

**CHICAGO BREAST CANCER QUALITY CONSORTIUM  
COMPONENT PATIENT SAFETY ORGANIZATION  
POLICIES AND PROCEDURES AS REVISED SEPTEMBER 1, 2010**

**Background:**

The Metropolitan Breast Cancer Task Force ("Task Force") is an Illinois not-for-profit corporation that was established for the purpose of improving access to and quality of breast cancer screening and treatment for all women across the Metropolitan Chicago area and reducing morbidity and mortality rates for all women in the Metropolitan Chicago area. The Chicago Breast Cancer Quality Consortium ("Consortium") is a division of the Task Force and acts on behalf of the Task Force. The Consortium's mission and primary activity is to improve patient safety and the quality of breast cancer screening and treatment by sharing data on quality measures for breast cancer screening and treatment and developing quality improvement projects based on analysis of this data. The Consortium is currently funded by Susan G. Komen for the Cure Foundation. Under the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act"), the Task Force is the "parent organization" and the Consortium is its "component organization." 42 C.F.R Part 3.

The Consortium has a Standing Committee and 4 Advisory Boards: The Mammography Quality Measure Advisory Board, the Treatment Quality Advisory Board, the Primary Care Advisory Board, and the Data and Research Advisory Board. (See attached Task Force/Consortium organizational chart). The Consortium also forms certain ad hoc advisory groups for specific work areas as needed eg. The Mammography Capacity Working Group, the Standing Referrals Working Group. The Mammography Screening Advisory Board shall develop the mammography screening measures and quality improvement projects and best practices related to mammography screening, the Treatment Advisory Board shall develop treatment quality measures and quality improvement projects based on best practices related to breast cancer treatment, the Data and Research Advisory Board shall examine the metrics being collected and provide advice regarding statistical and research methodology for projects, and the other Advisory Boards shall develop additional quality measures.

Susan G. Komen for the Cure Foundation has provided additional funding for more intensive analysis including environmental scanning of a subset of participating providers. The quality improvement projects based on best practices will be informed by both the data collected from this project including the environmental scanning project and the literature as reviewed by the Consortium-PSO staff and Advisory Board members.

**Definitions:**

**(1) Bona Fide Contract:** A written contract between a participating healthcare provider and the Consortium-PSO that is executed in good faith by individuals authorized to execute such contracts.

**(2) Component Organization:** An entity that: (1) is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization);

or (2) is owned, managed, or controlled by one or more legally separate parent organizations. (See 42 C.F.R. §3.20)

**(3) Component PSO:** A PSO listed by the Secretary that is a component organization.

**(4) Financial Relationship:** Any direct or indirect ownership or investment relationship between the Consortium-PSO or its parent organization, and a participating healthcare provider, shared financial interests or direct or indirect compensation arrangements whether cash or in-kind.

**(5) Identifiable Patient Safety Work Product:** Patient safety work product ("PSWP") that: (1) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in, or are responsible for, activities that are a subject of the work product; (2) constitutes individually identifiable health information as that term is defined in the HIPAA Privacy Rule at 45 CFR 160.103; or (3) is presented in a form and manner that allows the identification of an individual who in good faith reported information directly to the Consortium-PSO or to a provider with the intention of having the information reported to the Consortium-PSO.

**(6) Non-Identifiable PSWP:** PSWP that is not identifiable in accordance with the non-identification standards set forth at Sec. 3.212 of the Patient Safety Rule.

**(7) Participating Healthcare Provider:** Healthcare providers that have entered into a bona fide contract with the Consortium-PSO and have agreed to share data as laid out in the contract under the terms of such contract.

**(8) Patient Safety Act:** The Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b-21 through 299b-26, and 42 C.F.R. Part 3; Patient Safety and Quality Improvement: Final Rule, all as may be amended from time to time.

**(9) Patient Safety Activities:** The following activities carried out by or on behalf of the Consortium-PSO or a participating healthcare provider:

- (i) efforts to improve patient safety and the quality of health care delivery;
- (ii) the collection and analysis of PSWP;
- (iii) the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- (iv) the utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
- (v) the maintenance of procedures to preserve confidentiality with respect to PSWP;

(vi) the provision of appropriate security measures with respect to PSWP

(vii) the utilization of qualified staff; and

(viii) activities related to the operation of a patient safety evaluation system- the collection, management, or analysis of information for reporting to or by a PSO ("PSES") and to the provision of feedback to participants in a PSES. (*See* 42 C.F.R. §3.20).

**(10) PSWP:** Except as provided in paragraph (iii) of this definition, PSWP 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 participating healthcare provider for reporting to the Consortium-PSO and are reported to the Consortium-PSO, which includes information that is documented as within a PSES for reporting to the Consortium-PSO, and such documentation includes the date the information entered the PSES; or

(B) are developed by the Consortium-PSO or its subcontractors 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 PSES.

(iii) PSWP 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 PSES. Such separate information or a copy thereof reported to the Consortium-PSO shall not by reason of its reporting be considered PSWP.

(iv) PSWP assembled or developed by a participating healthcare provider for reporting to the Consortium-PSO may be removed from the participating healthcare providers' PSES and no longer considered PSWP if:

(A) the information has not yet been reported to the Consortium-PSO; and

(B) the participating healthcare provider documents the act and date of removal of such information from its PSES.

(v) nothing in this policy shall be construed to limit information that is not PSWP 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. (*See* 42 C.F.R. §3.206).

**(11) Patient Safety Evaluation System:** The collection, management, or analysis of information for reporting to or by the Component-PSO. (*See* 42 C.F.R. §3.20).

**(12) Reporting Relationships:** Relationships by which a participating healthcare provider has access to information regarding the work and operation of the Consortium-PSO that is not available to other participating healthcare providers.

**(13) Data Sharing Agreement:** The agreement between the Consortium-PSO and each Participating Healthcare Provider to collect data from years 2006-2012 relating to breast cancer screening and treatment.

**(14) Disclosure:** The release, transfer, provision of access to, or divulging in any other manner of PSWP by: (i) an entity or natural person, including a participating healthcare provider and the Consortium-PSO, holding the PSWP, to another legally separate entity or natural person outside the entity holding the PSWP; or (ii) the Consortium-PSO to another entity or natural person outside the Consortium-PSO.

**(15) Common Formats:** The term common formats is used to describe the technical requirements and reporting specifications that allow participating healthcare providers to collect and submit standardized information regarding patient safety events to the Component-PSO. Common formats may include formats developed by the Agency for Healthcare Research and Quality (AHRQ), or other formats developed by the Consortium-PSO that allow participating healthcare providers to collect and submit PSWP to the Component-PSO in a standardized manner that permits valid comparisons of similar cases.

**(16) Healthcare Operations:** Activities defined at 45 C.F.R. § 164.501, including patient safety activities, for which covered entities, including participating healthcare providers, are authorized to use and disclose protected health information, in accordance with the HIPAA Privacy Rule.

**(17) Business Associate:** A person or entity, including the Consortium-PSO, which performs or assists a covered entity, including a participating healthcare provider, in the performance of a function or activity involving the use or disclosure of protected health information, as required by the regulations contained at 45 C.F.R. Parts 160 and 164, as amended from time to time (“the HIPAA Privacy Rule”).

**Purpose:**

To create a component patient safety organization in accordance with the Patient Safety Act.

**Policy:**

The Consortium-PSO is seeking to establish itself as a PSO listed by the Secretary of Health and Human Services ("Secretary") as a component of the Task Force.

**Procedures:**

(1) The Task Force has as its purpose to improve access to and quality of breast cancer screening and treatment for all women across the Metropolitan Chicago area and reduce morbidity and mortality rates for all women in the Metropolitan Chicago area.

(2) The Consortium has as its purpose to bring health care providers from the Metropolitan Chicago area together to collaborate on improving the quality of breast cancer screening and treatment by sharing data on quality measures for breast cancer screening and treatment and developing quality improvement projects based on analysis of this data.

(3) The Consortium is a division of the Task Force and acts on behalf of the Task Force. Under the Patient Safety Act, the Task Force is the "parent organization" and the Consortium is its "component organization." (see attached Task Force/Consortium organizational chart).

(4) The Consortium-PSO shall ensure its mission and primary activity is to conduct activities that improve patient safety and the quality of healthcare delivery in participating healthcare providers through patient safety and quality activities.

(5) The Consortium-PSO shall have appropriately qualified staff, including licensed or certified medical professionals that will work under the direct supervision of the PSO.

(6) The Consortium-PSO currently has and will ensure to retain, within each sequential 24-month period thereafter, two or more bona fide contracts, each of a reasonable period of time and with a different participating healthcare provider, for the purpose of receiving and reviewing PSWP.

(7) The Consortium-PSO is not, and is not a component of: a health insurance issuer, a regulatory agency, an organization that serves as an agent of a regulatory agency, an accreditation and licensure entity, or an entity that administers a Federal, State, local, or tribal patient safety reporting system to which health care providers are required to report by law or regulation (*See* 42 CFR §3.102(a)(2)(ii)).

(8) The Consortium-PSO shall meet the requirements in the Patient Safety Act to fully disclose to the Secretary, within 45 days from the date on which the Consortium-PSO enters into a bona fide contract with a participating healthcare provider, if applicable, its relationships, and those of its parent organization, with such participating healthcare provider. The Consortium-PSO shall fully disclose (a) any financial, reporting, or contractual relationship between the Consortium-PSO and any provider that contracts with the Consortium-PSO and (b) if applicable, the fact that the Consortium-PSO is not managed, controlled, and operated independently from any provider

that contracts with the entity. The Consortium-PSO shall use the appropriate forms and narratives outlined in 42 C.F.R. §3.102(b)(2)(ii) for such disclosures.

(9) The Consortium-PSO shall collect PSWP from participating healthcare providers in a standardized manner that permits valid comparisons of similar cases among similar providers, in accordance with the Consortium-PSO Common Format Policy.

(10) The Consortium-PSO shall utilize PSWP for the purpose of providing direct feedback and assistance to participating healthcare providers to effectively minimize patient risk and improve quality of care.

(11) The Consortium-PSO shall maintain PSWP separately from the rest of the Task Force, and establish appropriate security measures to maintain the confidentiality of the PSWP.

**Related Policies:**

- (1) Consortium-PSO Common Format Policy
- (2) Consortium-PSO Staffing Policy
- (3) Consortium-PSO Confidentiality and Privilege of PSWP Policy
- (4) Consortium-PSO Data Security Policy
- (5) Consortium-PSO PSES Policy
- (6) Consortium-PSO PSQI Policy
- (7) Consortium-PSO PSWP Policy
- (8) Consortium-PSO Conflict of Interest Policy

**ORGANIZATIONAL CHART**  
**THE TASK FORCE**

