

(2) Describe or pertain to one or more actions or failures to act by an identifiable provider.

(d) *Implementation and enforcement by the Secretary.* The confidentiality provisions shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

(e) *No limitation on authority to limit or delegate disclosure or use.* Nothing in subpart C of this part shall be construed to limit the authority of any person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this subpart.

§ 3.208 Continued protection of patient safety work product.

(a) Except as provided in paragraph (b) of this section, patient safety work product disclosed in accordance with this subpart, or disclosed impermissibly, shall continue to be privileged and confidential.

(b)(1) Patient safety work product disclosed for use in a criminal proceeding pursuant to section 922(c)(1)(A) of the Public Health Service Act, 42 U.S.C. 299b-22(c)(1)(A), and/or pursuant to § 3.206(b)(1) of this subpart continues to be privileged, but is no longer confidential.

(2) Non-identifiable patient safety work product that is disclosed is no longer privileged or confidential and not subject to the regulations under this part.

(3) Paragraph (b) of this section applies only to the specific patient safety work product disclosed.

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

Notwithstanding any other provision in this part, providers, PSOs, and responsible persons must disclose patient safety work product upon request by the Secretary when the Secretary determines such patient safety work

product is needed to investigate or determine compliance or to seek or impose civil money penalties, with respect to this part or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

§ 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