

**National Medicare Prescription Drug Congress
HIPAA Compliance, Enforcement and Patient Care**

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HIPAA AdminSimp -- Compliance Day Is Here
Dispassionate Enforcement or Compassionate Persecution?

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February 2004

The Administrative Simplification Subtitle of the Health Insurance Portability and Accountability Act of 1996, known as HIPAA, will revolutionize how health information is, and patients are, treated privacy-wise, security-wise, and otherwise. The transactions and data codes sets rule requirements under HIPAA, as well as privacy and security, will be included in the enforcement part of HIPAA. Because of the many changes in health care delivery that HIPAA will require, lots of anxiety has been created about penalties. Certainly few areas of the HIPAA law are more important than the enforcement provisions.

Covered entities will need to address their de facto enforcement obligations with respect to business associates in order to avoid governmental enforcement against covered entities. But a careful reading of the law should provide comfort and encouragement that notwithstanding the hype, the enforcement procedure likely will not be so bad after all. Covered entities and business associates who study and learn can be prepared to meet the challenges of the HIPAA law. Note also that not discussed further below are possible state law enforcement activities based upon HIPAA and the new national standard set by HIPAA and likely to be embraced by state Attorneys General and judges in state courts in evaluating privacy and security compliance in health care with respect to breach of contract, negligence and class action litigation.

In fact, the civil enforcement provisions of the HIPAA law evidence a Congressional mandate that civil sanctions – that is, monetary fines -- under HIPAA should be imposed leniently and in a way that will encourage compliance and not make covered entities feel as if they are being persecuted for inadvertent violations of the HIPAA law.

Although the Office for Civil Rights, to which the Department of Health and Human Services delegated the privacy enforcement responsibility, has not promulgated a proposed

enforcement rule, the HIPAA law provides a clear indication of Congressional intent regarding how enforcement should proceed. It can therefore be expected that the OCR enforcement rule will mirror the HIPAA law enforcement provisions and the enforcement language already set forth in the HIPAA final privacy rule. CMS will enforce the transactions and security rules.

These civil penalty enforcement provisions of the HIPAA law begin as follows:

"GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS

SEC. 1176. (a) GENERAL PENALTY.--

(1) IN GENERAL.--Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part 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 (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."

Thus the magnitude of a penalty assessment surely can add up, particularly for repeated transactional defaults. But Congress provided a generous and unusual opportunity in HIPAA to prevent, to deflect and possibly to avoid any penalty (*emphasis supplied*):

"(b) LIMITATIONS.--

"(1) OFFENSES OTHERWISE PUNISHABLE.--A penalty may *not* be imposed under subsection (a) with respect to an act if the act constitutes an offense punishable under section 1177 [namely, "HIPAA For Crooks": the criminal provisions].

(2) NONCOMPLIANCE NOT DISCOVERED.--A penalty may *not* be imposed under subsection (a) with respect to a provision of this part 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."

So, if a covered entity is able to satisfy the Office for Civil Rights that the covered entity did not know, and by exercising reasonable diligence would not have known, of a violation of the HIPAA law, no penalty may be imposed under (a).

And even if the covered entity did know, or by exercising reasonable diligence would have known that the covered entity would be a violator (*emphasis supplied*), the possibility of deflecting a penalty would still exist:

"(3) FAILURES DUE TO REASONABLE CAUSE.--

(A) IN GENERAL.--Except as provided in subparagraph (B), a penalty may ***not*** be imposed under subsection (a) if--

"(i) the failure to comply was due to reasonable cause and ***not*** to willful neglect; and

"(ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred."

Accordingly, no penalty would be imposed if a failure to comply with the HIPAA law – which failure a covered entity knew would be a failure – was due to reasonable cause and not to willful neglect, and the failure is corrected within thirty days after the first date on which the covered entity knew, or by exercising reasonable diligence could have known (whether or not, it appears, there was actual knowledge on the part of the covered entity) that the failure occurred. So, after receiving a complaint from the Office for Civil Rights, the possibility exists that a covered entity could promptly correct the problem and thereby avoid any penalties.

And more opportunities will exist to have penalties abated (***emphasis supplied***):

"(B) EXTENSION OF PERIOD.--

(i) NO PENALTY.--The period referred to in subparagraph (A)(ii) ***may be extended*** as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

(ii) ASSISTANCE.--If the Secretary determines that a person failed to comply because the person was ***unable*** to comply, the Secretary may provide ***technical assistance*** to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary."

So, the thirty-day correction and cure period could be extended by the Office for Civil Rights and during that additional period, the Office for Civil Rights could provide technical assistance. This could mean that the violation would be able to be corrected without any penalty being imposed by the OCR.

And finally, a penalty may be reduced (***emphasis supplied***):

"(4) REDUCTION.--In the case of a failure to comply which is due to ***reasonable cause*** and ***not*** to willful neglect, any penalty under subsection (a) that is ***not*** entirely waived under paragraph (3) ***may be waived*** to the extent that the payment of such penalty would be excessive relative to the compliance failure involved."

Thus even if a penalty was going to be imposed, the Office for Civil Rights could reduce the penalty if deemed to be "excessive." As this review of the enforcement part of the HIPAA law indicates, Congress would seem to have intended the civil enforcement procedure to

be a conciliatory and encouraging process and not a process of persecution, because there are so many avenues for “mercy” to be shown by OCR and CMS (and maybe the Department of Justice).

Although we have seen the preliminary rules that are being prepared by the Office for Civil Rights and CMS now, we can only hope that the final enforcement rules adhere to what Congress said in HIPAA. And regardless, the courts are bound to respect the HIPAA law.

We don’t know what will be done regarding the criminal penalties under HIPAA. Perhaps the Department of Justice will offer some guidance regarding what “knowingly” and what “intent” will be viewed by the DOJ as meaning, under the HIPAA law, when HIPAA criminal prosecutions occur. In any event, the criminal part of HIPAA penalties follows:

"WRONGFUL DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

SEC. 1177. (a) OFFENSE.--A person who knowingly and in violation of this part--

- (1) uses or causes to be used a unique health identifier;
 - (2) obtains individually identifiable health information relating to an individual; or
 - (3) discloses individually identifiable health information to another person,
- shall be punished as provided in subsection (b).

(b) PENALTIES.--A person described in subsection (a) shall--

- (1) be fined not more than \$50,000, imprisoned not more than 1 year, or both;
- (2) if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and
- (3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both.”

Questions raised by “HIPAA for crooks” include what “knowingly” will be found to mean under HIPAA; what “intent” will be found to mean under HIPAA; whether the confusion that arose under the anti-fraud and anti-kickback laws in health care relative to “the sole purpose” or “only one of several purposes” will find its way into HIPAA criminal enforcement; how the law of false claims, conspiracy and obstruction of justice and other such laws will relate to HIPAA enforcement; and how the Office for Civil Rights, CMS and federal prosecutors will determine which alleged violations are treated as civil violations and which alleged violations are treated as criminal violations. Surely all covered entities will want to have corporate compliance programs established and maintained in a manner consistent with the Federal Sentencing Guidelines, in order to endeavor either to avoid or to reduce the severity of criminal penalties.

With all the foregoing in mind, certainly the sooner covered entities begin the process of getting ready for HIPAA enforcement, the better. The key to avoiding penalties will be having

policies and procedures in place that evidence a good faith intention to endeavor to comply with the HIPAA law including US Sentencing Commission corporate compliance programs. Recall also that federal conspiracy, aiding and abetting, and other laws can likely apply to those who are not covered by HIPAA directly.

A summary of some of what to do to endeavor to avoid HIPAA penalties follows:

- Use reasonable diligence to know as much as you can about HIPAA
- Establish policies that evidence a reasonable approach to prevention
- Don't be neglectful, willfully or otherwise, or reckless
- Try to cure breaches within 30 days
- Ask for an extension if necessary
- Seek technical advice if necessary
- Be sure to document everything done in furtherance of HIPAA corporate compliance, preparation, implementation, education and training.

Supplement

There has been a distressing development with respect to HIPAA Administrative Simplification Subtitle enforcement recently. An Assistant US Attorney, and several speakers at national events, have been talking about the question whether criminal sanctions can be imposed, under or with respect to HIPAA, against someone or some entity other than a HIPAA covered entity, including a non-covered entity business associate or a covered entity employee.

Some appear to believe that a "person" under HIPAA criminal provisions includes a non-covered entity, contrary to the position taken by the Office for Civil Rights with respect to the civil enforcement provisions of HIPAA. Indeed, there is now much talk about the risk of federal prosecution, either directly under HIPAA, or indirectly via a federal anticonspiracy, or antiaiding and abetting, or antiobstruction of justice statute, might be possible against, by way of example, non-business associate contractor or vendor, a landlord, a vendor, a business associate, or an employee of a covered entity, a contractor or vendor, a landlord, a lender, or a business associate, or anyone else. And note that the HIPAA criminal provision does not require a prosecutor to prove that an alleged violation was "willful" because merely "knowingly" violating the law can be alleged; as can violations with "intent" (but without willfulness being a necessary part of the government's prosecution), thus making a prosecutor's task much easier than under the anti-fraud and abuse laws, by way of example.

Sometimes it may be to the benefit of a non-HIPAA covered entity to enter into a HIPAA business associate agreement; and it is always wise to determine whether, when receiving medical information, a so-called "pathway" for permission under HIPAA exists for the disseminator to give the receiver of the information what in the disseminator's possession is HIPAA protected health information, in order to address any criminal violation allegation risk.

Many had thought that HIPAA enforcement was limited to HIPAA covered entities, but some now disagree publicly and talk about it regularly. This is yet another reason that a U. S. Sentencing Commission Guidelines corporate compliance program should be initiated and maintained by each and every nursing home, health plan, third party administrator, assisted living residence, home health agency, and management company, and others involved in health care as well. Such a program can provide extraordinary benefits, including abatement of penalties or cessation of prosecution.

HIPAA enforcement continues to be a complex and challenge area of concern, but hopefully the Department of Justice will clarify the criminal prosecution issue discussed above and otherwise provide guidelines for understanding HIPAA criminal enforcement.

ASG/tt

February 2004

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"(2) PROCEDURES.--The provisions of section 1128A (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.

"(b) LIMITATIONS.--

"(1) OFFENSES OTHERWISE PUNISHABLE.--A penalty may not be imposed under subsection (a) with respect to an act if the act constitutes an offense punishable under section 1177.

"(2) NONCOMPLIANCE NOT DISCOVERED.--A penalty may not be imposed under subsection (a) with respect to a provision of this part 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.

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"(i) NO PENALTY.--The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

"(ii) ASSISTANCE.--If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary.

"(4) REDUCTION.--In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

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"**SEC. 1177.** (a) OFFENSE.--A person who knowingly and in violation of this part--

"(1) uses or causes to be used a unique health identifier;

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shall be punished as provided in subsection (b).

"(b) PENALTIES.--A person described in subsection (a) shall--

"(1) be fined not more than \$50,000, imprisoned not more than 1 year, or both;

"(2) if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and

"(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both.

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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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.

Statutory Background

HIPAA became law in 1996 (Public Law 104-191). Subtitle F of Title II of HIPAA, entitled "Administrative Simplification," requires the Secretary of HHS 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 (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 access to that information, the statute also requires national standards to protect the security and privacy of the information.

The HIPAA provisions, by statute, 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 1320d-2(a)(1) of this title.

42 U.S.C. 1320d-1(a)

Collectively, these entities are known as "covered entities." The statute requires certain consultations with industry as a predicate to the issuance of standards and gives most covered entities 2 years (small health plans have 3 years) to come into compliance with the standards, once adopted. 42 U.S.C. 1320d-1(c), 42 U.S.C. 1320d-4(b). The statute establishes civil money penalties and criminal penalties for violations. 42 U.S.C. 1320d-5, 42 U.S.C. 1320d-6. HHS will enforce the civil money penalties, while the U.S. Department of Justice will enforce the criminal penalties.

HIPAA's civil money penalty ("CMP") provision authorizes the Secretary to impose CMPs, 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.

42 U.S.C. 1320d-5(a)

Subsection (b) of section 1320d-5 sets out a number of substantive limitations on the Secretary's authority to impose CMPs. First, a CMP may not be imposed with respect to an act that "constitutes an offense punishable" under the criminal penalty provision. 42 U.S.C. 1320d-5(b)(1). Second, a CMP 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." 42 U.S.C. 1320d-5(b)(2). Third, a CMP 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. 42 U.S.C. 1320d-5(b)(3). Finally, a CMP may be reduced, if not waived entirely, "to the extent that the payment of such penalty would be excessive relative to the compliance failure involved." 42 U.S.C. 1320d-5(b)(4).

As noted above, HIPAA incorporates by reference certain provisions of section 1128A of the Act (42 U.S.C. 1320a-7a). Those provisions, as relevant here, provide a number of procedural requirements with respect to the imposition of CMPs. The Secretary may not initiate a CMP action "later than six years after the date" of the occurrence that forms the basis for the CMP. The Secretary may initiate a CMP action by serving notice "in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure." 42 U.S.C. 1320a-7a(c)(1). A person upon whom the Secretary seeks to impose a CMP 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." 42 U.S.C. 1320a-7a(c)(2). There are provisions authorizing the sanctions the hearing officer may impose for misconduct in connection with the CMP proceeding, judicial review of the Secretary's determination in the United States Court of Appeals for the circuit in which the person resides, and the

issuance of subpoenas by the Secretary and the enforcement of those subpoenas. 42 U.S.C. 1320a-7a(c)(4), (e), (j). These provisions are discussed more fully below.

Regulatory Background

As noted above, HIPAA requires the Secretary of HHS to adopt a number of national standards to facilitate the exchange of certain health information. The Secretary has already issued a number of these HIPAA standards by regulation. We summarize these HIPAA Administrative Simplification rules below.

- Regulations implementing the statutory requirement for the adoption of standards for transactions and code sets ("Transactions Rule") were published on August 17, 2000 (65 FR 50312), and were recently modified (68 FR 8381, February 20, 2003). 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, 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 must be in compliance with the Transactions Rule, as modified, by October 16, 2003.

- Regulations implementing the statutory requirement for the adoption of privacy standards were published on December 28, 2000 (65 FR 82462) ("Privacy Rule"). The Privacy Rule became effective on April 14, 2001, with an initial compliance date of April 14, 2003 for covered entities other than small health plans. Modifications to the Privacy Rule were published on August 14, 2002 (67 FR 53182), and compliance with the modified privacy standards is required by the initial compliance date, April 14, 2003, for those covered entities that must comply by that date.

- Regulations implementing the statutory requirement for the adoption of an employer identifier standard were published on May 31, 2002 (67 FR 38009) and became effective on July 30, 2002. The initial compliance date is July 30, 2004 for most covered entities; small health plans have until July 30, 2005 to come into compliance.

- Regulations implementing the statutory requirement for the adoption of security standards were published on February 20, 2003 (68 FR 8334). They

are effective on April 21, 2003, and 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 comply.

The authority for administering and enforcing compliance with the Privacy Rule has been delegated to the Office for Civil Rights ("OCR") of HHS.¹ Responsibility for administering and enforcing the remaining HIPAA rules has been assigned to the Centers for Medicare & Medicaid Services ("CMS").²

II. General Approach

As the discussion above makes clear, the duty to comply with certain of the HIPAA rules is now a reality for many, if not most, covered entities. The immediacy of the compliance obligation brings with it the issue of how these rules will be enforced. Accordingly, we lay out below our general approach to enforcement. We then discuss how the rules below will fit in with the projected Enforcement Rule in its entirety and the basic approach of the interim final rule.

HHS's General Approach to Enforcement

The Department intends to seek and promote voluntary compliance with the rules promulgated to carry out the HIPAA provisions. With respect to the Privacy Rule, OCR has developed and is continuing to produce guidance and a wide array of other technical assistance materials to help covered entities effectively implement the Privacy Rule. These materials are available on the OCR Privacy web site at <http://www.hhs.gov/ocr/hipaa>. These efforts will continue after the April 14, 2003 compliance date, as OCR learns from its compliance activities and from those who are implementing the Privacy Rule where additional guidance and assistance are needed. Other components of the Department are also developing guidance and technical assistance on the Privacy Rule for their partners.

This approach reflects the requirements in 45 CFR part 160, subpart C, that, to the extent practicable, OCR will seek the cooperation of covered entities in obtaining compliance with the Privacy Rule, and may provide technical assistance to help covered entities voluntarily comply with the Rule. See 45 CFR 160.304. As further provided in 45 CFR 160.312(a)(2), OCR will seek to resolve

matters by informal means before issuing findings of non-compliance, under its authority to investigate and resolve complaints, and to engage in compliance reviews.

With respect to enforcement of the remainder of the HIPAA rules, the enforcement approach of CMS is similar. "Enforcement activities will focus on obtaining voluntary compliance through technical assistance. The process will be primarily complaint driven and will consist of progressive steps that will provide opportunities to demonstrate compliance or submit a corrective action plan." HHS press release of October 15, 2002, announcing assignment of enforcement responsibility to CMS. CMS provides a wide variety of technical assistance and informational materials on its Web site, at <http://www.cms.gov/hipaa/hipaa2>.

HHS's Approach to the Enforcement Rule

As noted above, HHS intends to issue an Enforcement Rule in furtherance of its implementation of 42 U.S.C. 1320d-5. The Enforcement Rule, in its entirety, will address a number of substantive issues relating to the imposition of CMPs under section 1320d-5, such as the Department's policies for determining violations and calculating CMPs. In addition, the Enforcement Rule will establish various procedures for the imposition of CMPs, including the procedures for providing notice and a hearing on the Secretary's determination to impose a CMP. This interim final rule implements this latter aspect of the Enforcement Rule.

Administrative Procedure Act

We recognize that under the Administrative Procedure Act ("APA") most of the above-described provisions of the Enforcement Rule must be promulgated through notice-and-comment rulemaking. We intend to do so. However, to allow covered entities and the public to be informed as soon as possible of procedural requirements that will apply as compliance proceeds, we are expediting the publication of these procedural rules in final form. These rules set out the procedures for provision by the agency of the statutorily required notice and hearing and procedures for issuing administrative subpoenas. Such provisions are exempted from the requirement for notice-and-comment rulemaking under the "rules of agency * * * procedure, or practice" exemption at 5 U.S.C. 553(b)(3)(A). Even though notice-and-comment rulemaking is, therefore, not required with respect

to the procedural rules adopted below, HHS is interested in input from the public, and thus is requesting public comment on them. We expect to augment these procedural rules with provisions that, while related to procedure, are substantive in nature. We anticipate including those provisions in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule. In any event, we plan to revise the procedural rule by the expiration date.

Approach of the Interim Final Rule

As noted above, the provisions of 42 U.S.C. 1320a-7a apply to the imposition of a CMP under 42 U.S.C. 1320d-5 "in the same manner as" they apply to the imposition of CMPs under section 1320a-7a itself. Within HHS, section 1320a-7a is implemented by the Office of Inspector General ("OIG") and, as pertinent here, through the OIG regulations that are codified at 42 CFR parts 1003, 1005, and 1006. We have used the OIG regulations as the platform for the rules below for two reasons. First, we read the "in the same manner as" language of the statute as indicating that the procedures for the imposition of CMPs under 42 U.S.C. 1320d-5 should be, in general, similar to those used by the OIG under 42 U.S.C. 1320a-7a. Second, HHS and much of the health care industry have operated under the OIG regulations implementing section 1320a-7a for more than a decade. There is, thus, a significant body of experience with, and understanding of, the OIG procedural rules, both within HHS and in a large part of the regulated universe. Based on this experience, we believe that the rules below will be workable and promote the efficient resolution of cases where the Secretary's proposed imposition of a CMP is challenged.

Accordingly, the rules below are based upon, and are in many respects the same as, the OIG regulations at 42 CFR parts 1003, 1005, and 1006. We have adapted, re-ordered, or combined the OIG language in a number of places for clarity of presentation or to reflect concepts peculiar to the HIPAA provisions or rules. To avoid confusion, we have also employed certain language usages in order to make the usage in the rules below consistent with that in the other HIPAA rules (for example, for mandatory duties, "must" instead of "will" or "shall"; for discretionary duties, "may" instead of "has the authority to"). We do not discuss those nonsubstantive changes below. Where we have materially changed the language of the OIG regulations, however, we discuss our reasons for doing so.

¹ On December 28, 2000, the Secretary delegated to the Director of OCR authority to enforce, administer, interpret, and implement the Privacy Rule. 65 FR 82381.

² HHS press release of October 15, 2002.

We also note that the rules below, as well as the Enforcement Rule as a whole, are not HIPAA standards, and thus the requirement for industry consultations in 42 U.S.C. 1320d-1(c) does not apply. Therefore, we have not engaged in such consultations with respect to the interim final rule below. For the same reason, HIPAA's timeframes for compliance (42 U.S.C. 1320d-4) do not apply to the interim final rule below.

III. Provisions of the Interim Final Rule

We discuss the interim final rule on a provision-by-provision basis below. As a general matter, we note that the provisions adopted are in many cases the same as or similar to analogous provisions of the OIG regulations. Where we have closely followed the OIG regulations, we have done so because we believe that these procedures work and satisfactorily address issues of concern addressed in prior rulemakings by the OIG. We do not reiterate those concerns, or their resolutions, here, but they have informed our decisionmaking on these rules.

Applicability

Section 160.500 states that the procedures established by this subpart are applicable to investigations, imposition of penalties, and hearings conducted as a result of a proposed imposition of civil money penalties. We use "applicability" instead of the basis and purpose statement of the OIG regulations, because we have followed a different format in the remainder of the HIPAA rules and wish to be consistent with that approach. Furthermore, this preamble constitutes the requisite basis and purpose statement.

Definitions

Definitions for the terms used in this new subpart that are not set forth elsewhere in part 160 are included in § 160.502.

- *ALJ* means an administrative law judge, the natural person who presides at and conducts a hearing requested by a respondent pursuant to this subpart.

- *Entity* means a legal person that is not a natural person. The term is intended to include all manner of organizations, such as corporations, associations, partnerships, and other entities that have a legal existence, other than a natural person. The term "entity" is necessary for this subpart to distinguish such legal persons from natural persons, because certain procedures in this rule, such as those involving subpoenas, are different for

entities than they are for natural persons.

The term "entity" should not be confused with the regulatory term "covered entity." The latter term, which is defined at § 160.103, denotes those entities to which the HIPAA rules apply. The term "entity," as used in this interim final rule, describes a broader class of persons. For example, subpoenas could be directed to entities that are not covered entities under § 160.504 below.

- *Penalty* is defined to mean the amount calculated under 42 U.S.C. 1320d-5. This section of HIPAA sets a penalty of not more than \$100 for each violation, subject to a calendar-year cap of \$25,000 for all violations of an identical requirement or prohibition. The term includes the plural form of the word.

- *Person* is defined to mean a natural person or a legal person (such as an entity described above). The term includes, but is not limited to, covered entities. The term is broader than "covered entities," because some sections of the provisions below by their nature apply to persons other than covered entities in certain circumstances. For example, the provisions for subpoenas relate to natural persons who will be called to testify, and many, if not most, of these persons will not be covered entities. While the term "person" is used generically throughout the HIPAA rules, we have provided a definition of the term "person" for use in this subpart to provide a clear and efficient way of permitting these distinctions to be drawn. This definition is not intended to define "person" as that term is used in HIPAA.

- *Respondent* means a person (as defined herein) upon whom a penalty has been imposed, whether proposed or final, by the Secretary. Respondents will necessarily be covered entities. See the discussion below of § 160.506.

Investigational Subpoenas and Inquiries

Section 160.504 provides procedures for the issuance of subpoenas to both named persons and unnamed persons associated with subpoenaed entities. A subpoenaed entity is required to name a natural person or persons knowledgeable about the subjects on which information is sought. This procedure is similar to that provided for in Rule 30(b)(6) of the Federal Rules of Civil Procedure. Subpoenas issued under this section may require either testimony or the production of evidence.

The procedures adopted in this section are similar to those in 42 CFR

part 1006. Like § 1006.4, § 160.504 provides that investigational inquiries are non-public proceedings conducted by the Secretary. A witness is entitled to be represented by an attorney during an investigational inquiry. However, while this section provides for the taking of witness testimony, it does not include all of the provisions of § 1006.4 regarding claims of privilege or objections, clarification of answers by the witness, corrections to the transcript, or the use by the Secretary of testimony or evidence obtained in an investigational inquiry. We anticipate addressing these issues in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule.

Basis for Penalty

Under § 160.506, CMPs are imposed for violations of 42 U.S.C. 1320d-1320d-8, section 264 of Pub. L. 104-191, or the implementing regulations at parts 160, 162 or 164 of this subchapter. CMPs may be imposed only on covered entities. As we have stated in prior rulemakings, it is the view of HHS that only covered entities are subject to the HIPAA provisions and rules. Thus, only covered entities can be liable for a CMP under 42 U.S.C. 1320d-5. See, for example, 67 FR 53252. Regulatory definition of what constitutes a violation requiring imposition of a CMP will be addressed in the subsequent notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule. This section, thus, functions to clarify and establish the linkage of the procedural rules to the criteria and processes for the substantive determinations that are to be developed through notice-and-comment rulemaking.

Amount of Penalty

Under § 160.508, the amount of the penalty is determined in accordance with 42 U.S.C. 1320d-5 and the provisions of this part. We anticipate addressing how penalties will be determined in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule. This section thus functions to clarify and establish the linkage of the procedural rules to the criteria and processes for the substantive determinations that are still to be developed.

Authority To Settle

Section 160.510 enunciates the authority of the Secretary to settle any issue or case or to compromise any penalty during the process addressed in this subpart. This authority is the same

as that set forth in § 1003.106(f)(3) of the OIG regulations and implements statutory authority provided by the first sentence of 42 U.S.C. 1320a–7a(f). It provides for flexible resolution of cases and issues between the Secretary and a respondent. We anticipate that factors to be taken into account in determinations regarding the amount of penalties, like those set forth in § 1003.106(a) through § 1003.106(e) of the OIG regulations, will be addressed in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule. This section, like the preceding sections, thus serves to link substantive provisions yet to be developed into the procedural process put in place by the rules below.

Notice of Proposed Determination

Section 160.514 sets forth the requirements for the notice to a respondent sent when the Secretary proposes a penalty under this part. These requirements are substantially the same as those in § 1003.109 of the OIG regulations. Statistical sampling provisions, however, are not included in this section at this time. We anticipate addressing statistical sampling in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule.

Failure To Request a Hearing

Under § 160.516, when a respondent does not timely request a hearing on a proposed penalty, the Secretary will impose the proposed penalty or any less severe penalty permitted by 42 U.S.C. 1320d–5. The penalty is then final, and the respondent has no right to appeal a penalty imposed under these circumstances. This section is similar to § 1003.110 of the OIG regulations. This section simply states the necessary consequence of a respondent's failure to exercise the right to a hearing.

Collection of Penalty

Section 160.518 provides that once a determination to impose a penalty has become final, the penalty must be collected by the Secretary. The penalty may be recovered in a civil action in United States District Court, or by deduction from any sum owed to the respondent by the United States or a State agency. If the Secretary seeks to recover the penalty in a civil action, the respondent is prohibited from raising in that proceeding any matter that was raised or could have been raised in a hearing or appeal under this subpart. These provisions restate statutory provisions at 42 U.S.C. 1320a–7a(f) and (g).

Limitations

Section 160.522 sets forth the 6-year limitations period provided for by 42 U.S.C. 1320a–7a(c)(1). The section includes only the part of the statutory language that is relevant to the imposition of penalties in the context of the HIPAA rules. The statutory language concerning the “claim was presented” and “request for payment” are not included, because these phrases pertain to violations described in the parts of 42 U.S.C. 1320a–7a that are not incorporated by reference into 42 U.S.C. 1320d–5. Section 160.522 accordingly differs in this respect from § 1003.132 of the OIG regulations.

Hearing Before an ALJ

The requirements for a hearing request are contained in § 160.526. The parties to a hearing are the party against whom the Secretary has proposed a penalty (the respondent) and the Secretary. We recognize that the HHS party will be OCR and/or CMS. We have not described the party more specifically here, however, for several reasons. First, it is not feasible to parse out which component will actually appear for the Secretary, because the appropriate component (if both are not) will depend on the facts of the case. Second, the designation of the proper party component can be handled through the normal delegation process. Third, similar issues arise in other sections of this interim final rule (*see*, for example, § 160.514), and they are handled this way in those sections as well. A consistent approach is less confusing and more manageable.

The respondent may request a hearing following receipt of a notice of a proposed determination. The request for a hearing must be in writing. If the respondent fails to timely request a hearing, or thereafter withdraws or abandons the request for a hearing, or if the hearing request fails to raise any issue that may properly be addressed in a hearing, the administrative law judge (ALJ) is required to dismiss the hearing request. In such a case, the penalty becomes final, with no further appeal permitted.

Paragraph (c) of § 160.526 differs slightly from the corresponding paragraph in § 1005.2. Our provision requires specific admissions, denials or explanations in a respondent's hearing request. The degree of specificity required generally parallels the requirements applicable to the notice of proposed determination at § 160.514. Based on experience in prior administrative hearings, we believe that such additional specificity will assist

the parties and the ALJ in ascertaining the findings of fact and conclusions of law that are actually in dispute in a case. This certainty will promote procedural regularity and permit more timely and efficient resolution of the case between the parties or adjudication of the case by the ALJ.

Rights of Parties; Authority of the ALJ

The provisions in § 160.528 and § 160.530 list the rights of the parties and the authorities of the ALJ not specifically provided elsewhere in this part. These sections are based upon § 1005.3 and § 1005.4 of the OIG regulations, but do not address attorneys' fees under 42 U.S.C. 406 or any limitation on the ALJ's authority to review the Secretary's exercise of discretion to impose a penalty. We anticipate addressing such issues in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule. We have clarified in § 160.530 that a summary judgment decision constitutes a hearing on the record.

Ex-parte Contacts

The provisions of § 160.532 are designed to ensure the fairness of the hearing by prohibiting ex-parte contacts with the ALJ on matters in issue. Routine questions about administrative procedures or the status of the case are permitted. These requirements are generally applicable to administrative hearings under 5 U.S.C. 554(d)(1) and are the same as those in § 1005.5 of the OIG regulations.

Prehearing Conferences

The provisions of § 160.534 closely track the provisions of the analogous OIG regulation at § 1005.6. The ALJ is required to schedule at least one prehearing conference, in order to narrow the issues to be addressed at the hearing and thus expedite the formal hearing process. Matters that may be discussed at a prehearing conference are identified and include the protection of the privacy of individually identifiable health information submitted into evidence, if appropriate.

Settlement

The Secretary has exclusive authority to settle any issue or case at any time and need not obtain the consent of the ALJ. This provision in § 160.536 tracks § 1003.126 of the OIG regulations.

Discovery

Consistent with the approach of § 1005.7 of the OIG regulations, § 160.538 provides for limited discovery in the form of the production for

inspection and copying of documents that are relevant and material to the issues before the ALJ. Like the OIG, we are specifically not authorizing other forms of discovery, such as depositions and interrogatories. Prehearing discovery is not provided for under the APA and is rarely available in administrative hearings. Full-scale discovery is inappropriate in administrative hearings, as it would unduly delay the streamlined administrative process. These regulations do, however, provide for exchange of relevant and material documents, as well as the exchange of witness lists, prior witness statements, and exhibits before the hearing, as provided in § 160.540 of the rule.

Exchange of Witness Lists, Statements, and Exhibits

Section 160.540 provides for the prehearing exchange of certain documents, including witness lists, copies of prior statements of witnesses, and copies of hearing exhibits.

Paragraph (a) of this section differs slightly from the corresponding paragraph in § 1005.8 of the OIG regulations, in that it provides for the exchange of witness lists, witness statements and exhibits at least 15 days before the hearing, but also allows the ALJ to order an earlier exchange if he or she deems it necessary.

Paragraph (b) provides that the ALJ must exclude witnesses and documents offered by a party that did not provide those materials before the hearing, except where there is good cause for the failure, or where there is not substantial prejudice to the objecting party. As with the OIG regulations, this provision is mandatory and serves to prevent the parties from litigating by surprise and to promote the procedural regularity of the hearing. Paragraph (b)(3) provides that where the witnesses or exhibits are not excluded, the ALJ must recess the hearing for a reasonable time to allow the objecting party the opportunity to prepare and respond to them, unless the objecting party agrees to proceed. This paragraph differs from § 1005.8(b)(3) of the OIG regulations, under which the decision to postpone the hearing is within the ALJ's discretion. This modification is equally beneficial to both parties to a hearing and will reduce the potential for unfair surprise during a hearing. It is preferable to the OIG provision that grants the ALJ discretion, because it provides clear notice to the parties and clear direction to the ALJ in the event witnesses or exhibits are not excluded.

Finally, any documents exchanged before the hearing would be deemed

authentic for purposes of admissibility at the hearing unless a party objected to a particular document before the hearing.

Subpoenas for Attendance at the Hearing

Section 160.542 outlines procedures for the ALJ to issue, and for parties and prospective witnesses to contest, subpoenas to appear at the hearing. Subpoenas are authorized by 42 U.S.C. 1320a-7a(j) and may be issued by an ALJ pursuant to 5 U.S.C. 556(c). Either party may request that the ALJ issue a subpoena, if the appearance of a witness and the testimony are reasonably necessary for the party's case. The subpoena procedures here are the same as those at § 1005.9 of the OIG regulations.

Fees

Section 160.544 provides for the payment of witness fees by the party requesting a subpoena. This section tracks § 1005.10 of the OIG regulations.

Form, Filing, and Service of Papers; Computation of Time

Section 160.546 sets forth requirements for documents filed with the ALJ. Section 160.548 outlines the method for computing time periods under this part. These provisions track, respectively, § 1005.11 and § 1005.12 of the OIG regulations.

Motions

The provisions of § 160.550 set forth requirements for the content of motions and the time allowed for responses. This section tracks § 1005.13 of the OIG regulations.

Sanctions

Section 160.552 outlines the sanctions an ALJ may impose on parties and their representatives for failing to comply with an order or procedure, failing to defend an action, or other misconduct. These sanctions are specifically provided for by the statutory provision at 42 U.S.C. 1320a-7a(c)(4). This section tracks § 1005.14 of the OIG regulations.

The Hearing

Section 160.554 provides for a public hearing on the record. It allows for the admission of rebuttal evidence not exchanged before the hearing.

This section is based upon § 1005.15 of the OIG regulations, which also addresses the burden of proof at the hearing, and provides that the hearing is not limited to the items and information set forth in the notice of proposed determination. We anticipate addressing those issues in the notice-and-comment

rulemaking that we plan for the remainder of the Enforcement Rule.

Witnesses

Under § 160.556, the ALJ may allow testimony to be admitted in the form of a written statement or deposition so long as the opposing party has a sufficient opportunity to subpoena the person whose statement is being offered. This section also allows an HHS investigator or other expert to be a witness, in addition to assisting counsel for the Secretary at counsel table during the hearing. These provisions closely track § 1005.16 of the OIG regulations.

Evidence

With certain limited exceptions, the Federal Rules of Evidence are not binding on the ALJ. However, the ALJ may apply the Federal Rules of Evidence to exclude unreliable evidence. Section 160.558 is substantially similar to § 1005.17 of the OIG regulations, but does not contain a paragraph corresponding to § 1005.17(j) regarding evidence as to the respondent's willingness and/or ability to enter into a corrective action plan. We anticipate addressing this issue in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule.

The Record

Section 160.560 provides for recording and transcription of the hearing, and for the record to be available for inspection and copying by any person. For good cause, the ALJ may order appropriate redactions made to the record. These provisions track § 1005.18 of the OIG regulations.

Post-Hearing Briefs

Section 160.562 provides that the ALJ has discretion to order post-hearing briefs, although the parties may file post-hearing briefs in any event if they desire. This section tracks § 1005.19 of the OIG regulations.

ALJ Decision

Section 160.564 provides that not later than 60 days after the filing of post-hearing briefs, the ALJ shall serve on the parties a decision making specific findings of fact and conclusions of law. The ALJ's decision is the final decision of the Secretary.

Section 1005.20 of the OIG regulations, upon which this section is based, provides for the ALJ to issue an "initial decision," which is then reviewable by the Departmental Appeals Board if properly appealed. We have not provided for a second level of administrative review in this rule, and

thus this section refers to the "ALJ decision" rather than to an "initial decision." Neither section 1320a-7a nor the APA requires a second level of administrative review, although this is generally available in Department hearings. We anticipate addressing the issue of further administrative review in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule.

Judicial Review; Stay of ALJ Decision

Section 160.568 provides for judicial review of penalties imposed under this part, as authorized by 42 U.S.C. 1320a-7a(e). Section 160.570 provides that a respondent may request a stay of the effective date of a penalty pending judicial review. This section tracks § 1005.22(b) of the OIG regulations.

IV. Impact Statement and Other Required Analyses

Paperwork Reduction Act

We reviewed this interim final rule to determine whether it invokes issues that would subject it to the Paperwork Reduction Act (PRA). While the PRA applies to agencies and collections of information conducted or sponsored by those agencies, 5 CFR 1320.4(a) exempts collections of information that occur "during the conduct of . . . an administrative action, investigation, or audit involving an agency against specific individuals or entities," except for investigations or audits "undertaken with reference to a category of individual or entities such as a class of licensees or an entire industry." The rules adopted below come squarely within this exemption, as they deal entirely with administrative investigations and actions against specific individuals or entities. Therefore, we have determined that the PRA does not apply to this rule.

Executive Order 12866; Unfunded Mandates Reform Act of 1995; Regulatory Flexibility Act; Small Business Regulatory Enforcement Fairness Act of 1996; Executive Order 13132

We have examined the impacts of this rule as required by E.O. 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and E.O. 13132.

E.O. 12866 (as amended by E.O. 13258, which merely reassigns responsibility of duties) 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 in any 1 year). HHS has concluded that this rule should be treated as a "significant regulatory action" within the meaning of section 3(f)(4) of E.O. 12866 because the HIPAA provisions to be enforced have extremely broad implications for the nation's health care system, and because of the novel issues presented by, and the uncertainties surrounding, compliance among covered entities. However, E.O. 12866 requires a full economic impact analysis only for "economically significant" rules, which are defined in section 3(f)(1) of the order as rules that may "have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." Because this rule is procedural in nature, it has no intrinsic significant economic impact; therefore, no economic impact analysis has been prepared.

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. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million in any 1 year. This interim final rule is purely procedural in nature and, as such, HHS has determined that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation simply implements procedures necessitated by enactment of HIPAA, in order to allow the Secretary to enforce subtitle F of Title II of HIPAA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 (proposed documents)/604 (final documents) of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not have a

significant impact on small rural hospitals. The rule implements procedures necessary for the Secretary to enforce subtitle F of Title II of HIPAA.

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 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. Because this rule is procedural in nature, it will not impose a burden large enough to require a section 202 statement under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*).

E.O. 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule does not have "Federalism implications." The rule does not have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government" and therefore is not subject to E.O. 13132 (Federalism).

The Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) requires that rules that will have an impact on the economy of \$100 million or more per annum be submitted for Congressional review. Because this rule is procedural in nature, it will not impose a burden large enough to require Congressional review under the statute.

List of Subjects in 45 CFR Part 160

Administrative practice and procedure, Computer technology, Healthcare, Health facilities, Health insurance, Health records, Hospitals, Investigations, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter C, part 160 as set forth below.

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 160 is revised to read as follows:

Authority: 42 U.S.C. 1302(a), 42 U.S.C. 1320d-1320d-8, and sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(*note*)).

■ 2. Add a new subpart E to part 160 to read as follows:

Subpart E—Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings

Sec.	
160.500	Applicability.
160.502	Definitions.
160.504	Investigational subpoenas and inquiries.
160.506	Basis for penalty.
160.508	Amount of penalty.
160.510	Authority to settle.
160.512	[Reserved]
160.514	Notice of proposed determination.
160.516	Failure to request a hearing.
160.518	Collection of penalty.
160.520	[Reserved]
160.522	Limitations.
160.524	[Reserved]
160.526	Hearing before an ALJ.
160.528	Rights of parties.
160.530	Authority of the ALJ.
160.532	Ex parte contacts.
160.534	Prehearing conferences.
160.536	Settlement.
160.538	Discovery.
160.540	Exchange of witness lists, witness statements, and exhibits.
160.542	Subpoenas for attendance at hearing.
160.544	Fees.
160.546	Form, filing, and service of papers.
160.548	Computation of time.
160.550	Motions.
160.552	Sanctions.
160.554	The hearing.
160.556	Witnesses.
160.558	Evidence.
160.560	The record.
160.562	Post hearing briefs.
160.564	ALJ decision.
160.566	[Reserved]
160.568	Judicial review.
160.570	Stay of ALJ decision.
160.572	[Reserved]

Subpart E—Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings

§ 160.500 Applicability.

This subpart applies to investigations conducted, penalties imposed, hearings conducted, and subpoenas issued, under the authority of 42 U.S.C. 1320d-5, relating to the imposition of civil money penalties.

§ 160.502 Definitions.

For the purposes of this subpart:

ALJ means Administrative Law Judge.

Entity means a legal person.

Penalty means the amount calculated under 42 U.S.C. 1320d-5, as determined in accordance with this part, and includes the plural of that term.

Person means a natural or legal person.

Respondent means the person upon whom the Secretary has imposed, or proposes to impose, a penalty.

§ 160.504 Investigational subpoenas and inquiries.

(a) The provisions of this paragraph govern subpoenas issued by the Secretary in accordance with 42 U.S.C. 405(d) and (e), 1320a-7a(j), and 1320d-5 to require the attendance and testimony of witnesses and the production of any other evidence during an investigation pursuant to this part.

(1) A subpoena issued under this paragraph must—

(i) State the name of the person to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any documents or items required to be produced; and

(v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the named entity must designate one or more natural persons who will testify on its behalf, and must state as to each person so designated that person's name and address and the matters on which he or she will testify. The person so designated must testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by—

(i) Delivering a copy to the natural person named in the subpoena or to the entity named in the subpoena at its last principal place of business; or

(ii) Registered or certified mail addressed to the natural person at his or her last known dwelling place or to the entity at its last known principal place of business.

(3) A verified return by the natural person serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, constitutes proof of service.

(4) Witnesses are entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Fees need not be paid at the time the subpoena is served.

(5) A subpoena under this section is enforceable through the District Court of the United States for the district where the subpoenaed natural person resides or is found or where the entity transacts business.

(b) Investigational inquiries are non-public investigational proceedings conducted by the Secretary.

(1) Testimony at investigational inquiries will be taken under oath or affirmation.

(2) Attendance of non-witnesses is discretionary with the Secretary, except

that a witness is entitled to be accompanied, represented, and advised by an attorney.

(3) The proceedings will be recorded and transcribed. The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

§ 160.506 Basis for penalty.

The Secretary shall impose a penalty on a person who is a covered entity and who the Secretary determines in accordance with this subpart has violated a provision of—

(a) 42 U.S.C. 1320d-1320d-8, as amended;

(b) Section 264 of Pub. L. 104-191 (42 U.S.C. 1320d-2(note)); or (c) Parts 160, 162 or 164 of this subchapter.

§ 160.508 Amount of penalty.

The penalty imposed under § 160.506 must be in accordance with 42 U.S.C. 1320d-5 and the applicable provisions of this part.

§ 160.510 Authority to settle.

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

§ 160.512 [Reserved]

§ 160.514 Notice of proposed determination.

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include—

(1) Reference to the statutory basis for the penalty;

(2) A description of the findings of fact regarding the act(s) or omission(s) with respect to which the penalty is proposed;

(3) The reason(s) why the act(s) or omission(s) subject(s) the respondent to a penalty;

(4) The amount of the proposed penalty;

(5) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty without the right to a hearing under § 160.554 or a right of appeal under § 160.568, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed

penalty by filing a request therefor in accordance with § 160.526 of this subpart.

§ 160.516 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 160.526, the Secretary must impose the proposed penalty or any less severe penalty permitted by 42 U.S.C. 1320d-5. The Secretary must notify the respondent by certified mail, return receipt requested, of any penalty that has been imposed and of the means by which the respondent may satisfy the penalty. The respondent has no right to appeal under § 160.568 with respect to a penalty with respect to which the respondent has not timely requested a hearing.

§ 160.518 Collection of penalty.

(a) Once a determination of the Secretary to impose a penalty has become final, the penalty must be collected by the Secretary.

(b) The penalty may be recovered in a civil action brought in the United States district court for the district where the respondent resides, is found, or is located.

(c) The amount of a penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under 42 U.S.C. 1320a-7a(e) may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 160.520 [Reserved]

§ 160.522 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 160.514 of this subpart, within 6 years from the date on which the latest act or omission that is the subject of the action occurred.

§ 160.524 [Reserved]

§ 160.526 Hearing before an ALJ.

(a) The respondent may request a hearing before an ALJ. The parties to the hearing proceeding consist of—

- (1) The respondent; and
- (2) The Secretary.

(b) The request for a hearing must be made in writing signed by the respondent or by the respondent's attorney and sent by certified mail, return receipt requested, to the address specified in the notice of proposed determination. The request for a hearing

must be mailed within 60 days after notice of the proposed determination is received by the respondent. For purposes of this section, the respondent's date of receipt of the notice of proposed determination is presumed to be 5 days after the date of the notice unless the respondent makes a reasonable showing to the contrary to the ALJ.

(c) The request for a hearing must clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the respondent has any knowledge. If the respondent has no knowledge of a particular finding of fact and so states, the finding shall be deemed denied. The request for a hearing must also state the circumstances or arguments that the respondent alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty.

(d) The ALJ must dismiss a hearing request where—

- (1) The respondent's hearing request is not filed as required by paragraphs (b) and (c) of this section;
- (2) The respondent withdraws the request for a hearing;
- (3) The respondent abandons the request for a hearing; or
- (4) The respondent's hearing request fails to raise any issue that may properly be addressed in a hearing.

§ 160.528 Rights of parties.

(a) Except as otherwise limited by this part, each party may—

- (1) Be accompanied, represented, and advised by an attorney;
- (2) Participate in any conference held by the ALJ;
- (3) Conduct discovery of documents as permitted by this subpart;
- (4) Agree to stipulations of fact or law that will be made part of the record;
- (5) Present evidence relevant to the issues at the hearing;
- (6) Present and cross-examine witnesses;
- (7) Present oral arguments at the hearing as permitted by the ALJ; and
- (8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) A party may appear in person or by a representative. Natural persons who appear as an attorney or other representative must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.

§ 160.530 Authority of the ALJ.

(a) The ALJ must conduct a fair and impartial hearing, avoid delay, maintain order, and ensure that a record of the proceeding is made.

(b) The ALJ may—

- (1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

- (2) Continue or recess the hearing in whole or in part for a reasonable period of time;

- (3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

- (4) Administer oaths and affirmations;

- (5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

- (6) Rule on motions and other procedural matters;

- (7) Regulate the scope and timing of documentary discovery as permitted by this subpart;

- (8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

- (9) Examine witnesses;

- (10) Receive, rule on, exclude, or limit evidence;

- (11) Upon motion of a party, take official notice of facts;

- (12) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone; and

- (13) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact. A summary judgment decision constitutes a hearing on the record for the purposes of this subpart.

(c) The ALJ may not—

- (1) Find invalid or refuse to follow Federal statutes or regulations or delegations of authority by the Secretary;
- (2) Enter an order in the nature of a directed verdict;
- (3) Compel settlement negotiations; or
- (4) Enjoin any act of the Secretary.

§ 160.532 Ex parte contacts.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 160.534 Prehearing conferences.

(a) The ALJ must schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

- (1) Simplification of the issues;
 - (2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;
 - (3) Stipulations and admissions of fact or as to the contents and authenticity of documents;
 - (4) Whether the parties can agree to submission of the case on a stipulated record;
 - (5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;
 - (6) Limitation of the number of witnesses;
 - (7) Scheduling dates for the exchange of witness lists and of proposed exhibits;
 - (8) Discovery of documents as permitted by this subpart;
 - (9) The time and place for the hearing;
 - (10) The potential for the settlement of the case by the parties; and
 - (11) Other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings, including the protection of privacy of individually identifiable health information that may be submitted into evidence, if appropriate.
- (c) The ALJ must issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 160.536 Settlement.

The Secretary has exclusive authority to settle any issue or case without the consent of the ALJ.

§ 160.538 Discovery.

- (a) A party may make a request to another party for production of documents for inspection and copying that are relevant and material to the issues before the ALJ.
- (b) For the purpose of this section, the term “documents” includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form accessible to the requesting party.
- (c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.
- (d) This section may not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of

persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request must either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part must be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. The party receiving a request for production may also file a motion for protective order any time before the date the production is due.

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

- (i) Is irrelevant;
 - (ii) Is unduly costly or burdensome;
 - (iii) Will unduly delay the proceeding; or
 - (iv) Seeks privileged information.
- (3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

§ 160.540 Exchange of witness lists, witness statements, and exhibits.

(a) The parties must exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 160.556, at least 15 days before the hearing, unless the ALJ orders an earlier exchange.

(b) (1) If at any time a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ must determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of that evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure timely to exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party’s case-in-chief—

- (i) The testimony of any witness whose name does not appear on the witness list; and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of that evidence would cause substantial prejudice to the objecting party. If the ALJ finds that there is no substantial prejudice, the evidence may be admitted. If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or, if he or she does not exclude the evidence, must postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence, unless the objecting party waives postponement.

(c) Unless the other party objects within a reasonable period of time before the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 160.542 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any person at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party’s case.

(b) A subpoena requiring the attendance of a person in accordance with paragraph (a) of this section may also require the person (whether or not the person is a party) to produce relevant and material evidence at or before the hearing.

(c) When a subpoena is served by a respondent on a particular employee or official or particular office of HHS, the Secretary may comply by designating any HHS representative to appear and testify.

(d) A party seeking a subpoena must file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. That motion must—

- (1) Specify any evidence to be produced;
- (2) Designate the witnesses; and
- (3) Describe the address and location with sufficient particularity to permit those witnesses to be found.

(e) The subpoena must specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena must serve it by delivery to the person named, or by certified mail addressed to that person at the person's last dwelling place or principal place of business.

(h) The person to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in 42 U.S.C. 405(e).

§ 160.544 Fees.

The party requesting a subpoena must pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage must accompany the subpoena when served, except that when a subpoena is issued on behalf of the Secretary, a check for witness fees and mileage need not accompany the subpoena.

§ 160.546 Form, filing, and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ must include an original and two copies.

(2) Every pleading and paper filed in the proceeding must contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper must be signed by and must contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Secretary must, at the time of filing, serve a copy of the document on the other party. Service upon any party of any document must be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service must be made upon the attorney in lieu of the party.

(c) *Proof of service.* A certificate of the natural person serving the document by personal delivery or by mail, setting forth the manner of service, constitutes proof of service.

§ 160.548 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government must be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 160.526.

§ 160.550 Motions.

(a) An application to the ALJ for an order or ruling must be by motion. Motions must state the relief sought, the authority relied upon and the facts alleged, and must be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions must be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to the motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny the motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all outstanding motions before the beginning of the hearing.

§ 160.552 Sanctions.

The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. The sanctions must reasonably relate to the severity and nature of the failure or misconduct. The sanctions may include—

(a) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating the refusal as an admission by deeming the matter, or certain facts, to be established;

(b) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(c) Striking pleadings, in whole or in part;

(d) Staying the proceedings;

(e) Dismissal of the action;

(f) Entering a decision by default;

(g) Ordering the party or attorney to pay the attorney's fees and other costs caused by the failure or misconduct; and

(h) Refusing to consider any motion or other action that is not filed in a timely manner.

§ 160.554 The hearing.

(a) The ALJ must conduct a hearing on the record in order to determine whether the respondent should be found liable under this part.

(b) The hearing must be open to the public unless otherwise ordered by the ALJ for good cause shown.

(c) After both parties have presented their cases, evidence may be admitted in rebuttal even if not previously exchanged in accordance with § 160.540.

§ 160.556 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing must be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony of witnesses other than the testimony of expert witnesses may be admitted in the form of a written statement. Any such written statement must be provided to all other parties along with the last known address of the witness, in a manner that allows sufficient time for the other party to subpoena the witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing must be exchanged as provided in § 160.540. The ALJ may, at his or her discretion, admit prior sworn testimony of experts that has been subject to adverse examination, such as a deposition or trial testimony.

(c) The ALJ must exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth;

(2) Avoid repetition or needless consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ must permit the parties to conduct cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses. This provision does not authorize the exclusion of—

(1) A party who is a natural person;

(2) In the case of a party that is an entity, the officer or employee of the party appearing for the party pro se or designated as the party's representative; or

(3) A natural person whose presence is shown by a party to be essential to the presentation of its case, including a person engaged in assisting the attorney for the Secretary.

§ 160.558 Evidence.

(a) The ALJ must determine the admissibility of evidence.

(b) Except as provided in this subpart, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence may be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs, or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. This evidence is admissible regardless of whether the crimes, wrongs, or acts occurred during the statute of limitations period applicable to the acts or omissions that constitute the basis for liability in the case and regardless of whether they were referenced in the Secretary's notice of proposed determination sent in accordance with § 160.514.

(h) The ALJ must permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.

§ 160.560 The record.

(a) The hearing must be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ.

(b) The transcript of the testimony, exhibits, and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§ 160.562 Post hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ must fix the time for filing the briefs. The time for filing may not exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. The briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 160.564 ALJ decision.

(a) The ALJ must issue a decision, based only on the record, which must contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase, or reduce the penalties imposed by the Secretary.

(c) The ALJ must issue the decision to both parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. If the ALJ fails to meet the deadline contained in this paragraph, he or she must notify the parties of the reason for the delay and set a new deadline.

(d) The ALJ's decision is the final decision of the Secretary.

§ 160.566 [Reserved]

§ 160.568 Judicial review.

Judicial review of a penalty that has become final is authorized by 42 U.S.C. 1320a-7a(e).

§ 160.570 Stay of ALJ 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.

§ 160.572 [Reserved]

Dated: April 11, 2003.

Tommy G. Thompson,
Secretary.

[FR Doc. 03-9497 Filed 4-14-03; 3:54 pm]

BILLING CODE 4120-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[CC Docket Nos. 96-45, 97-21; FCC 03-59]

Federal-State Joint Board on Universal Service; Changes to the Board of Directors of the National Exchange Carrier Association, Inc.

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission amends its rules to extend the filing deadline by which the independent auditor hired by the Universal Service Administrative Company (USAC) must submit its draft audit report to the Wireline Competition Bureau (formerly known as the Common Carrier Bureau). At USAC's request, we extend the filing deadline from 60 days to 105 days after the end of the audit period.

DATES: Effective May 19, 2003.

FOR FURTHER INFORMATION CONTACT: Katherine Tofigh, Attorney or Sharon Webber, Deputy Division Chief, Wireline Competition Bureau, Telecommunications Access Policy Division, (202) 418-7400.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order in CC Docket Nos. 96-45 and 97-21; FCC 03-59, released on March 26, 2003. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street, SW., Washington, DC 20554.

1. In this Order, we amend § 54.717(f) of the Commission's rules to extend the filing deadline by which the independent auditor hired by the