CHICAGO BREAST CANCER QUALITY CONSORTIUM
COMPONENT PATIENT SAFETY ORGANIZATION
CONFIDENTIALITY AND PRIVILEGE OF
PATIENT SAFETY WORK PRODUCT POLICIES AND PROCEDURES

TITLE: CONSORTIUM-PSO Confidentiality and Privilege of Patient Safety Work Product Policies and Procedures

EFFECTIVE DATE: September 1, 2009 and revised September 1, 2010

Purpose:

To establish a process for identifying the patient safety work product ("PSWP") disclosed to and by the Consortium-PSO that is privileged and confidential in accordance with the Patient Safety Act and to establish procedures to ensure such legal protections are safeguarded by the Consortium-PSO.

Policy:

To ensure PSWP disclosed to and from the Consortium-PSO remains privileged and confidential in accordance with the provisions of the Patient Safety Act and, as applicable, the HIPAA Privacy Rule and as laid out in the Data Sharing Agreement between each participating healthcare provider and the Consortium-PSO.

Procedures:

(1) In general, aggregate de-identified data will be provided by participating healthcare providers to the Consortium-PSO and such data will not contain protected health information as defined by the HIPAA Privacy Rule. An exception may exist whereby the Chicago Department of Public Health provides the Consortium-PSO with a list of patients for the purpose of data matching to determine follow up care at a provider other than CDPH. In such instance, the Consortium-PSO will enter into a business associate agreement with CDPH for the purpose of data matching.

(2) In addition to the retrospective de-identified data identified above, the Consortium-PSO will be establishing in 2010 an environmental scan project working with the Center for Business Models in Healthcare. This project will develop a standardized survey tool to collect data from a subset of participating providers. A common format will be used at each participating site. This data may include patient interviews but in such instance, the data retained will be de-identified with respect to patient identity. All data collected through this survey will be done in conformance with HIPAA and the Patient Safety Act and the data will be marked as PSWP.

(3) If in the future the Consortium-PSO does get access to protected health information, the Consortium-PSO shall enter into business associate agreements with participating healthcare providers in accordance with the requirements set forth in the HIPAA Privacy Rule to ensure the confidentiality and security of any PSWP. The Consortium-PSO shall comply with the provisions of its business associate agreements with respect to any disclosure of identifiable PSWP authorized herein. The individually identifiable patient information will remain at the provider's site and will not be transmitted to the Consortium-PSO in individually identifiable form.

(4)While data collected by the Consortium-PSO will not include individually identifiable health information as defined by the HIPAA Privacy Rule, and data transmitted to the Consortium-PSO by participating healthcare providers will be aggregated, de-identified data, a participating healthcare provider may request assistance from the Consortium-PSO staff with respect to data collection and such assistance would expose the Consortium-PSO staff to individually identifiable health information. In such instances, a business associate agreement will be entered into between that provider and the Consortium-PSO. The Consortium-PSO staff will only have access to such identifiable information for the purpose of assisting the participating healthcare provider in data collection and shall keep such information confidential.

(5) The data sharing provider agreement will include relevant language to include the environmental scanning, as Patient Safety Work Product under the Patient Safety Act.

(6) The Consortium-PSO shall treat PSWP reported to or developed by the Consortium-PSO as privileged and confidential and it is intended that such PSWP shall not be:

(i) subject to a Federal, State, local, or Tribal civil, criminal, or administrative subpoena or order, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a participating healthcare provider;

(ii) subject to discovery in connection with a Federal, State, local, or Tribal civil, criminal, or administrative proceeding, including in a Federal, State, local, or Tribal civil or administrative disciplinary proceeding against a participating healthcare provider;

(iii) subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, local, or Tribal law;

(iv) admitted as evidence in any Federal, State, local, or Tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a participating healthcare provider; or

(v) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law. (*See* 45 C.F.R. §160.103)

(5) Pursuant to the Patient Safety Act, the privilege afforded PSWP reported to or developed by the Consortium-PSO shall not apply to one or more of the following disclosures:

(i) disclosure of relevant PSWP for use in a criminal proceeding, subject to the conditions at Sec. 3.206(b) (1) of the Patient Safety Act.

(ii) disclosure to the extent required to permit equitable relief, subject to the conditions at Sec. 3.206(b) (2) of the Patient Safety Act.

(iii) disclosure pursuant to provider authorizations, subject to the conditions at Sec. 3.206(b) (3) of the Patient Safety Act.

(iv) disclosure for patient safety activities, subject to the conditions at Sec 3.206(b) (4) of the Patient Safety Act.

(v) disclosure of non-identifiable PSWP, subject to the conditions at Sec. 3.206(b) (5) of the Patient Safety Act.

(vi) disclosure for research, subject to the conditions at Sec. 3.206(b) (6) of the Patient Safety Act.

(vii) disclosure for business operations, subject to the conditions at Sec. 3.206(b) (9) of the Patient Safety Act.

(viii) disclosure to law enforcement, subject to the conditions at Sec. 3.206(b) (10) of the Patient Safety Act.

(ix) disclosures of relevant PSWP to or by the Secretary, if such PSWP is needed to investigate or determine compliance, or to seek or impose civil money penalties, with respect to the Patient Safety Act or the HIPAA Privacy Rule, or to make or support decisions with respect to listing of the Consortium-PSO as a PSO.

(6) The Consortium-PSO shall maintain the PSWP separately from the rest of the Task Force. The Consortium-PSO shall require that members of its workforce and any other contractor staff not make unauthorized disclosures of PSWP to the Task Force. Only Consortium-PSO staff and the Chair of the Mammography Advisory Board and the Treatment Advisory Board and will have access to identifiable PSWP. In addition, access may be granted to agents of the Consortium-PSO including, but not limited to, legal counsel, accountants, and outside medical consultants. Each of these individuals

will be required to sign a confidentiality agreement stating that they will not disclose any identifiable PSWP.

(7) The Consortium-PSO shall establish security measures to maintain the confidentiality of PSWP and shall not disclose PSWP, except as permitted by the Patient Safety Act or as required by law. When the Consortium-PSO makes a permitted disclosure, it shall disclose the least amount of identifiable PSWP appropriate for the disclosure. Subject to this and other relevant restrictions contained herein, the Consortium-PSO may disclose PSWP as follows:

(i) **Disclosure in Criminal Proceedings.** The Consortium-PSO may disclose relevant PSWP for use in a criminal proceeding, but only after a court makes an in-camera determination that:

(A) such PSWP contains evidence of a criminal act;

(B) such PSWP is material to the proceeding; and

(C) such PSWP is not reasonably available from any other source.

PSWP disclosed for this purpose shall no longer be confidential.

(ii) **Disclosure to Permit Equitable Relief for Reporters.** The Consortium-PSO may disclose PSWP to the extent required to permit equitable relief under section 922 (f)(4)(A) of the Public Health Service Act, provided the court or administrative tribunal has issued a protective order to protect the confidentiality of the PSWP in the course of the proceeding. PSWP thus disclosed remains confidential after disclosure.

(iii) **Disclosure Authorized by Identified Providers.**

(A) The Consortium-PSO may disclose identifiable PSWP consistent with a valid authorization if such authorization is obtained from each provider identified in such work product prior to disclosure. A valid authorization must:

1. Be in writing and signed by the provider from whom authorization is sought; and

2. Contain sufficient detail to fairly inform the provider of the nature and scope of the disclosures being authorized.

(B) A valid authorization must be retained by the Consortium-PSO for six years from the date of the last disclosure made in reliance on the authorization and made available to the Secretary upon request.

(iv) **Disclosure for Patient Safety Activities.**

(A) The Consortium-PSO may disclose PSWP for patient safety activities to the disclosing participating healthcare provider.

(B) The Consortium-PSO may disclose PSWP for patient safety activities to an entity with which it has contracted to undertake patient safety activities on its behalf. A contractor receiving PSWP for patient safety activities may not further disclose PSWP, except to the Consortium-PSO.

(C) The Consortium-PSO may disclosure PSWP for patient safety activities to another PSO or to another participating healthcare provider that has reported to the PSO, provided:

1. The following direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers are removed:

- Names;
- Postal address information, other than town or city, State and zip code;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers or taxpayer identification numbers;
- Provider or practitioner credentialing or DEA numbers;
- National provider identification number;
- Certificate/license numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers; [[Page 70806]]
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and

2. With respect to any individually identifiable health information in such PSWP, the direct identifiers listed at 45 CFR 164.514(e)(2) have been removed.

(D) PSWP disclosed for patient safety activities remain confidential after disclosure.

(v) **Disclosure of Non-Identifiable PSWP.** The Consortium-PSO may disclose non-identifiable PSWP when the PSWP meets the standard for nonidentification in accordance with Sec. 3.212 of the Patient Safety Act. In this context, non-identifiable means that the participating healthcare provider is not identifiable. Non-identifiable PSWP, once disclosed, shall no longer be confidential and may

be re-disclosed by a recipient. The non-identifiable PSWP will include community reports, presentations, publications and other methods of disseminating such information to the public for the purpose of improving patient safety and quality in this area.

(vi) **Disclosure for Research.**

(A) The Consortium-PSO may disclose identifiable PSWP to persons carrying out research, evaluation or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research and in conformance with the Data Sharing Agreement entered into with each Participating Healthcare Provider.

(B) If the PSWP disclosed for research purposes contains protected health information as defined by the HIPAA Privacy Rule, the Consortium-PSO, as a business associate of participating healthcare providers, may only disclose such PSWP in the same manner as participating healthcare providers would be permitted to make such a disclosure under the HIPAA Privacy Rule.

(C) PSWP thus disclosed shall remain confidential.

(vii) **Disclosure for Business Operations.**

(A) The Consortium-PSO may disclose identifiable PSWP for business operations to attorneys, accountants, and other professionals. Such contractors may not further disclose PSWP, except to the Consortium-PSO.

(B) The Consortium-PSO may disclose identifiable PSWP product for such other business operations that the Secretary may prescribe by regulation as consistent with the goals of the Patient Safety Act.

(viii) **Disclosure to Law Enforcement.**

(A) The Consortium-PSO may disclose PSWP to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the Consortium-PSO reasonably believes constitutes the commission of a crime, provided that the Consortium-PSO believes, reasonably under the circumstances, that the PSWP that is disclosed is necessary for criminal law enforcement purposes.

(B) Law enforcement personnel receiving PSWP pursuant to this policy only may disclose that PSWP to other law enforcement authorities as needed for law enforcement activities related to the event that gave rise to the disclosure.

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