



# Federal Register

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**Monday,  
April 18, 2005**

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**Part III**

**Department of  
Health and Human  
Services**

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**Office of the Secretary**

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**45 CFR Parts 160 and 164  
HIPAA Administrative Simplification;  
Enforcement; Proposed Rule**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**45 CFR Parts 160 and 164**

**RIN 0991-AB29**

**HIPAA Administrative Simplification; Enforcement**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Secretary of Health and Human Services is proposing rules for the imposition of civil money penalties on entities that violate rules adopted by the Secretary to implement the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191 (HIPAA). The proposed rule would amend the existing rules relating to the investigation of noncompliance to make them apply to all of the HIPAA Administrative Simplification rules, rather than exclusively to the privacy standards. It would also amend the existing rules relating to the process for imposition of civil money penalties. Among other matters, the proposed rules would clarify and elaborate upon the investigation process, bases for liability, determination of the penalty amount, grounds for waiver, conduct of the hearing, and the appeal process.

**DATES:** Comments on the proposed rule will be considered if we receive them at the appropriate address, as provided below, no later than June 17, 2005.

**ADDRESSES:** You may submit comments by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Include agency name and "RIN: 0991-AB29."
- E-mail:

*CS0010.Comments@hhs.gov*. Include "RIN: 0991-AB29" in the subject line of the message.

- Mail: U.S. Department of Health and Human Services, Office of General Counsel, Attention: HIPAA Enforcement Rule, 330 Independence Ave., SW., Washington, DC 20201.
- Hand Delivery/Courier: Attention: HIPAA Enforcement Rule, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

*Instructions:* Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:**

Carol Conrad, (202) 690-1840.

**SUPPLEMENTARY INFORMATION:**

**I. Public Participation**

We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the RIN number (RIN: 0991-AB29) and by preceding your discussion of any particular provision with a citation to the section of the proposed rule being discussed.

*A. Inspection of Public Comments*

Comments received timely will be available for public inspection as they are received, generally beginning approximately 6 weeks after publication of this document, at the mail address provided above, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call Karen Shaw, (202) 205-0154.

*B. Electronic Comments*

We will consider all electronic comments that include the full name, postal address, and affiliation (if applicable) of the sender and are submitted to either of the electronic addresses identified in the **ADDRESSES** section of this preamble. All comments must be incorporated in the e-mail message, because we may not be able to access attachments. Copies of electronically submitted comments will be available for public inspection as soon as practicable at the address provided, and subject to the process described, in the preceding paragraph.

*C. Mailed Comments and Hand Delivered/Couriered Comments*

Mailed comments may be subject to delivery delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. Comments mailed to the address indicated for hand or courier delivery may be delayed and could be considered late.

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*E. Electronic Access*

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*F. Response to Comments*

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive in accordance with the methods described above and by the date specified in the **DATES** section of this preamble. When we proceed with a final rule, we will respond to comments in the preamble to that rule.

**II. Background**

HHS proposes to amend or renumber existing rules that relate to compliance with, and enforcement of, the Administrative Simplification regulations (HIPAA rules) adopted by the Secretary of Health and Human Services (Secretary) under subtitle F of Title II of HIPAA (HIPAA provisions). These rules are codified at 45 CFR part 160, subparts C and E. In addition, this proposed rule would add a new subpart D to part 160. The new subpart D would contain additional rules relating to the imposition by the Secretary of civil money penalties on covered entities that violate the HIPAA rules. The full set of rules that will ultimately be codified at subparts C, D, and E of 45 CFR part 160 is collectively referred to in this proposed rule as the "Enforcement Rule." Finally, HHS proposes conforming changes to subpart A of part 160 and subpart E of part 164.

The statutory and regulatory background of the proposed rule is set out below. A description of HHS's approach to enforcement of the HIPAA provisions and the HIPAA rules in general, the approach of this proposed

rule in particular, and each section of the proposed rule follows. The preamble concludes with HHS's analyses of impact and other issues under applicable law.

#### A. Statutory Background

Subtitle F of Title II of HIPAA, entitled "Administrative Simplification," requires the Secretary to adopt national standards for certain information-related activities of the health care industry. The purpose of subtitle F is to improve the Medicare program under title XVIII of the Social Security Act (Act), the Medicaid program under title XIX of the Act, and the efficiency and effectiveness of the health care system, by mandating the development of standards and requirements to enable the electronic exchange of certain health information. Section 262 of subtitle F added a new Part C to Title XI of the Act. Part C (sections 1171–1179 of the Act, 42 U.S.C. 1320d–1320d–8) requires the Secretary to adopt national standards for certain financial and administrative transactions and various data elements to be used in those transactions, such as code sets and certain unique health identifiers. Recognizing that the industry trend toward computerizing health information, which HIPAA encourages, may increase the accessibility of that information, sections 262 and 264 of HIPAA also require the Secretary to adopt national standards to protect the security and privacy of the information.

Under section 1172(a) of the Act, 42 U.S.C. 1320d–1(a), the HIPAA provisions apply only to—

The following persons:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1173(a)(1).

These entities are collectively known as "covered entities." An additional category of covered entities was added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA). As added by MMA, section 1860D–31(h)(6)(A) of the Act, 42 U.S.C. 1395w–141(h)(6)(A), provides that:

a prescription drug card sponsor is a covered entity for purposes of applying part C of title XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

HIPAA requires certain consultations with industry as a predicate to the issuance of the HIPAA standards and provides that most covered entities have up to 2 years (small health plans have up to 3 years) to come into compliance with the standards, once adopted. The statute establishes civil money penalties and criminal penalties for violations. Act, sections 1172(c) (42 U.S.C. 1320d–1(c)), 1175(b) (42 U.S.C. 1320d–4(b)), 1176 (42 U.S.C. 1320d–5), 1177 (42 U.S.C. 1320d–6). HHS enforces the civil money penalties, while the U.S. Department of Justice enforces the criminal penalties.

HIPAA's civil money penalty provision, section 1176(a) of the Act, 42 U.S.C. 1320d–5(a), authorizes the Secretary to impose a civil money penalty, as follows:

(1) IN GENERAL. Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part [42 U.S.C. § 1320d *et seq.*] a penalty of not more than \$100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.

(2) PROCEDURES. The provisions of section 1128A [42 U.S.C. 1320a–7a] (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1128A.

For simplicity, we refer throughout this preamble to this provision, the related provisions at section 1128A of the Act, and other related provisions of the Act, by their Social Security Act citations, rather than by their U.S. Code citations.

Subsection (b) of section 1176 sets out limitations on the Secretary's authority to impose civil money penalties and also provides authority for waiving such penalties. Under section 1176(b)(1), a civil money penalty may not be imposed with respect to an act that "constitutes an offense punishable" under the criminal penalty provision. Under section 1176(b)(2), a civil money penalty may not be imposed "if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision." Under section 1176(b)(3), a civil money penalty may not be imposed if the failure to comply was due "to reasonable cause and not to willful neglect" and is corrected within a certain time. Finally, under section 1176(b)(4), a civil money penalty may be reduced or entirely waived "to the extent that the payment of such penalty

would be excessive relative to the compliance failure involved."

As noted above, HIPAA incorporates by reference certain provisions of section 1128A of the Act. Those provisions, as relevant here, establish a number of requirements with respect to the imposition of civil money penalties. Under section 1128A(c)(1), the Secretary may not initiate a civil money penalty action "later than six years after the date" of the occurrence that forms the basis for the civil money penalty. Under section 1128A(c)(2), a person upon whom the Secretary seeks to impose a civil money penalty must be given written notice and an opportunity for a determination to be made "on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person." Section 1128A also provides, at subsections (c), (e), and (j), respectively, requirements for: service of the notice and authority for sanctions which the hearing officer may impose for misconduct in connection with the civil money penalty proceeding; judicial review of the Secretary's determination in the United States Court of Appeals for the circuit in which the person resides or maintains his/its principal place of business; and the issuance of subpoenas by the Secretary and the enforcement of those subpoenas. In addition, section 1128A of the Act contains provisions relating to liability for civil money penalties and how they are dealt with, once imposed. For example, section 1128A(d) provides that the Secretary must take into account certain factors "in determining the amount \* \* \* of any penalty," section 1128A(h) requires certain notifications once a civil money penalty is imposed, and section 1128A(l) makes a principal liable for penalties "for the actions of the principal's agent acting within the scope of the agency." These provisions are discussed more fully below.

#### B. Regulatory Background

As noted above, HIPAA requires the Secretary to adopt a number of national standards to facilitate the exchange, and protect the privacy and security, of certain health information. The Secretary has already adopted many of these HIPAA standards by regulation.

- Regulations implementing the statutory requirement for the adoption of standards for transactions and code sets, Health Insurance Reform: Standards for Electronic Transactions (Transactions Rule), were published on August 17, 2000 (65 FR 50312), and were modified on February 20, 2003 (68 FR 8381). The Transactions Rule

became effective on October 16, 2000, with an initial compliance date of October 16, 2002 for covered entities other than small health plans. The passage of the Administrative Simplification Compliance Act (ASCA), Pub. L. 107-105, in 2001 enabled covered entities to obtain an extension of the compliance date to October 16, 2003 by filing a compliance plan by October 15, 2002. If a covered entity (other than a small health plan) did not file such a plan, it was required to comply with the Transactions Rule by October 16, 2002. All covered entities were required to be in compliance with the Transactions Rule, as modified, by October 16, 2003.

- Regulations implementing the statutory requirement for the adoption of privacy standards, Standards for Privacy of Individually Identifiable Health Information (Privacy Rule), were published on December 28, 2000 (65 FR 82462). The Privacy Rule became effective on April 14, 2001. Modifications to simplify and increase the workability of the Privacy Rule were published on August 14, 2002 (67 FR 53182). Compliance with the Privacy Rule, as modified, was required by April 14, 2003 for covered entities other than small health plans; small health plans were required to come into compliance by April 14, 2004.

The Privacy Rule adopted rules relating to compliance and enforcement. These rules are codified at 45 CFR part 160, subpart C. Subpart C presently applies only to compliance with, and enforcement of, the Privacy Rule.

- Regulations implementing the statutory requirement for the adoption of an employer identifier standard, Health Insurance Reform: Standard Unique Employer Identifier (EIN Rule), were published on May 31, 2002 (67 FR 38009) and became effective on July 30, 2002. The initial compliance date was July 30, 2004 for most covered entities; small health plans have until July 30, 2005 to come into compliance. These regulations were modified on January 23, 2004 (69 FR 3434), effective the same date.

- Regulations implementing the statutory requirement for the adoption of security standards, Health Insurance Reform: Security Standards, were published on February 20, 2003 (68 FR 8334), effective on April 21, 2003. The initial compliance date for covered entities other than small health plans is April 20, 2005; small health plans have until April 20, 2006 to come into compliance.

- An interim final rule promulgating procedural requirements for imposition of civil money penalties, Civil Money

Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings (April 17, 2003 interim final rule), was published on April 17, 2003 (68 FR 18895), was effective on May 19, 2003, with a sunset date of September 16, 2004 (as corrected at 68 FR 22453, April 28, 2003). The April 17, 2003 interim final rule adopted a new subpart E of part 160. The sunset date of the April 17, 2003 interim final rule was extended to September 16, 2005 on September 15, 2004 (69 FR 55515).

- Regulations implementing the requirement to issue standards for a unique identifier for health care providers, HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers (NPI Rule), were issued on January 23, 2004 (69 FR 3434), effective on May 23, 2005. The compliance date is May 23, 2007 for most covered entities; small health plans have until May 23, 2008 to come into compliance.

In addition to the foregoing regulations implementing the HIPAA provisions, HHS has adopted two other regulations that are relevant, for some covered entities, to compliance with those provisions.

- Section 3 of the ASCA amended section 1862 of the Act to require Medicare providers, with certain exceptions, to submit claims to Medicare electronically (and, thus, in conformity with the Transactions Rule) by October 16, 2003. Regulations implementing section 3, Medicare Program: Electronic Submission of Medicare Claims, were published on August 15, 2003 (68 FR 48805), effective on October 16, 2003.

- Regulations implementing the Medicare Prescription Drug Discount Card program under MMA and the statutory provision that Medicare prescription drug discount card sponsors are covered entities under HIPAA, were issued on December 15, 2003 (68 FR 69840), effective the same date. These rules require such sponsors to comply with the HIPAA rules when they become sponsors, except and to the extent that the Secretary temporarily waives the Privacy Rule requirements, and provides some rules regarding how these entities are to comply with the HIPAA rules. The Secretary has indicated that he does not anticipate that it will be necessary to waive the Privacy Rule requirements and has not done so. 68 FR 69871.

### III. General Approach

As the discussion above makes clear, the duty to comply with certain HIPAA rules is now a reality for all covered entities. The immediacy of the

compliance obligation brings with it the issue of how these rules will be enforced. Accordingly, we discuss below our general approach to enforcement, how the rules proposed below would fit in with the existing components of the Enforcement Rule, and the basic approach of the proposed rule.

#### A. HHS's General Approach to Enforcement

One of the Secretary's priorities is "One HHS": HHS's public health and welfare mission and message must be consistent, and HHS should speak with one voice. Because of the Secretary's One HHS policy and because there is one statutory provision for imposing civil money penalties on covered entities that violate the HIPAA rules, there is one enforcement and compliance policy for the HIPAA rules. We are committed to promoting and encouraging voluntary compliance with the HIPAA rules through education, cooperation, and technical assistance.

Many educational and technical assistance materials on HIPAA, including the HIPAA rules, are already available on HHS's Web sites. See <http://www.hhs.gov/ocr/hipaa> for the Privacy Rule and <http://www.cms.gov/hipaa/hipaa2> for the other HIPAA rules. We continue to work on educational and technical assistance materials, including additional guidance on compliance and enforcement and targeted technical assistance materials focused on particular segments of the health care industry. We anticipate developing additional materials relevant to new HIPAA rules as the need arises.

The authority for administering and enforcing compliance with the Privacy Rule has been delegated to the HHS Office for Civil Rights (OCR). 65 FR 82381 (December 28, 2000). The authority for administering and enforcing compliance with the non-privacy HIPAA rules has been delegated to the Centers for Medicare & Medicaid Services (CMS). 68 FR 60694 (October 23, 2003).

At present, our compliance and enforcement activities are primarily complaint-based. Although our enforcement efforts are focused on investigating complaints, they may also include conducting compliance reviews to determine if a covered entity is in compliance. When potential violations come to our attention through a complaint or a compliance review, OCR or CMS's Office of HIPAA Standards (OHS), as appropriate, attempts to resolve the matter informally. Many such matters are resolved at the initial stage of contact. However, even where a

matter is not resolved at this initial stage and the investigation continues, the matter can still be resolved through voluntary compliance (for example, by means of a corrective action plan); and OCR or CMS may provide technical assistance to help the covered entity achieve compliance. Resolving issues through such informal means is often the quickest and most effective means of ensuring that the benefits of the HIPAA rules are realized. However, if we are unable to obtain compliance effectively on matters within our jurisdiction through voluntary means, we may seek to impose civil money penalties. Moreover, matters subject to criminal penalties are referred to the Department of Justice.

#### *B. HHS's Approach to the Enforcement Rule*

The Enforcement Rule would bring together and adopt rules governing the implementation of the civil money penalty authority of section 1176 of the Act for all of the HIPAA rules. As previously noted, parts of the Enforcement Rule are already in place: subpart C of part 160 establishes certain investigative procedures for the Privacy Rule, and subpart E establishes interim procedures for investigations and for the imposition of, and challenges to the imposition of, civil money penalties for all of the HIPAA rules. This proposed rule would complete the Enforcement Rule by addressing, among other issues, our policies for determining violations and calculating civil money penalties, how we will address the statutory limitations on the imposition of civil money penalties, and various procedural issues, such as provisions for appellate review within HHS of a hearing decision, burden of proof, and notification of other agencies of the imposition of a civil money penalty.

In developing these regulations, several principles guided our choice of policies from among the available options. The Enforcement Rule should promote voluntary compliance with the HIPAA rules, be clear and easy to understand, provide consistent results in the interest of fairness, provide the Secretary with reasonable discretion, particularly in areas where the exercise of judgment is called for by the statute or rules, and avoid being overly prescriptive in areas where it would be helpful to gain experience with the practical impact of the HIPAA rules, to avoid unintended adverse effects.

With respect to many of the Enforcement Rule's provisions, we were also mindful that section 1176(a) requires the Secretary to apply the incorporated provisions of section

1128A to the imposition of a civil money penalty under section 1176 "in the same manner as" they apply to the imposition of civil money penalties under section 1128A itself. As we explained in the preamble to the April 17, 2003 interim final rule, the imposition of civil money penalties under section 1128A is administered by the HHS Office of the Inspector General (OIG). Accordingly, the rules proposed below, like those in the current Subpart E, generally look to the regulations of the OIG that implement section 1128A, which are codified at 42 CFR parts 1003, 1005, and 1006 (OIG regulations).

The Enforcement Rule does not adopt standards, as that term is defined and interpreted under HIPAA. Thus, the requirement for industry consultations in section 1172(c) of the Act does not apply. For the same reason, HIPAA's time frames for compliance, set forth in section 1175 of the Act, will not apply to the Enforcement Rule, when adopted in final form.

#### **IV. Provisions of the Proposed Rule**

The proposed rule would revise 45 CFR part 160 as follows: it would revise the existing subpart C, adopt a new subpart D, and revise the existing subpart E; a minor amendment of subpart A is also proposed. Subpart A, which contains general provisions, would be amended to include a definition of "person." Subpart C includes all provisions that relate to activities for determining compliance, including investigations and cooperation by covered entities. The proposed revisions of subpart C are largely technical, incorporating several provisions currently found in subpart E. We also propose to make subpart C applicable to the non-privacy HIPAA rules. The new subpart D would establish rules relating to the imposition of civil money penalties, including those which apply whether or not there is a hearing. Subpart D would also incorporate several provisions currently found in subpart E. Proposed subpart E would address the pre-hearing and hearing phases of the enforcement process. Many of the provisions of proposed subpart E were adopted by the April 17, 2003 interim final rule and would not be substantively changed, although they would, in general, be renumbered.

Finally, a conforming change to the privacy standards in subpart E of part 164 is proposed. This conforming change is discussed in connection with proposed § 160.316 at section IV.B.5 below.

#### *A. Subpart A*

We propose to amend § 160.103 to add a definition of the term "person." This would replace the definition of that term adopted by the April 17, 2003 interim final rule. We propose to place this definition in § 160.103 so that it applies to all of the HIPAA rules. The term "person" appears throughout the HIPAA rules, and the definition of the term we propose is a universal one that should work in each of the contexts in which the term "person" occurs. If the proposed placement would create problems, commenters should bring that to our attention.

In § 160.502 of the April 17, 2003 interim final rule, we defined a "person" as "a natural or legal person" to clarify, in the context of administrative subpoenas, the distinction between an entity (defined as a "legal person") and natural persons who would testify on the entity's behalf. The proposed rule would revise and expand this definition.

The statutory definition of a "person" that would otherwise apply to the HIPAA provisions is found in section 1101(3) of the Act. That section, which has been in the Act since it was originally enacted in 1935, defines a person as "an individual, a trust or estate, a partnership, or a corporation." However, Part C of title XI specifies that the class of "persons" to whom the HIPAA standards apply—health plans, certain health care providers, and health care clearinghouses—includes certain State and federal programs, which are not included in the definition of "person" in section 1101(3). For example, section 1171(2) defines a health care clearinghouse as a "public or private" entity. Under section 1171(3), a "health care provider" is defined to include a provider of services as defined in section 1861(u), for purposes of the Medicare program. The definition includes hospitals, which in turn include State or local government-owned hospitals. Finally, the definition of "health plan" in section 1171(5) includes State and federal health plans: section 1171(5)(A) includes a group health plan "as defined in section 2791(a) of the Public Health Service Act," and this definition includes State and local governmental group health plans; section 1171(5)(E) includes "the medicaid program under title XIX," which is a State program; and other provisions of section 1171(5) explicitly include as health plans various federal health plans, such as Medicare, the Federal Employee Benefit Health Plan, CHAMPUS, and the program of benefits for veterans. Section 1176, by its terms,





























































(d) There is no right to appear personally before the Board or to appeal to the Board any interlocutory ruling by the ALJ.

(e) The Board may not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the Board that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the Board may remand the matter to the ALJ for consideration of such additional evidence.

(g) The Board may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision of the ALJ is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the Board must serve on each party to the appeal a copy of the Board's decision and a statement describing the right of any respondent who is penalized to seek judicial review.

(j)(1) The Board's decision under paragraph (i) of this section, including a decision to decline review of the initial decision, becomes the final decision of the Secretary 60 days after the date of service of the Board's decision, except with respect to a decision to remand to the ALJ or if reconsideration is requested under this paragraph.

(2) The Board will reconsider its decision only if it determines that the decision contains a clear error of fact or error of law. New evidence will not be a basis for reconsideration unless the party demonstrates that the evidence is newly discovered and was not previously available.

(3) A party may file a motion for reconsideration with the Board before the date the decision becomes final under paragraph (j)(1) of this section. A motion for reconsideration must be accompanied by a written brief specifying any alleged error of fact or

law and, if the party is relying on additional evidence, explaining why the evidence was not previously available. Any party may file a brief in opposition within 15 days of receiving the motion for reconsideration and the accompanying brief unless this time limit is extended by the Board for good cause shown. Reply briefs are not permitted.

(4) The Board must rule on the motion for reconsideration not later than 30 days from the date the opposition brief is due. If the Board denies the motion, the decision issued under paragraph (i) of this section becomes the final decision of the Secretary on the date of service of the ruling. If the Board grants the motion, the Board will issue a reconsidered decision, after such procedures as the Board determines necessary to address the effect of any error. The Board's decision on reconsideration becomes the final decision of the Secretary on the date of service of the decision, except with respect to a decision to remand to the ALJ.

(5) If service of a ruling or decision issued under this section is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k)(1) A respondent's petition for judicial review must be filed within 60 days of the date on which the decision of the Board becomes the final decision of the Secretary under paragraph (j) of this section.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging the final decision of the Secretary must be sent by certified mail, return receipt requested, to the General Counsel of HHS. The petition copy must be a copy showing that it has been time-stamped by the clerk of the court when the original was filed with the court.

(3) If the General Counsel of HHS received two or more petitions within 10 days after the final decision of the Secretary, the General Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10 day period.

#### **§ 160.550 Stay of the Secretary's decision.**

(a) Pending judicial review, the respondent may file a request for stay of the effective date of any penalty with the ALJ. The request must be

accompanied by a copy of the notice of appeal filed with the federal court. The filing of the request automatically stays the effective date of the penalty until such time as the ALJ rules upon the request.

(b) The ALJ may not grant a respondent's request for stay of any penalty unless the respondent posts a bond or provides other adequate security.

(c) The ALJ must rule upon a respondent's request for stay within 10 days of receipt.

#### **§ 160.552 Harmless error.**

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the Board inconsistent with substantial justice. The ALJ and the Board at every stage of the proceeding must disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

### **PART 164—SECURITY AND PRIVACY**

1. The authority citation for part 164 is revised to read as follows:

**Authority:** 42 U.S.C. 1320d–1320d–8 and sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

2. Revise § 164.530(g) to read as follows:

#### **§ 164.530 Standard: refraining from intimidating or retaliatory acts.**

\* \* \* \* \*

(g) A covered entity—

(1) May not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the exercise by the individual of any right established, or for participation in any process provided for by this subpart, including the filing of a complaint under this section; and

(2) Must refrain from intimidation and retaliation as provided in § 160.316 of this subchapter.

\* \* \* \* \*

[FR Doc. 05–7512 Filed 4–14–05; 8:45 am]

BILLING CODE 4153–01–P