

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