

under § 3.526 of this part) of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(ii) The Secretary's proposed corrections to the record of transcript will be attached to the transcript.

§ 3.402 Basis for a civil money penalty.

(a) *General rule.* A person who discloses identifiable patient safety work product in knowing or reckless violation of the confidentiality provisions shall be subject to a civil money penalty for each act constituting such violation.

(b) *Violation attributed to a principal.* A principal is independently liable, in accordance with the federal common law of agency, for a civil money penalty based on the act of the principal's agent, including a workforce member, acting within the scope of the agency if such act could give rise to a civil money penalty in accordance with § 3.402(a) of this subpart.

§ 3.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and § 3.408 of this subpart.

(b) The Secretary may impose a civil money penalty in the amount of not more than \$11,000.

[73 FR 70796, Nov. 21, 2008, as amended at 74 FR 42779, Aug. 25, 2009]

§ 3.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary may consider as aggravating or mitigating factors, as appropriate, any of the following:

- (a) The nature of the violation.
- (b) The circumstances, including the consequences, of the violation, including:
 - (1) The time period during which the violation(s) occurred; and
 - (2) Whether the violation caused physical or financial harm or reputational damage;
- (c) The degree of culpability of the respondent, including:
 - (1) Whether the violation was intentional; and
 - (2) Whether the violation was beyond the direct control of the respondent.
- (d) Any history of prior compliance with the Patient Safety Act, including violations, by the respondent, including:
 - (1) Whether the current violation is the same or similar to prior violation(s);
 - (2) Whether and to what extent the respondent has attempted to correct previous violations;
 - (3) How the respondent has responded to technical assistance from the Secretary provided in the context of a compliance effort; and
 - (4) How the respondent has responded to prior complaints.
- (e) The financial condition of the respondent, including:
 - (1) Whether the respondent had financial difficulties that affected its ability to comply;
 - (2) Whether the imposition of a civil money penalty would jeopardize the ability of the respondent to continue to provide health care or patient safety activities; and
 - (3) The size of the respondent.
- (f) Such other matters as justice may require.

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the respondent.

(d) Any history of prior compliance with the Patient Safety Act, including violations, by the respondent, including:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the respondent has attempted to correct previous violations;

(3) How the respondent has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the respondent has responded to prior complaints.

(e) The financial condition of the respondent, including:

(1) Whether the respondent had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the respondent to continue to provide health care or patient safety activities; and

(3) The size of the respondent.

(f) Such other matters as justice may require.

§ 3.414 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 3.420 of this subpart, within 6 years from the date of the occurrence of the violation.

§ 3.416 Authority to settle.

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

§ 3.418 Exclusivity of penalty.

(a) Except as otherwise provided by paragraph (b) of this section, a penalty imposed under this part is in addition to any other penalty prescribed by law.

(b) Civil money penalties shall not be imposed both under this part and under the HIPAA Privacy Rule (45 CFR parts 160 and 164).