

§ 158.613 Notice of proposed penalty.

(a) *Contents of notice.* If HHS proposes to assess a penalty in accordance with this part, it must provide the issuer written notice of its intent to assess a penalty, which includes the following:

(1) A description of the requirements under this part that HHS has determined the issuer violated.

(2) A description of the information upon which HHS based its determination, including the basis for determining the number of affected individuals and the number of days or weeks for which the violations occurred.

(3) The amount of the proposed penalty as of the date of the notice.

(4) Any considerations described in § 158.607 through § 158.610 of this subpart that were taken into account in determining the amount of the proposed penalty.

(5) A specific statement of the issuer's right to a hearing.

(6) A statement that failure to request a hearing within 30 days after the date of the notice permits the assessment of the proposed penalty without right of appeal in accordance with § 158.615 of this subpart.

(b) *Delivery of notice.* This notice must be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required.