

**Carroll County Memorial Hospital
Risk Management Policy**

Subject: Confidentiality and Protection of Patient Safety Work Production (PSWP)
Effective: 12/11
Revised:
Pertains to: All Hospital Departments

Number:

Policy: It is the policy of Carroll County Memorial Hospital to maintain the confidentiality of information collected as PSWP. It is expected that all of Carroll County Memorial Hospital defined workforce members, health care providers with privileges, and affiliated providers participating within the Carroll County Memorial Hospital Patient Safety Evaluation System (PSES) will maintain the confidentiality of PSWP.

Rationale: Information appropriately defined and identified as PSWP for the purpose of reporting to a PSO is privileged and confidential. Assurance that information designated as PSWP is confidential will encourage robust reporting of patient safety information, which will support subsequent learning aimed towards informing patient safety activities and preventing adverse safety events.

Definitions: For the Purposes of this Policy, the following definitions apply:

1. **Affiliated Provider** shall mean a legally separate provider that is the parent organization of the provider, is under common ownership, management or control with the provider, or is owned, managed, or controlled by the provider.
2. **Disclosure** shall mean the release, transfer, provision of access to, or divulging in any other manner of PSWP by an entity or natural person holding the PSWP to another legally separate entity or natural person, other than a workforce member of, or a health care provider holding privileges with, the entity holding the PSWP.
3. **HIPAA Confidentiality Regulations** shall mean Regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).
4. **Patient Safety Work Product (PSWP)** shall mean any data, reports, records, memoranda, analyses, or written or oral statements which:
 - a. Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO; or

- b. are developed by a PSO for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or
 - c. Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES (42 USCA § 299b-21)
5. **Identifiable Patient Safety Work Product** shall mean PSWP that is presented:
- a. 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 activities that are a subject of the work product;
 - b. Constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or
 - c. In a form and manner that allows the identification of an individual who reported information in good faith, based upon fact, as specified in section 922(e).
6. **Non-identifiable Patient Safety Work Product** shall mean PSWP that is not identifiable in accordance with the Act and subsequent regulations. Non-identifiable PSWP is anonymized as to provider, deidentified as to protected health information, and contextually deidentified so that the provider, patient or reporter cannot be identified. As defined in § 3.206(b)(4) of the Final Rule, persons wishing to nonidentify patient safety work product must remove the direct identifiers listed in the anonymization standard at § 3.206(b)(4)(iv)(A)(1) through (13), as well as any additional geographic subdivisions smaller than a State that are not required to be removed by § 3.206(b)(4)(A)(2), e.g., town or city, all elements of dates (except year) that are directly related to a patient safety incident or event, and any other unique identifying number, characteristic, or code (except as permitted for reidentification).
7. **Patient Safety Evaluation System** shall be defined as set forth in Carroll County Memorial Hospital Policy RM05 Patient Safety Evaluation System.
8. **Patient Safety Activities** shall mean: Efforts to improve patient safety and the quality of health care delivery; the collection and analysis of PSWP; the development and dissemination of information with respect to improving patient safety; the utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk; the maintenance of procedures to preserve confidentiality with respect to PSWP; the provision of appropriate security measures with respect to PSWP; and, the utilization of qualified staff.
9. **Workforce** shall mean employees, volunteers, trainees, contractors, or other persons whose conduct, in the performance of work for Carroll County Memorial Hospital, is under the direct control of Carroll County Memorial Hospital, whether or not they are paid by Carroll County Memorial Hospital.

PRINCIPLES/PROCEDURE

- I. Information identified as PSWP according to Carroll County Memorial Hospital policy RM05 Defining Patient Safety Work Product shall be considered confidential.
- II. PSWP will be maintained within Carroll County Memorial Hospital PSES in accordance with Carroll County Memorial Hospital policy RM04 Patient Safety Evaluation System.
- III. Access to PSWP
 - A. PSWP may be shared among members of Carroll County Memorial Hospital workforce, a health care provider holding privileges with Carroll County Memorial Hospital, and affiliated providers as defined in 42 CFR § 3.20.
 1. Carroll County Memorial Hospital workforce shall include employees of Carroll County Memorial Hospital, Physicians with privileges at Carroll County Memorial Hospital, Contracted Patient Care Personnel, students performing clinicals at CCMH, Risk Management Consultants, members of the Governing Board and the legal representatives for Carroll County Memorial Hospital.
 2. Health care providers holding privileges with Carroll County Memorial Hospital shall include the members of the Medical Staff, EMCare Practitioners, Allied Health Professionals, VRC, and Medical Residents/Students .
 - B. Individuals identified as Carroll County Memorial Hospital workforce, health care providers holding privileges, or affiliated providers may have access to PSWP necessary for the performance of their work functions.
 1. *(How will PSWP be made available? Secure passwords limiting access to electronic data? Formal request to defined staff for hard copies of data? Reports generated on a regular basis?)*
 2. *(If PSWP may be accessed via computers outside of the PSES, what security measures are in place? Are computers where PSWP may be accessed password protected? Is identifiable PSWP permitted to be saved or maintained on computers outside of the PSES? Because the PSES may be identified broadly to fit the needs of the provider, consider where PSWP may need to be accessed for the conduct of patient safety activities- can those offices or computers be included within the PSES definition?)*
 3. Remote access to information from Carroll County Memorial Hospital PSES from a location separate from Carroll County Memorial Hospital, health care provider with privileges business location, or affiliated

providers business location is generally prohibited, except as is determined necessary by the Chief Nursing Officer.

IV. Acknowledgement of Confidentiality Requirements by Carroll County Memorial Hospital workforce, health care providers holding privilege, and affiliated providers

- A. Security and confidentiality protection responsibilities shall be defined in *(identify documents that provide guidance or govern the conduct of workforce, health care providers holding privileges, and affiliated providers that work within the facility's PSES with access to PSWP. These may include job descriptions, contractor agreement, medical staff bylaws, HIPAA workforce confidentiality agreements, standards of conduct etc.)*
- B. All Carroll County Memorial Hospital workforce, health care providers holding privileges, and affiliated provider designees who will have access to PSWP are to sign a confidentiality agreement pertaining to PSWP before they are permitted to access PSWP.
- C. All workforce members, health care providers with privileges, and affiliated providers required to sign the applicable confidentiality agreement shall receive training regarding PSWP confidentiality protections periodically.

(Will all workforce, providers with privileges, and affiliated provider workforce members receive training, or only those directly involved in working with PSWP. Will there be different levels of training? Consider how often such training will occur – in orientation? Annually?)

(See the PSO agreement between your organization and the Missouri Center for Patient Safety, Exhibit - Workforce Confidentiality Agreement for language to be included in a facility confidentiality agreement pertaining to PSWP)

- D. The terms of the applicable confidentiality agreements signed by Carroll County Memorial Hospital workforce, health care providers holding privileges, or affiliated provider designees will survive after the completion or termination of their relationship with Carroll County Memorial Hospital.

V. Disclosures

- A. Information collected by or submitted to Carroll County Memorial Hospital PSES as described in Carroll County Memorial Hospital policy no. RM04 shall be considered PSWP and shall not be disclosed.
- B. Identifiable PSWP subject to applicable exceptions to confidentiality as defined in 42 USC § 299b-22(2)(A)-(H) and 42 CFR §3.206 shall only be disclosed by the CEO, Quality Coordinator, Chief Nursing Officer, and Carroll County Memorial Hospital legal counsel. A written request for disclosure is required. *(Consider who*

is responsible for reviewing requests for disclosure, and authorizing disclosure of PSWP, such as risk management, administrative representative, legal counsel, etc. Consider if a written request for such disclosure will be required? What process is in place to determine whether the disclosure is an applicable exception to the confidentiality requirement?)

- C. Disclosure of identifiable PSWP may be made with the authorization of each provider identified in PSWP prior to disclosure. The authorization must:
 - 1. Be in writing and signed by the provider(s) from whom authorization is sought;
 - 2. Contain sufficient detail to fairly inform the provider of the nature and scope of the disclosure; and
 - 3. Be retained by Carroll County Memorial Hospital for at least six years from the date of the last disclosure made in reliance on the authorization. *(Consider how authorization for disclosure of PSWP will be obtained from providers).*
- D. Identifiable PSWP that is disclosed subject to an applicable exception to confidentiality or a disclosure permission may not be redisclosed by the individual or organization receiving the identifiable PSWP. *(Consider applicable redisclosure permissions pursuant to 42 CFR § 3.206(b) – is redisclosure expressly prohibited? How will this decision be made?)*
- E. Information that meets the standard for nonidentification pursuant to 42 CFR § 3.212 may be disclosed as nonidentifiable PSWP.
- F. Pursuant to 42 CFR § 3.206(e), Carroll County Memorial Hospital may delegate authority for applicable permitted disclosures (see 73 Fed. Reg. 70784) *(Consider what your process will be for making decisions regarding delegation of authority to make a disclosure).*

IX. Breach of Confidentiality

- A. In the event of a disclosure that is not authorized by Carroll County Memorial Hospital, Carroll County Memorial Hospital will make a good faith effort to notify the affected parties subject to an inappropriate disclosure or breach. The affected parties shall include each provider identified within the disclosed PSWP, and patient whose protected health information was disclosed, or released through a security breach *(Consider what constitutes an unauthorized disclosure. Who will be responsible for notifying the affected parties? How will the affected parties be determined? Will the notification be verbal or in writing, or both? Will any other notification of breach be provided within the facility?)*

- B. *(What is the internal procedure for notifying appropriate staff, such as risk management, legal counsel, technology staff, administration, and other entity staff of a disclosure or breach in order to trigger the notification process?)*

- C. In the event that the inappropriate disclosure or breach involves PSWP that has been submitted to the Missouri Center for Patient Safety Patient PSO (Center), Carroll County Memorial Hospital will make every effort to notify the Center's Executive Director of the inappropriate disclosure or breach. *(Consider who will notify, when the notification shall take place, and in what form notification will be made to the Center).*

Policy Number:	Original Approval Date:
Signature:	Reviewed and Revised: