

Statement on HIPAA Business Associate Agreements

The American National Red Cross performs a number of services related to blood. These services include collection, processing, distribution, crossmatching, testing, research, and clinical services. When it performs these services, the Red Cross is not a “covered entity” subject to the HIPAA Privacy Rule, nor is it a “business associate” of the hospitals and other customers to which it provides these services.

Blood Supply

Ordinarily, the Red Cross does not receive information about the patients who receive the blood the Red Cross supplies to its customers. Occasionally, a hospital shares patient information with the Red Cross to facilitate an investigation of a post-transfusion adverse event. A business associate agreement is not required to facilitate these types of disclosures because, under 45 CFR § 164.512(b)(1)(iii), a covered entity may disclose protected health information to an entity that is subject to the jurisdiction of the Food and Drug Administration (FDA) for quality and safety activities. Quality and safety activities include collecting and reporting information about adverse events and conducting recalls and lookbacks. In addition, when a hospital discloses patient information for an investigation, the Red Cross is not using the PHI to perform services for or on behalf of a covered entity, but instead to fulfill its own quality and regulatory purposes.

Clinical Services (Therapeutic Apheresis, Perioperative Autologous Collections Services, Peripheral Progenitor Stem Cell Collection, Therapeutic Phlebotomy)

The Red Cross is not a “business associate” when it provides a health care provider with clinical services, such as therapeutic apheresis, peripheral progenitor stem cell collection, or therapeutic phlebotomy. Under 45 CFR § 160.103, a health care provider like the Red Cross is not a business associate if another health care provider is disclosing patient information to it for treatment purposes.

Testing Services

The Red Cross is not a “business associate” when it provides a health care provider with testing services. Like clinical services, the Red Cross provides testing services for treatment purposes. Under 45 CFR § 160.103, a health care provider like the Red Cross is not a business associate if another health care provider is disclosing patient information to it for treatment purposes.