I. POLICY SUMMARY

The policy of the [redacted] is to participate in patient safety activities conducted in accordance with the **Patient Safety and Quality Improvement Act (PSQIA) of 2005** and its implementing regulations (collectively, the Act). as well as [redacted] State quality and public health laws. [redacted] collects **patient safety work product (PSWP**) and is a member of the[redacted] **atient Safety Organization** [redacted] for the purpose of engaging in comprehensive patient safety activities to improve the quality of health care services as well as reduce the risk that adverse events pose to [redacted]patients, its member hospitals, and its affiliated licensed health care facilities and workforce (See Appendix 1, Definitions). [redacted] reports information about adverse events to the PSO using [redacted] and hereinafter known as[redacted]

[redacted] is the [redacted]platform for the following: Patient Safety, Peer Review and Service Feedback. The platform **automatically** submits **patient safety events** from the Patient Safety module to the PSO. Peer review is considered PSWP and the investigations related to patient safety complaints and grievances are also considered PSWP.

[redacted] entered into a contract wit[redacted] and may contract with other PSOs in the future to fully effectuate the patient safety activities and reporting of PSWP in accordance with the procedures described herein. All of the **patient safety data** on the [redacted] platform is PSWP.

PSWP containing protected health information (PHI) continues to be subject to federal and state health information privacy and security laws and regulations including but not limited to HIPAA [Health Insurance Portability and Accountability Act of 1996, 45 CFR Part 160 and [redacted]f such PHI shall conform to all laws, regulations, and[redacted]' privacy and security policies.

II. PROCEDURAL SUMMARY

This policy covers the **use** and **disclosure** of PSWP both internal and external to[redacted] (see Appendix 1, Definitions). The Risk Management **and** Patient Safety Department (hereinafter Risk Management) and/or Legal Department should be contacted for any internal request for **use** or **disclosure** of PSWP for reasons unrelated to quality assurance or patient safety. **Risk Management and Patient Safety** has operational and oversight responsibility for the **Patient Safety Program**, which includes but not limited to system-wide event/occurrence reporting, investigation of adverse events and the Serious Adverse Event (SAE) program, which includes serious adverse event review and the performance of an RCA (see [redacted] QAPI plan, Appendix 3). The Risk Management Department and/or Legal Department should also be contacted for any external requests from an individual, regulatory agency, company, etc. for use and/or disclosure of PSWP.

III. COMPLIANCE / RESPONSIBILITIES

The [redacted] Office of the Chief Medical Officer, the Office of Medical Affairs, Risk Management and Patient Safety, Quality Assurance and Regulatory, [redacted] Medical Boards and Patient Relations/Experience are responsible for the oversight of quality, patient safety, and performance improvement processes that create, analyze, and store PSWP. The [redacted] Board of Trustees is ultimately responsible for the quality of care provided. The Risk Management Department and/or Legal Department is responsible for consultation around PSWP protections, use, and disclosure.

IV. DEFINITIONS

Terms are defined either at first use or in **Appendix 1**. A full list of terms and definitions released by the Agency for Healthcare Research and Quality (AHRQ) can be found at https://pso.ahrq.gov/resources/psqia

V. POLICY TEXT

The policy of [redacted] is to participate in patient safety activities conducted in accordance with the Patient Safety and Quality Act of 2005 (PSQIA) and its implementing regulations (collectively, the Act). [redacted] collects PSWP and is a member of [redacted] for the purpose of engaging in comprehensive patient safety activities that can improve the quality of health care services, as well as reduce the risk that adverse events pose to [redacted] patients, its member hospitals, and its affiliated licensed health care facilities and workforce.

A **Patient Safety Concern** includes:

- A patient safety event that reached the patient, whether or not there was harm;
- A near miss or close call - a patient safety event that did not reach the patient; or
- An unsafe condition - circumstances that increase the probability of a patient safety event.

A. [redacted]

[redacted]: Provides the [redacted] analysis of our adverse safety events and providing feedback, when appropriate, to promote learning and minimize patient risk. It allows [redacted] the ability to aggregate de-identified data from multiple providers, both within the [redacted] and with other members of the [redacted]

[redacted] (hereinafter, [redacted]): Adverse safety event reporting is a critical component of an effective patient safety program. [redacted] is the portal for which all employees and/or workforce can enter adverse safety events, near misses or unsafe conditions.

The following modules are part of [redacted]

- The **Patient Safety module** is used for the reporting, collecting and analysis of adverse safety events involving [redacted] patients and employees/workforce. The analysis is done by appropriately designated [redacted] staff, including, but not limited to

quality assurance, risk management and patient safety and other designated staff involved in patient safety/quality assurance activities. The module also includes analysis undertaken during the Root Cause Analysis process.

- **The** [redacted] module captures patient complaints, grievances and compliments and is intended to capture and include the Patient Experience/Relations Department's review and analysis of patient safety events (e.g patient grievance related to billing would NOT constitute PSWP).
- The [redacted] peer review and is a separate function from [redacted] (defined in the Appendix, but also included in PSWP). Peer review is performed by designated Quality Assurance provider(s) for the sole purpose of reviewing the specific event as it relates to their discipline.

The analysis within the Patient Safety module and the Peer Review module within [redacted] is only accessible by [redacted] Risk Management and **appropriately designated employees/workforce** for the purpose **of quality assurance/ patient safety activities**. Only Patient Experience/Relations staff and those staff specifically designed by Patient Experience may access the Feedback module.

B. What is Patient Safety Work Product (PSWP)

PSWP includes, but is **not limited to,** the following:

1. **Deliberations or Analysis (see Appendix 1)** are any activities carried out or information used for the purpose of quality and patient safety improvement, but **may not be directly reported to, or generated by the PSO, including but not limited to**
    a. Quality assurance/improvement and patient safety activities, communication (written, oral, or digital), and/or information reported, developed, or **captured directly or in minutes by individuals or committees** for activities relating to improving patient quality and reducing risks **including but not limited to**:
        - Notes including but not limited to chart reviews and interviews of involved providers
        - Data analyses reports and communication
        - Documents reflecting insights and action plans
        - Serious Safety Event Process, including Huddles and Debriefs
        - Event Debriefing documents and reviews
        - Root Cause Analyses (RCAs) documents, including process maps and causal trees
        - Patient Safety Solutions (PSS) documents
        - Critical Event reviews
        - Outcome reports
        - Research related to quality improvement and safety
        - Data collected and reported to third-party organizations [redacted] has partnered with as reflected in [redacted] Quality Assurance and Performance Improvement (QAPI) Plan (**See Appendix 3)**
        - Dashboards: e.g. Quality, Patient Safety, Risk Management

- Patient Safety Committee minutes
- Quality Assurance/Performance Improvement Committee/Workgroup minutes
- Social determinants of health and health equity activities
- Failure Mode Effects Analyses (FMEAs)
- Any additional Risk Management activities, **excluding** claims and litigation activities
- Patient Experience/Relations activities related to **patient safety events**
- Collection/tracking of patient complaints/grievances related to **patient safety events**
- Collection/tracking of patient rounding data and information gathered during rounding related to **patient safety**
- Customer Service activities related to **patient safety**
- Patient grievance and complaint investigation pursuant to patient safety
- Videos and/or recordings of surgery or procedures(e.g. [redacted]) for patient safety and/or quality assurance/improvements
- Peer Review related to a specific patient safety event
- Peer Review ([redacted]and departmental level) – performance enhancement activity as set forth in the Medical Staff Bylaws and associated policies, including but not limited to, credentialing assessments, Focused Professional Practice Evaluations (FPPE),Ongoing Professional Practice Evaluations (OPPE), peer review notes, Leadership Council meetings, etc.
- Reviews prompted by recall notices
- Written statements by providers involved in patient care
- Patient safety data contained on [redacted] Teams site(s), Risk Management shared drives and/or other [redacted]platforms (e.g. [redacted]).

b. Data and documents that support quality assurance/improvement and patient safety activities that are created, derived from, and/or obtained during or for the above activities.

c. The development and implementation of committees and programs to address quality and patient safety improvement, whether permanent or ad-hoc, and conducted at the **department, division, group, or hospital/system level**. These committees and programs include **but are not limited** to:

- Committee on Quality (COQ) of the Board of Trustees (BOT)
- [redacted]Quality Leadership Council (QLC)
- All [redacted] Medical Boards and all Medical Staff Committees accountable to the Medical Board (outlined in Medical Staff Bylaws and the Medical Staff Rules & Regulations)
- Clinical Specialty Review Committees
- Network Performance Group
- [redacted]Center for Performance Improvement
- [redacted]Health System Quality Collaborative
- Ethics Committee

- Patient Safety Committees
- Serious Safety Event (SSE) / Never Event Review(NE) Committees
- Quality and Performance Improvement Committees
- Serious Adverse Event Review (SERT)Committees
- Medical Risk Reduction Committee (MRRC)
- Committee on Professionalism in Healthcare (COPHE)
- Division Councils
- Antibiotic Stewardship and Infection Control Committees
- [redacted] Medical Group Quality Improvement and Informatics Committees
- Enterprise Data and Information Management and Business Intelligence
- Centers for Excellence Quality Improvement, including but not limited to:
  - Nursing Magnet
  - Comprehensive Stroke Center
  - Primary Stroke Center
- Solid Organ Transplant Quality Committees
  - Solid Organ Transplant Quality Committee and Specific Organ Transplant QI Committee
  - Specific Organ Tranplant Peer Learning Sessions
  - [redacted]Peer Learning Sessions
  - [redacted]Clinical Case Review & Education Committee
  - [redacted]QA/PI Regulatory Committee
  - Specific Organ QA/PI Committee
- Transplant Clincial Quality Committee
- Transplant Center Steering and Executive Committee(s)
- Ambulatory Care Quality Safety Advisort Group (QSAG)
- Departmental Quality Improvement Committee minutes
- Medication Safety Committees
- Organ Donor Councils
- Clinical Competency Committees (GME)
- Interdisciplinary Review Committees
- Patient Experience Steering Committees
- Healthcare Associated Infection (HAI) Committees
- Patient Safety Indicator (PSI) Committees
- Cardiac Arrest/Code Committees
- Airway Committees
- Departmental Peer Learing Sessions (previously Morbidity and Mortality Conferences)
- Clinical Departments Peer Learning Sessions, Quality Assurance/Improvement and Patient Safety curricular sessions
- Clinical Review Committee(CRC)
- Health Care Equity Commitees
- Training Grants (such as the Learning Health System and Health Equity Research and Training Award)
- Hospital Acquired Infection reduction committees and clinical review meetings

- Sepsis reduction committees
- Infection Prevention and Control Committees
- Infection prevention and control practices and work products;Infection cluster/outbreak/unusual occurrence reviews
- Medication Alerts Committee
- Leapfrog, USNWR and CMS Star Ratings committees
- Health System and local Pharmacy and Therapeutics (P&T)committees
- **Ad hoc committees formed in response to identified need for improving the quality and safety of patient care and services provided at [redacted].**

Any committee not listed above but included in [redacted] QAPI Policy (**Appendix 3**) is incorporated by reference herein for above referenced policies.

2. The Direct Reporting pathway to the PSO includes any information, data, or document entered, submitted, or uploaded by [redacted] employees/workforce into [redacted] used for storing patient safety data **including but not limited to:**

a. Adverse Event Documentation
b. [redacted] Data, including documentation on the debrief, RCA and patient safety solutions
c. Interview summaries/Risk Management interviews as it pertains to patient safety
d. Investigation decisions
e. Comments

3. All **patient safety data** on the [redacted] and PSO Platform generated by or for [redacted] is PSWP
4. The following is **NOT** PSWP:
    a. Information relating to activities involving the actual delivery of patient care and the supporting services directly related thereto including all original records reflecting the actual delivery of patient care and the supporting services directly relating thereto (e.g., medical records, orders, billing, and discharge information).
    b. **Copies** of such non-PSWP records that are used for quality assurance/improvement and patient safety activities are PSWP if intended for reporting to a PSO (See **Appendix 1** for Copies definition).
    c. Information relating to activities which are not permitted activities or uses of PSWP (e.g. information required to be collected, maintained, and reported to any local, state, or federal regulatory agency).
    d. Videos, photography, recordings, and all media created for the purposes of **treatment or communication** and shared with a patient/patient family/designee are not PSWP.
    e. Any investigation into employee conduct pursuant to Just Culture and/or progressive discipline just cause standards under existing collective

bargaining agreements by Human Resources (See Appendix 1.A for Progressive Discipline and Just Cause Standards definition).

- Any investigation into employee conduct by Quality Assurance and Risk Management/Patient Safety **is PSWP.**

C. Creation of PSWP

1. PSWP is created when information or communications related to patient safety or quality assurance/improvement activities are developed within, or entered into, the PSES for the purpose of improving patient safety or health care quality. PSWP protections apply immediately.
2. To ensure that information qualifies as PSWP and receives legal protections:
    - Employees must enter information about patient safety events, near misses, or quality assurance/improvement activities into [redacted] and/or submit it to the PSO using the approved **reporting channels**.
    - Any additional information added to an existing report—such as updates, clarifications, or follow-up findings—should also be entered in[redacted] or the PSO system. This additional content becomes PSWP as well.
3. PSWP protections apply immediately upon entry of the information into [redacted] or the PSO, as reflected by the system's date stamps.
4. All Deliberations or Analyses identified in Section V(B1) above automatically become PSWP upon creation within this PSES Policy.
5. Once created,PSWP remains PSWP until and unless it is de-designated/dropping out (**See Appendix 1 definitons**) to no longer be PSWP. Date stamp when it was dropped out must also be included. Documentation should include the reason why it is was dropped out, which would be reviewed by designated staff in Risk Management and Patient Safety and/or the Legal Department. Once dropped out, it can no longer be added back as PSWP. [redacted]

Use of PSWP by the[redacted]

1. PSWP may be used by [redacted] for a variety of activities including:
    a. Performance Improvement and Patients Safety Activities that address systems issues that contribute to patient harm, improving the quality of patient care, improving the efficiency of care, reducing medical malpractice liability and the cost of malpractice liability and identifying performance improvement progress and priorities.
    b. These safety activities described above may be conducted by an individual, committee, or body that has assigned responsibility for any such activities. The [redacted] workforce includes faculty, staff, trainees, volunteers, and contractors, who perform work under the direct control of [redacted] These include the following as detailed in[redacted] QAPI (Appendix 3)but are **not limited** to:
        - Medical Board(s)
        - Committee on Quality of the Board of Trustees

- All [redacted] Medical Boards and all Medical Staff Committees accountable to the Medical Board (outlined in Medical Staff Bylaws and the Medical Staff Rules & Regulations)
- Clinical Specialty Review Committees
- Quality and Performance Improvement Committee(s)
- Ethics Commitee
- Network Performance Group
- [redacted]enter for Performance Improvement
- [redacted] Health System Quality Collaborative
- Bioethics Committees
- Patient Safety Committees
- Serious Adverse Event Review Committee (SERT)
- Division Councils
- Antibiotic Stewardship and Infection Control Committee
- [redacted] Medical Group Quality Improvement and Informatics
- Enterprise Data and Information Management and Business Intelligence
- Centers for Excellence Quality Improvement
  - Nursing Magnet
  - Stroke Center
- Solid Organ Transplant Quality Committees
- Medication Safety Committees
- Organ Donor Councils
- Peer Learning Sessions (Morbidity and Mortality Committees)
- Committee on Professionalism in Healthcare (COPHE)
- Clinical Competency Committees (GME)
- Interdisciplinary Review Committees
- **Ad hoc committees formed in response to identified need for improving the quality and safety of patient care and services provided at** [redacted]

2. PSWP can be used for any purpose within a hospital and is treated as a "use" and not a disclosure. Identifiable facility PSWP can be shared throughout the [redacted] via the affiliated entity disclosure exception and not considered a “use”.

   a. PSWP may be disclosed to other Affiliates providers **of** [redacted] for the purpose of improving quality and safety of patient care and reducing patient harm.
      - For purposes of this Policy only, “Affiliate” is defined in the Act as a legally separate provider that is the parent organization of the provider, or is under common ownership, management, or control with the provider, or is owned, managed, or controlled by the provider.
   b. Any individual or committee needing to use PSWP for purposes prohibited by the Act **may not** use the information that is maintained within the PSES for the prohibited purposes, unless:
      - All identified providers authorize the disclosure (See **Appendix 1.F**).

- The identifiable information can be effectively removed (See **Appendix 1.C2**).

3. PSWP may be shared with outside attorneys, accountants, or other approved consultants as approved by HHS who assist [redacted] in the conduct of [redacted]' business operations and is considered a business disclosure exception and not a "use". These individuals may not further disclose the PSWP .

4. Anyone with a reasonable need to know information to conduct assigned responsibilities or related **patient safety activities** may be given access to PSWP or copies of PSWP. PSWP may not be used or disclosed for purposes prohibited by the Act, including, in particular:

   a. PSWP may not be provided in response to any subpoena or other order in any federal, state, local, or tribal civil, criminal, or administrative proceeding including but not limited to a disciplinary proceeding against any healthcare provider.
   b. PSWP may not be admitted into evidence in any federal, state, local, or tribal civil, criminal, or administrative proceeding including but not limited to a disciplinary proceeding against any healthcare provider.
   c. PSWP may not be admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

D. Maintaining Confidentiality of PSWP / Claiming the Privilege

1. Confidentiality

a. PSWP is confidential. All access to and use of PSWP must be structured to honor and maintain this confidentiality.
b. All communications and activities conducted within appropriate channels of communication (written, oral and/or digital) and intended to improve safety and quality are permitted.
c. Use of PSWP for [redacted] business operations (as described in Section V.D.) is permitted **within appropriate channels of communication**.
d. Those who access or use PSWP shall be made aware of its confidential nature and will not disclose the information except to others as permitted above.
e. Questions about these parameters should be referred to [redacted]Risk Management and/or Legal Department.
f. Exceptions to confidentiality are described **in Section V.D.3.**

2. Privilege

a. PSWP is "Privileged" (i.e., not subject to compulsory discovery or disclosure). Thus, in addition to prohibiting [redacted] from itself using the information for certain purposes (as described Section V.D) other persons or entities are likewise prohibited from gaining access to the information via subpoena, court order, administrative order, inspection processes, or the like.

b. If any governmental agency or any individual or organization seeks access to or disclosure of PSWP, [redacted] Risk Management and/or Legal Department should be contacted immediately so they may assert the PSWP privilege.

c. All PSWP, whether deliberations or analysis and/or reported to the PSO should be prominently labeled as *"Confidential and Privileged Patient Safety Work Product" or "Confidential and Privileged Quality (Safety) Patient Safety Work Product"* or "*PSWP:Confidential and Privliged*" to better enable later identification of privileged documents when responding to requests for access or disclosure. [redacted] may select other clearly discernable text to be used as the label and modify the Policy appropriately – *e.g., This email is subject to the confidentiality and privilege rules governed by* [redacted] *Patient Safety Evaluation System pursuant to the federal law, Patient Safety and Quality Improvement Act of 2005- 42 U.S.C. 299b:21-26 as well as* [redacted] *Any unauthorized review, use, disclosure, or distribution is prohibited. If you are not the intended recipient, please contact me by reply email and destroy all copies of the original message.* **However, the absence of any such labels does not render PSWP non-privileged.**

3. Exceptions

a. There are a number of exceptions that permit disclosure of PSWP in limited circumstances and subject to specific requirements. These exceptions relate to disclosures relating to the following areas, and the specific requirements of each exception are described [redacted]

- Criminal Proceedings and/or to law enforcement
- Equitable relief actions
- Provider authorization
- Non-identifiable PSWP
- Research
- Food and Drug Adminstration (FDA)
- Accrediting Bodies
- Independent contractors

E. Required Reporting

1. PSWP may not be used to satisfy mandated reporting by any federal, state, or other governmental agency and should not be provided as the required report.

a. Whenever a patient safety concern is also a serious reportable event or an unusual occurrence that is required to be reported, original non-PSWP records and/or communications with individuals involved in the event or occurrence may provide the information needed to complete the report.

b. Any information that is prepared to meet federal, state, or local health reporting requirements is **not PSWP.** A **copy of the report** may be treated as PSWP if reported to the PSO or deemed **Deliberations or Analysis** if subsequently reviewed within the PSES.

c. The **actual (original**) RCA document prepared for **submission** to the [redacted] State Department of Health under [redacted] Patient Occurrence and Tracking System (NYPORTS) **is not PSWP**. A **copy of the form** reported per state or federal law, may reside in the PSES deliberative files or reported to the PSO. **All the information gathered and documents used to create the reporting document may be collected within the PSES processes and hence considered PSWP.**

d. A patient's medical record, billing, discharge information, or other information that is collected, maintained, or developed separately from the PSES, may be provided as part of these reporting requirements.

e. PSWP may be voluntarily disclosed to the Joint Commissionsnd subject to compliance with [redacted]

F. Medical Staff Peer Review

1. PSWP may be accessed and used in the process for making decisions around medical staff performance management decisions.

2. The Act prohibits a provider organization from taking an adverse "employment action" or "adverse action related to medical staff membership or clinical privileges", against an individual if the action would be based upon the fact that the individual, in good faith, reported to the provider organization with the intention of having the information reported as patient safety or quality improvement activity or reported directly to a PSO. This does not, however, preclude peer review actions that are taken for other reasons, such as enforcing [redacted] Just Culture procedures. [redacted] "Just Culture" framework is referenced in [redacted] QAPI **(**[redacted]**)**. Medical staff or medical peer review activities are conducted within the PSES, unless otherwise stated and documented as disciplinary review proceeding.
3. Incorporating information into the PSES shall be deemed in furtherance of the responsible medical staff committee's responsibilities with respect to evaluation and improvement of the quality of care rendered at [redacted] or for the peer review body and does not waive any evidentiary protections or privileges associated with that information.
4. Practitioner Specific Peer Review, Practitioner Specific Performance Improvement Activities, Ongoing Professional Practice Evaluation, and Focused Professional Practice Evaluation Activities
    a. Practitioner Specific Peer Review, OPPE/FPPE activities, and Practitioner Specific Performance Improvement Activities are functions of the organized Medical Staff for licensed, credentialed and privileged Practitioners. All OPPE/FPPE activities and Professional PI Activities shall

be conducted according to the Medical Staff Bylaws, Medical Staff Rules & Regulations and associated Policies & Procedures.

b. All processes related to OPPE/FPPE Peer Review, and Professional PI Activities are part of the PSES and the work product is PSWP.
c. All practitioner performance monitoring evaluations, documentation or other performance tools are developed within the PSES and are PSWP.

G. [redacted] Personnel Actions

a. Investigation, deliberation, and employment decisions and/or discipline conducted at the direction of clinical leadership by or through Human Resources(HR) pursuant to Just Culture and progressive discipline just cause standards are not PSWP.
b. HR can access and review PSWP in the performance of their HR responsibilities, but need to create their own work product, investigations, etc., outside of the PSES. This work product is not PSWP and can be placed in the employee's file.
c. PSWP should not be included in this file because it cannot be introduced into evidence to defend the hospital in the event that a terminated employee later sues the hospital in state or federal court.

H. Grievances

In some cases, patient complainants/ grievances may involve patient safety concerns. When that is the case, all documents *(other than the patient/complainant's original written grievance, grievance log, and the response back to the patient/complainant*), data, evaluations, and all other associated documents are deemed PSWP.
Information that is reported to the patient/complainant or any outside agency must not include PSWP.

I. [redacted]Peer Learning Sessions (formerly known as Morbidity and Mortality (M&M) Conferences)

Learning sessions are conducted within the PSES and are designed to provide opportunities to learn from adverse outcome patient safety events in order to facilitate quality and safety improvements in systems and processes of care.

a. A case is de-identified and then presented to staff (who will benefit from learning about the case);
b. Staff participating shall adhere to PSWP confidentiality;
c. Peer Learning Sessions can occur on the department, facility or system level.

J. Malpractice Risk Reduction Committee (MRRC)

Malpractice Risk Reduction Committee (MRRC) is a collaborative committee between [redacted] and Healthcare Risk Advisors(HRA) to identify and advance projects that promote better clinical/patient outcomes, and mitigate [redacted] Hospital Professional Liability (HPL) and Medical Professional Liability (MPL) risks, and reduce HPL/MPL losses. The MRRC is organized pursuant to [redacted]– *M as part of a*

medical malpractice prevention/reduction program and will report to the [redacted] Quality Performance Improvement Committee (QPIC) and the Committee on Quality of the BOT.

K. [redacted] Patient Safety Organization (PSO) Feedback

1. The PSO provides feedback and/or recommendations that could assist [redacted] to enhance existing patient safety initiatives or to develop new initiatives for the improvement of patient care.
2. [redacted] will utilize clinical personnel to evaluate such PSO feedback and/or recommendations. All deliberations concerning such feedback and/or recommendations must take place within the PSES and is, itself, considered to be PSWP under the Patient Safety Act.
3. [redacted] will disseminate de-identified PSWP and learnings related to its patient safety activities in the interest of improving the delivery of patient care or implementing new initiatives in conformity with these Policies and Procedures. The best practices are developed in the PSES and are PSWP.

***L*. Serious Adverse Event (SAE) Program:**

1. The review of all patient safety occurences and potential serious adverse events, including senitinel events are done by Risk Management and Patient Safety. This process has been developed for the prompt identification of of unanticipated serious adverse events which may impact the safety of patients or staff/practitioners, as well as for the prompt identification and reporting to [redacted] Office of Health Systems Management via the NYPORTS program. **Huddles, debriefs and Root Cause Analysis (and patient safety solutions if indicated) are the key components of the SAE program**. This work is cons[redacted]d Federal Law 109-41 in addition to being PSWP.
2. Serious adverse events, including sentinel events, will be reported internally and externally, per hospital policy. External reporting will be performed in accordance with all state, federal and regulatory body rules, laws and requirements. A report to the Committee on Quality of the Board of Trustees regarding serious adverse events/outcomes and actions to improve patient safety is provided annually. *See [redacted] Patient Safety Occurrence/Event Reporting, [redacted] 133 and [redacted]erious Adverse Event Investigation [redacted] 134.*
3. Core Components of SAE program
    a. A **huddle** is conducted in the immediate aftermath of a Serious Adverse Event. Staff gathers immediately to share their understanding of what occurred. The huddle is led by the most senior local staff and aims to mitigate any ongoing harm as well as determine factually what happened. Part of the huddle is to also escalate to leadership and Risk Management. Within 24-72 hours after the event, a debriefing is expected to occur.
    b. The **debrief** is led by the Chief Medical Officer (or designee) and Risk Management and Patient Safety and includes all involved individuals and quality leadership of

involved departments. The debrief aims to clarify the chronology of events and develop action plans, including when necessary, referring individual practitioners to Medical Affairs for evaluation under the Performance Enhancement policy and procedure. Labor Relations and legal counsel are not included in the SAE process. Huddles and debriefs are confidential and the information obtained is not disclosed to Labor Relations. Staff must participate when requested.

c. The aforementioned debrief committee determines if a **Root Cause Analysis (RCA**) is required and whether or not the case is reportable to external agencies. If an RCA is conducted, **corrective action plans/patient safety solutions** will be created as necessary. Performance improvement tools (e.g.process maps and casual trees) are utilized and the Just Culture rubrix followed.

M. Triaging Patient Safety Concerns

1. The [redacted]Risk Manager is responsible to review event reports and determine if they involve patient safety concerns. The Risk Managers and other authorized individuals are notified through an electronic notification process via an email and link to the adverse event identified by[redacted]. Who receives notification and how is determined through a filtering process established by the authorized user(e.g. Risk Management).

2. Risk Management filters for events that are potentially compensable as well as those adverse events that could or do cause serious harm. Other authorized individuals filter adverse event notification based upon their clinical judgment. The safety event will be investigated according to our Adverse Event Investigation policy (**See Appendix 2**).

3.Those matters that Risk Management deems to be a potentially compensable event (PCE) are sent to Healthcare Risk Advisors (HRA), the[redacted] third party administrator (TPA) for handling PCE, claims and lawsuits. If Risk Management determines that an adverse event is either a claim or highly likely to become a lawsuit, Risk Management informs the HRA Claims Department of the patient's name and may upon request, secure outside counsel representation for the matter. When Risk Management informs HRA's Claims Department of a potential claim or lawsuit during this process, **no PSWP** is shared with HRA's Claims Department. [redacted]**Risk Managers are prohibited from and do not share, send or disclose any PSWP to HRA Claims Department.**

N. Communication and Resolution Program

1. The [redacted] believes that patients should be treated with openness and honesty at all times, and that their right to know their medical status is respected. Patients have the right to receive accurate, timely and understandable information in order that they may make informed decisions regarding their care, and fully participate in the decision-making process.

2. Full disclosure of results, including results that differ significantly from what was anticipated enables patients to make informed decisions about future medical care. *See*[redacted] *234 Communication and Disclosure of Unanticiapted Patient Events and Outcomes.*

3. The disclosure with the patient and/or family is not privileged, the investigation and analysis which result from the disclosed events is privileged and considered PSWP.

O. Removing Direct Identifiers and Rendering PSWP Non-Identifiable

1. **Removal of Direct Identifiers versus Non-Identifiable PSWP**
   a. By removing direct identifiers of patients and caregivers, certain disclosures of some information that would otherwise be deemed PSWP may be disclosed to other PSOs or to other providers, including non-affiliated providers for patient safety activities. The requirements for removing patient and caregiver direct identifiers are less rigorous than the requirements for rendering "non-identifiable PSWP". Since the requirements are less rigorous, there is a corresponding limitation on how the PSWP may be used. (i.e., only for patient safety activities).
      - The requirements for removing patient and caregiver identifiers are set out in [redacted]
   b. Non-identifiable PSWP is PSWP that has been sufficiently scrubbed of all meaningful identifiers to permit disclosure without restrictions on use.
      - The requirements for non-identification are therefore more rigorous as described in [redacted]
   c. [redacted] Risk Management and Patient Safety and/or Legal Affairs are authorized to disclose information pursuant to this appendix and must document in writing that all factors listed in this appendix have been considered and determined satisfied
2. **Removing Direct Identifiers**
   a. Removing Direct Identifiers on PSWP is accomplished by removing all of the following direct identifiers of any practitioners and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the [redacted]workforce, or household members of such practitioner:
      - Names
      - Postal address information, other than town or city, State, and zip code (i.e., town or city, State, and/or zip code may be disclosed)
      - Telephone Numbers
      - Fax numbers
      - Email addresses
      - Social Security Numbers or taxpayer identification numbers
      - Provider or practitioner credentialing or DEA numbers
      - National provider identification numbers
      - Certificate/License Numbers
      - Web URLs
      - IP Addresses
      - Biometric identifiers, including finger and voice prints
      - Full face photographic images and any comparable images
      - With respect to any individually identifiable health information in such PSWP all direct identifiers required to develop a limited data set under HIPAA in accordance with applicable policy. Note, however, that since a data use agreement is not used, the resulting PSWP does not meet the HIPAA definition of "limited data set."

3. **Rendering Information as Non-Identifiable**
   a. PSWP is deemed non-identifiable with respect to any particular provider, and hence may be disclosed, if an appropriately knowledgeable person determined that the risk is "very small" that the information could be used alone, or in combination with other reasonably available information, by an anticipated recipient to identify either a provider or a reporter.
   b. Alternatively, PSWP may be rendered non-identifiable if all of the direct identifiers have been removed with respect to any identifiable provider or reporter, or any affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the [redacted] workforce, and household members of the provider and reporter.

P. Exception to Non-Disclosure Requirements

[redacted] Risk Management and Patient Safety and/or Legal Department must be apprised of and approve in writing any request for PSWP pursuant to this appendix and will be responsible to coordinate any such disclosure.

1. **Criminal Proceedings and Law Enforcement**
   a. Criminal Proceedings – While as a general matter, PSWP is not subject to disclosure, even in criminal proceedings, there is a process whereby a court may review *in camera* (i.e., in the judge's chambers) the circumstances and determine that the PSWP contains evidence of a criminal act, is material to the proceeding, and is not reasonably available from other sources.
   b. Law Enforcement – PSWP may be disclosed to appropriate law enforcement authorities relating to a patient safety concern that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime, if the PSWP is reasonably believed to be necessary for criminal law enforcement purposes.
      - The law enforcement officials shall be apprised of the controlling regulation (42 CFR Part 3, section 3.206(b)(10)) that the information is PSWP, and that the information may only be disclosed to other law enforcement authorities as needed for law enforcement activities related to the Patient Safety Concern at issue. Attached as **Appendix 1.E** to these Policies and Procedures is a written statement, Notification of PSO Act Limitations on Use of Information, to be provided to law enforcement apprising them of these responsibilities.

2. **Equitable Relief**
   Individuals who are seeking equitable relief (e.g., an injunction) associated with a claim that they have been the subject of an adverse employment action relating to their having reported information to a provider or a PSO may have a right to access and use PSWP to pursue that equitable relief.

3. **Provider Authorization**
   a. PSWP may be disclosed for specified purposes pursuant to written authorization of all identified providers. Any such written authorization must:
      - Be signed by the identified provider

- Contain sufficient detail to inform fairly the identified provider of the nature and scope of the disclosure that he/she is authorizing
- Be retained by the disclosing entity for 6 years from the date of the last disclosure made pursuant to the authorization

b. See **Appendix 1.F** for the Authorization Form to be used for this purpose. Authorization pursuant to any other form must be approved, in writing, by [redacted] Risk Management and Patient Safety and/or Legal Department.

3. Non-Identifiable PSWP

Non-identifiable PSWP may be disclosed without restriction. See **Appendix 1.B.3** for a description of non-identifiable PSWP.

4. Independent Contractors

Disclosure of identifiable PSWP may be disclosed to an Independent Contractors required for patient safety activities.

5. Research

PSWP may be disclosed to persons carrying out research, evaluation or demonstration projects that have been authorized, funded, certified, or otherwise sanctioned by the Secretary of Health and Human Services. Disclosure pursuant to this exception must be approved, in writing, by a responsible Institutional Review Board and [redacted]Legal Department.

6. Food and Drug Administration (FDA)

PSWP may be disclosed to the FDA and entities required to report to the FDA. This exception relates to FDA oversight of FDA regulated products or activities.

7. Accrediting Bodies

a. PSWP may be disclosed to The Joint Commission (TJC) or other body responsible for accreditation of a [redacted] health care provider, if all individually identified providers agree to the disclosure, or all identifiers described in **Appendix 1.B.2** have been removed.

b. Once authorization has been obtained, or identifiers have been removed, the following are authorized to release information to an accrediting body:

- [redacted] Risk Management and Patient Safety
- Quality Assuarance and Regulatory
- The Hospital CEO, or their designee
- The Vice President of Medical Affairs, or their designee, with respect to any member of the medical staff or any advanced practice providers for whom the medical staff has oversight or credentialing responsibility.

c. See **Appendix 5** for examples of what can be provided to regulatory bodies in accordance to PSQIA.

8 PSWP may be disclosed to the **Secretary of Health and Human Services** if needed to investigate or determine compliance with the Act or with the HIPAA Privacy Rule, or to make or support decisions with respect to listing of a PSO.

9. Assistant United States Attorney

a. PSWP may be disclosed upon request to the Assistant United States Attorney (AUSA) assigned to any matter that has been deemed covered by the Federal Tort Claims Act where [redacted] is not a co-defendant in the action. Any disclosure of PSWP to the AUSA would be a **disclosure exception** and **MUST** be approved by the [redacted] Legal Department and/or their designee. The AUSA may not disclose the PSWP exchanged to any other third party consistent with the requirements of the Act.

b. PSWP may not be disclosed to the AUSA assigned to any matter that has been deemed covered by the Federal Tort Claims Act where [redacted] is a co-defendant in the action. Any request for disclosure of PSWP under these circumstances must be escalated to, and evaluated by, the [redacted] Legal Department and/or their designee.

10. The Legal Department and/or their designee, including but not limited to Risk Management and Patient Safety must be apprised of and approve any request for PSWP pursuant to this appendix and will be responsible to coordinate any such disclosure.

Note: There is no provision in the Act for disclosure of PSWP to other regulatory agencies. If a regulatory agency (other than one described above) requests access to PSWP, it must be declined, with reference to the confidentiality requirements of the Act. Only information that is non-identifiable, as described **in Appendix 1.B.3** may be provided to regulatory agencies. See **Appendix 1.D** for information for regulatory agencies regarding access to PSWP that can be used to assist in this communication. In the event the regulatory agency challenges this position, the matter shall be immediately referred to [redacted] Risk Management and/or Legal Department. See Appendix 5.E

Q. Information for Federal and State Regulators

See Appendix 5.E

Information for State & Federal Regulators (or others seeking compulsory access to PSWP):
The information you have requested is protected by federal law (the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 et. seq., and 42 C.F.R. Part 3, §§ 3.10 et. seq.) as Patient Safety Work Product. Identifiable PSWP may not be disclosed outside of this facility. Any questions about access to this information should be directed to [redacted] Risk Management and/or Legal Department.

R. Information for Law Enforcement

See Appendix 5.E

Information for Law Enforcement Officials About Permitted Uses and Disclosure of Patient Safety Work Product

To: [insert name of law enforcement official and agency to whom PSWP is given]. The information you have requested is protected by federal law (the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 et. seq., and 42 C.F.R. Part 3, §§ 3.10 et. seq.) as Patient Safety Work Product. These provisions permit your access to this information only in the following circumstances and subject to the following conditions:

42 CFR 3.206(b)(10) Disclosure to law enforcement.

(i) Disclosure of patient safety work product to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commissionof a crime, provided that the disclosing person believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

ii) Law enforcement personnel receiving patient safety work product pursuant to paragraph (b)(10)(i) of this section only may disclose that patient safety work product to other law enforcement authorities as needed for law enforcement activities related to the event that gave rise to the disclosure under paragraph (b)(10)(i) of this section.

By your signature below, you confirm that your request for access to this information is consistent with the above-cited federal law, and that you will maintain confidentiality of the information as required by federal law.

Date: _____ Signature:

_____

Retain signed original for [redacted] files; a copy of this document should be provided to the law enforcement official who obtains a copy of the PSWP.

S. Provider Authorization to Disclose PSWP

Provider Authorization to Disclose PSWP

Name of Provider:

_____
_____

The above named provider hereby authorizes disclosure to:

_____
_____
[insert name of individual or entity to which PSWP may be disclosed]
Of the following Patient Safety Work Product:

_____
_____

_____
_____

_____
_____
[insert description and purpose of the information to be disclosed]

Date: _____ Signature:
_____

For [redacted] Use:

Information was disclosed pursuant to this authorization on: *[list below all dates upon which disclosure was made]*

Date: *Signature: [of designated person releasing information]*

This authorization is to be delivered to [redacted] Legal Department and/or their designee and retained for 6 years from the date of the last disclosure made pursuant to this authorization.

VI. TRAINING

[redacted] Risk Management and Patient Safety Department, Chief Medical Officers, Medical Affairs, Clinical Department Leadership, Quality Management, Quality and Regulatory Affairs, Patient Experience, Privacy and Compliance, Nursing Leadership, Research Compliance, Labor and Employment, Human Resources and Legal Departments or their designee, and any and all other departments, shall undergo training to assure sufficient knowledge of the requirements of the Act, these Policies and Procedures and the [redacted] uses of PSWP and conduct of Patient Safety Activities.

[redacted] Risk Management Department and/or their designees shall be responsible to conduct or arrange sufficient training of all [redacted] personnel who will be accessing PSWP as to the permitted uses of PSWP and appropriate measures to maintain confidentiality in accordance with these Policies and Procedures.

VII. GOVERNANCE

The [redacted] is responsible for patient safety activities within its facilities.

1. The Patient Safety Evaluation System (PSES)is established to provide leadership, oversight, and resources for patient safety and quality assurance/improvement activities system-wide. This system allows each facility specified to share PSWP, including RCA information between the [redacted] and each facility provider. The parent may conduct centralized peer review, may share RCA information or may conduct safe tables within its PSES.
2. Members of the Facility PSES Team includes: [redacted] Legal Department, Office of the Chief Medical Officer, the Office of Medical Affairs, Risk Management and Patient Safety, [redacted] Medical Boards and Patient Relations/Experience.

VIII. RELATED INFORMATION

1. Patient Safety and Quality Improvement Act of 2005 and its implementing regulations. – Patient Safety and Quality Improvement Act of 2005 | PSO (ahrq.gov)
2. Patient Safety Rule – Patient Safety and Quality Improvement Rule (Patient Safety Rule) | PSO (ahrq.gov)
3. Patient Safety and Quality Improvement Act of 2005 - HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations (*May 2016*) - HHS Guidance | PSO (ahrq.gov)
4. HIPAA [Health Insurance Portability and Accountability Act of 1996, 45 CFR Part 160 and Subparts A and E of Part 164 (1996)] – Summary of the HIPAA Privacy Rule | HHS.gov
5. [redacted]
6.
7.
8.

IX. FREQUENTLY ASKED QUESTIONS

1. AHRQ FAQs- AHRQ-FAQs

X. REVISION HISTORY

This policy is subject to revision to reflect updates to applicable law, regulatory guidance, organizational practices, or other relevant considerations. [redacted] reserves the right to revise this policy, in whole or in part, at its sole discretion and without prior notice. We encourage all relevant personnel to review this policy periodically.

XI. Appendices

Appendix 1– Definitions
Appendix 2 – Referenced Policies
Appendix 3 – [redacted] QAPI plan
Appendix 4- Examples of PSWP
Appendix 5- Response to Regulators for PSWP
Appendix 6- Miscellanous Documents

APPENDIX 1

A. Definitions

Adverse Event: An unanticipated occurrence or set of circumstances that caused or could cause harm to patient, workforce(staff member, employee, volunteer), or visitor, and that is not consistent with the routine care of a particular patient and/or the routine operation of the facility. An Adverse Event is one that reaches a patient, and either resulted in harm or could have caused harm.

Copy: The **Patient Safety Rule** refers to the term "copy" in two ways in the definition of patient safety work product. First, when information meets all of the applicable requirements for protection as patient safety work product, any copy of the PSWP is also protected. Second, if information is not eligible for protection as PSWP (e.g., it is from the medical record or a report sent to regulatory authorities) the provider can still send a copy of the information to its PSO. While the copy held by the PSO or by the provider's PSES is protected, that protection does not apply to the original information that exists elsewhere (e.g., the medical record or the copy held by the regulator).

De-Designated: Pertains to the **Drop-Out Provision**. The Patient Safety Rule provides a limited opportunity for a provider to **remove patient safety work protections** from information that the provider entered into its patient safety evaluation system (PSES) for reporting to a PSO. The drop-out provision can be used for any reason, provided the information that the provider had placed in its PSES has not been reported to a PSO and the provider documents the action and its date. Upon removal, the information is no longer protected. **The drop-out provision cannot be used if the information has been reported to a PSO and it does not apply to information that describes or constitutes the deliberations or analyses of a PSES**.

Deliberations or Analyses (D or A): A means of creating PSWP that includes, **but is not limited to,** all verbal discussions, dialogues and other forms of communication, electronic or otherwise, as well as documents, reports, studies and all other forms of work product relating to identified patient safety activities which are conducted within a licensed health care provider's patient safety evaluation system (PSES) for the purpose of improving patient safety and the quality of health care services. D or A also includes communications and work product regarding the development of a PSES, and whether such information constitutes PSWP or whether or not to report PSWP to a PSO. **Communications and work product which are identified as D or A automatically become PSWP and need not be reported to a PSO in order to qualify as PSWP.**

Disclosure: A **disclosure** is sharing PSWP to an **unrelated third party** which meets one of the permissible disclosure exceptions, i.e. independent contractors, Accrediting bodies, Affiliated entities, from one PSO to another PSO. PSWP that is released, transferred, provided or divulged in any other manner by an entity of or person holding the PSWP to

another legally separate entity or person other than a workforce member of or health care provider holding privileges with the entity holding the PSWP or a componenet PSO to another entity or person outside the component PSO and within the legal entity of which the component PSO is a part.

Event Reporting System (ERS): The [redacted] system for workforce reporting of events is [redacted] (internally known as [redacted]

HIPAA: Health Insurance Portability and Accountability Act of 1996.

Near Miss: A Patient Safety Event that did not reach a patient. For example, discovery of a dispensing error by a nurse as part of the process medication administration to a patient (which if not discovered would have become a Patient Safety Incident) or discovery of a mislabeled specimen in a laboratory (which if not discovered might subsequently have resulted in an Adverse Event). May also be referred to as a **"Great Catch".**

Patient Complaint: An issue raised verbally by a patient/representative/family member which is resolved promptly by staff present and to the patient/representative/family member's satisfaction.

Patient Grievance: A formal or informal written or verbal complaint that is made to the hospital by a patient, or the patient's representative regarding the patient's care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the hospital's compliance with the CMS Hospital Conditions of Participation (CoPs), or a Medicare beneficiary billing complaint related to rights and limitations. **Billing issues are not usually considered grievances for the purposes of these requirements.**

Patient Safety and Quality Improvement Act of 2005 (PSQIA/the Act) . Authorized criteria of a national program through which health care providers may voluntarily report Risk Management, Quality and Patient Safety information through a certified Patient Safety Organization (PSO).

Patient Safety Activities: Activities carried out on behalf of [redacted] providers, [redacted] workforce, and/or the contracting PSO that involve Patient Safety Concerns, and are intended to improve patient safety and quality of health care delivery, including but not limited to:

- Collection and analysis of PSWP
- Development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information about best practices.
- Using PSWP to support a culture of safety and provide feedback and assistance to reduce patient risk
- Maintaining and securing PSWP confidentiality
- Other activities related to operation of the PSES and dissemination of information to PSES participants.

Patient Safety Concern: An Adverse Event, Near Miss, or an Unsafe Condition

Patient Safety Evaluation System (PSES): A structured process within a healthcare organization that is designed to collect ,manage and analyze information about patient safety events, incidents, near misses and medical errors. PSES encompasses deliberations or analysis and information reported to the PSO. The purpose of a PSES is to facilitate the information and data for trending, analysis, and improvement in patient safety and patient outcomes as organized through the Patient Safety and Quality Improvement Act of 2005.

Patient Safety Organization (PSO): An entity certified by the Secretary of Health and Human Services pursuant to 42 U.S.C. 299B-24, and with which [redacted] has contracted, on behalf of each [redacted] health care provider, for the delivery of PSWP and the conduct of Patient Safety Activities. [redacted]has contracted with[redacted] for these purposes, and in the future may elect to contract with other PSOs as well. Any such election will be accompanied by an Appendix to these Policies and Procedures clarifying any unique requirements applicable to interactions with other PSOs. Except as otherwise documented, references in these Policies and Procedures to PSO shall mean [redacted]nd any other PSOs with which [redacted]may contract with.

Patient Safety Work Product (PSWP):

- Patient Safety Work Product includes any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of these material), which could improve patient safety, health care quality, or health care outcomes, that are assembled or developed by a provider for reporting to a PSO and are reported to a PSO. It also includes information that is documented as within a patient safety evaluation system that will be sent to a PSO and information developed by a PSO for the conduct of patient safety activities.
- Patient Safety Work Product includes all deliberations and analysis as reflected in **Section B1.**
- 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.
- Patient Safety Work Product must not be disclosed, except in very specific circumstances and subject to very specific restrictions as specified in [redacted]

Peer Review means any review of clinical care, quality of care, or professional performance and includes any activity that involves case to measure, assess, and improve professional practice and the quality of patient care. It is employed to determine if appropriate standards of care have been met, and assess any risk to patient safety, after the identification of a quality problem. The results of Peer Review activities are used to identify opportunities that include but are not limited to improving patient care, improving clinical judgment, technical skill, providing information related to clinical competency, and

determination for continuing to grant clinical privileges.. Peer Review is conducted by the involved department(s) and results are shared through the quality structure. The Peer Review process may involve referrals from the following sources:

- Chief Medical Officers
- Medical Affairs
- Department Clinical Specialty Review Committees
- Risk Management and Patient Safety
- Quality Assurance & Regulatory Affairs
- Medical Staff Committees set forth in the Medical Staff Bylaws and Medical Staff Rules & Regulations
- Peer Leraning Sessions
- Other practitioners/staff
- Department monitoring data or other performance measurement data
- Committee on Professionalism in Healthcare (COPHE)

[redacted]**Adverse Event Reporting System**: [redacted]' system for voluntary adverse event reporting. (**Appendix 2)**

Progressive Discipline & Just Cause Standards: Just Cause is the labor and employment law standard, which establishes whether an employer had good reason to discipline a staff member. Just Cause is both defined in a collective bargaining agreement as well as shaped over time through arbitration decisions involving the discipline of covered employees. Progressive discipline is defined as a process of using increasing severe steps of discipline when a staff member fails to correct a problem after being given a reasonable opportunity to do so. Some staff conduct may result in immediate discharge without the need to follow the progressive discipline continuum when taking disciplinary action.

Risk Management and Patient Safety: Risk Management & Patient Safety has operational and oversight responsibility for the **Patient Safety Program**, which includes but not limited to system-wide event/occurrence reporting, investigation of adverse events and the Serious Adverse Event (SAE) program, which includes serious adverse event review and the performance of an RCA (see [redacted]QAPI plan).

Root Cause Analysis (RCA): An RCA is a structured, facilitated team process to identify root causes of an event that resulted in an undesired outcome and develop corrective actions/patient safety solutions. The RCA process identifies breakdowns in processes and systems that contributed to the event and how to prevent future events. The RCA is part of the Serious Adverse Event (SAE) program, which also includes huddles, debriefs and patient safety solutions.

Sentinnel Event: A sentinel event is a patient safety event that results in death, permanent harm, or severe temporary harm.

Unsafe Condition: Any circumstance that increases the probability of an adverse event; includes a defective or deficient input to or environment of a care process that increases the risk of an unsafe act, care process failure or error, or patient safety event. An unsafe condition does not necessarily involve an identifiable patient. For example, an out-of-date medicine on a shelf represents an unsafe condition. It might be given to a patient, but the identity of such patient is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient would either represent a near miss (if not administered) or an incident (if administered).

Use: PSWP that is **used and distributed or shared** within a single entity or health care provider holding privileges with the entitiy holding the PSWP for any legitimate business or other purpose.

Workforce: All faculty, associates, staff, trainees, volunteers, contracted employees, voluntary physicians, and contractors, who perform work and/or clinical care under the direct control o[redacted] and may need to access PSWP in order to carry out any employment or other duty/responsibility.

APPENDIX 2

Referenced [redacted] Policies

- [redacted] Patient Safety Occurrence/Event Reporting, [redacted] 133
- [redacted] Serious Adverse Event Investigation [redacted] 134
- [redacted] atient Complaints and Grievances, including ADA/Section 504 Grievance Procedure, Centralization and Management [redacted] 113; Patient Compliments, Concerns, Complaints and Grievances MSSN OF-ADM-030r
- [redacted] Communication and Disclosure of Unanticipated Patient Events and Outcomes to Patients and Families, [redacted]4
- System Professional Enhancement (Peer Review) Policy [redacted]1.10; Focused Professional Practice Evaluation (FPPE) Policy [redacted] 1.06; MSSN OF-PI-111
- [redacted] Staff Bylaws and Medical Staff Rules & Regulations
- [redacted] Medical Staff Bylaws and Medical Staff Rules & Regulations
- [redacted]Medical Staff Bylaws and Medical Staff Rules & Regulations
- [redacted] Staff Bylaws and Medical Staff Rules & Regulations
- [redacted] Staff Bylaws and Medical Staff Rules & Regulations

APPENDIX 3 :
[redacted]QAPI Plan
The [redacted]
2025 Quality and Patient Safety
Performance Improvement Plan

Table of Contents

The purpose of this document is to describe the Quality and Patient Safety Performance Improvement Program for the [redacted], (hereinafter referred to as the [redacted] and/or [redacted]).

The goals, objectives and scope of the Quality and Patient Safety Performance Improvement Plan are supported and approved by the Board of Trustees. The Quality and Patient Safety Performance Improvement Plan builds upon the strategic initiatives of each respective hospital within [redacted] that are designed to achieve excellence in the delivery of patient care.

I. [redacted]Mission, Values, Foundation and Strategy

Mission
Always provide patient-centered care of the highest quality and safety with a commitment to excellence and equity for the communities we serve.

Core Values

- Safety
- Equity
- Agility
- Creativity
- Empathy
- Teamwork

Foundation

- Consistent Interaction with Hospital Leadership
- Clear and Consistent Messaging of Priorities
- Leadership Development
- Performance Improvement Coaching
- Access to Relevant and Actionable Data

Strategy

As part of its Quality and Patient Safety Strategy, the [redacted]ill:

- Identify opportunities to examine healthcare disparities within existing quality dashboards
- Examine trends in patient safety events and identify opportunities for improvement
- Incorporate the patient perspectives where possible when analyzing a serious adverse event

Our work aligns with the mission, vision, and objectives of [redacted] in promoting patient safety and enhancing the quality of care, treatment, and services. At [redacted], quality and patient safety are the responsibility of every [redacted] team member and an integral component of daily practice. The objective of zero preventable harm at [redacted] applies not only to our patients but also to our team members.

II. [redacted]Quality and Patient Safety (QPS) Goals

What are the QPS Goals?

On an annual basis[redacted]develops system-wide QPS Goals with priorities based on high-volume, high-risk, or problem prone areas, including prior goals that did not achieve or sustain planned improvement. QPS Goals shall include the specification of the frequency of data collection. QPS Goals are also established based on current National Patient Safety Goals, results of regulatory activity, adverse event reports, findings from risk assessments and root cause analysis as well as other organizational priorities as determined by senior leadership. The goals are approved annually by the Annual QPS Taskforce and Quality Performance Improvement Committee (QPIC). The progress and status of each goal is assessed regularly and reported to senior leadership throughout the year.

How 2025 QPS goals were selected?

A multidisciplinary system-level taskforce was convened to determine which identified areas of opportunity should rise to the level of an annual QPS goal. Our performance on over 250 internal and external measures was evaluated. Additionally, organizational priorities and external mandates were reviewed to ensure alignment of goals with the overall strategic plan. The QPS goals were selected based on case volume at risk, alignment with penalty and incentive programs, existing quality improvement efforts, strategic hospital priorities, and anticipated cost.

The Quality and Patient Safety Goals are noted in Appendix

Operating under the "Agreement among Affiliated Hospitals," the hospitals within the [redacted] collaborate with one another to improve the quality and safety of health care services and may share their quality improvement and patient safety information with each other and with the quality assurance committee of their respective Governing Body. It is understood and agreed that these activities are medical quality assurance functions under [redacted] Public Health Law 2805-j, 2805-k, 2805-l and 2805-m and are peer review activities under [redacted] Education Law 6527 and the federal Health Care Quality Improvement Act, 42 U.S.C 11101 et seq.

III. Quality and Safety Organizational Framework

- **Scope and Structure**

The Quality and Patient Safety Performance Improvement Program oversees activities of all hospital and patient services (inpatient, outpatient and ambulatory) to enhance quality and safety of patient care, to identify actual and potential problems concerning patient care and clinical performance, and develop and implement strategies to prevent harm. The program measures, analyzes and tracks quality indicators, including adverse events and other aspects of performance that assess processes of care, hospital service and operations.

The scope of the Quality and Patient Safety Performance Improvement Program includes the full range of safety issues, from "near-misses" to hazardous conditions and sentinel events. (Appendix C and D). The Program includes, but is not limited to the following:

- Identification of actual or potential problems concerning patient care and clinical performance;
- Assessment of the cause and scope of problems identified;
- Development and recommendation of proposed courses of action to address identified problems;
- Use of information gathered regarding problems for reviewing and making revisions to hospital policies and procedures;
- Use of established mechanisms to implement corrective actions to identified problems;
- Monitoring and evaluation of actions taken and implementation of remedial actions to confirm effectiveness;
- Provision of a system for blame-free internal reporting of system or process failures;
- Establishment of processes to support staff who have been involved in an adverse or sentinel event; and
- Documentation of the measures outlined above.

The Quality and Patient Safety Performance Improvement program includes proactive risk assessments of high risk processes and problem prone concerns. The program analyzes and supports leadership in the use of information about system or process failures and proactive risk assessments, including dissemination of lessons learned.

The Quality Performance Improvement Committee (QPIC)

The hospital-wide committee that oversees the quality improvement activities of the clinical, support departments and multidisciplinary committees across [redacted] QPIC assures the ongoing monitoring, measurement and evaluation of high risk processes and the development and implementation of performance improvement strategies designed to enhance patient care and bring value to patient care processes. QPIC provides a venue for the enrichment of performance improvement strategies and uses trends to make recommendations to the clinical departments, senior [redacted] leadership, including the respective hospital presidents and CEO, the respective Medical Boards and the Committees on Quality of the Board of Trustees regarding cross-functional performance improvement initiatives.

The committee meets on a regular basis and is chaired by the Chief Medical Officer and is comprised of multidisciplinary members of the hospital and medical departments. The committee reports to the Committee on Quality of the Board of Trustees.

[redacted]uses data and information to guide decisions and to understand variation in the performances and processes supporting safety and quality. The Quality Performance Improvement Committee and leadership provides guidance and direction in the type and manner of data presentations specific to clinical and operational metrics.

Data is obtained from internal sources including medical records, observations, staff and patient surveys as well as external databases and registries. The hospital collects data to monitor its performance.

Comparison with external benchmarks is used to assess performance relative to peer institutions. In addition to the indicators defined by external sources, the clinical services or service lines also identify performance indicators.

Establishing Performance Improvement Priorities

Setting priorities for performance improvement is a collaborative process of the Board of Trustees, Medical Staff, Administrative Leadership and Hospital Staff. The following criteria shall be considered in establishing priorities:

- Mission, vision, and values
- Patient Safety
- National Patient Safety Goals (NPSG)
- Strategic Plan
- Community needs
- Needs/expectations of patients and families via our customer/patient satisfaction program

- Input from medical and hospital staff
- High volume/high risk diagnoses/procedures/processes
- Problem prone procedures/processes
- Input from external sources (licensing, regulatory agencies, professional groups and benchmarking information)
- Clinical competency and training needs
- Best practices
- Current performance (results on ongoing QI activities)
- Key publicly reported indicators
- Consistency with the [redacted] Quality and Patient Safety Priorities

Case Review: Serious Adverse Events, Sentinel Events and Peer Review

Targeted review of cases occurs when:

- Trended performance measures significantly and undesirably vary from that of other organizations;
- Trended performance measures significantly and undesirably vary from recognized standards/thresholds, or statistical process controls;
- The occurrence of an event is questionable, or too infrequent to make judgments about patterns of care, or to perform an analysis to detect statistical significance;

Peer Review

Peer Review is employed to determine if appropriate standards of care have been met after the identification of a quality problem. Peer review activites are conducted by the clinical departments and through the system professional enhancement committee and the results are shared through the medical staff peer review structure, reporting to each Medical Board.

The Peer Review process may involve referrals from the following sources:

- Chief Medical Officers
- Medical Affairs
- Risk Management
- Quality & Regulatory Affairs
- Medical Board Committees
- Departmental Morbidity & Mortality Conferences
- Other providers/staff
- Department monitoring data or other performance measurement data
- Committee on Professionalism in Healthcare
- Practitioner Wellness Committee

Evaluation of Individual Practitioners

[redacted] has a credentialing, privileging and performance enhancement process which evaluates individual practitioner's competency and monitors professional conduct upon initial appointment and then on an ongoing basis thereafter. The process is monitored accordingly through the Joint Credentials Committee and the Performance Enhancement Committee, both of which are Medical Staff Committees accountable to the Medical Board, and ultimately to the Boards of Trustees.

All relevant information gathered in accordance with the Quality and Patient Safety Performance Improvement and Risk Management Programs, including focused professional practice evaluations and ongoing professional practice evaluations shall be used in the ongoing evaluation of the performance of individual practitioners on an ongoing basis.

- **Methodology**

Methodologies[redacted] employs the fundamentals of leading improvement methodologies to assure the right tools are used for each improvement effort. The overarching methods are Lean, A3 Problem Solving, and Plan-Do-Check-Act (PDCA). The Plan-Do-Check-Act (PDCA) cycle is a systematic approach utilized in the work environment to evaluate and execute changes, hence expediting the process of improvement. The Lean methodology places significant emphasis on the proactive elimination of waste and the exclusion of products or services that fail to contribute value to the overall process. Utilizing the aforementioned techniques, interdisciplinary teams, under the guidance of improvement professionals, evaluate interdisciplinary challenges and obstacles hindering enhanced performance, and formulate solutions. These recommendations may encompass minor adjustments to existing procedures or substantial overhauls of systems. The Lean A3 Problem Solving methodology is a cyclical approach that encompasses several key components, namely Background, Current State, Goal, Analysis, Recommended Changes, Action Items, and Measures and Follow-up. This iterative process aims to showcase the effects of problem-solving efforts, document and disseminate acquired knowledge, and continuously monitor and evaluate performance.

- **Patient Safety Program**

The purpose of the patient safety program is to improve patient safety and reduce risk to patients through an environment that encourages:

- Recognition and acknowledgement of risk to patient safety and serious adverse events.
- Initiation and ongoing proactive reduction to reduce these risks utilizing the FMEA method of review, as appropriate.
- Internal reporting and effective responses to actual occurrences and near misses.
- A focus on processes and systems.
- Just Culture and blame-free approach
- Learning about unanticipated adverse events and sharing of knowledge and best practices to improve patient safety.

- Internal reporting of what has been identified and the actions taken to analyze and reduce risk.

The interdisciplinary Patient Safety/Patient Grievance Committee will have administrative oversight of the patient safety program, as reported through the Quality Performance Improvement Committee.

PATIENT SAFETY EVENTS

Serious Adverse Event Review

All staff and providers within the hospital (patient care and non-patient care) are responsible for reporting patient safety occurrences and potential serious adverse events to the Department of Risk Management. [redacted]an electronic reporting system, was established to assist staff with reporting incidents. Serious Adverse Events are communicated via a formalized notification chain as outlined in the SAE process flow.

A huddle is conducted in the immediate aftermath of a Serious Adverse Event. Staff gathers immediately to share their understanding of what occurred. The huddle is led by the most senior local staff and aims to mitigate any ongoing harm as well as determine factually what happened. Within 24-72 hours after the event, a debriefing is expected to occur. The debriefing is led by the Chief Medical Officer or designee and includes all involved individuals and their leadership. The debrief aims to clarify the chronology of events and develop action plans, including when necessary, referring individual practitioners to Medical Affairs for evaluation under the Performance Enhancement policy and procedure. Huddles and debriefs are confidential and the information obtained is not disclosed to Labor Relations. Staff must participate when requested. All cases are reviewed and discussed at the Patient Safety/Patient Grievance Committee which meets biweekly.

The committee determines if a Root Cause Analysis (RCA) is required and whether or not the case is reportable to external agencies. If a RCA is conducted, corrective action plans/safety solutions will be created as necessary. This process has been developed for the prompt identification and reporting to [redacted] of unanticipated serious adverse events which may impact the safety of patients or staff/providers.

The philosophy of the hospital is to support team members both professionally and emotionally when a serious adverse event occurs. The [redacted]program was established to meet this need.

Staff and providers will receive education and training during their initial orientation process, annually and on an ongoing basis regarding job-related aspects of patient safety, including the need and method to report serious adverse events, as well as hazardous or unsafe situations.

Serious adverse events, including sentinel events, will be reported internally and externally, per hospital policy. External reporting will be performed in accordance with all state, federal and regulatory body rules, laws and requirements.

A report to the Committees on Quality of the Board of Trustees regarding serious adverse events/outcomes and actions to improve patient safety is provided annually.

Trending and Failure Mode Effect Analysis (FMEA)

Through review of internal data reports and reports from external sources (including, but not limited to, Sentinel Event/Quick Safety Alerts, National Patient Safety Recommendations, Core Measure performance data, occurrence reporting, benchmark data from state and federal sources, current literature and participation in collaborative efforts with [redacted], the hospital will select at least one high-risk safety process for proactive risk assessment at least every 18 months (FMEA).

Proactive Risk Assessment

The hospital conducts risk assessments on key processes that impact the quality and safety of patient care. Risk assessments are initiated to address system weaknesses identified during a significant event investigation or changes in regulations governing the delivery of healthcare. The hospital may include internal and external expert consultants and advisors to provide benchmarking assessments and input as part of any such risk assessment and any patient safety and quality improvement information provided to such experts shall remain privileged and confidential as part of the medical quality assurance functions of the hospital.

Proactive assessment is a team-based, systematic, and proactive method of preventing process problems before they occur. The approach identifies and improves steps in a process, thereby supporting a safe and clinically desirable outcome.

Grievance Review Process

The Committees on Quality of the Board of Trustees has reviewed and approved the patient grievance process and has delegated responsibility for the review and resolution of patient grievances to the Patient Safety/Patient Grievance Committee.

The Office of the Chief Medical Officer (CMO), in collaboration with the Patient Representative Department, has established and implemented a process to address all grievances, whatever the source. The Chief Medical Officer or designee, the Chair/Director of the appropriate department and the Patient Representative Department or designee investigates the grievance. The results of the investigation are appropriately addressed with the involved staff, documented in the grievance database which allows aggregate reporting (Patient Representative Office) and, when appropriate, noted in departmental files. The results of the investigation are shared with

the patient and/or their designee and responded to in the appropriate timeframes as noted in our policy and in accordance with CMS.

REGULATORY AFFAIRS

[redacted] is incorporated into routine processes at each site in order to maintain compliance with regulations from accrediting bodies such as CMS, TJC, and DOH. Each site is required to have an [redacted] Program structure which supports a continuous process to improve quality and patient safety.

[redacted]Quality and Regulatory Affairs Departments, along with subject matter experts from across the health system, shall provide education and conduct mock tracers/surveys to assess compliance with regulatory standards. Continuous performance improvement efforts shall include such areas as health care equity, maternal health, workplace violence, infection prevention and control, environment of care/life safety and national patient safety goals.

IV. Quality and Safety Leadership Responsibilities

Board of Trustees

Duties and Responsibilities: The Board of Trustees has the ultimate authority and responsibility for the operation of the hospital, including the assurance of the quality of patient care as specified in the Medical Staff Bylaws and as required by Federal and State laws, The Joint Commission standards, regulatory agencies and third-party payers. The Board of Trustees reviews plans for improvement and monitoring as implemented in the hospital, sets improvement priorities and takes actions on matters requiring Board of Trustee approval, including Medical Staff Bylaws amendments, modifications of Medical Staff or Advanced Practice Staff Membership and/or Clinical Privileges, and revision of major hospital policies and plans.

The Committees on Quality of the Board of Trustees, acting on behalf of the Board, is responsible for the oversight of all major activities relating to the hospital's performance improvement activities.

Leadership

Duties and Responsibilities: Leadership must foster an environment for all employees to engage in all aspects of quality, safety, and performance improvement along with participation/reporting in CMS sponsored inpatient and outpatient pay-for-performance programs: For example:

- CMS Star Ratings
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)
- Healthcare Associated Infections (HAI) through the National Health Safety Network (NHSN)
- Hospital-Acquired Condition (HAC) Reduction Program
- Hospital Value-Based Purchasing (HVBP)
- Hospital Readmissions Reduction Program (HRRP)
- Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program
- Hospital Inpatient Quality Reporting Program
- Hospital Outpatient Quality Reporting Program

Medical Board

Duties and Responsibilities: The Medical Board plays a significant leadership role in performance improvement. As specified in the Medical staff Bylaws, the Medical Board is responsible for directing the organization and conduct of the medical staff and other credentialed practitioners, and establishing and implementing a planned process for the systematic monitoring and evaluation of the quality and appropriateness of patient care.

The Quality Performance Improvement Committee (QPIC) which integrates quality monitoring activities of the hospital and makes recommendations on opportunities for improvement minutes are shared with the Medical Board for approval.

Contracted Services

[redacted] provides patient-centered care, regardless of whether the services are delivered directly by [redacted] or facilitated through contractual agreements with third-party vendors or external contractors. The monitoring of care, treatment, and services offered to patients at [redacted] is conducted based on contractual performance metrics, namely through contractual agreements such as clinical services contracts. The leadership of [redacted] is responsible for the supervision and assessment of clinical service contracts in order to evaluate the safety and efficacy of patient care services delivered by vendors. Any performance issues that are found are directed to the external contractor or vendor for resolution.

Orientation and Annual Hospital Training

The hospital offers a comprehensive orientation program to all its team members, which encompasses essential hospital policies and procedures necessary for delivering safe and high-quality treatment within the organization. Orientation is offered for every job category within each department to ensure the attainment of initial competencies necessary for delivering patient care. The organization also offers new management orientation for recently hired management team members or personnel, as well as for team members who have been promoted internally. Every year, it is mandatory for all team members of [redacted] to participate in the Annual Hospital Training. The purpose of this compulsory training is to provide team

members with updated information on crucial safety subjects. The curriculum has multiple modules that have been customized to cater to both clinical and non-clinical audiences. Each team member is assigned to either the clinical or non-clinical curriculum, depending on their job description. In addition to their regular duties, all medical staff are required to complete the hospital's annual training modules tailored to their needs. Furthermore, staff are encouraged to attend and complete the Continuous Improvement Academy (CIA). The [redacted] CIA offers a series of courses that aim to educate employees on how to implement initiatives and activities that create the most value for the patients while simultaneously reducing any waste or inefficiencies that surround processes.

V. Annual Evaluation of the Quality and Patient Safety Performance Improvement Program

The Quality and Patient Safety Performance Improvement program shall be re-evaluated annually for the purpose of determining its effectiveness in improving patient care processes, patient safety and outcomes, individual performance and utilization of hospital resources. The Quality Performance Improvement Committee shall coordinate the annual evaluation of the program for review by the Board of Trustees.

The Quality and Patient Safety Performance Improvement Plan shall be re-evaluated at least annually to address performance improvement priorities and update it to reflect any changes in strategic priorities and in response to changes in the internal or external environment.

The appraisal shall include the effectiveness of the program in improving quality and safety and achievement of the program objectives. The criteria used in evaluation of areas for improvement include review of the following priorities: high volume areas, high risk/problem prone areas, quality and risk management trends, The Joint Commission sentinel event trends, serious adverse events/medical errors, Joint Commission standards, Quality and Patient Safety Goals, customer satisfaction and required performance improvement measurements, benchmarking data and publicly reported indicators.

VI. Confidentiality

All quality related information including data; committee minutes, reports, and recommendations shall be maintained by the Quality and Regulatory Affairs Department. Copies shall be made and distributed as necessary to meet the objectives of the Clinical Quality and Patient Safety Performance Improvement Program. The Program shall be in compliance with HIPAA requirements.

All quality related information will be labeled “Privileged and Confidential. Prepared in accordance with [redacted]; j through m, and [redacted] Education Law 6527; and Federal Law 109-41.”

APPENDIX A

2025 QUALITY AND PATIENT SAFETY GOALS

Hospital Acquired Infection: Achieve an SIR below the QHIP cutoff for CMS reportable HAIs in each acute care hospital.

Nursing Quality Indicators: Increase percent of days out of bed by 10% across all inpatient units.

Advancing Equity in Quality: Establish a data structure to provide accurate, actionable data for real-time monitoring, process improvement, reporting, and strategic decision-making.

Hospital Readmission: Leverage innovative technology to enhance the current process for identification of patients at discharge with CMS priority conditions and optimize the efficiency of the care transition programs to reduce readmissions.

Patient Experience: Improve patient experience by increasing the percentage of top-box responses in key areas of teamwork, communication, and responsiveness.

Patient Identification: Improve patient identification by implementing best practices and risk mitigation tools to reduce identification errors.

APPENDIX B

GLOSSARY OF TERMS

Adverse Event: An event resulting in an undesirable or unanticipated patient outcome, which under normal conditions is not the result of the natural courses of the patient's illness or underlying condition.

Just Culture: A just culture acknowledges that human error occurs, and expects and encourages open communication about such errors with the goal to improve the organizational structures that support work that is as error-free as possible. The focus is on the systems that result in error, rather than the errors themselves.

National Patient Safety Goals (NPSG): The NPSGs were established by the Joint Commission to help accredited organizations address specific areas of concern in regards to patient safety.

Occurrence Review: Ongoing intra- and inter-departmental activity performed by medical or other clinical staff to review and asses aspects of clinical care, and when indicated recommend performance improvement on a departmental or organization-wide basis. The goal is a systematic review of specific occurrences to illuminate themes of organizational behavior that point to opportunities for improvement.

Patient Safety: A process or structure that emphasizes the reporting, analysis, and prevention of medical error that often leads to adverse events.

Peer Review: means the ongoing process by which qualified health care professionals evaluate the clinical performance, competence, and professional conduct of their peers. This includes both continuous assessment of a practitioner's overall performance and the review of individual cases to determine whether the applicable standard of care was met. The purpose of peer review is to promote quality improvement, patient safety, and accountability within the health care setting.

Permanent Harm An event or condition that reaches the individual, resulting in any level of harm that permanently alters and/or affects an individual's baseline.

Quality Improvement: A structure that supports quality-related initiatives. The goal of quality improvement is to effect meaningful change in the process of care so that the process of care and related outcomes are measurably improved.

Risk Management: Risk Management is defined as the systematic process of identifying, evaluating and addressing potential and actual risk.

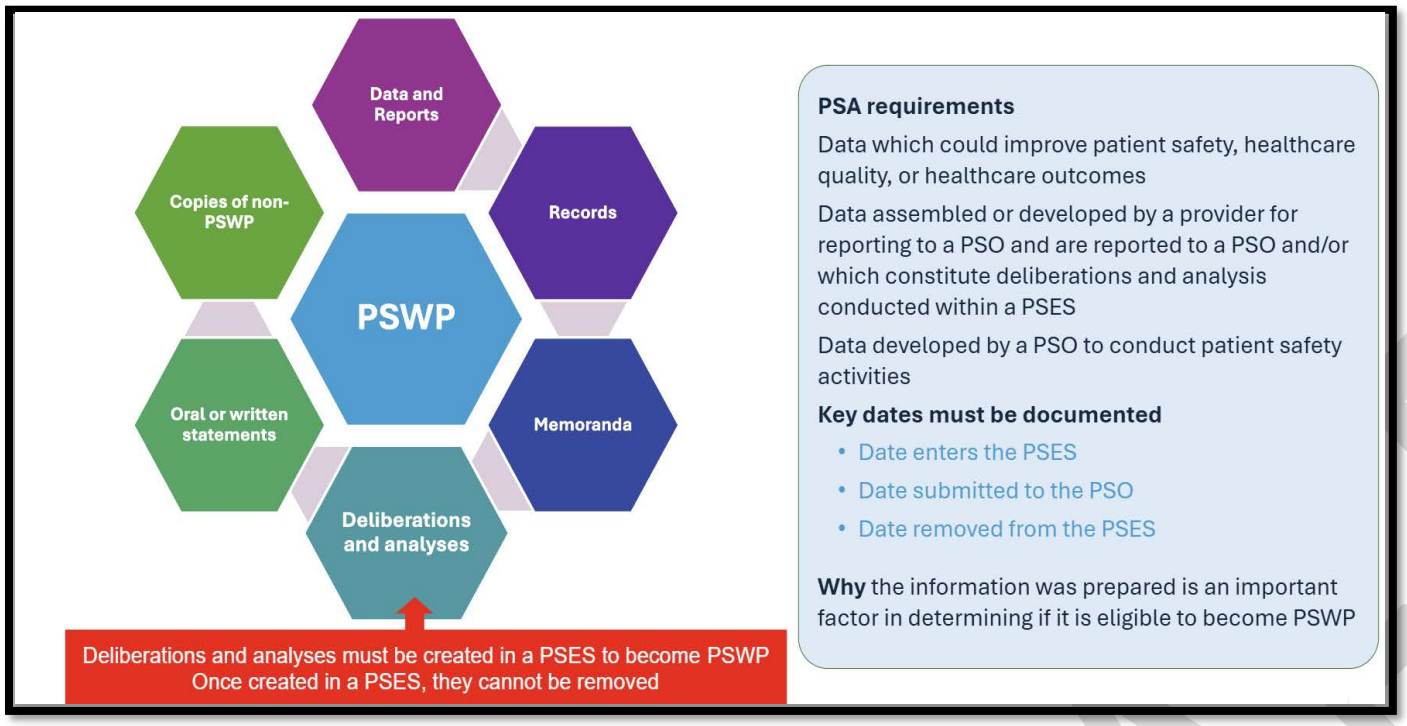
Root Cause Analysis: Root cause analysis (RCA) is a method of problem solving that tries to identify the root causes of faults or problems that cause events.

Sentinel Event: A Sentinel Event is defined by The Joint Commission as patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm).

Severe Harm: An event or condition that reaches the individual, resulting in life threatening bodily injury (including pain or disfigurement) that interferes with or results in loss of functional ability or quality of life that requires continuous physiological monitoring or a surgery, invasive procedure, or treatment to resolve the condition.

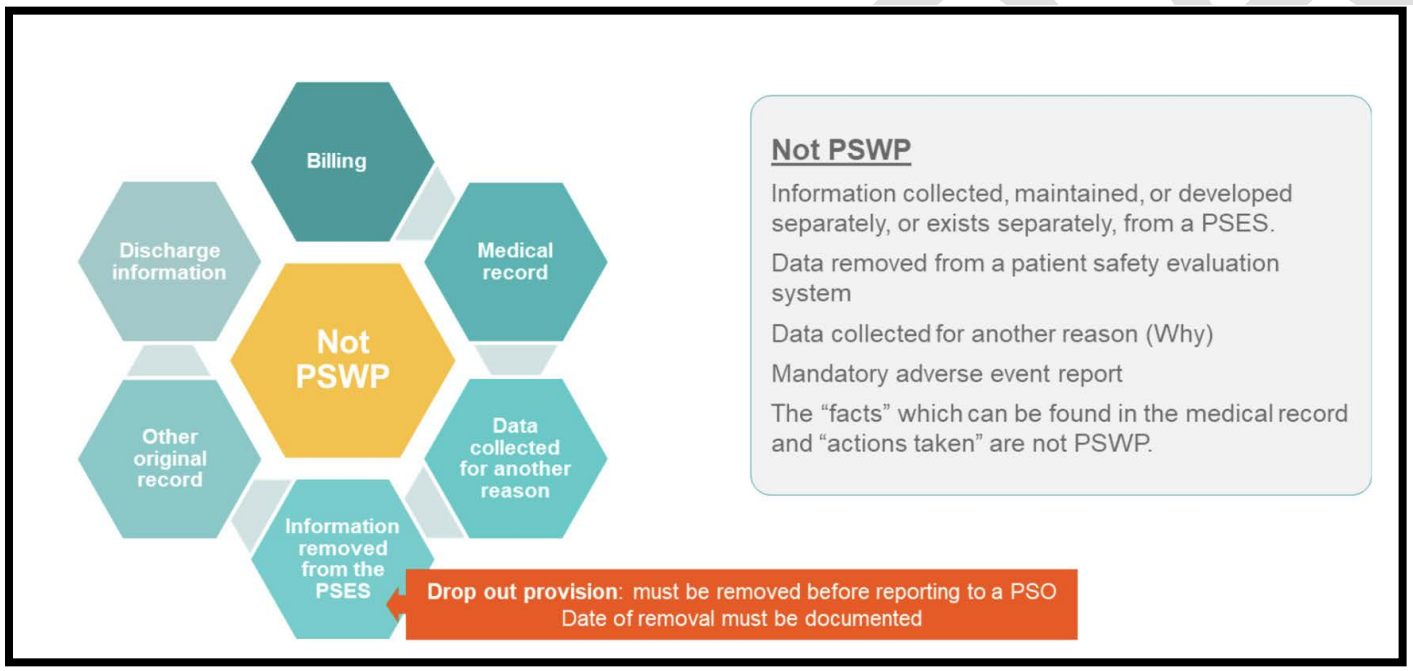
APPENDIX 4:

What is PSWP ?



***Preverity Patient Safety Organization**

What is NOT PSWP?



***Preverity Patient Safety Organization**

APPENDIX 5

Response to Regulators Request for PSWP

A. Determine if they are here on behalf of CMS and/or the state.

- Review requested documents and determine whether any of the requested information is PSWP or privileged under [redacted]
- [redacted] "CMS Guidane to Surveyors" form https://www.cms.gov/files/document/qso-23-24-hospital.pdf

1. If acting on behalf of CMS, contact the applicable CMS Regional Office to confirm/discuss that the facility is not required to turn over PSWP
2. If acting on behalf of the State, contact the applicable agency administrator or other key contact in the appropriate office that has supervision and oversight over the regulator.
3. If all the above attempts to satisfy regulators are not successful, providers may decide to disclose only the PSWP necessary to demonstrate compliance pursuant to the "Authorization by Identified Provider" disclosure exception

B. Essential Documentation

- PSO certification letter from AHRQ
- Copy of [redacted]' PSO member agreement
- [redacted] PSES policy
- Screen shots or blank/redacted forms of PSWP
- Copies of any non-privileged information
- Medical/patient care records
- Relevant policies and procedures
- Action plan relating to the incident if not PSWP
- Permt interviews of involved personnel (they cannot discuss or disclose PSWP)

C. Examples of PSWP NOT Available to Regulators

- Root cause analysis of specific case
- Research regarding solutions/standards of care
- Substance of deliberations and analysis during team meetings regarding safety issues and events (or interviews with team members on those topics)
- Substantive information from QA meetings and QAPI team meetings
- Expert consultation reports
- Identifiable information furnished to or received from the PSO
- Records of investigatory interviews
- Statistical compilations prepared specifically as part of the investigation of an event or safety issue
- Statistical compilations prepared to help the participant identify events or safety issues (QAPI surveillance)
- Records of measurements or observations not related to a specific plan of correction

D. Examples of Non-PSWP Available to Regulators

- Patient name and other demographic information about the patient and the event (date, place, time, etc.)
- Brief description of event
- Names of witnesses and staff involved (for interviews)
- Medical record, care plans, etc.
- Staff for interviews (information about their knowledge of anything outside of PSES can't be protected; all their factual knowledge about the event or routine facility operations is available)
- Simple compilations of information about events (falls in last 90 days, etc.). Possibly basic logs for falls, etc.
    - MDS data and quality measure reports (can't be protected)
    - Information about changes made/plans of correction developed after an event
    - Records regarding the implementation of changes specified in a submitted plan of correction

E. HHS Guidance

1.If acting on behalf of CMS, provide them with the following statement that is set forth in the HHS guidance regarding PSWP and a provider's external obligations:

a. "Regulatory agencies and other entities requesting information of providers or PSOs are reminded that, subject to the limited exceptions set forth in the Patient Safety Act and Patient Safety Rule, PSWP is privileged and confidential, and it may not be used to satisfy external obligations. Therefore, such entities should not demand PSWP from providers or PSOs."
(41 Fed. Reg. at 32659 (May 26, 2016 HHS Guidance))

F. Additional Actions

1. If acting on behalf of CMS, contact the applicable CMS Regional Office to confirm/discuss that the facility is not required to turn over PSWP
2. If acting on behalf of the State, contact the applicable agency administrator or other key contact in the appropriate office that has supervision and oversight over the regulator.
3. If all the above attempts to satisfy regulators are not successful, providers may decide to disclose only the PSWP necessary to demonstrate compliance pursuant to the "Authorization by Identified Provider" disclosure exception

APPENDIX 6: **Miscellanous Documents**

A. **Sample Credentaling Application Language-Provider Authorization**

- Authorize the hospital, to gather information concerning me and to disclose that information to any person or entity within the hospital, including, without limitation, any of the Hospitals, Medical Groups, any of the physician-hospital organizations, networks or local integrated delivery systems, clinics, or other entities affiliated with the hospital ("Hospital Affiliates"). I hereby further release each of these organizations and their

respective agents and representatives from liability for gathering and disclosing any information in good faith and without malice; and
- Authorize each Hospital and any Affiliates, including all directors, officers, employees, agents and assigns, medical staff members, attorneys, and consultants, to release confidential information regarding my professional qualifications, competence, and conduct to the hospital and/or any Hospital(s) or Affiliates. I understand that the production of confidential information for these purposes shall be considered confidential and privileged and does not constitute a waiver of the peer review, medical review, or any other privilege under federal or state law that may apply to such information; and

- Agree that this form shall serve as a standing written authorization to share my identifiable patient safety work product under the federal Patient Safety and Quality Improvement Act of 2005 (the "Act") with a Patient Safety Organization and within the hospital, including all Hospitals, Medical Groups, and other Affiliates as authorized by the Act

B. OPMC Response

Confidential Pursuant to Public Health Law Article 28 and Public Health Law Section 230

[redacted]

Re: OPMC

To Whom It May Concern:

This letter is in response to your request, that the hospital provide to OPMC "a complete, certified copy" of the materials listed in your correspondence relating to Dr. XXXX from "XXX Date" to the present. We are able to provide much of the information you requested for the period through DATE joined the pso . Please see the attached documents for that period. However, for the period from SAME DATE AS ABOVE to the present the hospital is only permitted under Federal law to provide some of the information and documents you requested. The hospital recognizes the importance of OPMC investigation authority and as such is providing herewith the medical record numbers for those patients under the care of Dr. XXX whose treatment was reviewed through the hospital's peer review/quality review processes for the period of DATE AS ABOVE through the present date instead of the peer review/quality review information and documents. The quality and peer review information and documents you requested in your letter for the period from DATE AS ABOVE, to the present has been either reported to the hospital's [redacted]SO and/or consists of internal deliberations and analysis that is privileged and confidential work product pursuant to the Patient Safety Improvement

and Quality Improvement Act of 2005 (42 USC 299b-21 et. seq, and 42 CFR Part 3, Sections 3.10 et. seq) (PSQIA)[1]

Under the PSQIA, information gathered or generated for the purposes of improving patient care which is either reported to a PSO or treated as internal deliberations or analysis is privileged and confidential work product in all state and federal proceedings and therefore not subject to discovery or admissibility into evidence. In addition, Health and Human Services in a May 26, 2016 Guidance Regarding Patient Safety Work Product and Provider's External Obligations stated as follows (a copy of which is attached to this letter): "Regulatory agencies and other entities requesting information of providers or PSOs are reminded that, subject to limited exceptions set forth in the Patient Safety Act and Patient Safety Rule, PSWP is privileged and confidential and may not be used to satisfy external obligations. Therefore, such entities should not demand PSWP from providers or PSOs." (41 Fed. Reg., at 32659). Of note, medical records and patient billing information are not privileged under the PSQIA.

Furthermore, Section 3.204(a)(4) and (5) of the Final Patient Safety Rule states in part: "[P]atient safety work product shall be privileged and shall not be:…(4) 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 provider; or (5) Admitted in a professional disciplinary proceeding of a professional disciplinary body or specifically authorized under State law."

We are therefore able to provide much of the information which the OPMC is requesting except for those PSWP documents that are statutorily confidential and have attendant privilege protections afforded under the PSQIA[2]

The attached materials are as follows:
1. Credentials – XXX to the present
2. Personnel File – XXX to the present
3. Quality Assurance File – XXX to DATE AS ABOVE
4. Departmental File – XXX to the present
5. Peer Review File – XXX to DATE AS ABOVE
6. All Incident Reports and records of complaints – XXX to DATE AS ABOVE

Please do contact me directly if further information is required.

[redacted]