§3.10

3.210 Required disclosure of patient safety work product to the Secretary.

3.212 Nonidentification of patient safety work product.

Subpart D—Enforcement Program

- 3.304 Principles for achieving compliance.
- 3.306 Complaints to the Secretary.
- 3.308 Compliance reviews.
- 3.310 Responsibilities of respondents.
- 3.312 Secretarial action regarding complaints and compliance reviews.
- 3.314 Investigational subpoenas and inquiries.
- 3.402 Basis for a civil money penalty.
- 3.404 Amount of a civil money penalty.
- 3.408 Factors considered in determining the amount of a civil money penalty.
- 3.414 Limitations.
- 3.416 Authority to settle.
- 3.418 Exclusivity of penalty.
- 3.420 Notice of proposed determination.
- 3.422 Failure to request a hearing.
- 3.424 Collection of penalty.
- 3.426 Notification of the public and other agencies.
- 3.504 Hearings before an ALJ.
- 3.506 Rights of the parties.
- 3.508 Authority of the ALJ.
- 3.510 Ex parte contacts.
- 3.512 Prehearing conferences.
- 3.514 Authority to settle.
- 3.516 Discovery.
- 3.518 Exchange of witness lists, witness statements, and exhibits.
- 3.520 Subpoenas for attendance at hearing.
- 3.522 Fees.
- 3.524 Form, filing, and service of papers.
- 3.526 Computation of time. 3.528 Motions.
- 3.530 Sanctions.
- 3.532 Collateral estoppel.
- 3.534 The hearing.
- 3.538 Witnesses.
- 3.540 Evidence.
- 3.542 The record.
- 3.544 Post hearing briefs.
- 3.546 ALJ's decision.
- 3.548 Appeal of the ALJ's decision.
- 3.550 Stay of the Secretary's decision.
- 3.552 Harmless error.
- AUTHORITY: 42 U.S.C. 216, 299b-21 through 299b-26; 42 U.S.C. 299c-6.

SOURCE: 73 FR 70796, Nov. 21, 2008, unless otherwise noted.

Subpart A—General Provisions

§3.10 Purpose.

The purpose of this part is to implement the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109– 41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 *et* seq.) by adding sections 921 through 926, 42 U.S.C. 299b-21 through 299b-26.

§3.20 Definitions.

As used in this part, the terms listed alphabetically below have the meanings set forth as follows:

Affiliated provider means, with respect to a provider, a legally separate provider that is the parent organization of the provider, is under common ownership, management, or control with the provider, or is owned, managed, or controlled by the provider.

AHRQ stands for the Agency for Healthcare Research and Quality in HHS.

ALJ stands for an Administrative Law Judge of HHS.

Board means the members of the HHS Departmental Appeals Board, in the Office of the Secretary, which issues decisions in panels of three.

Bona fide contract means:

(1) A written contract between a provider and a PSO that is executed in good faith by officials authorized to execute such contract; or

(2) A written agreement (such as a memorandum of understanding or equivalent recording of mutual commitments) between a Federal, State, local, or Tribal provider and a Federal, State, local, or Tribal PSO that is executed in good faith by officials authorized to execute such agreement.

Complainant means a person who files a complaint with the Secretary pursuant to \$3.306.

Component organization means an entity that:

(1) Is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization); or

(2) Is owned, managed, or controlled by one or more legally separate parent organizations.

Component PSO means a PSO listed by the Secretary that is a component organization.

Confidentiality provisions means for purposes of subparts C and D, any requirement or prohibition concerning confidentiality established by sections 921 and 922(b)-(d), (g) and (i) of the Public Health Service Act, 42 U.S.C. 299b-21, 299b-22(b)-(d), (g) and (i) and the