



CENTER FOR PATIENT SAFETY

FAQs regarding Participation in the AABB Center for Patient Safety:

Question 1: What are the benefits of joining the AABB Center for Patient Safety?

Answer: The AABB Center for Patient Safety is a “patient safety organization” recognized by the Agency for Healthcare Research and Quality since 2008. When your facility joins the AABB Center for Patient Safety, you agree to grant us permission to access your data on adverse events and near misses submitted by your facility to the National Healthcare Safety Network (“NHSN”) Hemovigilance Module managed by the CDC. Access is granted using the “group” function in the Hemovigilance Module. No additional NHSN data entry is required. Once we access your facility’s data, we analyze the data to identify and communicate best practices and to design interventions to improve patient safety and the quality and efficiency of patient care. We then provide benchmark reporting and other useful information back to your facility.

Question 2: How is my facility’s data protected by the AABB Center for Patient Safety?

Answer: When granted permission by your facility, the AABB Center for Patient Safety accesses information submitted by your facility to the CDC’s NHSN Hemovigilance Module. While the CDC (and not the AABB Center for Patient Safety) manages the Hemovigilance Module, we note that the CDC states that information submitted to the Hemovigilance Module is confidential and can only be used and disclosed in accordance with the Public Health Service Act.

Once your facility’s data is accessed by the AABB Center for Patient Safety, we consider your facility’s data “patient safety work product” (or “PSWP”) under the Patient Safety and Quality Improvement Act of 2005 (the “Patient Safety Act”), and we protect it accordingly. This means that we do not use or disclose your facility’s data except as specifically permitted by the Patient Safety Act. The benchmark and other information provided back to your facility by the AABB Center for Patient Safety is also protected as PSWP under the Patient Safety Act. Any Protected Health Information obtained from your facility is protected in accordance with HIPAA. (See more about HIPAA below.)

Question 3: How does the recent AHRQ/OCR issued “Guidance Regarding Patient Safety Work Product and Providers’ External Obligations” impact my participation in the AABB Center for Patient Safety?

Answer: The impact of the new Guidance is less significant than for participants in other PSOs since data you enter into the NHSN’s Hemovigilance Module is not PSWP; instead, the CDC notes that it is protected under the Public Health Service Act. We protect your data as PSWP once it is accessed by us for patient safety-related activities. Please consult your own legal counsel for advice on how the new Guidance impacts your organization’s Patient Safety Evaluation System, as AABB cannot provide legal advice to third parties, including PSO participants.

Question 4: Does the AABB Center for Patient Safety require my facility to provide Protected Health Information (or PHI) as defined by HIPAA?

Answer: When granted permission by your facility, the AABB Center for Patient Safety accesses information submitted by your facility to the NHSN's Hemovigilance Module. The only elements of Protected Health Information that the AABB Center for Patient Safety receives through such access are the date of birth, date of service, and date of death (when applicable) related to a patient. No patient name, patient address, or other patient-identifying information is required. However, because the date of birth, date of service, and date of death could be considered Protected Health Information under HIPAA, as part of your facility's onboarding process, the AABB Center for Patient Safety enters into a Business Associate Agreement with your facility that requires the AABB Center for Patient Safety to safeguard that Protected Health Information in accordance with HIPAA.

Question 5: Do I have to maintain a record of the disclosures of Protected Health Information to the AABB Center for Patient Safety?

Answer: While we can't provide legal advice to your facility regarding HIPAA compliance, we note that disclosures to a patient safety organization like the AABB Center for Patient Safety are generally considered to be disclosures for health care operations. The definition of "health care operations" at 45 CFR 164.501 includes patient safety activities. The HIPAA regulation that requires a Covered Entity to provide a patient with an accounting of all disclosures of his or her Protected Health Information specifically exempts from the accounting those disclosures made to carry out health care operations. See 45 CFR 164.528. (We are aware of the language in the HITECH Act and in the May 31, 2011 Notice of Proposed Rulemaking regarding changes to the accounting requirement, but to date, the HIPAA regulation still exempts disclosures for health care operations from the accounting requirement.)

Question 6: What is the relationship between AABB Center for Patient Safety and AABB?

Answer:

The AABB Center for Patient Safety, a component PSO, operates independently of its parent, AABB, and AABB's accreditation programs. Patient safety data reported to the AABB Center for Patient Safety are not shared with AABB or AABB accreditation.

AABB offers voluntary accreditation for all aspects of transfusion medicine, cellular therapies, transplantation, and relationship testing. AABB's Accreditation Program specifically assesses quality systems and operational areas for compliance with AABB's standards, the U.S. Code of Federal Regulations and federal guidance documents. AABB accreditation has been granted deemed status from CMS under the Clinical Laboratory Improvement Amendments of 1988 to assess organizations for the following specialty/subspecialties of microbiology, chemistry, diagnostic immunology, hematology, mycology, and immunohematology activities. Deemed status is granted to accrediting organizations that have Standards that are as stringent or more stringent than those found in federal regulations.