

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary****45 CFR Part 160****[CMS-0010-IFC]****RIN 0938-AM63****Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings****AGENCY:** Office of the Secretary, HHS.**ACTION:** Interim final rule; request for comments.

SUMMARY: This interim final rule establishes rules of procedure for the imposition, by the Secretary of Health and Human Services, of civil money penalties on entities that violate standards adopted by the Secretary under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). We intend that this be the first installment of a rule that we term the "Enforcement Rule." The Enforcement Rule, when issued in complete form, will set forth procedural and substantive requirements for imposition of civil money penalties. In the interim, we are issuing these rules of procedure to inform regulated entities of our approach to enforcement and to advise regulated entities of certain procedures that will be followed as we enforce the Administrative Simplification provisions of HIPAA.

DATES: *Effective Date:* This interim final rule is effective May 19, 2003.

Comment Date: Comments on the interim final rule must be received by June 16, 2003.

Expiration Date: This interim final rule will cease to be in effect on September 16, 2003.

ADDRESSES: In commenting, please refer to file code CMS-0010-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile ("FAX") transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0010-IFC, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445-G, Hubert H. Humphrey ("HHH") Building,

200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

Comments may also be submitted electronically to the following e-mail address: CMS0010.Comments@hhs.gov. For e-mail procedures, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

For further information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Karen Shaw, (202) 690-7711.

SUPPLEMENTARY INFORMATION:**Inspection of Public Comments**

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of this document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call Sharon Jones at (410) 786-9994.

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 the electronic address 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 same process described, in the preceding paragraph.

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This document is available electronically at the following web sites of the Department of Health and Human Services ("HHS" or the "Department"): <http://www.hhs.gov/ocr/hipaa/> and <http://www.cms.gov/hipaa/hipaa2>. It is also available at the web site of the Government Printing Office at <http://www.access.gpo.gov/nara/index.html>.

I. Background

This interim final rule establishes rules of procedure for the imposition, by the Secretary of Health and Human Services, of civil money penalties on entities that violate the Administrative Simplification regulations ("HIPAA rules") adopted by the Secretary under subtitle F of Title II of HIPAA ("HIPAA provisions"). We intend this interim final rule to be the first installment of a rule termed the "Enforcement Rule." The Enforcement Rule, when issued in complete form, will set forth procedural and substantive requirements for imposition of civil money penalties. In the interim, we are issuing these rules of procedure to inform regulated entities of our approach to enforcement and to advise regulated entities of certain procedures that will be followed with regard to enforcement. We intend to revise the procedural rule by the expiration date provided above.

We set out below the statutory and regulatory background of the rule, describe our approach to enforcement of the HIPAA provisions and rules in general and this rule in particular, and then discuss each section of the interim final rule. We also set out our analyses of impact and other issues under applicable law.