Public Health Service, HHS

§ 3.212 Nonidentification of patient safety work product.

(a) Patient safety work product is nonidentifiable with respect to a particular identified provider or a particular identified reporter if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an identified provider or reporter; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of such provider or reporter and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers or reporters are removed:

(A) The direct identifiers listed at §3.206(b)(4)(iv)(A)(1) through (13) of this subpart;

(B) Geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people;

(C) All elements of dates (except year) for dates directly related to a patient safety incident or event; and

(D) Any other unique identifying number, characteristic, or code except as permitted for re-identification; and

(ii) The provider, PSO or responsible person making the disclosure does not
§ 3.304 Principles for achieving compliance.

(a) Cooperation. The Secretary will, to the extent practicable, seek the cooperation of providers, PSOs, and responsible persons in obtaining compliance with the applicable confidentiality provisions.

(b) Assistance. The Secretary may provide technical assistance to providers, PSOs, and responsible persons to help them comply voluntarily with the applicable confidentiality provisions.

§ 3.306 Complaints to the Secretary.

(a) Right to file a complaint. A person who believes that patient safety work product has been disclosed in violation of the confidentiality provisions may file a complaint with the Secretary.

(b) Requirements for filing complaints. Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the person that is the subject of the complaint and describe the act(s) believed to be in violation of the applicable confidentiality provision(s).

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the FEDERAL REGISTER.

(c) Investigation. The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the respondent and of the circumstances regarding any alleged violation. At the time of initial written communication with the respondent about the complaint, the Secretary will describe the act(s) that are the basis of the complaint.

§ 3.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether a respondent is complying with the applicable confidentiality provisions.

§ 3.310 Responsibilities of respondents.

(a) Provide records and compliance reports. A respondent must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the respondent has complied or is complying with the applicable confidentiality provisions.

(b) Cooperate with complaint investigations and compliance reviews. A respondent must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the respondent to determine whether it is complying with the applicable confidentiality provisions.