

subjects who participated in research during any time the authorization was in effect.

PART 3—PATIENT SAFETY ORGANIZATIONS AND PATIENT SAFETY WORK PRODUCT

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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