

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