SAMPLE- Credentialing 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.

SAMPLE

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

New York State Department of Health
Office of Professional Medical Conduct
90 Church Street, 4th Floor
New York, NY 10007

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 January 1, 2010 to the present. We are able to provide much of the information you requested for the period through December 30, 2019. Please see the attached documents for that period.

However, for the period from December 31, 2019 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 December 31,2019 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 December 31, 2019, to the present has been either reported to the hospital's Pascal Metrics PSO 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."

[1] On December 31,2019 the hospital became a member of Pascal Metric's Patient Safety Organization when it entered into a contract with Pascal Metrics Patient Safety Organization (PSO) pursuant to the PSQIA (42 USC 299b-21 et. seq, and 42 CFR Part 3, Sections 3.10 et. seq). *Note: A copy of the PSO membership agreement is attached.*

SAMPLE

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 – January 1, 2010 to the present
2. Personnel File – January 1, 2010 to the present
3. Quality Assurance File – January 1, 2010 to December 30, 2019
4. Departmental File – January 1, 2010 to the present
5. Peer Review File – January 1, 2010 to December 30, 2019
6. All Incident Reports and records of complaints – January 1, 2010 to December 30, 2019.

Please do contact me directly if further information is required.

SAMPLE

[2] The hospital treats an employed physician's information in their Quality Assurance, Departmental, and Peer Review files, along with incident reports and records of complaints, as PSWP, for period beginning December 31, 2019.

SAMPLE PSES

PATIENT SAFETY EVALUATION SYSTEM
SAMPLE

TABLE OF CONTENTS:

I. POLICY SUMMARY 2

II. PROCEDURAL SUMMARY 2

III. COMPLIANCE / RESPONSIBILITIES 2

IV. DEFINITIONS 2

V. POLICY TEXT 2

A. Pascal Metrics Risk Trigger Monitor and Adverse Event Monitor Platforms 3
B. What is Patient Safety Work Product (PSWP) 3
C. Creation of PSWP by 6
D. Use of PSWP 6
E. Maintaining Confidentiality of PSWP / Claiming the Privilege 7
F. Required Reporting 9
G. Medical Staff Peer Review 9
H. Personnel Actions 9
I. Grievances 9

VI. TRAINING 10

VII. RELATED INFORMATION 10

VIII. FREQUENTLY ASKED QUESTIONS 10

IX. REVISION HISTORY 10

X. APPENDIX 1 10

A. Definitions 10
B. Triaging Patient Safety Concerns 12
C. Removing Direct Identifiers and Rendering PSWP as Non-Identifiable 13
D. Exceptions to Non-Disclosure Requirements 14
E. Information for Federal and State Regulators 16
F. Information for Law Enforcement 16
G. Provider Authorization to Disclose PSWP 17

XI. APPENDIX 2 18

A. Referenced Policies 18
B. Pascal Metrics' PSES 19

SAMPLE

SAMPLE PSES

I. POLICY SUMMARY

The policy of the hospital is to participate in patient safety activities conducted in accordance with the Patient Safety and Quality Improvement Act of 2005 and its implementing regulations (collectively, the Act), as well as New York State quality and public health laws. The hospital collects patient safety work product (PSWP) and engages in comprehensive patient safety activities, as a member of the Patient Safety Organization (PSO), Pascal Metrics (hereinafter, "Pascal"). The purpose of collecting PSWP and engaging in comprehensive patient safety activities is to improve the quality of health care services as well as to reduce the risk that adverse events pose to patients, its member hospitals, and its affiliated licensed health care facilities and providers. The hospital reports information about adverse events to the PSO using Pascal's platform, Risk Trigger Monitor (RTM). Pascal then analyzes that information in an effort to assist the hospital in improving quality and patient safety. In addition, Pascal uses RTM to gather data that indicates the possibility of an adverse event through an automated trigger process and provides the hospital with analyses of the gathered patient safety data and adverse event reports. All of the data on the Pascal RTM platform is PSWP. Effective 12/31/2019, the hospital entered into a contract with Pascal Metrics Patient Safety Organization and may contract with other Patient Safety Organizations to fully effectuate the patient safety activities and reporting of PSWP in accordance with the procedures described herein.

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 Subparts A and E of Part 164 (1996)], New York Public Health Law §2782, New York State Education Law §6527(3), New York Public Health Law §2805 J-M, New York Mental Hygiene Law §33.13, and New York Health Law Article 27F. Any use of such PHI shall conform to all laws, regulations, and privacy and security policies.

II. PROCEDURAL SUMMARY

This policy covers the use and disclosure of PSWP both internal and external to the hospital. The Risk Management Department should be contacted for any internal request for use or disclosure of PSWP for reasons unrelated to quality or patient safety. The Risk Management Department should also be contacted for any external requests from an individual, regulatory agency, company, etc. for use and/or disclosure of PSWP. The Risk Management Department can be reached at (718) 920-6733 from 9am to 5pm every weekday and can be reached off hours and on weekends through the page operator.

III. COMPLIANCE / RESPONSIBILITIES

The Office of the Chief Quality Officer, the Office of Medical Affairs, and Quality Management are responsible for the oversight of quality, patient safety, and performance improvement processes that create, analyze, and store PSWP. The Risk Management 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. 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 the hospital is to participate in patient safety activities conducted in accordance with the Patient Safety and Quality Improvement Act of 2005 and its implementing regulations (collectively, the Act). The hospital collects patient safety work product (PSWP) and is a member of the Patient Safety Organization (PSO), Pascal

Metrics (hereinafter, "Pascal") 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 patients, its member hospitals, and its affiliated licensed health care facilities and providers.

A. Pascal Metrics Risk Trigger Monitor and Adverse Event Monitor Platforms

The Pascal Metrics Risk Trigger Monitoring (RTM) system scans the electronic health information system for standardized triggers associated with patient harm. When a trigger fires in the RTM system, Pascal's expert clinical review nurses and physician authenticators review the medical record to determine if a true adverse event occurred. Once the triggers are validated as adverse events, a corresponding Adverse Event Document is created on the RTM platform. The hospital then analyzes the information in the Adverse Event Document to determine whether the event details are accurate and enter any additional information about the event into the RTM platform. The hospital contracts with a third-party risk management administrator, Healthcare Risk Advisors (HRA), to provide risk management services that includes dedicated patient safety adverse event investigators (AEIs). To assist Risk Management in their efforts to investigate patient harm events, Pascal Metrics created a separate workspace within each Adverse Event Document called Adverse Event Monitor (AEM). This workspace is only accessible to Risk Management and HRA Patient Safety Adverse Event Investigators (AEIs). For additional information about the Pascal RTM and AEM platforms, please refer to Appendix 1.B and Appendix 2.B. Pascal analyzes the information it has generated together with the additional information the hospital has reported into the RTM and AEM platforms and provides insight on the impact adverse events have on the hospital's safety profile.

B. What is Patient Safety Work Product (PSWP)

PSWP includes the following:

1. Deliberations or analyses 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 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 including but not limited to:
        - Notes including but not limited to chart reviews and interviews
        - Data analyses reports and communication
        - Documents reflecting insights and action plans
        - Root Cause Analyses (RCAs)
        - Critical Event reviews
        - Event Debriefing forms
        - Outcome reports
        - Research related to quality improvement and safety
        - Data collected and reported to third-party organizations the hospital has partnered with as reflected in the hospital's Quality Assessment and Performance Improvement (QAPI) Policy (See Appendix 2.A)
        - Quality dashboards
        - Patient Safety dashboards
        - Voluntary reporting of adverse events (See Appendix 2.A)
        - Social determinants of health and health equity activities
        - Failure Mode Effects Analyses (FMEAs)
        - Risk Management activities
        - Patient Experience activities

SAMPLE

- Collection/tracking of patient complaints
- Collection/tracking of patient rounding data, and information gathered during rounding
- Customer Service activities
- Videos and/or recordings of surgery or procedures
- Focused Professional Practice Evaluations (FPPE) and Ongoing Professional Practice Evaluations (OPPE)
- Reviews prompted by recall notices
- Written statements by providers involved in patient care

b. Data and documents that support quality 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, conducted at the department, division, group, or hospital level. These committees and programs include but are not limited to:
   - Medical Committee of the Board of Trustees
   - Quality Council
   - Medical Executive Committee
   - Network Performance Group
   - Center for Performance Improvement
   - Quality Collaborative
   - Peer Review Board
   - Bioethics Committee
   - Patient Safety Committee
   - Serious Safety Event (SSE) / Never Event (NE) Committee
   - Serious Adverse Event Review Committee
   - Division Councils
   - Antibiotic Stewardship and Infection Control Committee
   - Quality Improvement and Informatics
   - Enterprise Data and Information Management and Business Intelligence
   - Centers for Excellence Quality Improvement
     - Nursing Magnet
     - Comprehensive Stroke Center
     - Primary Stroke Center
     - Ventricular Assist Device Program
     - Joint Replacement Center
     - Spine Surgery Center
     - Solid Organ Transplant Quality Committee and Specific Organ Transplant QI Committee
   - Solid Organ Transplant Quality Committee
   - Medication Safety Committee
   - Organ Donor Council
   - Morbidity and Mortality Committees
   - Resident Clinical Review
   - Interdisciplinary Review Committee
   - Patient Experience Steering Committee
   - Healthcare Associated Infection (HAI) Committee
   - Patient Safety Indicator (PSI) Committee
   - Cardiac Arrest Committee
   - Airway Committee
   - Department of Medicine, Faculty Development in Quality Improvement Program

SAMPLE

- Department of Medicine, The Philip Lief Quality Improvement Program for Residents and Fellows
- Department of Medicine Residency Program Conferences on Patient Safety and Quality Improvement
- Department of Medicine Residency and Fellowship curriculum
- Department of Medicine ad hoc quality improvement initiatives for departmental clinical priorities
- 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 Committee
- 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 committees

Any committee not listed above but included in the hospital's QAPI Policy (Appendix 2.A) is incorporated by reference herein. See Appendix 2.A for above referenced policies.

2. Reporting includes any information, data, or document entered, submitted, or uploaded by the hospital and/or AEIs into the Pascal Metrics RTM and/or AEM platforms including but not limited to:

    a. Adverse Event Documents
    b. Midas Data
    c. Interview Summary Sheets
    d. AEI Review Documents
    e. Investigation Decisions
    f. Comments

3. All data on the Pascal RTM and AEM platforms generated by or for the hospital are PSWP. Pascal Metrics' description of its PSWP as described in its PSES is incorporated by reference (See Appendix 2.B).

4. The following is not PSWP:

    a. Activities involving the actual delivery of patient care and the supporting services directly related thereto; and 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).
        - Copies of non-PSWP that are used for quality and patient safety activities are PSWP (See Appendix 1.A for Copies definition).
    b. Information or 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).
    c. Videos, photography, recordings, and all media created for the purposes of treatment or communication with a patient/patient family/designee are not PSWP.
    d. 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 Just Cause Standards definition).
        - Any investigation into employee conduct by Quality Management, Patient Safety, and/or Risk Management is PSWP.

SAMPLE

C. Creation of PSWP

1. PSWP is created and entered into the PSES when quality and patient safety improvement activities and/or communications occur. PSWP protections will apply immediately.

2. PSWP is created and entered into the PSES when any information regarding patient safety adverse events and/or quality and patient safety improvement is entered into the Pascal Metrics PSO. Additional quality and patient safety information entered into the Pascal Metrics PSO that adds to, enhances, and/or modifies the information initially generated by Pascal is also PSWP. All information entered by the hospital into the Pascal Metrics PSO is incorporated into Pascal's analysis of patient safety adverse events as well as quality and patient safety improvement efforts. PSWP protections will apply immediately upon entry into the Pascal Metrics PSO as reflected by the corresponding date stamps.

3. PSWP is created within the Pascal RTM platform as described in Pascal Metrics' PSES.

D. Use of PSWP

1. PSWP may be used by the hospital 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 hospital workforce includes faculty, staff, trainees, volunteers, and contractors, who perform work under the direct control of the hospital. These include the following as detailed in the hospital's QAPI (Appendix 2.A), but are not limited to:
        - Medical Committee of the Board of Trustees
        - Quality Counsel
        - Medical Executive Committee
        - Network Performance Group
        - Center for Performance Improvement
        - Quality Collaborative
        - Peer Review Board
        - Bioethics Committee
        - Patient Safety Committee
        - Serious Safety Event (SSE) / Never Event (NE) Committee
        - Serious Adverse Event Review Committee
        - Division Councils
        - Antibiotic Stewardship and Infection Control Committee
        - 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 Committee
        - Medication Safety Committee
        - Organ Donor Council

SAMPLE

- Morbidity and Mortality Committees
- Resident Clinical Review
- Interdisciplinary Review Committee
- Ad hoc committees formed in response to identified need for improving the quality and safety of patient care and services provided.

2. Use of PSWP within the hospital for business operations does not constitute a "disclosure" of PSWP. This includes the hospital workforce as well as members of its health care providers' medical or allied health professional staff.

    a. PSWP may be disclosed to other Affiliates of the hospital 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. PSWP may be disclosed to the hospital's contractors for the conduct of Patient Safety Activities. Contractors may not further disclose the PSWP.
    c. 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.G).
        - The identifiable information can be effectively removed (See Appendix 1.C.2).

3. Except as otherwise described in these Policies and Procedures, PSWP may not be disclosed outside of the hospital.

    a. "Disclosure" means the release, transfer, provision of access to, or divulging in any other manner of PSWP to a legally separate entity or person outside of the hospital

    b. PSWP may be shared with outside attorneys, accountants, or other approved consultants as approved by HHS who assist the hospital in the conduct of business operations. These individuals may not further disclose the PSWP and any use of the PSWP is subject to Section V.D.2.

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.

E. Maintaining Confidentiality of PSWP / Claiming the Privilege

1. Confidentiality

    a. PSWP is confidential. All access and use must be structured to honor and maintain this confidentiality.

SAMPLE

b. All communications and activities conducted within appropriate channels of communication and intended to improve safety and quality are permitted.

c. Use of PSWP for business operations (as described in Section V.D.2) 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 Office of Legal Counsel and/or their designee, including but not limited to, Risk Management, Legal Affairs, or internal legal counsel.

f. Exceptions to confidentiality are described in Section V.E.3. and Appendix 1.D.

2. Privilege

a. PSWP is "Privileged" (i.e., not subject to compulsory discovery or disclosure). Thus, in addition to prohibiting the hospital 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, Office of Legal Counsel and/or their designee, including but not limited to, Risk Management, Legal Affairs, or internal legal counsel should be contacted immediately so they may assert the PSWP privilege.

c. All PSWP (as defined in Section V.B), whether deliberations or analysis and/or reported to the PSO, created for the purposes of comprehensive quality and patient safety improvement, should be prominently labeled as "Confidential and Privileged Patient Safety Work Product" or "Confidential and Privileged Quality (Safety) Patient Safety Work Product" to better enable later identification of privileged documents when responding to requests for access or disclosure. The hospital may select other clearly discernable text to be used as the label and modify the Policy appropriately – e.g., "PSWP: Confidential and Privileged". 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 relate to the following, and the specific requirements of each exception are described in Appendix 1.D:
   - Criminal Proceedings and/or to law enforcement
   - Equitable relief actions
   - Provider authorization
   - Non-identifiable PSWP
   - Research
   - FDA
   - Accrediting Bodies
   - Independent contractors

SAMPLE

F. 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. 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.
    d. An RCA document prepared for submission to the New York State Department of Health under New York Patient Occurrence and Tracking System (NYPORTS) is not PSWP.
    e. PSWP may be voluntarily disclosed to the Joint Commission subject to compliance with Appendix 1.D.8.

G. Medical Staff Peer Review

PSWP may be accessed and used in the process for making decisions around medical staff disciplinary proceedings.

The Act prohibits a provider organization from taking an adverse "employment action" 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 the hospital's Just Culture procedures. The hospital's "Just Culture" framework is referenced in the hospital's QAPI (Appendix 2.A). Medical staff or medical peer review activities are conducted within the PSES, unless otherwise stated and documented as disciplinary review proceeding.

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 the hospital or for the peer review body and does not waive any evidentiary protections or privileges associated with that information.

H. Personnel Actions

Investigation, deliberation, and employment decisions and/or discipline conducted at the direction of clinical leadership by or through Human Resources pursuant to just culture and progressive discipline just cause standards under existing collective bargaining agreements are not PSWP.

I. Grievances

In some cases, patient/complainant 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.

SAMPLE

VI. TRAINING

Risk Management, Office of the Chief Quality Officer, Office of the Medical Director, Clinical Department Leadership, Quality Management, Patient Safety, Regulatory Affairs, Patient Experience and Customer Service, Privacy and Compliance, Nursing Leadership, Research Compliance, Labor and Employment, Human Resources, The Learning Network, and Legal Affairs 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 hospital's uses of PSWP and conduct of Patient Safety Activities.

Risk Management Department and/or their designees shall be responsible to conduct or arrange sufficient training of all 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. 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. New York State Education Law §6527 [3]
6. New York Public Health Law § 2805 J-M
7. New York State Public Health Law § 2782 - Confidentiality and Disclosure
8. New York State Mental Hygiene Law § 33.13 – Confidentiality

VIII. FREQUENTLY ASKED QUESTIONS

1. AHRQ FAQs- AHRQ-FAQs

IX. REVISION HISTORY

X. APPENDIX 1

A. Definitions

Adverse Event: An unanticipated occurrence or set of circumstances that caused or could cause harm to patient, personnel (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 no 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).

SAMPLE

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.

HRA Patient Safety Adverse Event Investigators (AEIs): Individuals that assist Risk Management with the evaluation of adverse events, and access the Pascal Metrics AEM platform. The AEIs role is limited to investigating adverse events and is prohibited from performing any activity related to professional liability claims or lawsuits.

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

Midas Adverse Event Reporting System: The hospital's system for voluntary adverse event reporting. (Appendix 2.A)

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).

Patient Safety Activities: Activities carried out on behalf of health care providers, the 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 informationto PSES participants.

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

Patient Safety Evaluation System (PSES): The collection, management or analysis of information for reporting to a PSO.

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 the hospital has contracted, on behalf of each health care provider, for the delivery of PSWP and the conduct of Patient Safety Activities. The hospital has contracted with Pascal Metrics 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 asotherwise documented, references in these Policies and Procedures to PSO shall mean Pascal Metrics and any other PSOs with which the hospital has contracted.

SAMPLE

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 Appendix 1.D.

Pascal Metrics: Patient Safety Organization (see additional definition of PSO within policy text).

Progressive Discipline & Just Cause Standards: Just Cause is the labor and employment law standard, which establishes whether an employer had good reason to discipline an employee. 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 an employee fails to correct a problem after being given a reasonable opportunity to do so. Some employee conduct may result in immediate discharge without the need to follow the progressive discipline continuum when taking disciplinary action.

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)

B. Triaging Patient Safety Concerns

Pascal Metrics Risk Trigger Monitoring (RTM) uses automated trigger methodology to identify adverse events. Risk Managers and other authorized individuals are notified through an electronic notification process via an email and link to the adverse event identified by Pascal. Who receives notification and how is determined through a filtering process established by the authorized user, of which includes Risk Management. 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. Upon notification of the event, Risk Managers or his/her/their designee and other authorized users review the Adverse Event in the Pascal RTM platform, which contains the event description, the triggers identified to date and possible causes amongst other relevant data held in the RTM platform. In addition, those matters that Risk Management deems to be potentially compensable are flagged to a separate platform in the PSO called Adverse Event Monitor (AEM), which is used by the hospital's third-party administrator, HRA. HRA Patient Safety Adverse Event Investigators assist Risk Management in its evaluation and investigation of patient safety adverse events. 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. HRA's Patient Adverse Event Investigators, as well as Risk Managers are prohibited from sharing, sending, or disclosing any PSWP to HRA Claims Department.

SAMPLE

C. 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 (i.e., other than any PSO to which the hospital has reported the information), 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 Appendix 1.C.2.

    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 Appendix 1.C.3.

    c. Office of Legal Counsel and/or their designee, including but not limited to, Risk Management, Legal Affairs, or internal legal counsel 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 providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers:
        - 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

SAMPLE

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 workforce, and household members of the provider and reporter.

D. Exception to Non-Disclosure Requirements

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 relatedto the Patient Safety Concern at issue. Attached as Appendix 3 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

   a. 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.G for the Authorization Form to be used for this purpose. Authorization pursuant to any other form must be approved, in writing, by Office of Legal Counsel and/or their designee, including but not limited to, Risk Management, Legal Affairs, or internal legal counsel.

4. Non-Identifiable PSWP

SAMPLE

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

5. Independent Contractors

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

6. Research

a. 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 Office of Legal Counsel and/or their designee, including but not limited to, Risk Management, Legal Affairs, or internal legal counsel.

7. Food and Drug Administration (FDA)

a. 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.

8. Accrediting Bodies

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

b. Once authorization has been obtained, or identifiers have been removed, the following persons are authorized to release information to an accrediting body:
- Risk Manager, or their designee
- The Director of Regulatory Affairs, or their designee
- 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 allied health professional for whom the medical staff has oversight or credentialing responsibility.

9 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.

10. 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 the hospital is not a co-defendant in the action. Any disclosure of PSWP to the AUSA must be approved by the Office of Legal Counsel 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 the hospital is a co-defendant in the action. Any request for

SAMPLE

disclosure of PSWP under these circumstances must be escalated to, and evaluated by, the Office of Legal Counsel and/or their designee.

11. Office of Legal Counsel and/or their designee, including but not limited to, Risk Management, Legal Affairs, or internal legal counsel 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.C.3 may be provided to regulatory agencies. See Appendix 1.E 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 Office of Legal Counsel and/or their designee, including but not limited to, Risk Management, Legal Affairs, or internal legal counsel for resolution.

E. Information for Federal and State Regulators

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 andQuality 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 Patient Safety Work Productmay not be disclosed outside of this facility.

Any questions about access to this information should be directed to Office of Legal counsel and/or their designee, including but not limited to, Risk Management, Legal Affairs, or internal legal counsel: *[insert contact information]*

F. Information for Law Enforcement

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.

SAMPLE

(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 hospital files; a copy of this document should be provided to the law enforcement official who obtains a copy of the PSWP.

G. 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 Hospital 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 Office of Legal Counsel and/or their designee and retained for 6 years from the date of the last disclosure made pursuant to this authorization.

SAMPLE

XI. APPENDIX 2

A. Referenced Policies

Guidelines for Complex Care Review
Critical Event
Disclosure of Unanticipated Events
Escalation of Clinical Issues
Patient Complaint and Grievance Policy
Quality Improvement Plan (JQ01.0)
QAPI Policy
Incident Reporting to NYS Department of Health (NYPORTS)
Occurrence and Incident Review and Reporting
Peer Review

SAMPLE

SAMPLE PSES

B. Pascal Metrics' PSES

SAMPLE