renewal of an election under a collective bargaining agreement.* (i) If protracted negotiations with respect to a new agreement result in an extension of the term of the prior agreement (as provided under paragraph (b)(2)(i)) under which an election under this section was in effect, the plan must comply with the enrollee notification requirements of paragraph (f)(1), and, following closure of the collective bargaining process, must file an election renewal with CMS as provided under paragraph (d)(2) of this section.

(ii) If a single plan applies to more than one bargaining unit, and the plan is governed by collective bargaining agreements of varying lengths, paragraph (d)(2) of this section, with respect to an election renewal, applies to the plan as governed by the agreement that results in the earliest filing date.

(h) *Certification and disclosure of creditable coverage.* Without regard to an election under this section, a non-Federal governmental plan must provide for certification and disclosure of creditable coverage under the plan with respect to participants and their dependents as specified under § 146.115. CMS enforces this requirement as provided under paragraph (k) of this section.

(i) *Effect of failure to comply with certification and notification requirements.* (1) *Substantial failure.* (i) *General rule.* Except as provided in paragraph (i)(1)(iii) of this section, a substantial failure to comply with paragraphs (f) or (h) of this section results in the invalidation of an election under this section with respect to all plan enrollees for the entire plan year. That is, the plan is subject to all requirements of this part for the entire plan year to which the election otherwise would have applied.

(ii) *Determination of substantial failure.* CMS determines whether a plan has substantially failed to comply with a requirement of paragraph (f) or paragraph (h) of this section based on all relevant facts and circumstances, including previous record of compliance, gravity of the violation and whether a plan corrects the failure, as warranted, within 30 days of learning of the violation. However, in general, a plan's failure to provide a notice of the fact and consequences of an election under this section to an individual at the time of enrollment, or on an annual basis before a given plan year expires, constitutes a substantial failure.

(iii) *Exceptions.* (A) *Multiple employers.* If the plan is sponsored by multiple employers, and only certain employers substantially fail to comply with the requirements of paragraphs (f) or (h) of this section, then the election is invalidated with respect to those employers only, and not with respect to other employers that complied with those requirements, unless the plan chooses to cancel its election entirely.

(B) *Limited failure to provide notice.* If a substantial failure to notify enrollees of the fact and consequences of an election is limited to certain individuals, the election under this section is valid only if, for the plan year with respect to which the failure has occurred, the plan agrees not to apply the election with respect to the individuals who were not notified and so informs those individuals in writing.

(2) *Examples.* (i) *Example 1:* A self-funded non-Federal group health plan is co-sponsored by 10 school districts. Nine of the school districts have fully complied with the requirements of paragraph (f) of this section, including providing notice to new employees at the time of their enrollment in the plan, regarding the group health plan's exemption under this section from requirements of this part. One school district, which hired 10 new teachers during the summer for the upcoming school year, neglected to notify three of the new hires about the group health plan's exemption election at the time they enrolled in the plan. The school district has substantially failed to comply with a requirement of paragraph (f) with respect to these individuals.

The school district learned of the oversight six weeks into the school year, and promptly (within 30 days of learning of the oversight) provided notice to the three teachers regarding the plan's exemption under this section and that the exemption does not apply to them, or their dependents, during the plan year of their enrollment because of the plan's failure to timely notify them of its exemption. The plan complies with the requirements of this part for these individuals for the plan year of their enrollment. CMS would not require the plan to come into compliance with the requirements of this part for other enrollees.

(ii) *Example 2:* Same facts as in Example 1, except the noncompliant school district failed to notify any enrollees regarding an election under this section. That is, the school district failed to provide the annual notice to current plan enrollees as well as the notice at the time of enrollment to new enrollees. The school district has substantially failed to comply with the requirements of paragraph (f) of this section. At a minimum, the election is invalidated with respect to all enrollees of the noncompliant school district for the plan year for which the substantial failure has occurred. In this example, the plan decides not to cancel its election entirely. The election with regard to the other nine school districts remains in effect.

(iii) *Example 3.* Two non-Federal governmental employers cosponsor a self-funded group health plan. One employer substantially fails to comply with the requirements of paragraph (f) of this section. While the plan may limit the invalidation of the election to enrollees of the plan sponsor that is responsible for the substantial failure,

the plan sponsors determine that administering the plan in that manner would be too burdensome. Accordingly, in this example, the plan sponsors choose to cancel the election entirely. Both plan sponsors come into compliance with the requirements of this part with respect to all enrollees for the plan year for which the substantial failure has occurred.

(iv) *Example 4:* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from certain requirements of this part. The collective bargaining agreement applies to five plan years, 2001 through 2005. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2001 through December 31, 2005. Prior to the dissemination of the annual notice for the 2004 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2001 through December 31, 2005. Accordingly, CMS would not invalidate the election for the 2004 plan year.

(v) *Example 5:* A non-Federal governmental employer has elected to exempt its self-funded plan from certain requirements of this part. An individual terminates employment with the governmental employer, which fails to automatically provide a certificate of creditable coverage within the period specified in § 146.115(a)(2)(ii)(A). (The governmental employer generally provides certificates to terminated employees on an automatic basis, but neglected to do so in this case.) The oversight is brought to the employer's attention when the individual inquires as to why he has not received his certificate of creditable coverage. The governmental employer promptly (within 30 days) forwards a certificate to the individual. CMS would not view that situation as constituting a substantial failure and would not invalidate the election under this section.

(j) *Election invalidated.* If CMS finds cause to invalidate an election under this section, the following rules apply:

(1) CMS notifies the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) in writing that CMS has made a preliminary determination that an election is invalid, and states the basis for that determination.

(2) CMS's notice informs the plan sponsor that it has 45 days after the date of CMS's notice to explain in writing why it believes its election is valid. The plan sponsor should provide applicable statutory and regulatory citations to support its position.

(3) CMS verifies that the plan sponsor's response is timely filed as provided under paragraph (d)(3) of this section. CMS will not consider a response that is not timely filed.

(4) If CMS's preliminary determination that an election is invalid remains unchanged after CMS considers the plan sponsor's timely response (or in the event that the plan sponsor fails to respond timely), CMS provides written notice to the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) of CMS's final determination that the election is invalid. Also, CMS informs the plan sponsor that, within 45 days of the date of the notice of final determination, the plan, subject to paragraph (i)(1)(iii) of this section, must comply with all requirements of this part for the specified period for which CMS has determined the election to be invalid.

(k) *Enforcement.* To the extent that an election under this section has not been filed or a non-Federal governmental plan otherwise is subject to one or more requirements of this part, CMS enforces those requirements under part 150 of this subchapter. This may include imposing a civil money penalty against the plan or the plan sponsor, as determined under § 150.305.

(l) *Construction.* Nothing in this section should be construed to prevent a State from taking the following actions:

(1) Establishing, and enforcing compliance with, the requirements of State law (as defined in § 146.143(d)(1)), including requirements that parallel provisions of title XXVII of the PHS Act, that apply to non-Federal governmental plans or sponsors.

(2) Prohibiting a sponsor of a non-Federal governmental plan within the State from making an election under this section.

(Catalog of Federal Domestic Assistance Program No. 93.773), (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: December 7, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 20, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–17621 Filed 7–25–02; 8:45 am]

BILLING CODE 4120–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1804 and 1852

Security Requirements for Unclassified Information Technology Resources

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This final rule adopts with changes the interim rule published in the **Federal Register** on July 12, 2001. The interim rule amended the NASA FAR Supplement (NFS) to clarify information technology (IT) security requirements for sensitive information contained in unclassified automated information resources

EFFECTIVE DATE: July 26, 2002.

FOR FURTHER INFORMATION CONTACT: Karl Beisel, NASA Headquarters, Code HC, Washington, DC 20546, (202) 358–0416, *kbeisel@mail.hq.nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

NASA published an interim rule in the **Federal Register** at 66 FR 36490 on July 12, 2001, revising NFS section 1804.470 and the clause at 1852.204–76, Security Requirements for Unclassified Information Technology Resources. These sections address security requirements for unclassified IT resources. The action implemented The Computer Security Act of 1987 and Appendix III of the Office of Management and Budget (OMB) Circular No. A–130, Security of Federal Automated Information Resources, which require adequate security be provided for all Agency information collected, processed, transmitted, stored, or disseminated. NFS section 1804.470 contains the requirement for all NASA contractors and subcontractors to comply with Federal and NASA policies in safeguarding unclassified NASA data held via information technology (IT).

Public comments were received from one source. The comments were considered in developing this final rule.

Changes are made in this final rule to section 1804.470–1, Scope, to reference Federal policies that are implemented through NASA's Procedures and Guidelines (NPG) 2810.1, Security of Information Technology, and amend paragraph (d)(3)(i) of the clause at 1852.204–76 to remove the exemption of certain information contained in Standard Form 85P, Questionnaire for Public Trust Positions.

NASA understands that the FAR Council is working with the OMB