

AABB's Patient and Donor Safety Center Firewall Policy

Purpose: The purpose of this firewall policy is to ensure that AABB's Patient and Donor Safety Center (PDSC), which supports the U.S. Biovigilance Network, complies with the provisions of the Patient Safety and Quality Improvement Act of 2005 (PSA) and its implementing regulations, as amended from time to time, relating to requirements for component Patient Safety Organizations (PSO).

Responsibility: Responsibility for compliance with this policy shall rest with the Director, PDSC and the PDSC Oversight Committee or its designee, who shall conduct periodic assessments to ensure compliance. AABB's Whistleblower Policies shall govern the handling of complaints and grievances relating to this policy.

Definitions: For purposes of this policy and the processes and procedures that flow from it, the following definitions shall apply:

AABB Staff: The term includes AABB's staff, individuals working for AABB on a contract basis, and volunteers, including the AABB Board of Directors.

PDSC Staff: The term includes PDSC staff, individuals working for PDSC on a contract basis, as well as volunteers under the direct control of PDSC.

Provider: The term includes hospitals, blood centers, and other providers of Patient Safety Work Product reporting into PDSC.

Patient Safety Work Product (PSWP): The term is as defined in section 3.20 of the PSA final rule (e.g., individual adverse reaction reports, individual incident reports, aggregate data from the CDC's National Healthcare Safety Network):

- (1) Except as provided in paragraph (2) of this definition, patient safety work product means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)
 - (i) Which could improve patient safety, health care quality, or health care outcomes; and
 - (A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such documentation includes the date the information entered the patient safety evaluation system; or
 - (B) Are developed by a PSO for the conduct of patient safety activities; or
 - (ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.
- (2) (i) Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.
 - (ii) Patient safety work product assembled or developed by a provider for reporting to a PSO may be removed from a patient safety evaluation system and no longer considered patient safety work product if:
 - (A) The information has not yet been reported to a PSO; and
 - (B) The provider documents the act and date of removal of such information from the patient safety evaluation system.
 - (iii) Nothing in this part shall be construed to limit information that is not patient safety work product from being:
 - (A) Discovered or admitted in a criminal, civil or administrative proceeding;
 - (B) Reported to a Federal, State, local or Tribal governmental agency for public health or health oversight purposes; or

(C) Maintained as part of a provider's recordkeeping obligation under Federal, State, local or Tribal law.

Person: The term means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Policy: The elements of this policy, which are set forth in the chart appearing on the following page, are divided into two sections:

Section 1: Elements pertaining to AABB staff

Section 2: Elements pertaining to PDSC staff

This policy shall be reviewed externally every three years. In addition, this policy shall be made publicly available on the AABB Web site.

AABB Staff

- PSWP shall not be disclosed to AABB staff in any manner, except as specifically provided for in this Policy.
- AABB staff other than Accreditation and Standards staff may be granted access to identifiable PSWP by PDSC provided that there is a written agreement permitting access only under the following conditions: (i) access is granted to enable authorized AABB staff to assist PDSC in its conduct of patient safety activities; (ii) authorized AABB staff agree to take appropriate security measures to prevent unauthorized disclosures; and (iii) authorized AABB staff agree to comply with the other certifications that PDSC made in accordance with the PSA.
- PSWP shall not be disclosed to Accreditation or Standards staff under any circumstances.
- Any AABB marketing material relating to PDSC or the U.S. Biovigilance Network, including Web sites, shall clearly state that the PDSC operates independently from AABB.
- AABB staff may discuss with PDSC staff generic issues and share generic information relating to the U.S. Biovigilance Network, so long as no PSWP is disclosed.
- AABB staff shall receive training on this policy.
- All AABB staff shall sign statements annually verifying that they have read and agree to comply with this policy.
- AABB staff may not communicate with PDSC staff about specific facility accreditation decisions or variance requests not otherwise publicly available and may not discuss information relating to specific assessments.

AABB's Patient and Donor Safety Center (PDSC) Staff

- PDSC shall not disclose PSWP except as necessary to carry out its mission and in accordance with this policy
- PDSC shall stamp or electronically mark all PSWP as "PATIENT SAFETY WORK PRODUCT -- Confidential and Privileged."
- PDSC shall maintain all PSWP in both paper and electronic form securely and separately so that it is not accessible by unauthorized individuals, including other AABB staff. This includes the use by PDSC staff of printers, fax machines, scanners and telephone numbers in a manner that keeps all PSWP separate and secure from access by other AABB staff.
- PDSC may disclose PSWP to AABB staff other than Accreditation and Standards staff, only under the following conditions: (i) access is granted to enable authorized AABB staff to assist PDSC in its conduct of patient safety activities; (ii) authorized AABB staff agree to take appropriate security measures to prevent unauthorized disclosures; (iii) authorized AABB staff agree to comply with other certifications that PDSC made in accordance with the PSA; and (iv) there is a written agreement between PDSC and authorized AABB staff setting forth agreement to these conditions.
- PSWP shall not be disclosed to Accreditation or Standards staff under any circumstances.
- PDSC shall inform its participants that it operates independently from AABB's other programs. Included in participant agreements shall be the statement that participation in the U.S. Biovigilance Network has no impact on a facility's current or future accreditation status.
- PDSC and U.S. Biovigilance Network promotional materials, including Web sites, shall identify PDSC as an independent component of AABB.
- PDSC may discuss with AABB staff generic issues and share generic information relating to the U.S. Biovigilance Network, so long as no PSWP is disclosed.
- PDSC staff shall ensure that there is no conflict of interest between the mission of PDSC, the U.S. Biovigilance Network and AABB.
- PDSC staff shall receive training regarding this policy.
- PDSC staff shall sign statements annually verifying that they have read and agree to comply with this policy.