Orientation Resources
For Credentialed Providers

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1. Trinity Mission and Background
Saint Joseph Health System is part of Trinity Health.

Our Mission, Vision, and Values inform our past, present, and future and will endure.

Our Mission
We, Trinity Health, serve together in the spirit of the Gospel as a compassionate and transforming healing presence within our communities.

Our Vision
As a mission-driven innovative health organization, we will become the national leader in improving the health of our communities and each person we serve. We will be the most trusted health partner for life.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. Trinity Health includes 92 hospitals, as well as 106 continuing care locations that include PACE programs, senior living facilities, and home care and hospice services. Its continuing care programs provide nearly 2 million visits annually.

Based in Livonia, Mich., and with annual operating revenues of $19.3 billion and assets of $27 billion, the organization returns $1.2 billion to its communities annually in the form of charity care and other community benefit programs.

Trinity Health employs about 125,000 colleagues, including 7,500 employed physicians and clinicians. Committed to those who are poor and underserved in its communities, Trinity Health is known for its focus on the country’s aging population. As a single, unified ministry, the organization is the innovator of Senior Emergency Departments, the largest not-for-profit provider of home health care services — ranked by number of visits — in the nation, as well as the nation’s leading provider of PACE (Program of All Inclusive Care for the Elderly) based on the number of available programs.
2. Saint Joseph Health System

   a. SJHS Background
   b. SJHS Executive Council
   c. Code of Conduct
   d. Medical Staff Mission Statement
   e. Diversity, Equity & Inclusion (“DEI”)
   f. Ethical & Religious Directives for Catholic Health Services
   g. Just Culture
   h. Business Courtesies
   i. SJHS Available Clinical Services
Saint Joseph Health System (click link to the left)

Saint Joseph Health System is a not-for-profit, multi-hospital health system located in North Central Indiana.

Our system includes:

- 254-bed acute-care hospital at the Mishawaka Medical Center
- 58-bed acute-care hospital at the Plymouth Medical Center
- More than 85 providers in the Saint Joseph Physician Network
- Community health centers and additional points of access
- St. Paul’s with 316 suites for independent living, assisted living, skilled nursing care, rehabilitation and wellness and memory care.
- Holy Cross with 168 suites for rehabilitation and wellness and skilled nursing care
- Trinity Tower with 84 affordable senior apartments
- Health Insurance Services
- VNA Home Care

Saint Joseph Health System continues the legacy of caring for Michiana begun by the Sisters of the Holy Cross and the Poor Handmaids of Jesus Christ more than 150 years ago. Saint Joseph Health System is a Regional Ministry Organization of Trinity Health that provides compassionate, faith-based care paired with the latest in advanced medical technology and procedures.

In addition to acute-based hospital care, we are proud to provide a wide range of community-based and post-acute services including: community wellness, physical rehabilitation, home care, physician clinics, outpatient services, independent and assisted senior living, memory care and affordable senior apartments.

At Saint Joseph Health System, our values give us strength. That character guides every decision we make - even when those decisions are complicated, costly or hard. We honor our mission to care for every man, woman and child who needs us by investing in technology, people and capabilities that allow us to set the stand.
Our character guides every decision we make - even when those decisions are complicated, costly, or hard. We are fortunate to have a strong leadership team who understands that we answer to a higher calling.

Meet the members of our SJHS Executive Council.
**Title:** MEDICAL STAFF MISSION STATEMENT AND CODE OF CONDUCT POLICY

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Printed copies are for reference only. Please refer to the electronic copy for the latest version.

**MEDICAL STAFF MISSION STATEMENT**
The Medical Staff of SJRMС, Mishawaka and SJRMС, Plymouth are organized to promote the health of our community. The Medical Staff is committed to excellent patient care and embraces the highest standards of the profession in its relationship with patients, SJRMС associates and our peers.

**MEDICAL STAFF CODE OF CONDUCT**
A. Collaboration, communication, and collegiality are essential for the provision of safe and competent patient care. As such, all Medical Staff members and Allied Health Professionals practicing in the Hospital must treat others with respect, courtesy, and dignity and conduct themselves in a professional and cooperative manner.

B. When a Medical Staff member or Allied Health Professional encounters circumstances suboptimal to the care of their patient it is their responsibility to document the occurrence by entering it into the Midas reporting system, or by reporting it to administrative personnel or by contacting the Medical Staff Office.

C. Medical Staff members and Allied Health Professionals will refrain from disruptive behavior as outlined in the policy statement below.

D. Medical Staff members and Allied Health Professionals will abide by the Bylaws, Rules and Regulation and Policy and Procedure manuals, which have been adopted by the Medical Staff.

E. Medical Staff members and Allied Health Professionals will follow mandated guidelines as defined by HIPAA, EMTALA and they shall refrain from conflicts of interest as defined by state and federal laws and regulations.

F. Medical Staff members and Allied Health Professionals will attend patients when called upon to do so without regard to ethnicity, gender or financial status as outlined in anti-discrimination law.

G. Medical Staff members and Allied Health Professionals will agree to provide consulting service within the practitioner's defined area of expertise when called upon to do so without regard to ethnicity, gender or financial status according to Medical Staff Bylaws 2A3c.

H. Medical Staff members and Allied Health Professionals shall participate in peer review, quality improvement and assigned committees as requested by his/her department chairperson or other medical staff leaders.

I. Medical Staff members and Allied Health Professionals shall bring concerns regarding peer behavior to the attention of the medical staff leadership in order to promote timely investigation and when appropriate collegial intervention. The principle of confidentiality and patient safety are paramount concerns governing this reporting.

**POLICY:**
It is the policy of the Medical Staff, which includes physicians and allied health professionals ("Practitioner") that all individuals within SJRMС facilities be treated with courtesy, respect, and dignity. To that end, all Practitioners shall conduct themselves in a professional and cooperative manner in the hospital.
If a Practitioner fails to conduct him or herself appropriately, the matter shall be addressed in accordance with the following policy.

1. Collaboration, communication, and collegiality are essential for the provision of safe and competent patient care. As such, all Practitioners practicing in the Hospital must treat others with respect, courtesy, and dignity and conduct themselves in a professional and cooperative manner.

2. A Practitioner, treating patients at SJRMC-Mishawaka and SJRMC-Plymouth, may encounter circumstances suboptimal to the care of their patient. This may occur from deficiencies in supplies or equipment or from deficiencies in hospital personnel working on their behalf. Hospital policies and procedures will require upgrades from time to time with changes in medical knowledge. The Practitioner is encouraged to document perceived substandard care and to work towards possible solutions. This should occur in a constructive manner. The SJRMC Midas reporting system allows for appropriate documentation of such events and a means by which they can be analyzed by hospital personnel. The system is intended to promote useful dialogue and a platform for problem solving, ultimately resulting in improved patient care. Documenting an occurrence can be accomplished by:

A. Document in writing the date, description, patient name, witnesses (if any) of any occurrence and submit this documentation to one of the following individuals. (See attached form)
   1) Medical Staff President - 335-2353
   2) VP Quality Improvement - 335-1035
   3) Medical Staff Office, Mishawaka– 335-2383
   4) Medical Staff Office, Plymouth – 948-5005

B. or, enter an occurrence directly into Midas:
   1) Go to Daily Dose
   2) Click on Favorites
   3) Go to SJRMC Websites and Click on Midas RDE
   4) Click on Risk
   5) Select the Appropriate Risk Form depending on occurrence
   6) Select the correct Facility – Mishawaka or Plymouth.
   7) Enter incident date
   8) Choose patient or non-patient incident and click Next (the next screens vary based on patient or non-patient)

9) Patient:
   a) Enter patients medical record number or name
   b) Choose incident type by clicking on the drop down arrow to the right
   c) Enter factors contributing to incidence by clicking on magnifying glass and select the factor(s) from the right side of the screen – then click OK
   d) Enter where the incident took place by clicking on the magnifying glass and select unit from the menu at the right side of the screen – then click OK
   e) Enter shift – Also enter time and room if information is available
   f) Enter your last name and hit tab – select your first name if multiple options
   g) Enter narrative of incident
   h) Click Save
Title: MEDICAL STAFF MISSION STATEMENT AND CODE OF CONDUCT POLICY

10) Non-Patient:
   a) Choose incident type by clicking on the drop down arrow to the right
   b) Enter factors contributing to incidence
   c) Enter where the incident took place
   d) Enter shift – also enter time and room if information is available
   e) Enter non-patient type by clicking on magnifying glass and select type from the right side of the screen
   f) Enter non-patient name
   g) Complete “entered by” by entering your last name and hit tab – select your first name if multiple options
   h) Enter narrative of incident
   i) Click Save

C. You can also document the above by calling the Physician Concern Line at 285-5899 (Mishawaka only) and leave the details including the date, description, patient name, witnesses (if any) of any occurrence and a Midas entry will be made on your behalf.

3. This Policy outlines collegial and educational efforts that can be used by the SJRMC-Mishawaka and SJRMC-Plymouth Medical Staff to address conduct that does not meet this standard. The goal of these efforts is to arrive at voluntary, responsive actions by the individual to resolve the concerns that have been raised, and thus avoid the necessity of proceeding through the disciplinary process in the Credentials Policy.

4. This Policy also addresses issue of alleged sexual harassment of employees, patients, other Practitioners of the Medical Staff, and others, which will not be tolerated.

5. In dealing with all incidents of inappropriate conduct, the protection of patients, employees, physicians, and others in the Hospital and the orderly operation of the Medical Staff and Hospital are paramount concerns. Complying with the law and providing an environment in which the highest ethical and professional standards are maintained.

6. All efforts undertaken pursuant to this Policy shall be part of the Hospital’s performance improvement and professional and peer review activities.

7. If there is a possibility of an impairment issue, the Medical Staff Impaired and Dysfunctional Physician Policy should be referenced and consideration of referring the physician/practitioner to the Medical Staff Well-Being Committee should take place.

8. Reports shall be kept in the peer review protected practitioner's confidential file. These confidential files are retained in the Medical Staff Office.

GUIDELINES

A. A single egregious incident or repeated incidents shall initiate an investigation. Summary suspension may be appropriate pending this process. If it is unclear whether the conduct was actually disruptive, the Chief Medical Officer of the hospital and/or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth) may seek the expert opinion of an impartial individual experienced in such matters.

   1) Issues of employee conduct will be dealt with in accordance with the Hospital's Human Resources Policies. Issues of conduct by members of the Medical Staff or Allied Health Professionals will be addressed in accordance with this Policy.
Title: MEDICAL STAFF MISSION STATEMENT AND CODE OF CONDUCT POLICY

2) Every effort will be made to coordinate the actions contemplated in this Policy with the provisions of the Credentials Policy. In the event of any apparent or actual conflict between this Policy and the Credentials Policy, the provisions of this Policy shall control.

3) This Policy outlines collegial steps (i.e., counseling, warnings, and meetings with a practitioner) that can be taken to address complaints about inappropriate conduct by practitioners. However, a single incident of inappropriate conduct or a pattern of inappropriate conduct as determined by an appropriate investigation may be so unacceptable that immediate disciplinary action is required. Therefore, nothing in this Policy precludes an immediate referral of a matter being addressed through this Policy to the Executive Committee or the elimination of any particular step in the Policy.

4) Except as otherwise may be determined by the Chief Medical Officer of the hospital and/or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth), the practitioner’s counsel shall not attend any of the meetings described in this Policy.

5) The Medical Staff leadership and Hospital Administration shall make employees, Practitioners of the Medical Staff, and other personnel in the Hospital aware of this Policy and shall institute procedures to facilitate prompt reporting of inappropriate conduct and prompt action as appropriate under the circumstances.

B. Unacceptable disruptive conduct may include, but is not limited to, behavior such as:

1) attacks – verbal or physical – leveled at other appointees to the medical staff, hospital personnel, or patients, that are personal, irrelevant, or beyond the bounds of fair professional conduct.

2) degrading or demeaning comments regarding patients, families, nurses, physicians, Hospital personnel, or the Hospital;

3) profanity or similarly offensive language while in the Hospital and/or while speaking with nurses or other Hospital personnel;

4) inappropriate physical contact with another individual that is threatening or intimidating;

5) unfocused non-constructional derogatory comments about the quality of care being provided by the Hospital, another Practitioner, or any other individual outside of appropriate Medical Staff and/or administrative channels;

6) inappropriate medical record entries impugning the quality of care being provided by the Hospital, Medical Staff Practitioner or any other individual;

7) imposing onerous requirements on the nursing staff or other Hospital employees;

8) refusal to abide by Medical Staff requirements as delineated in the Medical Staff Bylaws, Credentials Policy, and Rules and Regulations (including, but not limited to, emergency call issues, response times, medical record keeping, and other patient care responsibilities, failure to participate on assigned committees, and an unwillingness to work cooperatively and harmoniously with other Practitioners of the Medical and Hospital Staffs); and/or

9) "sexual harassment," which is defined as any verbal and/or physical conduct of a sexual nature that is unwelcome and offensive to those individuals who are subjected to it or who witness it. Examples include, but are not limited to, the following:

   a) Verbal: innuendoes, epithets, derogatory slurs, off-color jokes, propositions, graphic commentaries, threats, and/or suggestive or insulting sounds;

   b) Visual/Non-Verbal: derogatory posters, cartoons, or drawings; suggestive objects or pictures; leering; and/or obscene gestures;
Title: MEDICAL STAFF MISSION STATEMENT AND CODE OF CONDUCT POLICY

c) Physical: unwanted physical contact, including touching, interference with an individual's normal work movement, and/or assault; and
d) Other: making or threatening retaliation as a result of an individual's negative response to harassing conduct.

REPORTING OF INAPPROPRIATE CONDUCT

A. Documentation of disruptive conduct is critical because it is ordinarily not one incident that leads to disciplinary action, but rather a pattern of inappropriate conduct. Such documentation shall include:

1) Practitioners, nurses and other Hospital employees who observe, or are subjected to, inappropriate conduct by another Practitioner shall:
   a) notify the practitioner about the incident or,
   b) notify their supervisor about the incident or, if their supervisor's behavior is at issue,
   c) shall notify the Chief Medical Officer of the hospital and/or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth).

2) Any practitioner who observes such behavior by another practitioner is encouraged notify the Chief Medical Officer of the hospital and/or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth) directly.

3) The individual who reports an incident shall be requested to document it in writing. If he or she does not wish to do so, the supervisor or Chief Medical Officer of the hospital and/or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth) may document it, after attempting to ascertain the individual's reasons for declining and encouraging the individual to do so.

4) The documentation should include:
   a) the date and time of the incident;
   b) a factual description of the questionable behavior;
   c) the name of any patient or patient's family member who may have been involved in the incident, including any patient or family member who may have witnessed the incident;
   d) the circumstances which precipitated the incident;
   e) the names of other witnesses to the incident;
   f) consequences, if any, of the behavior as it relates to patient care, personnel, or Hospital operations;
   g) any action taken to intervene in, or remedy, the incident; and
   h) the name and signature of the individual reporting the matter.

5) Any physician or employee may report potentially disruptive conduct. The report shall be submitted to the medical director or a facility administrator and then forwarded to the Chief Medical Officer of the hospital and/or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth) for further consideration and or investigation as indicated.

INVESTIGATION

A. All reports of questionable behavior are fully investigated by risk management and medical staff services on behalf of the medical staff who may meet with the individual who prepared it and/or any witnesses to the incident to ascertain the details of the incident prior to any discussion with physician/practitioner. Once an incident is confirmed, a report will be forwarded to the Chief Medical Officer of the hospital and/or Medical Staff President (Mishawaka & Plymouth) or...
Title: MEDICAL STAFF MISSION STATEMENT AND CODE OF CONDUCT POLICY

President of the Hospital (Plymouth). Unconfirmed reports will be dismissed in which case the individual initiating such report will be apprised.

B. If there is a possibility of an impairment issue, the Medical Staff Impaired and Dysfunctional Physician Policy should be referenced and consideration of a self-referral or referral of the physician/practitioner to the Medical Staff Well Being Committee should take place.

C. If an incident of inappropriate conduct has likely occurred, then the Chief Medical Officer of the hospital and/ or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth) is informed and investigation will be conducted by medical staff leadership. Medical staff leadership has several options available, including, but not limited to, the following:

1) notify the practitioner and Department Chairperson that a complaint has been received and invite the practitioner to meet with the Department Chairperson, the Medical Staff President and if necessary the Chief Medical Officer of the Hospital (Mishawaka & Plymouth) or President (Plymouth) to discuss it in a collegial manner;

2) send the practitioner a letter of guidance about the incident;

3) educate the practitioner about administrative channels that are available for registering complaints or concerns about quality or services, if the practitioner’s conduct suggests that such concerns led to the behavior. Other sources of support may also be identified for the practitioner, as appropriate;

4) send the practitioner a letter of warning or reprimand, particularly if there have been prior incidents and a pattern may be developing;

5) all meetings will take place within 30 days of the date the report was received and verified and will be documented with and a copy placed in the physician’s medical staff file;

D. During an investigation the identity of an individual reporting a complaint of inappropriate conduct will not be disclosed to the practitioner. In any case, the practitioner shall be advised that any retaliation against the person reporting a concern, whether the specific identity is disclosed or not, will be grounds for immediate referral to the Executive Committee pursuant to the Credentials Policy.

E. If the Chief Medical Officer of the hospital and/ or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth) prepares any documentation for a practitioner's file regarding its efforts to address concerns with the practitioner, the practitioner shall be apprised of that documentation and given an opportunity to respond in writing. Any such response shall then be kept in the practitioner’s confidential file along with the original concern and the Chief Operating Officer of the Hospital and/or the President of the Medical Staff documentation.

F. If additional complaints are received concerning a practitioner, the Chief Medical Officer of the hospital and/ or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth) may continue to utilize the collegial and educational steps noted in this Section as long as it believes that there is still a reasonable likelihood that those efforts will resolve the concerns.

ACTION

A. A single confirmed incident warrants a discussion with the offending physician; the medical staff leadership designee shall initiate such a discussion and emphasize that such conduct is inappropriate and must cease. The initial approach should be collegial and helpful to the physician/practitioner and the hospital.

B. If it appears that a pattern of disruptive behavior is developing, the medical staff leadership and the Chief Medical Officer of the Hospital (Mishawaka & Plymouth) or President (Plymouth) or their designee shall discuss the matter with the physician/practitioner as outlined below:
Title: MEDICAL STAFF MISSION STATEMENT AND CODE OF CONDUCT POLICY

1) Emphasize that if such repeated behavior continues, more formal action will be taken to stop it. The MEC and CEO will be notified.

2) All meetings will take place within 30 days of the date the report was received and verified and will be documented with a copy placed in the physician’s medical staff file;

3) A follow-up letter to the physician/practitioner shall state the nature of the problem and inform the individual that he or she is required to behave professionally and cooperatively within the hospital.

4) The involved physician/practitioner may submit a rebuttal to the charge. Such rebuttal will be maintained as a permanent part of the record.

C. The presence of an attorney for the practitioner or the Hospital is allowed only after an investigation has been fully reviewed and a determination has been made in which the practitioner is entitled to a Hearing. i.e. suspension of privileges for longer than 30 days, revocation of membership or privileges, etc.

Referral to the Executive Committee

A. At any point, the Chief Medical Officer of the hospital (Mishawaka & Plymouth) or President of the Hospital (Plymouth) and/or medical staff leadership may refer the matter to the Executive Committee for review and action. The Executive Committee shall be fully apprised of the actions taken by the Chief Medical Officer of the hospital and/ or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth) or others to address the concerns.

B. If the Medical Executive Committee, after review of information provided, calls for an investigation then the matter is referred to the Credentials Committee, which becomes the investigative body of the medical staff. The Credentials Committee then issues a report to the Medical Executive Committee of its finding. The Medical Executive Committee may, based upon the facts and recommendations presented by the Credentials Committee, make recommendations for action including, but not limited to, the following:

1) require the practitioner to meet with the Board Chair;

2) require the practitioner to meet with the full Executive Committee;

3) issue a letter of warning or reprimand;

4) require the practitioner to obtain a psychiatric evaluation by a physician chosen by the Executive Committee;

5) require the physician to complete a behavior modification course;

6) impose a “personal” code of conduct on the practitioner and make continued appointment and clinical privileges contingent on the practitioner’s adherence to it; and/or

7) suspend the practitioner’s clinical privileges for less than 30 days.

The imposition of any of these actions does not entitle the practitioner to a hearing or appeal.

C. At any point, the Medical Executive Committee may also make a recommendation regarding the practitioner’s continued appointment and clinical privileges including, but not limited to, revocation and/or suspension for greater than 30 days that does entitle the practitioner to a hearing as outlined in the Credentials Policy, or may refer the matter to the Board without a recommendation. If the matter is referred to the Board, any further action, including any hearing or appeal, shall be conducted under the direction of the Board.
Title: MEDICAL STAFF MISSION STATEMENT AND CODE OF CONDUCT POLICY

Sexual Harassment Concerns

A. Because of the unique legal implications surrounding sexual harassment, a single confirmed incident requires the following actions:

1) A meeting shall be held with the Practitioner to discuss the incident. All meetings will take place within 30 days of the date the report was received and verified and will be documented with and a copy placed in the physician's medical staff file. If the practitioner agrees to stop the conduct thought specifically to constitute sexual harassment, the meeting shall be followed up with a formal letter of admonition and warning to be placed in the confidential portion of the practitioner's quality file. This letter shall also set forth those additional actions, if any, which result from the meeting.

2) If the practitioner refuses to stop the conduct immediately, this refusal shall result in the matter being referred to the Executive Committee for review pursuant to the Credentials Policy.

3) Any reports of retaliation or any further reports of sexual harassment, after the practitioner has agreed to stop the improper conduct, shall result in an immediate investigation by the Chief Medical Officer of the hospital and/or Medical Staff President (Mishawaka & Plymouth) or President of the Hospital (Plymouth), or designee(s). If the investigation results in a finding that further improper conduct took place, a formal investigation in accordance with the Credentials Policy shall be conducted. Should this investigation result in an action that entitles the individual to request a hearing under the Credentials Policy, the individual shall be provided with copies of all relevant complaints so that he or she can prepare for the hearing.

This policy shall be the sole process for dealing with egregious incidents and disruptive behavior, and shall be interpreted and enforced by the Medical Staff.

Attachment: Documentation Form
Retaliation and Retribution Hospital Policy
## PRACTITIONER USE – DOCUMENTATION OF OCCURRENCE

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<td></td>
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<tr>
<td>Patient Name/Medical Record Number: (if known)</td>
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<tr>
<td>Description of Occurrence:</td>
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<table>
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<th>Witnesses: (if any)</th>
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| Name of Practitioner Making Report: |  |

Submit this form to one of the following:

- Mishawaka
  - Medical Staff President-Ph: 335-2353
  - Fax: 335-1001
- Medical Staff Office – Mishawaka Plymouth
  - Ph: 335-2383
  - Ph: 948-5005
  - Fax: 335-1053
  - Fax: 948-5478

**References/Standards:**
- Policy Origin Date: May 1999
- Review Date: December 2009 (M), December 2012 (M), December 2015 (M), February 2016 (P), December 2018 (M)
- Revised Date: August 2007 (M), January 2012 (P)
- Effective Date: December 1999 (M), December 1999 (P)
- Reviewed/Recommended By: Medical Executive Committee
- Policy 154

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**TITLE: RETALIATION AND REtribution**

Expiration Date: 01/25/2025
Title: MEDICAL STAFF MISSION STATEMENT AND CODE OF CONDUCT POLICY

POLICY:

1. All employees, supervisors, physicians and trustees have a responsibility to report in good faith, concerns about actual or potential wrongdoing and are not permitted to overlook such situations. We are firmly committed to a policy that encourages timely disclosure of such concerns and prohibits any action directed against an employee, physician, trustee or volunteer for making a good faith report of their concerns.

2. No one at any level of SJRMC is permitted to engage in retaliation or any form of harassment against an employee, physician, trustee or volunteer reporting a concern. Anyone who engages in such retribution is subject to discipline, up to and including dismissal on the first offense. All substantive instances of retaliation or harassment against anyone reporting through the Four-Step Process will be brought to the attention of the Organizational Integrity Officer.

3. This does not mean that employees or others will be shielded from the consequences of doing something wrong simply by reporting their actions or from the consequences of their actions under current employment policies. However, a prompt and forthright disclosure, even if the error was willful, may be considered a constructive action.

References/Standards:

- Policy Origin Date: June 1998
- Review Date: September 2005, December 2012 (M), December 2015 (M), February 2016 (P), December 2018 (M), November 2021 (P), December 2021 (M)
- Revised Date:
- Effective Date: April 2009
- Reviewed/Recommended By: Organizational Integrity Team

Expiration Date: 01/25/2025
DEI Mission Statement:

Saint Joseph Health System values the divergent perspectives and contributions that are founded in individual differences in gender, race, age, national or ethnic origin, sexual orientation, thought, ancestry, religion, marital or parental status, physical or mental disability, education, veteran status, citizenship, genetic makeup, or any other characteristic.

Diversity celebrates individual differences, while inclusion joins the diverse members of a group into a cohesive whole. As a Catholic health provider, we value the dignity and individuality of every colleague, patient, and their families by providing a culturally welcoming environment that promotes health and healing for all. We believe that everyone benefits from an inclusive environment where diversity is valued and embraced.

Diversity and Inclusion Initiatives directly align with Saint Joseph Health System to care for self, colleagues, and those we serve. They are designed to result in improvements in:
- Recruitment and retention
- Patient satisfaction and colleague engagement
- Workforce training and education
- Diverse sourcing
- Community engagement
What is Just Culture?

Just Culture is a philosophy that:

- Provides a simple and powerful approach to change our way of thinking about safety, both for patients and colleagues.
- Helps us learn from undesirable outcomes and how the errors and behavioral choices that we make can impact our patients, one another, and the organization.
- Focuses on finding opportunities to reduce risk in our actions, environment, policies, procedures, and systems.
- Helps us create a continuous learning environment where we seek to learn from one another’s experiences to make a safer organization.
- Helps us be mindful of the opportunity to be finders and fixers of defects within our work environment.

Five Essential Elements

1. **Communicate Values and Expectations**
   - One step in creating better outcomes is to set expectations in a way that exhibit our commitment to our Mission, Core Values, and Vision.

2. **Design Safe Systems**
   - Good system design anticipates human error and captures errors before they become critical. Good system design also permits recovery when the consequences of our errors can cause harm. This is also defined as undesirable outcomes.

3. **Manage Behavioral Choices**
   - We anticipate that humans will make mistakes and that colleagues will drift from our policies and procedures.

4. **Create Learning Systems**
   - We can identify risk by observing the design of the systems in which we work, our behaviors, and the behaviors of those around us.

5. **Create a Just and Accountable Environment**
   - We are imperfect and we will drift from making safe choices. We must hold one another accountable for the quality of our systems and our choices in those systems.

Three Human Behaviors

1. **Human Error**:
   - an inadvertent action; inadvertently doing other than what should have been done; a slip, a lapse, a mistake.

2. **At-Risk Behavior**:
   - a behavioral choice that increases risk where risk is not recognized, or is mistakenly believed to be justified.

3. **Reckless Behavior**:
   - a behavioral choice that consciously disregards a substantial and unjustifiable risk.
Just Culture & Our Core Values

Our Mission and Core Values support a Just Culture in the following ways:

Reverence: We honor the sacredness and dignity of each person.
- Create relationships and a healthy work environment
- Support colleagues who commit a human error
- Treat everyone as a valued person

Commitment to those who are poor: We stand with and serve those who are poor, especially those most vulnerable.
- Show compassion
- Treat everyone with dignity
- Give others a voice

Justice: We foster right relationships to promote the common good, including sustainability of Earth.
- Show respect, dignity and fairness
- Advocate for those who have no voice

Stewardship: We honor our heritage and hold ourselves accountable for the human, financial and natural resources entrusted to our care.
- Take care of ourselves
- Sustain human, environmental, and financial resources

Integrity: We are faithful to who we say we are.
- Hold honest, truthful interactions with colleagues
- Follow thru with what we say we are going to do

How can each colleague help us build a Just Culture?

- Help leaders build a safer organization based on the five essential elements of Just Culture
- Understand the three manageable human behaviors, how they cause risk, and how to minimize the risk
- Accept that undesirable outcomes are the result of system design and behavioral choices, and that near misses are a window into the risk around the systems and behaviors
- Realize that at-risk behaviors can be reinforced when there is a positive outcome (nothing bad happened) and that we need to see these as near misses
- Reduce risk by reporting system design issues, human errors, and at-risk or reckless behavioral choices
- Contribute to a learning culture that allows us to share with others the risk that we see

Thanks for joining us on the journey to a Just Culture!

For more information about Just Culture, visit the following site:
Unified Clinical Organization (UCO) Just Culture Site:
http://uco.che.org/careopt/careclinical/jc/default.aspx

If you have questions, please email them to:
justculture@trinity-health.org

The Safe Choices training and these materials do not modify the at-will employment relationship with our Trinity Health colleagues.
Q. What is a Business Courtesy?

A. For purposes of Trinity Health policy, a Business Courtesy is any items of value given to a physician (or their immediate family member) for free or at discounted cost by a Trinity Health Medicare enrolled provider organization.

Q. What are common examples of Business Courtesies?

A. The following are common examples of Business Courtesies:

- Payment of meals and beverages held at off-campus locations
- Payment of greens, entry fees or other activities related to a golf outing
- Providing tickets to a sporting, concert or theatre event
- Providing flowers, perishable items or other gifts in recognition of a birthday, anniversary or other special occasion
- Payment of program costs for a continuing medical education program held at an off-campus location where CEUs are granted to participants
- Payment of travel and lodging expenses

Q. Does the Business Courtieses policy apply to items of value given by a Trinity Health organization to physicians employed by a Trinity Health organization?

A. No. Items of value given to employed physicians are not considered business courtesies for purposes of this policy, but would be covered by employee benefit policies and should be addressed by the entity responsible for the physician's payroll, compensation and benefits.

Q. What about gifts or other items of value given to individuals or entities that are not physicians or their immediate family members?

A. These courtesies are governed by the Trinity Health Code of Conduct – refer to Relationships with Suppliers and Other Business Partners for more information.
Q. Why are physicians subject to stringent restrictions regarding the giving and receiving of Business Courtesies and other items of value?

A. There are federal and state laws and regulations intended to curb fraud and abuse in government funded health care programs, such as Medicare and Medicaid. One such law, the Physician Self-Referral Law or "Stark" law, as it is commonly referred, prohibits physicians from referring Medicare and Medicaid patients to hospitals for certain services if the physician (or an immediate family member) has a financial relationship unless an exception is met. Business Courtesies are considered financial relationships and the law places strict limits on the amount and form of such items.

Q. What is the dollar limit for Business Courtesies?

A. Business Courtesies are subject to an annual limit of $398, individually and in total, for each physician (including gifts to immediate family members). This limit is as of 2017 and is subject to periodic updates by the Centers for Medicare and Medicaid Services.

Q. Can Business Courtesies be given to encourage or reward patient referrals?

A. No. Business courtesies or any other gifts of value may never be given to reward or induce referrals of any items or services payable by a federal health care program. While in some industries it may acceptable to reward those who refer business to you, it is a crime in federal and state health care programs.

Q. May a gift certificate or gift card be given as a Business Courtesy?

A. No. Cash equivalents, such as gift cards and gift certificates, may never be provided as a Business Courtesy.

Q. What happens if the annual Business Courtesy limit is exceeded?

A. The consequences for exceeding the limit can be serious. A facility may lose their ability to bill Medicare for services ordered by the physician receiving the Business Courtesy. Or, at the very least, a physician may be asked to repay the overage. For these reasons, accurate tracking of Business Courtesies is very important. Any identified overages should be immediately reported to your organizations Integrity & Compliance Officer or Legal Counsel for appropriate follow-up and corrective action.
Q. How do I ensure my organization does not exceed the annual Business Courtesies limit?

A. Each Trinity Health facility that is subject to the Stark Law limits on Business Courtesies is required to establish a tracking system to ensure the annual limit for each physician is not exceeded. If you are not familiar with your organization's process, please contact your Integrity & Compliance Officer for more information.

Q. What are Medical Staff Incidental Benefits? Are these the same as Business Courtesies?

A. Medical Staff Incidental Benefits are not Business Courtesies. The Stark Law allows hospitals and other health care facilities to provide low dollar items of value to physicians who are appointed members of the facility's medical staff provided all of the following requirements are met:

a. The value of each benefit may not exceed $33.00 per occurrence. This limit is as of 2017 and is adjusted periodically by the Centers for Medicare and Medicaid Services;
b. May not be cash or cash equivalents such as gift certificates, gift cards, vouchers or checks;
c. Are used by physicians while physically present on the campus of a Trinity Health facility;
d. Are offered during periods when physicians are making rounds or performing other duties at Trinity Health facilities for the benefit of Trinity Health and its patients;
e. The benefits are reasonably related to the delivery of medical services to Trinity Health patients;
f. The benefits are offered to all medical staff members practicing in the same specialty;
g. The benefits are consistent with the types of benefits offered to medical staff members in the community;
h. The benefits are not determined and do not taken into account the volume or value of referrals or other business between the physicians and Trinity Health facilities.

Q. What are common examples of Medical Staff Incidental Benefits?

A. Common examples of Medical Staff Incidental Benefits include:

a. Providing physicians a Continuing Medical Education program (e.g. "Ground Rounds") on-campus for benefit of hospital and patients
b. Free parking provided to physicians in a Trinity Health parking facility
c. Providing physicians with discounts while dining in the hospital cafeteria
d. Modest food or beverages provided in connection with attendance at meetings held on a hospital campus
e. Pagers for use while on the hospital campus
Q. My hospital has asked 3 medical staff members to participate in an off-site medical staff leadership development program. In order to ensure physician participation, the hospital is paying for the physician's travel and lodging as well as compensating the physicians for their time away from their practices. Is this a Business Courtesy that requires tracking?

A. The benefits described are definitely financial relationships subject to Stark Law requirements. However, the value of the benefits (travel, lodging and compensation) will far exceed the annual limit for Business Courtesies. The best option here is to work with your organization's Legal Counsel to draft a personal services agreement describing the benefits and compensation to be paid to the physicians in exchange for their participation in the leadership development program. If using a personal services agreement, tracking under the Business Courtesies policy would not be required.

Q. My hospital sponsors monthly "Grand Rounds" educational programs for our medical staff. The programs are offered on the hospital's campus and are open to all members of the medical staff. The programs address topics such as quality, accreditation, patient experience of care and other subjects. Continuing Medical Education (CEUs) credits are granted to participants. Are these programs considered Business Courtesies or Medical Staff Incidental Benefits?

A. The Grand Rounds programs described are provided on campus to members of the facility's medical staff, are considered low value (less than $33 per occurrence) and are primarily for the benefit of the hospital and its patients. These programs would meet the Medical Staff Incidental Benefits requirements and would not be subject to an annual limit or tracking by individual physician.

Q. Similar facts as the prior question, but the educational programs are held at off-campus locations. Hospital personnel plan and coordinate the programs and participating physicians receive CEU credits. The hospital rents the conference facilities, provides meals and pays for the travel and compensation of guest speakers. Do these programs still qualify as Medical Staff Incidental Benefits?

A. Because the programs are not held on the hospital's campus, they do not meet the Medical Staff Incidental Benefits requirements. The value of the benefits provided to each attending physician must be tracked in accordance with the Business Courtesies policy and are subject to the annual limits. Alternatively, the hospital could seek funding for the cost of the programs from via medical staff fund contributions, payments by attendees or a combination of both.

Q. The hospital's intake coordinator schedules a lunch meeting with staff of an independent physician office to discuss opportunities to improve coordination and communication on patient admissions. The physician office is not located on campus. There are four (4) physicians and ten
(10) staff in the office. The intake coordinator brings sandwiches and drinks costing $80.00 to the meeting for all attendees. How would the cost be treated for tracking under the Business Courtesies policy?

A. Since the lunch was not provided on the hospital's campus, the value ($80) must be tracked under the Business Courtesies policy. The $80 is allocated to each of the physicians in the office (4), even if one or more of the physicians did not attend the meeting. The value allocated to each physician for tracking against the annual Business Courtesies limit would be $20.

Q. A hospital administrator gives a gift of an oil painting valued at $1,000 to a 4-physician practice in appreciation for the group's leadership of a hospital led quality initiative. Is the value of the gift attributed to each physician for tracking purposes $250 ($1,000/4)?

A. The annual Business Courtesy limit cannot be aggregated to provide a larger gift to a group of physicians. In this case, the oil painting is considered indivisible and would require tracking the entire amount ($1,000) amount as a Business Courtesy provided to each physician. Because this amount exceeds the annual limit ($398 in 2017), the gift is prohibited.

Q. Physicians on the medical staff at our hospital receive a 10% discount on meals in the hospital cafeteria, the same discount offered hospital colleagues. Is the hospital required to track the value of the 10% discount?

A. Provided the value does not exceed $33 per occurrence (which would require the value of the meal to exceed $330, very unlikely), the cafeteria discounts do not need to be tracked. This is an example of a Medical Staff Incidental Benefit provided on the hospital's campus to ensure the availability of medical staff members for the benefit of the hospital and its patients.

Q. An administrator at the hospital takes an independent physician out to a restaurant to discuss operations in the hospital's orthopedic department. The total cost of the dinner is $150. Is this considered a Business Courtesy since there was a valid business purpose for the meeting and dinner?

A. Yes the value of the dinner would still require tracking under the Business Courtesies policy. The dinner was not held on the hospital's campus and was not of low value. For tracking purposes, the total cost of the dinner ($150) can be divided among the two attendees. Thus, $75 would be attributed to the physician for tracking against the Business Courtesies annual limit.

Q. Same scenario as above, but the physician's spouse also attended the dinner and the total cost was $225. How would the allocation change?
A. The Business Courtesies policy applies to both physicians and their immediate family members. Therefore a total of $150 would be allocated against the physician's annual Business Courtesies limit representing the cost per person of $75 ($225/3) multiplied by 2 for both the physician and the spouse.

Q. The hospital's CEO invites two independent members of the medical staff to attend a local sporting event. The costs of the tickets are $65 each. The CEO personally pays for the tickets and the dinner attended by all 3 before the game. How would this scenario be handled?

A. Since hospital funds were not used for the tickets and the CEO did not seek reimbursement from the hospital for the expenses, there is no requirement to track the value of the tickets under the Business Courtesies policy.
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- Sleep Disorders
- Sports Medicine
- Stroke Care
- Surgical Services

W
- Wellness & Weight Management
- Wound Healing

U
- Urology

V
- Vascular Care
3. Emergency Management

a. Disaster Criteria for Credentialing Policy
b. Disaster Response Letter
c. Physician Letter Hazmat
d. ERS Call and EMTALA Policy
e. Fire Plan Policy
Title: DISASTER CRITERIA FOR CREDENTIALING PHYSICIANS AND ALLIED HEALTH PRACTITIONERS

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Printed copies are for reference only. Please refer to the electronic copy for the latest version.

**POLICY:**
1. Any Practitioner providing patient care must be granted privileges prior to providing patient care, even in a disaster situation.
2. Medical Staff and Allied Health who are not members of the medical staff and who do not possess clinical or practice privileges may be granted privileges when only the two conditions are present:
   The Emergency Management Plan has been activated and the organization is unable to meet patient care needs. No application fee required. The medical staff shall oversee professional practice of each volunteer for the duration of the disaster. There shall be retrospective review of charts for patients treated by volunteers with disaster privileges.

**PROCEDURE:**
A. The Practitioner must present the following:
   1) Valid government issued photo ID issued by a state, federal or regulatory agency (i.e.: Driver’s license or passport). And at least one of the following:
      a) A current picture hospital ID card from a health care organization that clearly identifies professional capacity.
      b) Current license to practice, preferably IN license.
      c) Primary source verification of license shall occur as soon as the disaster is under control or within 72 hours from the time the volunteer licensed independent practitioner presents himself/herself to the hospital, whichever comes first. If primary source verification of a volunteer licensed independent practitioner’s licensure cannot be completed within 72 hours of the practitioner’s arrival due to extraordinary circumstances it is performed as soon as possible and the hospital documents all of the following:
         (1) Reason(s) it could not be performed within 72 hours of the practitioner’s arrival
         (2) Evidence of the licensed independent practitioner’s demonstrated ability to continue to provide adequate care, treatment and services
         (3) Evidence of the hospital’s attempt to perform primary sourced verification as soon as possible
      d) Identification indicating that the individual is a member of a Disaster Medical Assistance Team (DMAT), or MRC, ESAR-VHP, or other recognized state or federal organized group.
      e) Identification indicating that the individual has been granted authority by a government entity to render patient care, treatment or services in disaster circumstances.
      f) Presentation by current hospital or medical staff member(s) with personal knowledge regarding practitioner’s identity and ability to act as a physician in a disaster.
Title: DISASTER CRITERIA FOR CREDENTIALING PHYSICIANS AND ALLIED HEALTH PRACTITIONERS

B. The following information shall be made available and if possible, verified. Any remaining verifications will be completed as soon as the immediate situation is under control. A decision is made by the organization within 72 hours of the practitioner’s arrival if granted disaster privileges should continue.

1) Documentation Required for Disaster Privileges:
   a) Complete Disaster Intake Sheet
   b) Primary source verification of the following items is also require
      (1) Current licensure; and controlled substance registration and DEA
      (2) National Practitioner Data Bank Query
      (3) Federal Sanction Query and/or OIG sanction clearance
      (4) If needed, AMA and/or AOA Profile

C. Verification of the above information should be done as soon as possible by the medical staff office or as soon as feasible. Verification shall be completed utilizing the computer, phone or portable radio. A record of this information should be retained. It is recommended that the practitioner be paired with a currently credentialed medical staff member with similar clinical privileges and should act under the direct supervision of a medical staff member.

D. Privileges would be granted by the appropriate President of the Hospital or President of the Medical Staff handling the disaster, preferably upon recommendation of the Department Chairperson and/or President of the Medical Staff. If the Department Chairperson or the President of the Medical Staff were unavailable, their designee would be one of the following: 1) Vice President of the Medical Staff, 2) Secretary of the Medical Staff. The responsible individual(s) is not required to grant privileges to any individual and is expected to make such decisions on a case-by-case basis at his or her discretion. The Incident Commander or designee will be notified if none of the above individuals are available for signature.

E. When the emergency situation no longer exists as determined by the Medical Staff President, these temporary, emergency privileges terminate. If any of the above verifications identify negative findings, the practitioner’s privileges could be terminated immediately.

F. Upon granting of disaster/emergency privileges, the Practitioner will receive a photocopy of the signed approval form to serve as verification for staff to readily identify these individuals. (Temporary privilege form)

References/Standards:
• Joint Commission Standard - EM 02.02.13
• Policy Origin Date: November 2001
• Review Date: December 2009, December 2012, December 2015, December 2018, November 2021 (P), December 2021 (M)
• Revised Date: February 2008, Sept 2011, June 2014, June 2020
• Effective Date: November 2001
• Reviewed/Recommended By: Medical Executive Committee
Regarding: Role in emergency/Disaster Response

Dear Physicians,

In the interest of mitigation and preparedness for the provision of safe and effective patient care during emergencies or disasters, as a Licensed Independent Practitioner (LIP), you are an essential part of our organization and your expertise may be needed during a disaster. Accordingly, you may be asked to report to work when an emergency exists.

Communication during disasters will flow through the Hospital Command Center (HCC). Your professional commitment to continuity of services and quality patient care is commendable and deeply appreciated.

In case of an emergency, please report to the Hospital Command Center where you will be directed to the medical staff station. If you are given an assigned Hospital Incident Command leadership role, you will follow the instructions on your designated Job Action Sheet. You may also be asked to mentor a "Volunteer Licensed Independent Practitioner" during the course of the incident. Please reference the Incident Command System (ICS) policy as well as the Emergency Operations Plan (EOP) and the Disaster Credentialing of Volunteer Licensed Independent Practitioners policies for further details. These policies can be found on the Daily Dose in Policy Tech.

The Joint Commission on Accreditation of Healthcare Organizations: Emergency Management Standard: EM.02.02.07EP 8 requires that you are notified in writing in reference to your role. In emergency response and to whom you report to during an emergency. If you have any questions and/or concerns, please feel free to contact me. Again, on behalf of SJHS Mishawaka, thank you for your dedicated services.
The purpose of this memo is to provide you with information in reference to your role in a hazardous materials incident requiring patient decontamination. The Joint Commission Standard: EM02.02.05 EP 5 states:

*The Emergency Operations Plan describes the following: How the hospital will provide for radioactive, biological, and chemical isolation and decontamination.*

OSHA recommends how hospitals should respond to victims of a hazardous materials incident in its document, "OSHA Best Practices for Hospital-Based First Receivers of Victims from Mass Casualty Incidents Involving the Release of Hazardous Substances." In consideration of, and in compliance with these agencies, our policy "Hazardous Materials Incident Response Plan" addresses this issue.

With notification of arrival of victims of a hazardous materials incident, our Hazmat Team Members will be notified in accordance with the "Hazardous Materials Incident Response Plan".

Your role, in addition to the care and treatment of this particular type of patient, will be working directly with the Emergency Department Charge Nurse and/or the Incident Commander.

Thank You for your services and all that you do in the caring of our patients.
**Title:** EMERGENCY SERVICE (ERS) CALL & EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)

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**POLICY:**

1. **Emergency Services** - The Medical Staff Office shall work with the Medical Director of the Emergency Department to prepare an on-call list, including specialists and subspecialists, to ensure that applicable Medical Staff members are available to provide treatment necessary to stabilize individuals with Emergency Medical Conditions (as defined by the hospital’s Emergency Medical Treatment and Active Labor Act Policy.)

   A. When a Medical Staff member who is on-call, or his/her designee is called to treat an individual with an emergency medical condition, such Medical Staff member must respond to a page within fifteen (15) minutes. When the page is made for an emergency as defined above, the number paged will be prefaced with the notation “911.” If the initial page to the Medical Staff member is not responded to within fifteen (15) minutes of placing the page, the Medical Center shall try alternative contacts with the Medical Staff member for an additional five (5) minutes. If these alternative methods are unsuccessful, the Medical Center shall page the on-call Medical Staff member’s call group partners. If the backup call group partner does not respond within ten (10) minutes of placing the page, and cannot be reached with five (5) additional minutes of alternative contact methods, the Medical Center shall contact the applicable department chair to coordinate examination and treatment of the patient. After the medical Staff member has spoken to the Emergency Department physician, the Medical Staff member must arrive at the medical center within approximately forty (40) minutes of the ending of the telephone call if the patient is identified as having an Emergency Medical Condition and requiring the care of the on-call physicians.

   B. It is the responsibility of the Medical Staff member who is on-call to locate and coordinate a response by a backup Medical Staff member if the on-call Medical Staff member providing on-call coverage is unavailable for any reason during the assigned on-call period. All medical staff members providing on-call coverage are required to notify the Medical Staff office of all current page numbers, home telephone numbers, answering service numbers and call group partners or back-up physicians.

**References/Standards:**

- Policy Origin Date: May 2007
- Revised Date: June 2018
- Effective Date: March 2008
- Reviewed/Recommended By: Medical Executive Committee

Expiration Date: 01/24/2025
Title: FIRE PLAN

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**POLICY**: Saint Joseph Regional Medical Center – Plymouth will strive to maintain a safe working environment for our associates and a safe haven for our patients and visitors.

1. **PREPARING FOOD**: It is the responsibility of every associate to closely monitor any appliance while warming or cooking food. Associates warming or cooking any food will remain with the appliance that is being used to warm or prepare their food until the process is complete. Failure to observe this safety aspect may result in disciplinary action.

2. **NON-EMERGENCY FIRE ALARM**: Should the fire alarm be activated due to a non-emergency such as dust, over cooked food, or a pull station pulled as a prank, ONLY the Administrative Supervisor, Incident Commander, or Safety Officer has the authority to advise the fire department of the non-emergency.

3. **NOTIFICATION / COMMUNICATION**: The activation of the fire alarm system for any reason, other than a drill, is considered an actual event. The event may be an emergency or non-emergency; there are no false alarms. Administrative Supervisor is also able to communicate with the Plymouth Fire Department by calling the non-emergency county dispatch number at **936-3187** to provide an assessment of the situation and at what entrance Plymouth Fire Department should arrive. The Administrative Supervisor / designee should be at the entrance to direct the fire department. Associates and independent practitioners are to cooperate fully with firefighting authorities.

4. **FIRE PREVENTION**: Should a fire erupt, the main hospital, Saint Joseph Cancer Institute and Medical Office buildings 2, 3 and 4 are supplied with automatic sprinkler systems. The main hospital, St. Joseph Cancer Institute and Medical Office Buildings 2, 3 and 4 have smoke detection devices with a monitored self-alarming system directly to the alarm company. Medical Office Building #1 smoke detection devices are monitored self-alarming within the suite only and are not connected to the alarm company. All hallway doors in the hospital and Cancer Institute are fire resistant and close automatically to contain a fire.

5. **STAFF EDUCATION**: To provide an organized response in the event of a fire, all associates are fully trained upon hire in the fire plan procedures and use of a fire extinguisher and again through annual education training. To further enhance these efforts, associates participate in fire drills throughout the year.

6. **ORGANIZED RESPONSE**: Hospital fires are a serious hazard. The loss of life and property is minimized when well organized procedures have been established, and when all persons involved have carried out their instructions in a systematic organized and effective manner. For this reason, associates are educated to fully acquaint themselves with this plan.

Expiration Date: 07/25/2025
Title: FIRE PLAN

PROCEDURE

A. COMMUNICATION FAILURE UPON ACTIVATION OF AUTOMATIC FIRE ALARM:

1) TELEPHONE & PUBLIC ADDRESS SYSTEM FAILURE: When a fire alarm is activated, but a telephone and overhead paging system failure has occurred:
   a) The Registrar will alert the Administrative Supervisor and hospital departments to the location of the Fire Alarm by utilizing two-way radios and runners.
   b) In the event all in-house telephone lines are out, the red disaster telephones will function and will be used for internal and external communication purposes. Refer to: Disaster Recovery Red Telephones Policy
   c) The hospital’s electronic emergency communication system may also be used by the Administrative Supervisor or Registrar to send messages.

2) FIRE ALARM FAILURE: In the event of notification of fire or smoke and a fire alarm has failed to activate the Administrative Supervisor or designee will:
   a) Utilize the red disaster telephones or a cellular phone to contact 911 stating: Saint Joseph Regional Medical Center – Plymouth, the location of the alarm, and also indicating that the automatic signal is not operable.

B. ASSOCIATES AND LICENSED INDEPENDENT PRACTITIONERS RESPONSE TO SMOKE OR FIRE - AT FIRE POINT OF ORIGIN:

1) In the event the fire or smoke is present in your work area, follow the acronym RACE as designated:
   a) RESCUE persons in immediate danger (room evacuation).
   b) ALARM by pulling the closest fire alarm pull station or directing a co-worker to contact the “948-8888” operator.
   c) CONTAIN the fire by closing the door to the room or area.
   d) EXTINGUISH / EVACUATE: Extinguish the fire by using a portable fire extinguisher and the PASS acronym if you are able; do not put yourself at risk. Evacuate the area if necessary by following the "Evacuation Plan / Shelter –In-Place" policy and procedures.

2) Follow the acronym PASS in use of a fire extinguisher as designated:
   a) PULL and remove the safety pin at the top of the fire extinguisher.
   b) AIM the fire extinguisher at the base of the fire.
   c) SQUEEZE the handle of the fire extinguisher.
   d) SWEEP the fire extinguisher back forth at the base of the fire.

3) Consider and take the following steps as indicated:
   a) In the event the fire is in a patient care area and can be contained to a room or area without causing harm to other patients, visitors, or associates, staff should begin closing doors and windows to other patient rooms.
   b) Do not open a hot door (leave closed – wait for firemen).
   c) Place wet towels or blankets along bottom of doors to seal off room if smoke is present.
Title: FIRE PLAN

d) **EVACUATE** in the event the fire is in a patient care area and cannot be contained to a room or area without causing harm to other patients, visitors, or associates. Staff should immediately begin moving patients and visitors through egress routes past smoke/fire doors (horizontal or vertical evacuation). Refer to the hospital policy, "Evacuation Plan / Shelter-In-Place".

e) Take a count of patients (use patient census report if able), visitors, and staff in your department.

f) Supply oxygen masks via portable tanks to those in need.

g) Portable oxygen tanks should be moved away from fire area to a place of safety.

h) The wall oxygen system will be shut off as directed by the Administrative Supervisor or RN in charge of the department.

i) Associates and independent practitioners are to cooperate fully with firefighting authorities.

j) Elevators may only be used under the direction of the Fire Department.

k) Use telephones for emergency calls only.

l) Wait to receive further instructions (ex. Evacuation, Incident Command System, or “all clear”) and follow as ordered. Refer to any department specific procedures for additional responsibilities.

4) **AUTHORITY TO SHUT OFF MEDICAL GAS CONTROLS:** The authority to shut off or to direct the medical gas controls to be shut off in any department rests with the **Administrative Supervisor or the Charge Nurse of the department.** The Administrative Supervisor or Charge Nurse may direct Plant Operations personnel, Security personnel, or Respiratory Therapists to complete this function. The oxygen controls shut off more than one department or area, therefore, the Administrative Supervisor or Charge Nurse will ensure that the affected departments are aware and that medical gases are shut off appropriately.

C. **ASSOCIATES AND LICENSED INDEPENDENT PRACTITIONERS RESPONSE TO FIRE ALARM – AWAY FROM FIRE POINT OF ORIGIN:**

1) In the event the fire or smoke is not present in your work area, the following steps should be taken:

   a) Begin closing all doors and windows in your area.

   b) Contain patients and visitors to an area of safety within your department.

   c) Take a count of patients (use patient census report if able), visitors, and staff in your department.

   d) Associates and independent practitioners are to cooperate fully with firefighting authorities.

   e) Elevators may only be used under the direction of the Fire Department.

   f) Use telephones for emergency calls only.

   g) Begin taking steps to prepare / talk through evacuation.
Title: FIRE PLAN

h) Wait to receive further instructions (ex. evacuation, Incident Command System, or “all clear”) and follow as ordered. Refer to any department specific procedures for additional responsibilities.

D. FIRE RESPONSE ASSOCIATES AND LICENSED INDEPENDENT PRACTITIONERS:

1) The following in-house associates will report immediately to the announced area:
   a) Administrative Supervisor.
   b) Security.
   c) Any available associate.

E. FIRE RESPONSE ASSOCIATES AND LICENSED INDEPENDENT PRACTITIONERS – GENERAL RESPONSIBILITIES:

1) Respond to area with a fire extinguisher.
2) Assist with containing the fire.
3) Assist with extinguishing the fire, if able; do not put yourself at risk.
4) Do not open a hot door (leave closed – wait for firemen).
5) Place wet towels or blankets along bottom of doors to seal off room if smoke is present.

F. FIRE DEPARTMENT PERSONNEL:

1) Will assume command of the scene upon arrival.

G. FIRE RESPONSE ASSOCIATES AND LICENSED INDEPENDENT PRACTITIONERS – SPECIFIC RESPONSIBILITIES:

1) **ADMINISTRATIVE SUPERVISOR**
   a) Respond to alarm company notification and report to the announced area immediately with fire extinguisher.
   b) Quickly assess situation and report findings to Plymouth Fire Department at their inquiry or contact the Plymouth Fire Department (574-936-3187) and provide the entrance they should arrive at, and whether an emergency or non-emergency. Associates and independent practitioners are to cooperate fully with firefighting authorities.
   c) Consult with fire response associates present.
   d) **Always notify:**
      (1) Plant Operations Associate on-call at 574-780-4551 regardless of whether an emergency or non-emergency
      (2) Facilities Resources Manager / Safety Officer
      (3) Administrative Personnel
      (4) Administrator On Call
   e) May initiate Incident Command System.
   f) May order evacuation (refer to Evacuation Policy).
   g) May order “All Clear” announcement.
   h) Consult with Fire Department Personnel and cooperate fully with firefighting authorities.
Title: FIRE PLAN

2) **ADMINISTRATIVE PERSONNEL**
   a) Report to the announced area immediately if in house or called in.
   b) Assist with fire response duties.
   c) Assess situation.
   d) Consult with fire response associates present.
   e) May initiate Incident Command System (refer to Incident Command System Policy).
   f) May order evacuation (refer to Evacuation Policy).
   g) Consult with Fire Department Personnel and cooperate fully with firefighting authorities.

3) **FACILITIES RESOURCES MANAGER / SAFETY OFFICER**
   a) Report to the announced area immediately with fire extinguisher if in house or called in.
   b) Assist with fire response duties.
   c) Quickly assess situation.
   d) Consult with fire response associates present.
   e) May initiate Incident Command System (refer to Incident Command System Policy).
   f) May order evacuation (refer to Evacuation Policy).
   g) May order “All Clear” announcement.

4) **PLANT OPERATIONS / SECURITY PERSONNEL**
   a) An Associate will need to report to the alarm panel, an associate will monitor mechanical and utility systems and other available associates will report to the announced area immediately with fire extinguisher if in house or called in.
   b) Assist with fire response duties.
   c) Assist with securing area – keeping unauthorized associates or members of the public away.
   d) Take orders from and fully cooperates with Fire Department Personnel.

5) **RISK MANAGER**
   a) Report to the announced area immediately if in house or called in.
   b) Assist with fire response duties.
   c) Assess situation.
   d) Consult with fire response associates present.
   e) Contact legal department as necessary.
   f) Assist Emergency Management Coordinator with documentation.

H. **OBSTETRICAL DEPARTMENT SPECIFIC RESPONSE:**

1) A fire alarm may be activated as a diversion to facilitate an infant abduction. Therefore when a fire alarm is activated, all mothers and infants in the Obstetrics Department must be immediately united. The mother and child will remain together until an “all clear” is given.

2) At the onset of a fire alarm, a census will be taken immediately of all Obstetrics Department patients, along with a census of visitors and staff.
Title: FIRE PLAN

3) Assigned personnel will remain with the babies and mothers and travel with them if or when they are evacuated to other areas until an “all clear” is called.

4) In the Event of Evacuation:
   a) Personnel shall escort mothers able to walk out of the department along with their infant(s) in their crib(s). Incubator infants shall be taken to a safe place designated by the nurse in charge of the department.
   b) Mothers unable to walk will be moved by wheelchairs along with their infant(s) in their crib(s).
   c) Upon returning to the department, nurses will confirm the census at the time of the evacuation to assure that all mothers and babies are present.
   d) Reset infant security system.

I. BUILDING UTILITY NEEDS:
   1) When damage has been sustained refer to facility utility failure plans.

J. EMERGENCY TERMINATION – “ALL CLEAR” ANNOUNCEMENT:
   1) Administrative Supervisor, Incident Commander, or Safety Officer will contact the “8-8888” operator to give the “all clear”.
   2) Operator will provide an all-clear announcement.
   3) In the event of a communication failure (overhead paging), the operator will send a runner to all departments announcing the “all clear”.

K. AUTHORITY TO DEACTIVATE FIRE ALARM SYSTEM:
   1) The authority to deactivate (reset) the fire alarm system rests with the Plant Operations Department. In their absence, either the Security Officer or the Administrative Supervisor will assume this responsibility.

L. Interaction with News Media:
   1) The Administrative Personnel will contact the Public Relations Department, SJRMC-Mishawaka, to handle communications with the news media. Any inquiries will be referred to them through our Administrative officers or through the Incident Command System.

M. Associates and Licensed Independent Practitioners / Family Support – Incident Stress Debriefing:
   1) A debriefing session(s) will be held as necessary for all those involved in, or affected by the incident.
   2) Qualified chaplains are available through the Spiritual Care Department to assist patients, associates, and family members as needed.

N. Recovery:
   1) Resuming normal operations will be dependent upon the extent and location of damage, and the equipment and systems affected.
   2) Every effort will be made to coordinate the activities of personnel along with the assistance of outside agencies as necessary to restoring the facility to normal operations.
Title: FIRE PLAN

3) The department managers in consultation with Administration / Incident Command will handle any necessary adjustments to patient activities and provided services.

O. ASSOCIATES AND LICENSED INDEPENDENT PRACTITIONERS EDUCATION:
1) Upon hire and prior to their initial start date, all associates are educated on the "Fire Plan" policy and procedures and in the use of a fire extinguisher. Associates also receive annual Environment of Care training courses assigned through the computerized Health Stream education program. In addition, associates and licensed independent practitioners also receive education by participating in fire drills held throughout the year.

SITE SPECIFIC:

A. SAINT JOSEPH HEALTH CENTER: The Saint Joseph Health Center located off-campus is equipped with smoke detectors installed throughout with a monitored self-alarming system directly to the alarm company. The alarm company will contact the Health Center Manager when the alarm has been activated. The Health Center Manager will notify Plant Operations/Security and/or the Hospital Administrative Supervisor.

B. OUTPATIENT REHABILITATION SERVICES LIFEPLEX: The Outpatient Rehab Services located off-campus at the LifePlex facility will follow procedures as designated to their occupancy within the LifePlex complex. The LifePlex Manager will notify the hospital Plant Operations / Security and/or the Hospital Administrative Supervisor.
4. Provider’s Health and Wellness

   a. Michiana Wellness Letter
   b. Depression Website
   c. Process to Identify & Manage Matters of Individual Physician Health Separate from the Medical Staff Disciplinary Function
   d. Impaired or Dysfunction Physician Policy
Dear Colleague:

As many of you know, there has been much discussion and research on the high prevalence of burnout and depression among physicians. Saint Joseph Health System is committed to providing support to those facing these challenges.

Sometimes those pressures can negatively affect our happiness and disposition, our relationships with others, our job satisfaction, and even our feelings and beliefs about ourselves. If you feel this rings true for you, I encourage you to participate in a free and highly successful program offered by Saint Joseph Health System: The Michiana Wellness Program. This program is an important service offered to physicians and providers for the purpose of confidentially identifying those among us who suffer from burnout, depression, and other problems that interfere with professional, academic, and personal functioning, and providing a connection to available resources and treatment. This program was developed as a community initiative and included participation from Saint Joseph Health System, Goshen Health, and Beacon Health System and the American Foundation of Suicide Prevention for the wellness of our physicians and providers.

Please take a few moments to visit www.michianawellness.org, which offers a brief questionnaire (The Stress and Depression Questionnaire) that requires approximately five minutes. You will be asked to choose a User ID and a password to log in. The User ID and password will be the only two pieces of information required to return your completed questionnaire and you will be identified only by the User ID you choose. Your identity will be fully protected and will remain unknown unless you decide to share it.

A trained counselor will review each questionnaire and send a personal response to your User ID on the website, including a brief assessment of your responses and, if appropriate, recommendations for further evaluation or follow-up. You will then have the opportunity, if you choose, to communicate anonymously with the counselor to learn more about available resources and treatment options in your area. The goal is to help those with excessive stress, burnout, depression, or other mental health problems get help.

Completing this online questionnaire and participating in this program is completely free, voluntary and confidential, and I strongly urge all members of our physician community to participate.

Sincerely,

Chief Medical Officer
Saint Joseph Health System
The Stress and Depression Questionnaire (click on link to left)

After reviewing your questionnaire, a counselor will post a personal response to you on this secure website. The response will include information, recommendations, and options for next steps.

You decide what's next. You'll have the option of communicating with the counselor through this website. The counselor can provide you with resources and/or connect you with mental health professionals. Or, you can decide to do nothing further at this time.

It's up to you. No follow-up or service will be provided unless requested.

Sign Up

Protecting your privacy

Your identity will not be known to the counselor unless you decide to share it.

At the end of the questionnaire, you'll have the option of providing an email address so the computer system can notify you when the counselor's response is ready. Your email address will be encrypted and will not be revealed to anyone, including the counselor. As further protection, you may wish to set up a new email account (e.g. Gmail, Yahoo, etc) that does not contain any part of your first or last name. Having your email address will also enable the system to retrieve a forgotten User ID or password. If you don't give an email address, at the completion of the questionnaire you'll be told when to return to this website to get the counselor's response.

For Questions or Assistance
Contact Kayrn Delgado, CPM,SM, Manager, Medical Staff Services, Saint Joseph Health System, delgadoK@sjhc.com or 574.335.2363.

Additional Resources
Oaklawn: 574-533-1234
David Stone, MD and Associates
David Stone, MD and Ean Warner, PhD 574-271-6222
Family Physicians of South Bend
John Pederson, PA 574-230-8199
Kassie Hinchman, DO 574-286-6316
Sahayl J. Nair, MD 219-872-1500
If having trouble accessing a mental health provider please contact Oaklawn at 574-533-1234.
Process to Identify and Manage Matters of Individual Physician Health Separate from the Medical Staff Disciplinary Function

Physician Orientation

A central obligation of the medical staff organization is to protect patients from harm. In this regard, the medical staff together with hospital leadership is responsible to consider and address physician health issues which might jeopardize hospital operations and/or compromise quality of patient care.

The Centralized Well Being Committee of the medical staff (a group of knowledgeable, experienced, and seasoned physicians) is charged with overseeing the process of assistance and rehabilitation, rather than discipline, to aid medical staff members in retaining and regaining optimal professional functioning when physical, psychiatric, emotional illness or substance abuse is identified.

While education and prevention are paramount, physicians are not immune to disabling conditions. Confidential and systematic diagnosis, treatment, and rehabilitation of physicians suffering from potentially impairing conditions is maintained and supervised by the Centralized Well Being Committee.

Warnings which may signal existing or impending impairment include:

- Increased problems in quality
- Making rounds at odd or inappropriate times
- Inappropriate orders
- Unavailability or inappropriate responses to phone calls
- Social withdrawal
- Intoxication at social events
- Missing appointments
- Repeated “illnesses”
- Large weight gain or loss
- Disjointed thoughts
- Inappropriate levity

Although this issue is not a pleasant or popular topic of conversation for physicians, its importance goes well beyond compliance with regulatory bodies such as The Joint Commission. If we are serious about providing excellent healthcare to our patients and communities we must engage in taking care of ourselves and colleagues.

If you have concerns about a potentially impaired colleague, please approach your department chair or a member of the Centralized Well Being Committee.
Title: Impaired or Dysfunctional Provider

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<td>Department: Medical Staff Services (14001-80012)</td>
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**Printed copies are for reference only. Please refer to the electronic copy for the latest version.**

**BACKGROUND:**

1. The problem of impairment is complex, and the peer review investigation and hearing process may not be appropriate in this situation. The American Medical Association defines the impaired provider as “one who is unable to practice medicine with reasonable skill and safety to patients because of a physical or mental illness, including deterioration through the aging process or loss of motor skill, or excessive use or abuse of drugs, including alcohol.” This policy is intended to provide some overall guidance and direction on how to proceed when confronted with a potentially impaired provider.

2. Because of the independent nature of most providers’ practices and the serious implications of any disability, impairment is often difficult to identify early and is always difficult for the impaired provider to acknowledge. It is hard to face the problem with a provider. For all these reasons, the problem often goes unaddressed for too long. Nevertheless, it is the obligation of the hospital and medical staff leadership to address it. The following policy provides the framework within which to do it.

3. Because the term “impaired provider” includes a variety of problems, from age to substance abuse to physical or mental illness, the steps provided below will not be suitable in every circumstance. There can be no one policy to cover all situations. Specific needs and varying circumstances preclude a single inflexible mechanism for dealing with all impaired providers. The number and seriousness of incidents involving a provider, for example, may dictate the appropriate response by the hospital. If the “investigation” suggested in the policy is carried out, the individuals conducting the investigation will vary from hospital to hospital, depending upon personalities, circumstances, and the structure of the medical staff. Whatever mechanism a hospital chooses, the risk of patient harm must be of paramount concern. Immediate action may be necessary.

4. One exception to this policy is impairment due to age and irreversible medical illness or other factors not subject to rehabilitation. In such cases, the sections of the policy dealing with rehabilitation and reinstatement of the provider are not applicable.

5. Key factors to keep in mind while dealing with any issue relating to a provider’s illness or disabilities are state reporting statutes and the application of the Americans with Disabilities Act. These policies should, under any interpretation of the law, be legally appropriate, as with all matters with significant legal implications. Legal counsel should be consulted.

**POLICY:** Medical Staff policy regarding impaired providers

1. Report and investigation:
   A. If any individual working in the hospital has a reasonable suspicion that a provider appointed to the medical staff is impaired, the following steps should be taken:
      1) The individual who suspects the provider of being impaired must give an oral or, preferably, written report to the Chief Medical Officer or the Medical Staff Office for presentation to the President of the Hospital or the Medical Staff President (or the Well-Being Committee). The report must be factual and shall include a description of the incident(s) that led to the belief that the provider might be impaired. The individual
Title: Impaired or Dysfunctional Provider

making the report does not need to have proof of the impairment, but must state the facts that led to the suspicions.

2) If, after discussing the incident(s) with the individual who filed the report, the President of the Hospital or the Medical Staff President believes there is enough information to warrant an investigation, the President of the Hospital and/or Medical Staff President shall request that an investigation be conducted by the Centralized Well Being Committee which requires Drug and Alcohol testing of the individual per the Substance Abuse Drug Free Workplace Policy. A report of the test results and investigation findings will be rendered to the Centralized Well Being Committee and the Medical Staff President.

3) If the investigation produces sufficient evidence that the provider may be impaired, a member of the Well-Being Committee shall meet personally with that provider or designate another appropriate individual to do so. The provider shall be told that the results of an investigation indicate that the provider may suffer from an impairment that affects his or her practice. The provider should not be told who filed the report, and does not need to be told the specific incidents contained in the report.

4) Depending upon the severity of the problem and the nature of the impairment, the Well-Being Committee has the following options:

a) if the Physician provider Well-Being Committee believes that the physician provider can continue to treat patients without risk to the well-being of such patients, then the Well-Being Committee shall require the provider to undertake a rehabilitation program as a condition of continued appointment and clinical privileges; or

b) if the Well-Being Committee believes that the provider cannot treat patients without risk to the well-being of such patients, the Well-Being Committee shall seek voluntary relinquishment of such privileges and require the provider to undertake a rehabilitation program; or

c) recommend corrective action pursuant to Section 8.4 of the Medical Staff Bylaws.

5) The hospital shall seek the advice of hospital counsel to determine whether any conduct must be reported to law enforcement authorities or other government agencies, and what further steps must be taken.

6) The Well-Being Committee shall inform the individual who filed the report that follow-up action was taken.

7) Throughout this process, all parties shall avoid speculation, conclusions, gossip, and any discussions of this matter with anyone outside those described in this policy.

8) In the event there is an apparent or actual conflict between this policy and other policies of the Medical Staff—the provisions of this policy shall supersede such policies.

Rehabilitation

1. If rehabilitation is possible, hospital and medical staff leadership shall assist the provider in locating a suitable rehabilitation program. The Medical Staff shall not reinstate a provider, if such provider’s privileges have been reduced, suspended or revoked, until it is established, to the Medical Staff’s satisfaction, that the provider has successfully completed a rehabilitation program in which the Medical Staff has confidence.

Credentialed Provider as a Patient
Title: Impaired or Dysfunctional Provider

1. Credentialed practitioners cannot provide patient care while currently receiving direct medical care or under the influence of medication altering their cognitive function.
2. To protect our patients, below are circumstance where a credentialed provider or allied health practitioner are not allowed to provide medical care for any patient:
   A. If a practitioner is currently an inpatient
   B. If a practitioner is receiving direct medical care as an outpatient that renders him/her unable to respond to an urgent medical situation
   C. If the practitioner is under the influence of any medications or substance that adversely affects cognitive function.
3. When a practitioner is under direct medical care, he/she is to transfer their patients as soon as possible to call coverage practitioners or to the SJRMC hospitalist adult or pediatric services, if applicable.
4. Hospital staff is not to accept any patient care orders of a practitioner known to be directly receiving medical care or under the influence of any medication or substance that adversely affects cognitive function.
5. A practitioner who is directly receiving medical care shall not;
   A. round on their patients
   B. access the medical records for any decision making
   C. order any labs or tests
   D. provide any orders for treatment
6. A request for an exception to this policy can be made to the President of the Medical Staff who may consult the practitioner's attending provider for consideration.

References/Standards:
- EDUCATION REFERENCE:
  A. Medical Staff Orientation Binder
  B. Employee Orientation Material
- RESOURCE REFERENCE
  A. Indiana State Medical Association Physician Assistance Program
- Policy Origin Date: May 1999 (M)
- Review Date: December 2009, December 2012, December 2015 (M), December 2018, November 2021 (P), December 2021 (M)
- Revised Date: December 2014 (M), June 2016 (M)
- Effective Date: August 1999 (M), March 2016 (P)
- Reviewed/Recommended By: Medical Executive Committee
**Title: Impaired or Dysfunctional Provider**

*For Cause Urine Drug Screen for Credentials Providers, Employed and Independent*

<table>
<thead>
<tr>
<th>Suspicious behavior observed and documented by any individual</th>
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<tbody>
<tr>
<td>Verbal report, followed by written report to CMO or Medical Staff Office</td>
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<tr>
<td>Report made to one of the following or their designee:</td>
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<tr>
<td>1. President of the Hospital</td>
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<td>2. Medical Staff President</td>
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<td>3. Centralized Well Being Committee</td>
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<tr>
<td>If report validated, Centralized Well Being Committee begins investigation</td>
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<tr>
<td>CMO, President of the Hospital, Medical Staff President, Centralized Well Being Committee member or their designees, has conversation with Physician/Provider/Resident</td>
</tr>
<tr>
<td>MSO orders drug and alcohol test to be completed at the Physicians Immediate Care, Cleveland Road Mishawaka or Lifeplex Urgent Care for Plymouth. Hospital pays for testing.</td>
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<tr>
<td>CMO or MSO coordinate transportation to Physicians Immediate Care and transportation home</td>
</tr>
<tr>
<td>CMO and MSO are informed of the Test Results (usually takes 5-10 days)</td>
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<tr>
<td>Results are shared with Centralized Well Being Committee and Medical Staff President as part of the investigation</td>
</tr>
<tr>
<td>The Centralized Well Being Committee clears a physician or provider to return to work.</td>
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5. Quality and Peer Review Processes

   a. Focused Professional Practice Evaluation Policy (“FPPE”)
   b. Proctoring Policy and Procedures Policy
   c. Ongoing Professional Practice Evaluation Policy (“OPPE”)
   d. Occurrence Monitoring & Peer Review (Medical Staff) Policy
   e. Medical Staff Peer Review Policy
   f. Serious Reportable Events, Sentinel Events & Indiana Medical Errors
Title: Focused Professional Practice Evaluation (FPPE)

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POLICY:
1. The organized medical staff has defined the circumstances requiring monitoring and evaluation of a practitioner’s professional performance that does not have documented evidence of competency performing the privilege(s) at our hospital. This process is also used when a question arises regarding a currently privileged practitioner’s ability to provide safe, high quality patient care. The FPPE process is time-limited.
2. Evaluation of professional practice will be completed in the following specific circumstances:
   A. A period of focused professional practice evaluation is implemented for all initially requested privileges. This includes:
      1) All new practitioners
      2) All new privileges for existing practitioners
   B. Clearly delineated criteria as defined by the medical staff will be used for evaluation of the performance of practitioners when issues affecting the provision of safe, high quality patient care are identified (“triggered”) i.e. A.5.
   C. The FPPE process is delineated as follows:
      1) criteria for conducting performance evaluation
      2) method for establishing the monitoring plan specific to the requested privileges
      3) method to determine the duration of performance monitoring
      4) circumstances under which monitoring by an external source is required
   D. The FPPE process will be implemented consistently.
   E. The decision to assign a period of performance monitoring to further assess current competency is based on evaluation of a practitioner’s current clinical competency, practice behavior, and ability to perform the requested privilege. The type of monitoring will be determined by predefined criteria.

PROCEDURE/GUIDELINES:
A. Initially Requested Privileges:
   1) Criteria for Conducting Performance Monitoring:
      a) FPPE for practitioners identified below will be evaluated at least the first three months.
         (1) All new practitioners;
         (2) All new privileges for existing practitioners
      2) The monitoring plan will be specific to the requested privileges or group of privileges and may include proctoring, as applicable. Review for each practitioner will include review of the following data reports and information by the department/specialty representative.
Title: Focused Professional Practice Evaluation (FPPE)

a) Midas Statit Reports – These reports include inpatient and outpatient data for both the individual physician and comparison with the aggregate of the physicians in that specialty:

   (1) Admission Activity
   (2) Length of Stay Data (actual and expected)
   (3) Mortality Data (actual and expected)
   (4) Procedures by ICD
   (5) All Risk related occurrences
   (6) All Quality Indicator related occurrences

b) Proctoring requirements are delineated and developed according to the Medical Staff Proctoring policy.

c) Retrospective Chart Review

   (1) Chart reviews- The department chair or designated representative will complete three (3) retrospective chart reviews including one sedation case if sedation privileges are granted. For new privileges for existing practitioners, three (3) retrospective chart reviews are to be completed when proctoring is not required. Retrospective review will be utilized as the primary source of FPPE as well as supplemental data from other CMS-certified organization where the practitioner holds the same privileges, for the practitioners performing periodic on-call coverage for other physicians or groups.

   (2) The APNs and PAs will be asked for patient lists for their initial three (3) months for review.

3) Department Chair or Designated Physician Representative will document pertinent findings and recommendations to include:

a) Confirmation that the practitioner has been reviewed and there are no potential problems with performance or trends that would impact the quality of care and patient safety.

b) Request for additional review for an individual practitioner based on an identified issue. Information gathered for review may include, but not be limited to:

   (1) Drill down reports
   (2) Additional performance of a specific procedure
   (3) Additional Monthly Review
   (4) Direct Observation
   (5) Concurrent Monitoring
   (6) Retrospective Chart Review
   (7) Discussion with other individuals involved in the care of the practitioner’s patients including consulting physicians, assistants at surgery, nursing and administrative personnel.

c) The information gathered will be presented to the Department Chair or Designated Physician Representative to complete.

4) Method for determining the duration of performance monitoring:

a) The above process will continue for at least the first three months of each practitioner’s FPPE. The practitioner will then be reviewed for termination of FPPE. Continuation,
Title: Focused Professional Practice Evaluation (FPPE)

limitation, or revocation of any existing privileges will then be considered. This will provide a minimum of a three month evaluation period.

b) FPPE data may be obtained from a CMS-certified organization. However, any information received can be used only as supplemental information, not in lieu of collecting organization-specific data.

c) If no activity at the 3 month FPPE review, the practitioner will remain on FPPE and will continue to be monitored monthly. The sponsoring physician will be notified when an APN or PA does not have needed volumes.

(1) If a physician does not have any activity in their first 12 months, they will automatically move to Affiliate Medical Staff Status for administrative purposes. Physicians will be notified one month prior to staff status change. This administrative action does not entitle the physician to appeals.

(2) If an APN or PA does not have any activity in their first 12 months, their privileges and affiliation will automatically expire for administrative purposes. Practitioners and their sponsoring physician will be notified one month prior to staff status change. This administrative action does not entitle the practitioner to appeals.

d) The department chair or designated physician representative may request immediate action according to the Medical Staff Bylaws be taken at any time during the FPPE process, which may include, but not be limited to, forwarding concerns to the following committees:

(1) Credentials Committee for review and/or

(2) Physician Well Being Committee for review, as applicable

(3) Medical Executive Committee

e) Extension of evaluation period will continue until the Department Chair or Designated Physician Representative is either:

(1) Satisfied with the information received and reviewed, or

(2) Recommendations are made to the Credentials Committee or Physician Well Being Committee, as applicable, for review and recommendation to the Medical Executive Committee for action including, but not limited to, the initiation of the Collegial Investigation per the Medical Staff Bylaws Credentials Policy Manual.

5) Criteria for conducting FPPE for those practitioners who need evaluation of their performance as a result of an issue affecting the provision of safe, high quality patient care.

a) Evaluation will take place as soon as a “trigger” is identified. Triggers can be single incidents or evidence of a clinical practice trend.

b) Review will continue, at a minimum, on a monthly basis for the first three months. Triggers will be consistently identified and implemented.

(1) Triggers may include, but are not limited to, data obtained from quality indicators, risk indicators, utilization indicators, unexpected deaths, medical leave of absence, Hospital and Medical Staff Bylaws, Rules & Regulations or policy violations. See Attachment from the Occurrence Monitoring and Peer Review Medical Staff Policy.

(2) FPPE may also be triggered during the OPPE review.
Title: Focused Professional Practice Evaluation (FPPE)

6) Data elements and supporting documentation will be reviewed by the department chair or designated physician representative of each practitioner under FPPE whose review was initiated (triggered) by practice indicators.

7) Administration review, department chair or designated physician representative review and the duration of monitoring will be conducted as outlined in Procedure 1.

8) Circumstances under which monitoring by an external source is required:
   a) Need for specialty review, when there are a limited number or no medical staff members within the required specialty on the medical staff.
   b) The peer review / Credentials Committee is unable to make a determination and requests an external opinion.

9) If behavior is identified as a possible issue at the time of initial appointment of a new applicant or if a behavior occurrence triggers a FPPE, the Medical Staff Code of Conduct Policy will be followed.

10) Upon completion of the above review, and evaluation results will be presented to the Credentials Committee.

References/Standards:
- Joint Commission Hospital Accreditation Standards (HAS) 2010
- Proctoring And Current Competency Requirements List
- Policy Origin Date: February 2008 (M), February 2008 (P)
- Review Date: December 2009 (M), December 2012 (M), December 2009 (P), December 2012 (P), December 2015 (M), February 2016 (P), December 2017 (M&P), January 2019 (M & P), February (P) 3/18/2020 (M), 9/21/2020 (M), November 2021 (P), December 2021 (M)
- Revised Date: August 2008 (M), September 2010 (M), August 2008 (P), September 2010 (P), December 2017 (M&P), February 2019 (P), March 19 (M), 3/18/2020 (M & P), 9/21/2020 (M)
- Effective Date: February 2009 (M), February 2009 (P)
- Reviewed/Recommended By: Medical Executive Committee
**Title: Proctoring Policy and Procedure**

**Policy:**

1. The Mishawaka and Plymouth medical staff of Saint Joseph Regional Medical Center are committed to assuring the competencies of its members through established assessment processes.

2. Members of the Medical Staff Executive Committee are responsible to oversee activities to measure, assess, and improve performance on an organization-wide basis. The Credentials Committee of the Medical Staff Executive Committee is required to develop and conduct a properly designed proctoring process that includes the following structural elements:
   A. Definition of circumstances requiring proctoring
   B. Specification of participants to be involved in the proctoring process
   C. Timeframes to conduct proctoring activities and report results

3. Essential Functional Elements/Process goals include:
   A. Consistent - Proctoring is conducted according to defined procedures for all cases meeting the organization’s definition of circumstances requiring proctoring.
   B. Timely - The time frames specified in the proctoring procedures are adhered to reasonably.
   C. Defensible - The conclusions reached through the process are supported by a rationale that specifically addresses the issues for which the proctoring was conducted, including, as appropriate, reference to the literature and relevant clinical practice guidelines.
   D. Useful – The results of proctoring activities are considered in practitioner specific credentialing and privileging decisions and, as appropriate, in the organization’s performance improvement activities.
   E. Ongoing - Proctoring conclusions are tracked over time, and actions based on proctoring conclusions are monitored for effectiveness.
   F. Proctor: A practitioner whose clinical knowledge and expertise qualifies them for evaluating the performance of the proctoree.

4. All proctoring activities will be conducted in consideration and consistent with the hospital’s mission to ensure the provision of the best quality care to its patients.

**Purpose:**

1. To provide guidelines to assist the Medical Staff in determining the competency of:
   A. New practitioners, and
   B. Practitioners who seek privileges to perform new or rarely performed procedures, and
   C. Any Practitioner when circumstances arise reflecting a quality of care concern or potential for a concern to develop.
   D. Any practitioner as deemed necessary and appropriate by the Medical Staff Executive committee.
Title: Proctoring Policy and Procedure

PROCEDURE:
1. The appropriate department shall recommend the terms of proctoring, including the number of cases required.
2. The Credentials Committee shall approve the terms of proctoring and authorize acceptable non-credentialed proctors as delineated in the privilege criteria.
3. Proctoring may require one or any combination of the following:
   A. Retrospective chart review;
   B. Concurrent chart review within 24 hours (or earlier, if specified) of admission or the procedure in question;
   C. Availability on campus for immediate consultation and concurrent chart review within 24 hours of admission or the procedure in question; and/or
   D. The proctor’s presence during that portion of a procedure for which the Medical Staff requires proctoring. Proctoring is typically hands-off observation only. (Only a credentialed proctor is permitted - but not required - to intervene at any time during the observation to assist the proctored physician if he/she believes that such intervention is in the patient’s best interest. The proctor is not deemed the primary physician unless the proctoring program requires it; however, a credentialed proctoring physician is permitted to become the primary physician at any time during the case that he or she proctors.)
   E. Retrospective review will be utilized as the primary source of FPPE as well as supplemental data from other CMS-certified organization where the practitioner holds the same privileges, for the practitioners performing periodic on-call coverage for other physicians or groups.
4. Proctor responsibilities: Responsibilities may include as specified:
   • The practitioner to be proctored carries the responsibility of finding an appropriate proctor, which is determined to be a physician who is experienced in the field of the case being performed.
5. If proctoring is required, it is mandated that at least one (1) case be performed at each SJRMC campus where privileges have been granted.
6. Proctoring reports are acceptable from the following locations:
   A. St. Joseph, Elkhart and Marshall county facilities, and
   B. Any Trinity Health /CHE facility, and
   C. Company Proctors, and
   D. Any additional facility outside of the above requires preapproval on a case by case basis by the Department Chair.
7. Upon successful completion of the proctoring program, the Department Chair shall notify the practitioner of this new status, and will make a report to the Medical Staff Office for the physician’s Credential file.
8. If a “quality of care” issue is identified during the proctoring process it will be referred to the Department Chair. A quality of care issue is defined as “needs improvement” or “unsatisfactory” categories documented on the proctor form.
   A. The Department Chair shall submit a report to the appropriate Peer Review Committee or directly to the Credentials Committee.
   B. Following evaluation by the department chair and referral to the Peer Review Committee, a report/recommendation shall be forwarded to Credentials Committee by the Peer Review Committee for consideration for further action.
Title: Proctoring Policy and Procedure

C. An appointee of the appropriate Peer Review Committee and/or Credentials Committee shall present and discuss the report-recommendation with the proctored physician.

D. The report/recommendation shall be filed in the proctored physician’s Credentials file.

9. Waiver of Proctoring will be considered for the following:
   A. Similar to a leave of absence, if a resignation was approved less than 12 months prior to returning to the medical staff and there were no competence or behavior issues during their appointment, no additional proctoring will be required unless deemed necessary by the MEC.
   B. Similar to a reappointment cycle, if a resignation was approved less than 24 months prior to returning to the medical staff and there were no competence or behavior issues during their appointment and the physician maintained practice volumes elsewhere, modified proctoring may be considered requiring MEC approval.
   C. If a practitioner has been gone from SJRMC greater than 24 months, consideration of modified proctoring may be considered if there were no competence or behavior issues during their appointment and the physician maintain practice volumes elsewhere and there were no competence or behavior issues during their time away. This would require MEC approval.

10. SPECIAL PRECAUTIONS/ CONSIDERATIONS:
   A. In accordance with Indiana Statutes, Saint Joseph Regional Medical Center- Plymouth and Mishawaka maintain the strict confidentiality of all peer review information from unauthorized disclosure.
      • Additionally, confidentiality of all information related to patients, physicians, and all other health care providers through the review and reporting process is maintained.
   B. A professional health care provider, a peer review committee, and the governing board of the Medical Center may use information obtained by peer review committees for legitimate internal business purposes. This is based on I.C. 34-4-12.6-2

References/Standards:
- Policy Origin Date: May 2000
- Review Date: May 2012, December 2012, December 2015, December 2018, September 2021 (M & P), November 2021 (P), December 2021 (M)
- Revised Date: June 2012, March 2013, June 2014, September 20, 2021 (M), September 2021 (P)
- Effective Date: June 2000
- Reviewed/Recommended By: Medical Executive Committee
Title: ONGOING PROFESSIONAL PRACTICE EVALUATION (OPPE)

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<th>PI Team: N/A</th>
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Printed copies are for reference only. Please refer to the electronic copy for the latest version.

POLICY:

1. The OPPE requires that the medical staff conduct an ongoing evaluation of each practitioner’s professional performance. This process allows any potential problems with a practitioner’s performance or trends that impact quality of care and patient safety to be identified and resolved in a timely manner. The OPPE also fosters an efficient, evidence-based privilege renewal process. The information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privileges(s).

PROCEDURE:

A. The respective department chair(s) or designated physician representative(s) are responsible to coordinate the Ongoing Professional Practice Evaluation (OPPE) review. The OPPE will be performed on all practitioners every six months allowing an additional 60 day review period if necessary.

B. The type of information and the process for evaluation of each practitioner’s ongoing professional practice has been approved by the departments and through the Medical Executive Committee. The defined process is below.

C. At each six month review, every practitioner will be reviewed by the department/specialty Chair or designated physician representative. This review will be factored into the decision to maintain existing privilege(s), to revise existing privilege(s) or to revoke an existing privilege prior to or at the time of renewal. The fact that a practitioner doesn’t fall out on screening criteria does not meet the requirement for performance data review although zero data is in fact data and can be evidence of good performance, e.g. no returns to the OR, no complaints, etc. Review of privileges are evaluated at reappointment and consideration of the reason for zero or low volumes is taken into consideration, e.g. no longer performing the procedure, taking patients elsewhere for the procedure or privilege is typically a low volume procedure, etc.

D. Data reports and information that are included in the OPPE include, as applicable:

1) Midas Statit Specialty Profiles – These reports include inpatient and outpatient data for both the individual physician and comparison with the aggregate of the physicians in that specialty;

2) Midas Occurrence Report – Midas is a tool for collecting clinical practice concerns as well as patient and family concerns and compliments. The Occurrence Monitoring and Peer Review policy defines the process for collecting, investigating and addressing these concerns. This report includes individual and aggregated physician information on:

   a) Risk related occurrences

   b) Quality Indicators & Quality Indicator related occurrences

Expiration Date: 03/21/2026
Title: ONGOING PROFESSIONAL PRACTICE EVALUATION (OPPE)

3) No/Low Volume Practitioner –
   a) Attestation of Clinical Competence
   b) Peer Reference, as needed
   c) OPPE data may be obtained from a CMS-certified organization. However, any information received can be used only as supplemental information, not in lieu of collecting organization-specific data.
   d) If a practitioner does not have any activity for two consecutive OPPE cycles (12 months), they will automatically move to Affiliate Medical Staff Status for administrative purposes. Practitioners will be notified one month prior to staff status change. This administrative action does not entitle the physician to appeals.

E. The department chair or designated physician representative will document pertinent findings and recommendations in the Midas Statit database to include:
   1) Confirmation that the practitioner has been reviewed and there are no potential problems with performance or trends that would impact the quality of care and patient safety. The individual practitioner will then be reviewed again at their next sixth month OPPE.
   2) Request for additional review for an individual practitioner based on an identified issue. Information gathered for review may include, but not be limited to:
      a) Drill down reports
      b) Additional performance of a specific procedure
      c) Additional Monthly Review
      d) Direct Observation
      e) Concurrent Monitoring
      f) Retrospective Chart Review
      g) Discussion with other individuals involved in the care of the practitioner’s patients including consulting physicians, assistants at surgery, nursing and administrative personnel

3) This review process will continue until the Department Chair or designated physician representative is either:
   a) Satisfied with the information received and reviewed, or
   b) Recommendations are made to the Credentials Committee or Physician Well Being Committee, as applicable, for review and recommendation to the Medical Executive Committee for action including, but not limited to the initiation of the Collegial Investigation per the Medical Staff Bylaws Credentials Policy Manual.

4) Request for immediate action according to the Medical Staff Bylaws can be taken at any time during the OPPE process, which may include, but not limited to, forwarding concerns to the following committees:
   a) Credentials Committee for review
   b) Physician Well Being Committee for review (SJRMC-Mishawaka)
   c) Medical Executive Committee

F. The information gained by the review of the above information will be filed and incorporated into the two-year reappointment process. A summary report will also be forwarded to medial staff.
Title: ONGOING PROFESSIONAL PRACTICE EVALUATION (OPPE)

leaders. Single incidents or trending of quality and safety issues that impact the safety of patients will require immediate action by the medical staff.

G. “Trigger” - There may be circumstances where a single incident or evidence of a clinical practice trend may be identified through the OPPE process. If so, this will trigger a Focused Professional Practice Evaluation, which will be conducted according to Medical Staff Policy.

1) Triggers may include, but are not limited to, data obtained from quality indicators, risk indicators, utilization indicators, unexpected deaths, medical leave of absence, Hospital and Medical Staff Bylaws, Rules & Regulations or policy violations.

H. If behavior is identified as a possible issue, the Medical Staff Code of Conduct Policy will be followed as a component of the OPPE.

I. Relevant information obtained from the OPPE will be forwarded for inclusion into the performance improvement activities maintaining confidentiality.

References/Standards:

- Joint Commission Hospital Accreditation Standards (HAS)
- Joint Commission Perspectives, August 2019, Volume 39, Issue 8
- Reappointment Cycle with OPPE Table
- Policy Origin Date: October 2007 (M), October 2007 (P)
- Review Date: December 2009 (M), December 2012 (M), December 2009 (P), August 2010 (P), December 2012 (P), December 2015 (M), February 2016 (P), December 2018 (M), February 2020 (P), December 16, 2020 (M), November 2021 (P), December 2021 (M)
- Revised Date: August 2008 (M), September 2010 (M), December 2013 (M), August 2008 (P), September 2010 (P), September 2013 (P), September 2017 (M), March 2020 (P), December 16, 2020 (M)
- Effective Date: December 2007 (M), December 2007 (P)
- Reviewed/Recommended By: Medical Executive Committee
**Title:** Occurrence Monitoring & Peer Review (Medical Staff)

**POLICY:**

1. It is the policy of SJRMC to conduct review of Medical Staff indicators, appropriateness of care, complication and/or mortality rates, and resource utilization in a consistent and timely manner. To establish a uniform and consistent method of review, evaluation, and documentation of physician occurrences and peer review for the purpose of performance improvement, risk reduction, patient safety, appropriate utilization, and reduction of morbidity and mortality. Behavior issues will follow a separate review process according to the Medical Staff Code of Conduct Policy and will also be protected under peer review.

**PROCEDURE:**

A. Physician Performance Weekly Reviews - Triggered by Midas Reports, Chart Review and/or verbal notification.

1) Members Include:
   a) Chief Medical Officer
   b) Clinical Risk Manager, Clinical Operations Improvement
   c) Peer Review Coordinator, Clinical Operations Improvement
   d) Manager, Medical Staff Services

2) Issues Include:
   a) Quality – Review the summary of quality indicators identified and analyze for trends.
   b) Risk – Review the summary of risk indicators identified and analyze for trends.
   c) Bylaws/Rules and Regulations/ Medical Staff Policies - Review the summary of Bylaws/Rules and Regulations/Medical Staff Policy violations identified and analyze for trends.
   d) Utilization – Review the summary of utilization issues and analyze for trends.

B. Reports and/or data collected shall be maintained in a confidential manner in accordance with Indiana Law. Medical staff occurrences are entered into the MIDAS+ database for trending.

C. All occurrences are summarized by occurrence type and physician for review at the weekly Physician Performance Review meeting. From there, cases or trends can be referred to Department Chairs, an integrated performance improvement committee, a special peer review committee, and/or directly to Credentials or the Medical Executive Committee.

D. Participation in the peer review process by the practitioner whose performance is under review:

1) The individual whose case or trend is under review shall have the opportunity to present his or her information regarding case management to the committee performing peer review. The individual whose case is under review has the right to sit on the peer review committee during
the time the case is reviewed and discussed, to provide additional information to the individual(s) performing peer review as necessary.

E. All individuals whose cases are referred for committee peer review shall be notified of the medical record number and date of admission of the case to be reviewed, in addition to the reason for review, at least two weeks prior to the scheduled peer review meeting date. In cases of immediate referral to committee, as determined by the Department Chair, the Department Chair shall notify the individual whose case is under review, regarding the reason for review and the scheduled date of review, as soon as the Department Chair makes the determination that the case must be referred for formal peer review.

F. Clinical Operations Improvement staff shall take the issue forward for review to the weekly physician review meeting. If issues or questions are identified, the medical staff Department Chair or designee is notified. The peer physician will assign the appropriate level of significance (Level 1-5) to each occurrence.

NOTE: If the level of significance is not determined, the Credentials Committee Chair shall assist in the final determination.

G. Peer review activity time frames:

1) Cases forwarded to medical staff departments or peer review committees from the weekly physician review meeting are to be reviewed within one month of referral or the next committee meeting.

2) Issues believed to be of such severity or urgency that immediate action is warranted, the Director, Clinical Outcomes Improvement and/or the Manager, Medical Staff Affairs shall, upon the receipt of the report, immediately notify the Medical Staff President and/or Officers and the involved physician.

3) Time frames are adhered to in a reasonable fashion. All cases referred for peer review shall be reviewed within the time frames as listed above. In those instances where peer review falls out of the required time frames (medical record incomplete, practitioner under review is unavailable, reviewing committee rescheduling, etc.) the reasons for the delay will be documented. All efforts will be made to complete the peer review process as soon as practicable within the confines of the delay.

H. Action:

1) Level 1 issues will not require action. Recurrence or a pattern shall constitute a higher level of significance, thus requiring handling in a manner consistent with the level 2 or 3.

2) Level 2-5 issues require contact with the physician by the Department Chair or Vice Chair, with a written plan of action as applicable.

I. File Access:

1) Access by the physician will occur only during an investigation and with the appropriate approval and access granted by the person or committee involved in the investigation. (Indiana Code, Sec. 34-30-15-4). These are retained in the Medical Staff Office. Arrangements will be made for a review location on a case-by-case basis.

2) A Department Chair, Service Medical Director, and section chief may access the files of its members only for performance of the responsibilities of the position.

3) The President of the Medical Staff may have access to all Medical Staff Members’ files in performance of the responsibilities of the position.
4) The Chief Executive Officer, President of the Hospital, the Director of Outcomes Management or the Chief Medical Officer, Manager of Medical Staff Affairs, the Clinical Operations Improvement Clinical Risk Manager or Peer Review Coordinators may access all professional staff members’ files in performance of their responsibilities.

J. Performance Improvement

1) All cases undergoing peer review beyond the weekly physician review meeting will have a worksheet completed that lists the rationale for conclusion made by the reviewer(s).

2) All opinions regarding medical management, including minority opinions, will be considered in the ultimate determination of a case. This includes information and opinions from the individual whose case is under review.

3) Results of peer review are utilized at time of medical staff reappointment and to improve the organization’s performance in individual situations, and, as a whole.

4) Results of peer review activities are aggregated and reported ongoing and at time of medical staff reappointment to provide for practitioner specific appraisal of competency and renewal of clinical privileges.

5) Aggregated and trended results of peer review activities are utilized in the hospital-wide performance improvement program, via quarterly reporting to the Credentials Committee, to allow for organizational improvement as necessary.

6) Peer review conclusions, outcomes and actions resulting from peer review are monitored for effectiveness. Results of follow-up effectiveness monitoring are reported to the Medical Executive Committee.

DEFINITIONS:

1. Occurrence: An incident that is inconsistent with SJRMC procedures or routine patient care or results in serious physical or psychological injury or death.

2. Peer Review Component Definitions: Definitions of circumstances requiring peer review are listed below. Clinical Operations Improvement or the Credentials Committee may suggest revision to the lists, with final approval granted by the Medical Executive Committee. Circumstances requiring peer review include:

   A. Medical Staff Indicators (see annual Indicator list)
   B. Appropriate use of blood and components, medications, tests, procedures, level of care, etc.
   C. Deviation from external benchmarks identified for comparisons in screening for opportunities for improvement in management and outcomes.
   D. Risk occurrences (see annual Indicator list)

3. Peer review participants:

   A. A peer reviewer shall be defined as a member of the medical staff in good standing. In instances for occurrences involving clinical decision-making the opinions of a physician licensed in the same medical specialty as the individuals whose case is under review should be obtained.

   B. A peer review committee is either the medical staff department to which the physician is assigned or the physician component of an integrated performance improvement committee where the members are considered experts in the function being monitored.
Title: Occurrence Monitoring & Peer Review (Medical Staff)

C. An individual functioning as a peer reviewer will not have performed any medical management on the patient whose case is under review. However, opinions and information may be obtained from participants involved in the patient’s care.

D. A practitioner-focused review is defined as when a process becomes more practitioner specific and requires more in-depth review involving monitoring, analyzing and understanding individual practitioner performance.

4. External Peer Review

A. Circumstances that require external peer review include, but may not be limited to:
   1) Need for specialty review, when there are a limited number or no medical staff members of the institution with the identified specialty within the organization.
   2) The peer review committee is unable to make a determination and requests an external review.

5. Levels of Significance:

A. Level 1: Occurrence that did not directly put patient care at risk. The case is managed and documented appropriately.

B. Level 2: Occurrence that may impact patient safety or well-being or hospital operations. The case is managed appropriately, but documentation is not adequate.

C. Level 3: Occurrence or medical/ surgical case management is questionable with no potential for significant adverse effect on the patient or hospital operations.

D. Level 4: Occurrence or medical/ surgical case management is questionable with high potential for significant adverse effect on the patient or hospital operations.

E. Level 5: Occurrence or medical/ surgical case management with significant, adverse effects on the patient and / or is direct violation of any legal/ medical staff Bylaws/ Rules requirement.

References/Standards:
- Policy Origin Date: September 2001
- Review Date: December 2009, December 2012, December 2015, December 2018, November 2021 (P), December 2021 (M), November 2023 (M & P)
- Revised Date: January 2008
- Effective Date: October 2001
- Reviewed/Recommended By: Medical Executive Committee

Expiration Date: 11/27/2025
**Title:** Occurrence Monitoring & Peer Review (Medical Staff)

## INDICATORS

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<tr>
<td>Quality concern (reviewed)</td>
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<td>DVT / PE acquired after admission (trended)</td>
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<tr>
<td>Readmission for complication within 30 days (trended)</td>
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<tr>
<td>Unexpected death (see criteria below) (reviewed)</td>
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<tr>
<td>Iatrogenic disorder (adverse condition induced by effects of treatment) or iatrogenic complication (reviewed)</td>
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<tr>
<td>Sentinel events (reviewed)</td>
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### Pathology Review:

- Appropriateness
- Protocol deviation

### Risk Indicators
- Behavior
- Confidentiality
- Privacy / Dignity

### Verbal Communication
- Documentation /Documentation not meeting Bylaws/Inappropriate documentation
- Failure to diagnose, missed diagnosis or misdiagnosis

### Utilization Indicators
- Timeliness
- Discharge issues
- Utilization issue

### Bylaws Violations
- No response to page
- Failure to provide adequate coverage
- Failure to see patient in a 24 hour period
- Bylaws issue

### Unexpected Death Criteria

Unexplained death occurring in the hospitalized patient
- Death in outpatient setting, excluding the ED
- Deaths during *elective* surgical/invasive procedures
- Deaths within 72 hours of *elective* surgery/invasive procedure
- All pediatric deaths
- Death thought secondary to:
  - Medication reaction
  - Blood transfusion (hemolytic reaction)
  - Inpatient accident (e.g., fall)
  - Potential nosocomial infection as cause of death

*All indicators will be trended by physician and department.*
Title: Occurrence Monitoring & Peer Review (Medical Staff)

PEER REVIEW PROCESS
High Level Flow Chart

Reviewer screens that occurrence type selected is correct. Change if indicated.

↓ Trend

Summary of all occurrences are reviewed weekly for analysis of trends or need for Peer Review

No further review needed by case. No trends ID’d (Stop)

↓ Questioned case(s) or trend(s) ID’d

Peer Review Committee Review. May request additional information from involved practitioner

Acceptable (Stop)

↓ Questioned

Review performed by Medical Staff Professional Practice Council

Action(s): letter, review of additional similar cases, monitor of the following admissions for a defined timeframe, etc.

Resolved (Stop)

↓ Not resolved

MEC and/or Board

Resolved (Report resolution to MEC)

↓ Not resolved

Credentials Committee
May request a peer review panel
Or
External Peer Review

Report to National Practitioner Data Bank if indicated

MEC and/or Board

Final Decision

Resolved

Expiration Date: 11/27/2025
Title: Occurrence Monitoring & Peer Review (Medical Staff)

Medical Staff Peer Review Worksheet

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Abstract: See attached sheet

Peer Review Committee Comments:

PRC Level of Significance finding:
- Level 1 – Patient Care not directly at risk. Managed and documented appropriately
- Level 2 – Patient safety, well being or hospital operations may have been impacted. Managed appropriately, but documentation is not adequate.
- Level 3 – Case management is questionable with no potential for significant adverse effect of the patient or hospital operations.
- Level 4 – Case management is questionable with high potential for significant adverse effect of the patient or hospital operations.
- Level 5 – Case management results in significant adverse effect of the patient and/or is direct violation of any legal/medical Staff Bylaws / Rules requirement.

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Iatrogenic Complication:
- Grade 1 – Non-life threatening, no residual disability, no added LOS, no invasive procedure treatment required.
- Grade 2 – Potentially life threatening, no residual disability, no invasive procedure treatment required.
- Grade 3 – Potentially life threatening, no residual disability, invasive procedure treatment was required.
- Grade 4 – Complication with residual or persistence of life threatening conditions
- Grade 5 – Death due to complication(s)

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PRC Chair/Designee (date)/(time)

This review is confidential and protected peer review material pursuant to Indiana Statute (I.C. §34-30-15).
Title: MEDICAL STAFF PEER REVIEW

POLICY:

1. The medical staff has a leadership role in organizational performance improvement (PI) activities. When PI findings are relevant to an individual’s performance, the medical staff is responsible for determining their use in peer review for the ongoing evaluation of a licensed independent practitioner’s competence.

2. Members of the medical staff should be involved in activities to measure, assess, and improve performance on an organization-wide basis. They are required to develop and conduct a properly designed peer review process that includes the following structural elements:
   A. Definition of circumstances requiring peer review.
   B. Specification of participants in the review process, including definition of “peer”.
   C. Method for selecting panels for specific circumstances.
   D. Timeframes to conduct activities and report results.
   E. Circumstances where external peer review is required.
   F. Provision for participation by the individual whose performance is being reviewed.

3. Essential Functional Elements/Process goals include:
   A. Consistent - Peer review is conducted according to defined procedures for all cases meeting the organization’s definition of reviewable circumstances.
   B. Timely - the time frames specified in the peer review procedures are adhered to reasonably.
   C. Defensible - the conclusions reached through the process are supported by a rationale that specifically addresses the issues for which the peer review was conducted, including, as appropriate, reference to the literature and relevant clinical practice guidelines.
   D. Balance - Minority opinions and views of the reviewee are considered and recorded.
   E. Useful - the results of peer review activities are considered in practitioner specific credentialing and privileging decisions and, as appropriate, in the organization’s performance improvement activities.
   F. Ongoing - Peer review conclusions are tracked over time, and actions based on peer review conclusions are monitored for effectiveness.

4. Members of the medical staff are also involved in:
   A. The measurement of outcomes and of processes, as defined in the Organizational Performance Improvement plan, to identify opportunities for improvement.
   B. Evaluation of individuals with clinical privileges whose performance is questioned as a result of the measurement and assessment activities.
   C. Communication to appropriate medical staff members of the findings, conclusions, recommendations, and actions taken to improve organizational performance; and
Title: MEDICAL STAFF PEER REVIEW

D. Implementation of changes to improve performance.

5. The medical staff assumes a leadership role in the improvement of clinical processes that are dependent primarily on individuals with clinical privileges, such as surgery, physical examinations, and prescribing of medications.

6. All peer review activities will be conducted in consideration and consistent with the hospital’s mission to ensure the provision of the best quality care to its patients.

7. SPECIAL PRECAUTIONS/CONSIDERATIONS:
   A. In accordance with Indiana Statutes, Saint Joseph Regional Medical Center Plymouth maintains the strict confidentiality of all peer review information from unauthorized disclosure. Additionally, confidentiality of all information related to patients, physicians, and all other health care providers through the review and reporting process is maintained.
   B. A professional health care provider, a peer review committee, and the governing board of the Medical Center may use information obtained by peer review committees for legitimate internal business purposes. This is based on I.C. 34-4-12.6-2
   C. The activities of the Performance Improvement process are confidential and protected. They are not to be duplicated or released. This includes:
      1) Quality review and assessment
      2) Utilization review and management
      3) Risk Management and Opportunity reports and trends
      4) Safety prevention and correction
      5) Scientific, statistical and educational information
      6) Legal Defense
      7) Information for Credentialing purposes

8. CONFIDENTIALITY:
   A. Any organization that provides peer review services must demonstrate its commitment to absolute confidentiality and strict non-disclosure. Provisions pertaining to confidentiality will be routinely discussed in advance and included in any agreement, contract, or other document used to secure the services of outside consultants. Internal confidentiality will be maintained through the established hospital policies and procedures. All peer review findings will be stored in a secure file and maintained in the Risk Management Department until completed and then filed in the Medical Staff office under secured conditions.

9. OTHER CONSIDERATIONS:
   A. Minutes from all meetings where discussion of Peer Review information is a component will be maintained as confidential documents. All minutes will be maintained and secured in administrative or performance improvement offices.
   B. Access to the files containing Peer Review information will be limited to the following:
      1) Medical Staff Executive/Credentials Committee
      2) President of Medical Staff or designee
      3) President of the Hospital or appropriate Vice President
      4) Service chiefs of the individual practitioner
Title: MEDICAL STAFF PEER REVIEW

5) Risk Manager
6) Hospital Legal Counsel
7) Physician (May review own peer review file contents in the Administrative Suite. Outside legal counsel or other representatives may not be present with the physician during viewing)

C. All others listed above may examine the files only when it is necessary in the conduct of business.

D. Medical staff committee minutes containing peer review information may be reviewed in the administrative office by members of the committee. These minutes may not be copied or removed from the administrative office.

E. Any other requests for access to peer review and/or quality information shall be made in writing to the President of the Hospital for consideration.

F. All subpoenas of Medical Staff or quality records shall be referred to the President of the Hospital or her designee who may consult the President of the Medical Staff or legal counsel.

G. To assure active involvement by the individual physicians whose performance is being reviewed, the following will occur:
   1) The physician will receive a letter specifying which case has been reviewed as well as the outcome of that review. The letter will outline any requested action on the part of the physician as a result of that review.
   2) The physician will be provided an opportunity to respond to any identified concerns or disagreement with conclusions verbally, by appearance, or in writing. All such responses will be directed to the attention of the Medical Staff Executive Committee for consideration/further action.

10. EXTERNAL PEER REVIEW ORGANIZATION REQUIREMENTS:
   A. Availability of Clinical consultants located outside the geographic area of the practice under review;
   B. The ability to ensure that the physician reviewer has no knowledge of or connection to the physician being reviewed;
   C. Proof of a longstanding track record of consulting experience in the area of medical record review;
   D. An extensive network of board-certified clinical consultants nation-wide that includes all specialties;
   E. Availability of panel consultants who are currently in active clinical practice;
   F. The ability to provide a professional final report in a timely manner; and
   G. The ability to defend and support their findings if a subsequent fair hearing or litigation ensues.

PROCEDURE:
A. Potential cases for physician peer review are identified through the following sources:
   1) Routine Performance Improvement activities/trending/data analysis/quality indicators
   2) Routine Risk Management/Patient Relations activities.
   3) By request of physicians/other professional caregivers involved with the care of a patient.
Title: MEDICAL STAFF PEER REVIEW

4) By request of the Medical Staff Executive Committee.

B. All cases of concern will be entered into the quality module in MIDAS.

C. The Risk Manager will receive a SmartTrack worklist in MIDAS for all cases falling into the established criteria as being appropriate for potential peer review. The cases will be reviewed on a regular basis to evaluate the appropriateness for peer review screening/ potential peer review. The Clinical Outcomes Council Chairman may be consulted to assist in decision making/ provide screening of cases for further internal or external review measures and provide recommendations to the same.

D. On cases deemed appropriate for screening/ review, a peer review work sheet will be generated by the Risk Manager and forwarded to the appropriate physician in the HIM department with a cover sheet specifying the urgency for review.

E. The physician will review the case and enter the findings on the confidential Peer Review worksheet.

F. All findings will be returned to the Risk Manager and entered into MIDAS for trending/ data analysis purposes & reported regularly to MEC.

G. EXTERNAL PEER REVIEW PROCESS

1) Types of cases that may be deemed appropriate for external review:
   a) Physicians unavailable within the guidelines of a defined peer.
   b) Specialty cases where conflicts of interest might result
   c) Cases of an extremely sensitive nature perhaps involving litigation or as deemed appropriate by the Risk Manager upon approval by the President.
   d) Cases referred by the Medical Staff Executive Committee upon the recommendation of the Physician reviewer.

2) The process is essentially the same as outlined above in numbers 1-3.

3) On cases deemed appropriate for external review, the following will occur:
   a) Risk Manager is notified to prepare the case for external review.
   b) Determination is made on which peer organization will be utilized based on above criteria
   c) Notation is made in the QAR Midas entry to status/date external review.
   d) HIM is notified to prepare the record for external review:
      (1) copy the medical record
      (2) send the record to the external review organization based on established HIM handling policies.
      (3) As appropriate or when requested, a photocopy of the internal screening or review worksheet will accompany the record.

4) Upon receipt of the findings from the external review process, entry will be made to reflect the same in MIDAS under the QAR entry.

5) Appropriate circulation of findings and follow up will occur through established processes.
Title: MEDICAL STAFF PEER REVIEW

Related Documents:
- Medical Staff Bylaws

Definitions:
- PEER: A physician licensed to practice medicine that has similar but not necessarily identical training or experience.
- PEER REVIEW: The name given to the process by which medical staff members review the performance of their peers in a particular clinical setting.
- EXTERNAL PEER REVIEW: Involves the use of a licensed physician consultant who is not affiliated with the healthcare facility requesting the review and whose specialty training and practice setting are similar to that of the physician under review and who has no personal or professional interest in the outcome of the review process.

References/Standards:
- Policy Origin Date:
- Review Date: November 2021
- Revised Date:
- Effective Date: March 2011
- Reviewed/Recommended By: Medical Executive Committee
CONFIDENTIAL MEDICAL STAFF PEER REVIEW
I.C.34-4-12.6-2

MEDICAL RECORD #: ____________________________

DATE OF SERVICE: ____________________________

PHYSICIAN REVIEWER:

Internal Physician: ____________________________

External Organization: __________________________

REVIEW REQUESTED BY: __________________________

DATE REQUEST SUBMITTED: __________________________

URGENCY INDEX:

__________ EMERGENCY Review within 14 days/ incomplete record if necessary

__________ URGENT Review within 21 days/ complete record

__________ MODERATE Review within 30 days/ complete record

__________ ROUTINE Review as soon as conveniently possible
HOSPITAL INDICATORS

Sentinel Event (specify) ____________________________

Near Miss /Serious Event (specify) ____________________________

Unplanned readmission within 30 days for complication of previous stay

Unplanned Readmission (other reason) ____________________________

Inpatient admission following unscheduled return to ED within 72 hours

Cardiac or Respiratory Arrest (Code Blue) - *excludes pre-hospital codes

Unexpected death

Unscheduled return to surgery

Complication related to procedure

Other event (describe) ____________________________
EXTERNAL REVIEW PROCESS

CASES DETERMINED TO REQUIRE EXTERNAL PEER REVIEW DECISION ON WHAT E.R. ORG

RISK MANAGER NOTIFIED / NOTATION MADE IN MIDAS TO STATUS EXTERNAL REVIEW

MED RECORDS TO COPY RECORD AND SEND TO EXTERNAL REVIEW ORGANIZATION

FINDINGS TO RISK MANAGER/ ENTRY INTO MIDAS/ COMMUNICATION/ CIRCULATION THROUGH ESTABLISHED PROCESSES
Title: MEDICAL STAFF PEER REVIEW

PEER REVIEW PROCESS

SAINT JOSEPH REGIONAL MEDICAL CENTER-PLYMOUTH

INTERNAL REVIEW PROCESS

CASE OF CONCERN IDENTIFIED THROUGH ESTABLISHED PROCESSES

MIDAS ENTRY INTO QAE

RM RECEIVES CASE SCREENS

PEER REVIEW WORK SHEET GENERATED/PLACED IN DR FILE IN MEDICAL RECORD WITH URGENCY INDEX ASSIGNED

CASES TRENDED ON AN ONGOING BASIS

RECORD REVIEWED/FINDINGS TO RISK MANAGEMENT

MIDAS ENTRY/COMMUNICATION OF FINDINGS THROUGH ESTABLISHED PROCESSES

Expiration Date: 01/25/2025

Page 9 of 9
Title: Serious Reportable Events, Sentinel Events & Indiana Medical Errors

<table>
<thead>
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<td>Department: Administration</td>
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**Printed copies are for reference only. Please refer to the electronic copy for the latest version.**

**POLICY:**

1. Saint Joseph Regional Medical Center (SJRMC) is committed to providing quality care to all patients and preventing undesired patient outcomes or occurrences.

2. As part of the SJRMC’s commitment to quality care and patient safety, appropriate steps will be taken to prevent the occurrence of these events. The purpose of this policy is to provide a procedure to identify, investigate and manage Serious Reportable Events as reportable to Trinity Health (SRE), Sentinel Events as defined by The Joint Commission and Indiana Medical Error Reporting System (Indiana State Department of Health), as well as near misses and unexpected outcomes. This policy provides the procedure in place for the management of these events.

3. Attention will be focused on understanding the factors that contributed to the event as well as changing the hospital’s culture, systems and processes to reduce the probability of such an event in the future.

**PROCEDURE:**

A. All parties involved in the identification and reporting processes and activities will exercise confidentiality.

B. When a SJRMC associate or Medical Staff member becomes aware of an event, they will notify the Department Director or Supervisor. If Department Director /Supervisor are unavailable, a voicemail may be left and the Administrative Supervisor must be notified.

C. When an reportable event occurs the following should happen:

1) Take action to protect patients and to prevent similar events from occurring
2) Sequester any medical equipment or records necessary to conduct an investigation
3) Notify the Department Director/Supervisor or Administrative Supervisor (if not already aware)
4) The Administrative Supervisor will Notify the Administrator On-Call
5) The Administrator On-Call will determine if the COO/CMO/CNO and the Risk Manager/Patient Safety Officer or others need to be notified
6) A VOICE incident report or MIDAS incident report must be completed.

D. Within 24 hours the Department Director and Senior Leadership will conduct an initial investigation to determine if the event meets the definition of a Reportable Event. This team may include:

1) Risk Manager/Patient Safety Officer
2) Department Director/Manager
3) Director of Performance Improvement

Expiration Date: 01/31/2025
Title: Serious Reportable Events, Sentinel Events & Indiana Medical Errors

4) The designee of any of the above.
5) If necessary, other people with relevant functional expertise, i.e. Pharmacy, Lab or Radiology
6) President of Medical Staff
7) General Counsel
8) Chief Nurse Officer
9) Chief Medical Officer
10) Vice President of Medical Affairs
11) President

E. Trinity Health Reportable Events
1) Serious Reportable Events:
   a) The Risk Manager or designee will submit a report to the Trinity Home Office within five (5) business days of discovery thru STARS. Events that result in death or permanent harm should be reported in STARS immediately but no later than one (1) business day after the discovery of the event.
   b) When a RHM reports a SRE to Trinity Home Office that results in death or permanent harm the RHM CEO will call either the Executive Vice-President Chief Clinical Officer, or the Senior Vice President Chief Quality and Patient Safety or the Senior Vice President System Chief Nursing Officer no later than one (1) business day after discovery of the Event. When the CEO is unavailable to place the call, the executive next in line shall make the call. The CEO/RHM executive will be expected to discuss the facts of the event, investigation conducted to date, status of the Root Cause Analysis (RCA), risk manager involvement, status of disclosure to patient and/or family, staff support provided, 3rd party inquiry (i.e. press, local government authorities) and any response or needs the RHM may have related to the event. Questions about whether an event should be called to the EVP or SVP can be directed to a Loss Control Director in Insurance and Risk Management Services.

2) Adverse Clinical Events:
   a) It is an unexpected adverse clinical event that does not meet the definition of a Serious Reportable Event. The RHM CEO will call either the Executive Vice President Chief Clinical Officer, or the Senior Vice President Chief Quality and Patient Safety, or the Senior Vice President System Chief Nursing Officer no later than one (1) business day after discovery of an adverse clinical event when that event,
      (1) Results in death or permanent harm or
      (2) Could reasonably be expected to lead to reputational harm or
      (3) Could reasonably be expected to result in a review by a licensing or accrediting agency or
      (4) Requires securing non Trinity Health resources for advice, or consultation during the investigation state.
      (5) Could reasonably affect multiple patients
Title: Serious Reportable Events, Sentinel Events & Indiana Medical Errors

b) When the CEO is unavailable to place the call, the RHM executive next in line shall make the call. The CEO/RHM executive will be expected to discuss the facts of the event, investigation conducted to date, status of the RCA, risk manager involvement, status to patient and/or family, staff support provided, 3rd party inquiry (i.e. press, local government authorities), and any response, could reasonably affect multiple patients, and any needs the RHM may have related to the event.

F. ISDH procedure for reporting a reportable event is as follows:

1) The report shall:
   a) Be made to the Indiana State Department of Health
   b) Be submitted not later than 15 working days after the reportable event is determined to have occurred by the hospital
   c) Be submitted not later than 4 months after the potential reportable event is brought to the hospital's attention; and
   d) Identify the reportable event, the quarter of the occurrence, and the hospital, but shall not include any identifying information for any patient, for any licensed individual or any hospital employee involved, or any other information.

2) A potential reportable event may be identified by a hospital that:
   a) Receives a patient as a transfer, or
   b) Admits a patient subsequent to discharge, from another health care facility subject to a reportable requirement. In the event that a hospital identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying hospital shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility.

3) The report, and any documents permitted under this section to accompany the report, shall be submitted electronically to the Indiana State Department of Health.

G. The Joint Commission requirements for reporting:

1) Self-reporting of a sentinel event (SE) to the Joint Commission is not required. However, the expectation is to identify and respond appropriately to all sentinel events. A thorough and credible comprehensive systematic analysis and action plan is to be completed within 45 business days of the event or of becoming aware of the event. This includes a timely, thorough, and credible root cause analysis; developing an action plan to implement improvement to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements. Under the direction of Trinity Health, we do not report to TJC.

H. Root Cause Analysis (RCA) will be conducted for each SRE, SE and Indiana Medical Error as required.

1) A RCA team, including SJRMC associates and/or medical staff members involved in the event will be organized by the Risk Management/PI department to investigate identified events. The team will include associates at all levels closest to the issue and also those with decision-making authority. The team will clearly define the issues and be responsible for finding an opportunity for improvement.
Title: Serious Reportable Events, Sentinel Events & Indiana Medical Errors

2) If the event is a fall, a fall huddle form may replace the RCA unless the fall results in death or permanent loss of function as a direct result of the injuries sustained.

3) The RHM will complete a Root Cause Analysis (RCA) within three (3) weeks of discovery as required by Trinity Health. RCA for events that result in death or permanent harm should commence immediately or within 3 business days after discovery.

4) All Hospital acquired Stage 3, 4 and unstageable pressure ulcers require an intensive review. Discussions about the need for an RCA should be done in collaboration with the wound care specialist and the Risk Manager. The intensive review or RCA will be reported to the System Office within (3) weeks of discovery.

5) The RCA team will develop a corrective action plan which includes; action to be taken, implementation of the action plan and development of education to implement the action plan.

REALTED DOCUMENTS/INFORMATION:
- List of Reportable Events (attached above- Attachment A)

Definitions:
- Sentinel Event: A patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches the patient and results in any of the following:
  - Death, permanent harm or severe temporary harm. A listing of TJC Sentinel Events are in attachment A
- TJC - An adverse event is a patient safety event that resulted in harm to a patient
- TJC - A no-harm event is a patient safety event that reaches the patient but does not cause harm
- TJC - A close call (or "near miss" or "good catch") is a patient safety event that did not reach the patient
- TJC - A hazardous (or "unsafe") condition(s) is a circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.
- SRE’s (see attachment A link at top of document (paperclip)
- Root Cause Analysis (RCA): A process for identifying the most basic or causal factors that underlies variation in performance including the occurrence of a reportable event or near miss. The root cause analysis identifies potential improvements that could be made in systems and processes that would improve the level of performance and reduce further risk.
- Permanent Harm: A serious reportable event resulting in harm with no expected change in clinical condition; includes events resulting in permanent loss of organ, limb, physiologic or neurologic function
- Severe Temporary Harm: Critical potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.

Expiration Date: 01/31/2025
Title: Serious Reportable Events, Sentinel Events & Indiana Medical Errors

- Adverse Clinical Event is defined and listed as an event that would require a call to a System Office Senior Leader
  - Results in death or permanent harm or
  - Could reasonably be expected to lead to reputational harm or
  - Could reasonably be expected to result in a review by a licensing or accrediting agency or
  - Requires securing non Trinity Health resources for advice, or consultation during the investigation
  - Could reasonably affect multiple patients

References:
- Indiana Medical Error Reporting System
- The Joint Commission Sentinel Events Chapter
- Trinity SRE Policy
6. Health Information Management (Medical Records)

   a. Medical Records Completion Policy
   b. Medical Records – R&R Excerpt
   c. Abbreviations Policy
Title: Medical Records Completion

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Printed copies are for reference only. Please refer to the electronic copy for the latest version.

POLICY:

1. Electronic records are available at all times. Practitioners are expected to complete all records on an ongoing basis as defined by Joint Commission and CMS. Suspension for timely completion of medical records is deemed to be a non-clinical, administrative action.

   A. SUSPENSION OF MEMBERSHIP AND PRIVILEGES

      1) Health Information Management (HIM) Department will notify practitioners in writing and simultaneous phone call when records have aged to 14 days post discharge/disposition and include the suspension date. HIM will review records on a weekly basis.

      2) The 21 day notice will inform the practitioner that their records are delinquent. The practitioner will complete all delinquent records or their membership and privileges will be automatically relinquished (temporary suspension).

      3) If suspended, NO new admissions, surgeries or other elective procedures will be allowed after the date the physician’s clinical privileges have been suspended. Practitioners currently treating inpatients or have scheduled procedures/surgeries will be allowed to continue attending those patients until they are discharged.

      4) No reappointment will be made for any medical staff member or allied health provider with an outstanding balance owed.

      5) Medical Staff Office will notify practitioner and the appropriate medical staff departments that membership and clinical privileges are suspended immediately.

   B. TO REGAIN MEMBERSHIP AND PRIVILEGES AFTER AUTOMATIC RELINQUISHMENT

      1) The practitioner is required to: Complete all delinquent medical records and payment of reinstatement fee of $200.

      2) Upon completion of all delinquent records and upon receipt of a payment, the Health Information Management Department will notify the appropriate Medical Center departments that membership and clinical privileges are reinstated immediately.

      3) Requests for exceptions to the policy must be made in writing to the President of the Medical Staff. The Chief Medical Officer and Medical Staff Officers will review all requests for an exception. All delinquent records must be completed prior to the review. The Chief Medical Officer and Medical Staff Officers will grant exceptions to the policy on a “case-by-case” basis.

DEFINITIONS

Delinquency targets are defined as:
Title: Medical Records Completion

<table>
<thead>
<tr>
<th>Documents to be Completed by:</th>
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<tbody>
<tr>
<td>1. Charts to be complete within 21 days post discharge. (Everything must be completed and signed.) HIM will send written notice when records have aged to 14 days post discharge/disposition.</td>
</tr>
<tr>
<td>2. An operative report needs to be dictated or completed within 24 hours of the procedure. Dictation to be signed within 14 days of procedure.</td>
</tr>
<tr>
<td>3. Queries, while inpatient or after discharge, need to be responded to within 7 days of query.</td>
</tr>
<tr>
<td>4. Discharge summary dictation completed within (14 days Mishawaka), (24 hours Plymouth) after discharge with signature to be completed within 21 days post discharge.</td>
</tr>
<tr>
<td>5. Consultations are to be entered/dictated within 24 hours of notification of request for consultation. Dictations are to be signed within 14 days of dictation.</td>
</tr>
<tr>
<td>6. Emergency Room Dictation to be completed within 24 hours of disposition with signatures to be completed within 21 days of disposition.</td>
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</tbody>
</table>

References/Standards:
- Policy Origin Date: November 1998 (M)
- Review Date: December 2009 (M), December 2012 (M), December 2015 (M), February 2016 (P), December 2018 (M), March 2019 (M & P), November 2021 (P), December 2021 (M)
- Revised Date: September 2008 (M), December 2014 (M&P), March 2019 (M), May 2019 (P), June 2019 (M)
- Effective Date: March 2000 (M)
- Reviewed/Recommended By: Medical Executive Committee
Title: Abbreviations Policy

Policy:
1. To ensure that all abbreviations and symbols used in patient records are standardized and approved for patient safety.
2. Abbreviations that are defined in Trinity’s Health Abbreviation List may be used on patient medical records. For those abbreviations in which there are more than one use is listed, the context of the entry will reflect the designated use (i.e. BE used in a Radiology related entry would indicate Barium Enema and BE used in Blood Gas Report would be referring to Base excess).

Procedure:
Individuals who work at SJHS may use any abbreviations, acronyms, symbols and dose designations if:

A. Listed in the Trinity Health Services Approved Abbreviations: [http://tdd.trinity-health.org/tdd/](http://tdd.trinity-health.org/tdd/)
B. Noted in a “key” on an approved form.
C. Listed on the Periodic Table
D. For printed forms, any abbreviations must be spelled out the first time used, or must be listed in a key on the form.
E. Abbreviations cannot be used on consent forms.

Do Not Use abbreviations deemed “dangerous” and subject to miscommunication per Joint Commission, may not be used. See Do Not Use Abbreviations List below.

The following table shows abbreviations that must never be used.

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<tr>
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<tr>
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<td>unit</td>
</tr>
<tr>
<td>IU</td>
<td>international unit</td>
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# Abbreviations Policy

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<tr>
<td>Q.D., QD, q.d., qd</td>
<td>daily or every day</td>
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<tr>
<td>Q.O.D., QOD, q.o.d., qod</td>
<td>every other day</td>
</tr>
<tr>
<td>Trailing zero (X.0mg)</td>
<td>Never write a zero by itself after a decimal point, i.e. 5mg</td>
</tr>
<tr>
<td>Lack of leading zero (.X mg)</td>
<td>Always use a zero before a decimal point, i.e. 0.5mg</td>
</tr>
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<td>MS, MSO₄</td>
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</tr>
<tr>
<td>MgSO₄</td>
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* Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on pre-printed forms.

*Exception:* A “trailing zero” may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.

**Development of the “Do Not Use” List**

In 2001, The Joint Commission issued a *Sentinel Event Alert* on the subject of medical abbreviations. A year later, its Board of Commissioners approved a National Patient Safety Goal requiring accredited organizations to develop and implement a list of abbreviations not to use. In 2004, The Joint Commission created its “Do Not Use” List to meet that goal. In 2010, NPSG.02.02.01 was integrated into the Information Management standards as elements of performance 2 and 3 under IM.02.02.01

**References/Standards: 6/19**

- TJC IM 02.02.01

Expiration Date: 04/26/2024
7. COVID Website (Trinity)
Welcome to Trinity Health's site for COVID-19 and Seasonal Respiratory Viruses Resources.

What would you like to do?

- COVID-19 Vaccine Updates
- PPE & Safety Information
- Colleague Care
8. Infection Control
   
   a. Infection Control Program Policy
   b. Hand Hygiene Policy
   c. Personal Protective Equipment Policy
**Title:** INFECTION CONTROL PROGRAM

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<tr>
<th>Document Owner: Kring, Karen</th>
<th>PI Team: Infection Prevention</th>
<th>Date Created:</th>
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<th>Approver(s): Karam, Christopher; Schmidt, Loretta</th>
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<th>Location: Saint Joseph Regional Medical Center (SJRMCS)</th>
<th>Department: Infection Control &amp; Prevention</th>
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*Printed copies are for reference only. Please refer to the electronic copy for the latest version.*

**POLICY:**

1. The Saint Joseph Regional Medical Center Mishawaka Infection Control Program is established through collaboration and cooperation of the Medical Staff, Hospital Administration, Infection Prevention Department, all other hospital departments and personnel, the Environment of Care Committee, and all other hospital committees. The program is fluid, evolving to incorporate requirements of relevant government agencies, such as Occupational Safety and Health Administration (OSHA) and Centers for Medicare and Medicaid Services (CMS), and the Indiana State mandatory reporting activities; requirements of accrediting organizations, such as the Joint Commission (TJC) and Commission on Accreditation of Rehabilitation Facilities (CARF); and also of professional organizations and federal agencies, such as the Association for Professionals in Infection Control and Epidemiology (APIC), Society for Healthcare Epidemiology of America (SHEA), and Centers for Disease Control and Prevention (CDC).

2. The purpose of the Saint Joseph Regional Medical Center Infection Control Program is to develop, implement and evaluate effective measures to prevent infection, identify existing infections and to appropriately manage them so as to prevent their spread. The rationale for the program is based on the belief and fact that infections acquired in the hospital, or brought into the hospital from the community, are potential hazards for all persons having contact with the hospital. Therefore, the scope of the program includes patients, staff, and visitors.

**PROCEDURE:**

A. Defining Hospital Acquired Infections:

1) To provide for early uniform identification and reporting of infections.

2) To determine pertinent infection rates.

B. Developing a practical system for reporting, evaluating, and maintaining records of infections among patients and personnel:

1) To assign specific responsibility for the collection and analysis of such data.

2) To assign specific responsibility for required follow-up action.

C. Reviewing and evaluating all aseptic, isolation, and sanitation techniques performed in the Medical Center.

1) To assign specific responsibility for writing such policies and procedures.

2) To assign specific responsibility for reviewing patient policies and procedures.

D. Defining patient medical conditions requiring isolation:

1) To insure quality of care for isolated patients.

E. Developing practical surveillance activities related to the Medical Center environment:

1) To include practices related to sterilization, disinfection, food sanitation, and waste management.
Title: INFECTION CONTROL PROGRAM

F. Providing for laboratory support to making microbiological and serological determinations:
   1) To aid in identifying infections of patients and personnel
   2) To aid in identifying environmental reservoirs of disease-causing microbes
   3) To interpret significance of positive reports

G. Relating appropriate findings and recommendations to the Medical Center Employee Health Program.

H. Assisting in the development of education programs:
   1) To acquaint each employee with the existence of the hospital-wide Infection Control Program.
   2) To assure each employee’s appropriate involvement in the program.
   3) To encourage practices for documenting all education programs.

I. Coordinating with the Medical Staff for development of activities related to the clinical use of antibiotics:
   1) To utilize the antibiotic susceptibility/resistance trend studies.
   2) To assist the Medical Staff in any monitoring activities related to antibiotic utilization.

J. Developing mechanism for reviewing and revising all written policies and procedures related to the
   Hospital-wide Infection Control Program:
   1) To provide overall policies to guide the development of departmental policies.
   2) To provide expert evaluation of effectiveness of overall Infection Prevention Program and
      departmental policies and procedures.

K. Infection Prevention Committee:
   1) The Infection Prevention Committee shall include representatives of the appropriate clinical support
      services, and the Medical Staff.

L. The duties and functions of this committee shall be:
   1) To investigate the causes of infection.
   2) To institute preventive measures and establish control to assure that clean and aseptic techniques are
      practiced throughout Saint Joseph Regional Medical Center.
   3) To review practices and ascertain that aseptic procedures are being followed.

M. The committee shall meet
   1) Regularly

N. Written minutes of meetings are submitted through the Performance Improvement Structure to the
   Committees of the Medical Staff, and Administration.

O. Authority:
   1) The Medical Staff and Medical Center Administration vest authority for the committee’s functions
      through the committee chairman. Every three years the authority statement is reviewed and signed by
      the appropriate representative Medical Center Administration.
   2) Policies and clinical decisions shall be made by the committee only when an appropriate physician
      member is present.
   3) Reports: Through the Performance Improvement Structure to the Committees of the Medical Staff,
      and the Medical Center Administration.

P. Appointments: Executive Vice President, Medical Staff members are appointed with the approval of the
   President, SJRMC Medical Staff.

Q. Specific Responsibilities: The Infection Prevention Committee.
   1) Authorizing special studies for investigating, preventing and controlling, when possible, all infection
      at Saint Joseph Regional Medical Center, according to standards of Infection Prevention.
Title: INFECTION CONTROL PROGRAM

2) Review and make recommendations, when indicated, for all departments’ infection prevention policies and procedures.
3) Establishing guidelines for patient placement.
4) Monitor suspected or diagnosed infection in patients and staff.
5) Monitoring environmental systems of waste disposal and pest control.
6) Cooperating and providing input to other committees responsible for evaluation of patient care and/or employee continuing education.
7) Reviewing patient charts and recommending follow-up action to appropriate departments or persons when indicated.
8) Determine type of surveillance and reporting programs to be used based on risk assessment needs of patients and staff.
9) Provide guidelines for reporting infections.
10) Develop overall policies, criteria, and procedure specifications for coordinated implementation of the Infection Prevention Program.
11) Approve all personnel and environmental culturing, as part of epidemiologic investigations, quality monitor, educational training or other purpose deemed appropriate.

R. Specific Responsibilities of Infection Prevention Manager and Coordinator
1) Develop Policies and Procedures necessary to the department:
2) Assists department managers in the development and implementation of patient care and employee health policies and procedures.
3) Refers complex procedure development involving increased capital costs to Infection Prevention Committee.
4) Surveillance:
5) Directs surveillance activities within the Medical Center.
6) Provides consultation to Medical Center personnel in relation to identifying and managing infectious diseases.
7) Investigating clusters of infection above expected levels.
8) Single cases of unusual hospital acquired infections.
9) Monitors post-discharge surgical site infections through physician feedback, re-admission checks, and feedback from area-hospital Infection Prevention Practitioners.
10) Reports required infections to Indiana State Board of Health.
11) Provides Infection Control Committee with written reports, including analysis of Hospital Acquired Infections and summary of surveillance and monitoring activities.
12) Maintains reports as required by the Infection Control Committee.
13) Provides department managers with findings and recommendations resulting from surveillance activities.
14) Education:
15) Assists in the development of educational programs on Infection Prevention
16) Monitors with appropriate individuals the effectiveness of general orientation programs and departmental orientation programs related to Infection Prevention.

S. Infection Prevention Manager and Coordinator Patient Protocols: The Infection Prevention Manager and Coordinators are authorized to initiate protocols both verbally with associates and LIPs and written via the EMR in order to clarify and assure compliance with hospital policy as
Title: INFECTION CONTROL PROGRAM

established by the Infection Prevention Committee. Written and verbal protocols include the following:

1) Initiate and discontinue isolation precautions.
2) Clarification of barrier precautions needed to prevent spread of infection, i.e., frequency of hand washing, glove use, gowns, masks, eye protection, etc.
3) Patient bathing regimes such as daily anti-microbial bath.
4) Culturing to assure compliance with Infection Prevention Policy and Special Studies, which screen patients. This is a Saint Joseph Regional Medical Center cost, not a patient charge.
5) Patient room placement for disease spread by the airborne route.
6) Patient activity restrictions as appropriate to prevent transmission of infection, such as patient must stay in room, or therapies in room.
7) The Infection Prevention Coordinator will not order antibiotic therapy, or culturing for which the patient will be charged.
8) Education:
   a) Provides for the education of departmental personnel, utilizing the resources of the Infection Prevention Department and/or the Infection Prevention Committee.
   b) Surveillance:
   9) Ensures compliance with policy and procedures.
      a) Initiates appropriate reports when infection is identified or when an environmental breakdown occurs that has the potential for causing infection in patients or personnel.
      b) Cooperates with surveillance activities of Infection Control Coordinator.
      c) Establishes Infection Control attributes for the Performance Improvement Program.
      d) Acts on recommendations made by departmental staff, Infection Prevention Committee, and by Performance Improvement evaluators.

T. Responsibility to Infection Control Coordinator. The department manager should consult with the Infection Control Coordinator:
1) Develop appropriate departmental policies and procedures.
2) Develop, implement and evaluate orientation and continuing education programs related to Infection Control.
3) Identify potential Infection Control hazards within the department.
4) Monitor reported infections in patients and/or personnel.

U. Responsibility to Infection Prevention Committee:
1) Submits departmental policies and procedures and evidence of review to the Infection Prevention Committee based on the guidelines and format provided by the Infection Prevention Committee.
2) Cooperates with the Infection Prevention Committee on any recommendations to improve policies and procedures, to conduct studies within the department, and to identify Infection Control hazards or problems.

V. Identification Process of Infections – Patients:
1) Laboratory responsibility:
Title: INFECTION CONTROL PROGRAM

a) Maintains complete and accessible laboratory records to facilitate epidemiological investigations and quality control activities. These records include data that indicates emergence of highly infectious pathogens, multi-resistant organisms and clusters of unusual infections.

b) Cooperates with sampling procedures, as recommended by the Infection Prevention Committee, to identify potential sources of infection within the environment.

c) Sends a copy of cultures and other appropriate reports to the Infection Prevention Coordinator.

2) Nursing unit responsibility:

a) Highest standard of care for all patients regardless of known diagnosis. Standard Precautions for all patients and initiates Transmission Based Precaution Isolation as indicated.

b) Refers reportable communicable disease to the Infection Prevention Coordinator.

3) Infection Prevention Coordinator:

a) Utilizing the reports received from nursing units and physicians on suspected infections, culture reports from the laboratory, and patient admission diagnosis of infection, the Infection Prevention Coordinator assists in overseeing the management of all patients with suspected and confirmed infection diagnosis.

b) Generates the appropriate reporting mechanisms to the Infection Control Committee and/or to the chairman of the Infection Control Committee and the local Public Health Department and Environment of Care Committee.

W. Identification Process of Infections – Employees:

1) Employee responsibility:

a) Recognizes symptoms in self of infection and reports such infection to manager prior to undertaking work assignments. This is especially important if the employee’s assignment involves direct patient care.

b) Report to manager or supervisor any breaks in technique or injuries that exposed him/her to potential infection or contact with individual known to have communicable disease except in controlled situations, such as isolation precautions, or when the employee is immunized.

c) Use precautions at all times when dealing with patient’s secretions, excretions, and blood to prevent any possible exposures. (see Infection Control Standard Precautions).

d) Use good hygienic practices at all times to protect both patients and other personnel from minor or unapparent infections.

2) Managers responsibility:

a) Familiarizes self with the employee health program and utilizes the resources of the Employee Health Service and/or Infection Prevention Coordinator

b) When an employee with infectious symptoms has been counseled by the Employee Health Nurse and/or Infection Control Coordinator on how to prevent the transmission of their disease, it is the manager’s responsibility to monitor that employee and ensure compliance with the instructions given to the employee.

c) Recognizes the need to treat confidential information about an employee’s health status with the strictest confidentiality. While recognizing the need for strict
Title: INFECTION CONTROL PROGRAM

confidentiality, the manager retains the right to consult the Employee Health Nurse and/or Infection Prevention Coordinator per his/her discretion.

3) Infection Control Coordinator responsibility:
   a) Upon reports from employee or managers that infectious symptoms are present, the Infection Control Coordinator institutes protocols as designated in the Employee Health Program.
   b) Seeks, in cooperation with Employee Health, and screens employees who might have been unknowingly exposed to infectious conditions.
   c) Information about an employee’s health status will be treated with strict confidentiality. Violation of the confidentiality may result in disciplinary action.

X. Reports and records:

1) Targeted surveillance will be reviewed and objectives established annually by the Infection Control Committee. All Infection Control Committee members are given a copy of the Targeted Surveillance Reports. A copy is maintained with each set of minutes, and a copy is maintained by the Infection Control Coordinator.
   a) Infection Surveillance Guidelines Used To Determine Infections: CDC definitions for Hospital Acquired infections are adopted for use by the Infection Prevention Committee.
   b) To determine the Hospital Acquired Infection rate and monitor infections occurring in Saint Joseph Regional Medical Center
      (1) To identify, establish, and document hospital acquired infection levels:
      (2) To detect clusters of hospital acquired infections.
      (3) To detect sporadic outbreaks caused by resistant and/or unusual organisms.
      (4) To initiate proposals for Infection Prevention policy and procedure changes and/or associates education as necessary to improve patient care and employee safety. Coordinator to appropriately seek treatment or guidance for the employee with infectious symptoms.

Definitions:
- See definitions as per CDC

References/Standards:
- CDC Guideline http://www.cdc.gov/
- http://www.apic.org/AM/Template.cfm?Section=Practice
- http://www.in.gov/isdh/
- http://www.jointcommission.org/
**Title:** HAND HYGIENE

**Policy:**

1. CDC Guidelines for Hand Hygiene in the Healthcare Setting will improve the hand hygiene practices of healthcare workers and reduce the transmission of pathogenic microorganisms to patients and personnel in healthcare settings.

2. The intention of this policy is to provide a guideline for consistent hand hygiene using the CDC guideline for evidence based practice. Please refer to dietary policies for hand washing in dietary and surgical policies for hand washing in Surgery.

**Procedure:**

A. Wash hands with soap and water when hands are visibly soiled
   1) Wet hands first with warm water
   2) Apply 3-5 mls of soap to palm of one hand
   3) Rub hands together vigorously for 15 seconds
   4) Cover all surfaces of hands and fingers paying special attention to nails
   5) Rinse hands well and dry thoroughly with disposable paper towel
   6) Use paper towel to turn off the faucet
   7) Apply hospital approved hand lotion as needed.

B. Decontaminate hands with the hospital approved alcohol-based waterless antiseptic agent when hands are NOT visibly soiled.
   1) Apply product to the palm of one hand
   2) Rub hands together covering all surfaces of hands and fingers
   3) An adequate amount of product should take 15-25 seconds until dry
   4) Indications for hand hygiene:
   5) After contact with a patients intact skin (taking pulse, B/P etc.)
   6) Prior to entering a patient’s room.
   7) After contact with blood or body fluids, excretions, mucous membranes, non-intact skin, wound dressings, as long as hands are NOT visibly soiled
   8) If moving from a contaminated body site to a clean site during patient care
   9) Before caring for patients with severe neutropenia or other forms of immune suppression
   10) After contact with inanimate objects in the immediate vicinity of the patient (i.e. medical equipment)
Title: HAND HYGIENE

11) Before donning sterile gloves for non-surgical procedures
12) Before inserting foley catheters or other invasive procedures that are non-surgical
13) After removing gloves
14) After smoking, sneezing, or coughing

C. Indications for hand washing: Wash hands with soap and water:
1) Before eating
2) After toileting
3) If you work in food service and you must wash for 20 seconds
4) If your hands are dirty or have been visibly soiled with blood or body fluids or other proteinaceous material
5) When caring for patients with C-diff do not use hand sanitizer. Use soap and water only.

D. Additional hand hygiene practices:
1) Do not wear artificial nails, gels, wraps, etc. when working in Direct Patient Care areas
2) Keep natural nails less than ¼ inch long when working in Direct Patient Care areas
3) Change gloves during patient care when moving from a contaminated site to a clean body site
4) Wear gloves when it can be reasonably anticipated that contact with blood or other potentially infectious material, mucous membranes, or non-intact skin will occur
5) Do not wear the same pair of gloves to care for more than one patient
6) Report to Employee Health Services with any hand rashes, irritation, cuts or open areas

E. In cases where there is a Clostridium Difficile (C Diff) infection, performing hand hygiene with soap and water is recommended. Hand washing will be the policy at SJRMС in working with patients that have a C-Diff infection.

References/Standards:
- Infection Control and Hospital Epidemiology; “Effectiveness of Alcohol-Based Hand Rubs for Removal of Clostridium Difficile Spores from Hands”. June 2010, Vol. 31, No. 6.
- CR Guideline for Hand Hygiene in Health-Care Settings MMWR October 25, 2002/Vol. 51. No. RR-16
Policy: Personal Protection Equipment

Document Owner: Alonzo Richmond
PI Team: Environment of Care
Date Created: 08/03/2022

Approver(s): Samuel Alcala
Date Reviewed:
Date Approved: 08/03/2022

Location: Saint Joseph Regional Medical Center (SJRMC)
Department: Plant Operations
(14030_76900)

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Policy:
1. All maintenance staff must use personal protective equipment when performing daily work tasks. Gloves, goggles, face shields, ear protection, respiratory and other equipment as required by OSHA and the task being performed. All equipment will be used according to OSHA requirements and manufactures instructions.

A. Types of Eye Protection

Selecting the most suitable eye and face protection for employees should take into consideration the following elements:

- Ability to protect against specific workplace hazards.
- Should fit properly and be reasonably comfortable to wear.
- Should provide unrestricted vision and movement.
- Should be durable and cleanable.
- Should allow unrestricted functioning of any other required PPE.

The eye and face protection selected for employee use must clearly identify the manufacturer. Any new eye and face protective devices must comply with ANSI Z87.1-1989 or be at least as effective as this standard requires. Any equipment purchased before this requirement took effect on July 5, 1994, must comply with the earlier ANSI Standard (ANSI Z87.1-1968) or be shown to be equally effective.

An employer may choose to provide one pair of protective eyewear for each position rather than individual eyewear for each employee. If this is the case, the employer must make sure that employees disinfect shared protective eyewear after each use. Protective eyewear with corrective lenses may only be used by the employee for whom the corrective prescription was issued and may not be shared among employees.

Some of the most common types of eye and face protection include the following:

- Safety spectacles - These protective eyeglasses have safety frames constructed of metal or plastic and impact-resistant lenses. Side shields are available on some models.
- Goggles - These tight-fitting eye protections completely cover the eyes, eye sockets and the facial area immediately surrounding the eyes and provide protection from impact, dust and splashes. Some goggles will fit over corrective lenses.
Title: Personal Protection Equipment

- **Face shield** - These transparent sheets of plastic extend from the eyebrows to below the chin and across the entire width of the employee's head. Some are polarized for glare protection. Face shields protect against nuisance dusts and potential splashes or sprays of hazardous liquids but will not provide adequate protection against impact hazards. Face shields used in combination with goggles or safety spectacles will provide additional protection against impact hazards.

Each type of protective eyewear is designed to protect against specific hazards. Employers can identify the specific workplace hazards that threaten employees' eyes and faces by completing a hazard assessment as outlined in the earlier section.

**B. Types of Protective Gloves**

There are many types of gloves available today to protect against a wide variety of hazards. The nature of the hazard and the operation involved will affect the selection of gloves. The variety of potential occupational hand injuries makes selecting the right pair of gloves challenging. It is essential that employees use gloves specifically designed for the hazards and tasks found in their workplace because gloves designed for one function may not protect against a different function even though they may appear to be an appropriate protective device.

The following are examples of some factors that may influence the selection of protective gloves for a workplace.

- Type of chemicals handled.
- Nature of contact (total immersion, splash, etc.).
- Duration of contact.
- Area requiring protection (hand only, forearm, arm).
- Grip requirements (dry, wet, oily).
- Thermal protection.
- Size and comfort.
- Abrasion/resistance requirements.

Gloves made from a wide variety of materials are designed for many types of workplace hazards. In general, gloves fall into four groups:

- Gloves made of leather, canvas or metal mesh;
- Fabric and coated fabric gloves;
- Chemical- and liquid-resistant gloves;
- Insulating rubber gloves (See 29 CFR 1910.137 and the following section on electrical protective equipment for detailed requirements on the selection, use and care of insulating rubber gloves).
Leather, Canvas or Metal Mesh Gloves

Sturdy gloves made from metal mesh, leather or canvas provide protection against cuts and bums. Leather or canvass gloves also protect against sustained heat.

- **Leather gloves** protect against sparks, moderate heat, blows, chips and rough objects.
- **Aluminized gloves** provide reflective and insulating protection against heat and require an insert made of synthetic materials to protect against heat and cold.
- **Aramid fiber gloves** protect against heat and cold, are cut - and abrasive - resistant and wear well.
- **Synthetic gloves** of various materials offer protection against heat and cold are cut and abrasive resistant and may withstand some diluted acids. These materials do not stand up against alkalis and solvents.

Fabric and Coated Fabric Gloves

Fabric and coated fabric gloves are made of cotton or other fabric to provide varying degrees of protection.

- **Fabric gloves** protect against dirt, slivers, chafing and abrasions. They do not provide sufficient protection for use with rough, sharp or heavy materials. Adding a plastic coating will strengthen some fabric gloves.
- **Coated fabric gloves** are normally made from cotton flannel with napping on one side. By coating the un-napped side with plastic, fabric gloves are transformed into general-purpose hand protection offering slip-resistant qualities. These gloves are used for tasks ranging from handling bricks and wire to chemical laboratory containers. When selecting gloves to protect against chemical exposure hazards, always check with the manufacturer or review the manufacturer's product literature to determine the gloves' effectiveness against specific workplace chemicals and conditions.

Chemical - and Liquid - Resistant Gloves

Chemical-resistant gloves are made with different kinds of rubber: natural, butyl, neoprene, nitrile and fluorocarbon (Viton); or various kinds of plastic: polyvinyl chloride (PVC), polyvinyl alcohol and polyethylene. These materials can be blended or laminated for better performance. As a general rule, the thicker the glove material, the greater the chemical resistance but thick gloves may impair grip and dexterity, having a negative impact on safety.

Some examples of chemical-resistant gloves include:

- **Butyl gloves** are made of a synthetic rubber and protect against a wide variety of chemicals, such as peroxide, rocket fuels, highly corrosive acids (nitric acid, sulfuric acid, hydrofluoric acid and red-fuming nitric acid), strong bases, alcohols, aldehydes,
**Title: Personal Protection Equipment**

ketones, esters and nitro-compounds. Butyl gloves also resist oxidation, ozone corrosion and abrasion, and remain flexible at low temperatures. Butyl rubber does not perform well with aliphatic and aromatic hydrocarbons and halogenated solvents.

- **Natural (latex) rubber gloves** are comfortable to wear, which makes them a popular general-purpose glove. They feature outstanding tensile strength, elasticity and temperature resistance. In addition to resisting abrasions caused by grinding and polishing, these gloves protect workers' hands from most water solutions of acids, alkalis, salts and ketones. Latex gloves have caused allergic reactions in some individuals and may not be appropriate for all employees. Hypoallergenic gloves, glove liners and powderless gloves are possible alternatives for workers who are allergic to latex gloves.

- **Neoprene gloves** are made of synthetic rubber, offer good pliability, finger dexterity, and high density, and tear resistance. They protect against hydraulic fluids, gasoline, alcohols, organic acids and alkalis. They generally have chemical and wear resistance properties superior to those made of natural rubber.

- **Nitrile gloves** are made of a copolymer and provide protection from chlorinated solvents such as trichloroethylene and perchloroethylene. Although intended for jobs requiring dexterity and sensitivity, nitrile gloves stand up to heavy use even after prolonged exposure to substances that cause other gloves to deteriorate. They offer protection when working with oils, greases, acids, caustics and alcohols but are generally not recommended for use with strong oxidizing agents, aromatic solvents, ketones and acetates.

**Care of Protective Gloves**

Protective gloves should be inspected before each use to ensure that they are not torn, punctured or made ineffective in any way. A visual inspection will help detect cuts or tears but a more thorough inspection by filling the gloves with water and tightly rolling the cuff towards the fingers will help reveal any pinhole leaks. Gloves that are discolored or stiff may also indicate deficiencies caused by excessive use or degradation from chemical exposure.

Any gloves with impaired protective ability should be discarded and replaced. Reuse of chemical-resistant gloves should be evaluated carefully, taking into consideration the absorptive qualities of the gloves. A decision to reuse chemically-exposed gloves should take into consideration the toxicity of the chemicals involved and factors such as duration of exposure, storage and temperature.

**C. Hearing Protection**

Determining the need to provide hearing protection for employees can be challenging. Employee exposure to excessive noise depends upon a number of factors, including:

- The loudness of the noise as measured in decibels (dB).
- The duration of each employee's exposure to the noise.
- Whether employees move between work areas with different noise levels.
- Whether noise is generated from one or multiple sources.
Title: Personal Protection Equipment

Generally, the louder the noise, the shorter the exposure time before hearing protection is required. For instance, employees may be exposed to a noise level of 90 dB for 8 hours per day (unless they experience a Standard Threshold Shift) before hearing protection is required. On the other hand, if the noise level reaches 115 dB hearing protection is required if the anticipated exposure exceeds 15 minutes.

For a more detailed discussion of the requirements for a comprehensive hearing conservation program, see OSHA Publication 3074 (2002), “Hearing Conservation” or refer to the OSHA standard at 29 CFR 1910.95, Occupational Noise Exposure, section (c).

D. Respiratory Protection

All respirators, dust masks and other respiratory equipment will be used as required by OSHA for the task being performed.

PROCEDURE:
A. Use personal protective equipment in accordance with OSHA standards and manufactures instructions.

SITE SPECIFIC:
1. Mishawaka and Plymouth
9. Antimicrobial Stewardship

   a. Antimicrobial Stewardship @ SJHS (overview)
   b. Antimicrobial Processes @ SJHS
WHAT IS ANTIMICROBIAL STEWARDSHIP?
Antimicrobial stewardship is a coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes, reduces microbial resistance, and decreases the spread of infections caused by multidrug-resistant organisms.

WHAT IS ASP?
An antimicrobial stewardship Program (ASP) limits inappropriate and excessive use of antimicrobials while optimizing therapy to improve clinical outcomes for patients.

DOES SJHS HAVE AN ASP PROGRAM?
Yes! SJHS has had an effective ASP program since 2016 and is comprised of an Infectious Disease specialist, doctors, pharmacists, and nurses. They work to optimize antimicrobial care for each individual infected patient at SJHS.

DID YOU KNOW....

As of Jan 1, 2017, the Joint Commission and CMS require all hospitals to have an ASP
- 20-50% all antibiotics prescribed in U.S. are unnecessary or inappropriate
- Antimicrobials increase the risk of side effects such as adverse reactions, selection of pathogenic organisms (CDiff), emergence of resistance
- Estimated 2 million people infected with antibiotic-resistant organisms which equals ~23,000 deaths annually (CDiff adds additional 15,000 more deaths), $20 billion in excess healthcare costs
- Antimicrobials are the only class of drugs with potential for adverse impact on patients not even exposed to them

On Sept 18, 2014, President Obama issued a National Action Plan to implement the National Strategy for Combating Antibiotic-Resistant Bacteria. Its goal is to guide all healthcare in a common effort to address serious drug-resistant threats that affect people in the U.S. and around the world, with a specific target date by the year 2020.

ANTIBIOTIC STEWARDSHIP IN YOUR FACILITY WILL
DECREASE
- Antibiotic Resistance
- C. Difficile Infections
- Costs
INCREASE
- Good Patient Outcomes
What does the Antimicrobial Stewardship Program (ASP) at St Joseph Health System (SJHS), Mishawaka/Plymouth, currently look like?

ONGOING INITIATIVES

- Pharmacist review of antimicrobials with recommendations for new agents if needed, and de-escalation of others (narrowing antibiotic therapy to cover only a small number of specific organisms as opposed to broad coverage of multiple organisms)
- Pharmacist automatic IV to PO switch for those patients meeting criteria (helps patients transition out of the hospital on oral meds and saves money on drug and administration costs)
- Automatic pharmacist utilization of dose optimization for certain antibiotics (e.g., extended infusion Merrem/Zosyn, altered dosing schedules of cefazolin and cefepime) to enhance killing power of the antibiotic, reduce side effects, decrease costs
- NAAT testing with the SBMF (rapid blood culture reporting of resistance mechanisms and identified organisms) to help identify organisms quicker, allowing for more appropriate targeted antimicrobial therapy up to 24-48hr quicker
- Automatic pharmacist renal dose adjustment of antimicrobials to reduce toxicities of over-dosing medications in patients with renal insufficiency
- Pharmacist education and oversight on the utilization of the broad-spectrum class carbapenems (Merrem, Invanz) to decrease side effects of overusing this antibiotic, and keeping its use as a viable option when resistant organisms are present. See graph below on the success both Mishawaka and Plymouth Hospitals have had in the reduction of Merrem usage.

![Merrem Usage at SJHS, Mishawaka](image1)

![Merrem Usage at SJHS, Plymouth](image2)
6. Patient Safety Policies

   a. The Joint Commission National Patient Safety Standards 2024
   b. Abuse and Neglect Policy
   c. Patient Safety Evaluation System (PSES) Policy
   d. Patient’s Rights and Responsibility Policy
   e. Advance Directives Policy
   f. Clinical Conflict Resolution Policy
   g. Fall Risk Assessment & Prevention Policy
   h. Pain Management Policy
   i. Restraints and Seclusion Policy
   j. Suicide/Mental Health Precautions Policy
   k. Universal Protocol for Preventing Wrong, Site, Wrong Procedure, & Wrong Person Surgery Policy
   l. Diabetes
      i. Diabetes Education Center
      ii. Diabetes Education Referral Form
      iii. 2023 Standards
SJHS Quality and Safety (click on link to the left)

The vision of Saint Joseph Health System is to be the leader in providing quality care to our community creating an atmosphere of clinical and service excellence in the care experience. A continuous focus on improvement of our systems and processes is dependent on open communication with the health care team, patients, and our community.

SJHS regularly measures patient satisfaction and compares it to other hospitals and national standards as we continue to make improvements. There are customer cards located in all of our waiting rooms, and we encourage you to provide feedback about your care and service.

If you identify quality or safety concerns, please notify us in order that we can resolve the issue in the best interest of patient safety. If you do not feel your concern or issue was resolved, please allow administration an opportunity to address your concern. If we do not address your concern in a satisfactory manner, you are encouraged to notify The Joint Commission, 800.994.6610 or e-mail complaint@jointcommission.org.

Mishawaka Medical Center

A customer service representative will check on all inpatients and their families. This is an excellent opportunity to voice any concerns or needs. Should you need assistance, call Administration at 574.335.2456 and your concern will be addressed.

Plymouth Medical Center

A customer service representative will check on all inpatients and their families. This is an excellent opportunity to voice any concerns or needs. Should you need assistance, call Administration at 574.335.2456 and your concern will be addressed.
## 2024 Hospital National Patient Safety Goals

### Identify patients correctly
- **NPSG.01.01.01**
  - Use at least two ways to identify patients. For example, use the patient’s name and date of birth. This is done to make sure that each patient gets the correct medicine and treatment.

### Improve staff communication
- **NPSG.02.03.01**
  - Get important test results to the right staff person on time.

### Use medicines safely
- **NPSG.03.04.01**
  - Before a procedure, label medicines that are not labeled. For example, medicines in syringes, cups and basins. Do this in the area where medicines and supplies are set up.
- **NPSG.03.05.01**
  - Take extra care with patients who take medicines to thin their blood.
- **NPSG.03.06.01**
  - Record and pass along correct information about a patient’s medicines. Find out what medicines the patient is taking. Compare those medicines to new medicines given to the patient. Give the patient written information about the medicines they need to take. Tell the patient it is important to bring their up-to-date list of medicines every time they visit a doctor.

### Use alarms safely
- **NPSG.06.01.01**
  - Make improvements to ensure that alarms on medical equipment are heard and responded to on time.

### Prevent infection
- **NPSG.07.01.01**
  - Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning.

### Identify patient safety risks
- **NPSG.15.01.01**
  - Reduce the risk for suicide.

### Improve health care equity
- **NPSG.16.01.01**
  - Improving health care equity is a quality and patient safety priority. For example, health care disparities in the patient population are identified and a written plan describes ways to improve health care equity.

### Prevent mistakes in surgery
- **UP01.01.01**
  - Make sure that the correct surgery is done on the correct patient and at the correct place on the patient’s body.
- **UP01.02.01**
  - Mark the correct place on the patient’s body where the surgery is to be done.
- **UP01.03.01**
  - Pause before the surgery to make sure that a mistake is not being made.
Title: Abuse and Neglect and Violent Crime Policy

POLICY:
1. Victims of abuse or neglect may come to a hospital through a variety of channels. The patient may be reluctant or unable to speak of the abuse. It may not be obvious to the casual observer. Hospital staff members need to know if the patient has been abused or neglected, as well as the extent and circumstances to provide appropriate care. The criteria focus on observable evidence, not allegations alone. Violent crimes must be reported to the appropriate law enforcement agency.

2. Staff members are expected to make appropriate referrals for victims of suspected or know abuse or neglect. The hospital maintains a list of available community resources to provide assistance to the victims.

3. Staff are educated on Abuse/Neglect through general and department specific orientation and competencies. With any policy/criteria revisions, staff is educated prior to implementation.

4. The purpose of this policy is to assure the identification, evaluation and referral of victims of suspected abuse or neglect.

PROCEDURE:
A. Indiana State law makes it mandatory for health care workers to report all suspected cases of abuse, neglect and violent crime including:
   1) Child abuse and neglect
   2) Abuse and/or neglect of an endangered adult including elder abuse.
   3) Gunshot wounds
   4) Stabbing
   5) Animal bites
   6) Beatings/Assaults
   7) Drowning
   8) Suicide attempt (Refer to suicide policy)

B. Reporting of suspected child abuse is to be reported to the Department of Child Services (DCS) and the reporting of suspected endangered adult abuse is to be reported to Adult Protective Services (APS).

C. Identification of Possible Child Abuse and/or Neglect – not all inclusive

   The following is a list of potential physical and behavioral "indicators" of suspected abuse/neglect. It is not all inclusive. Indicators, as well as a history of suspicious injuries, child's age and child's verbal report should be considered when assessing for alleged abuse/neglect.

Expiration Date: 03/08/2024
Title: Abuse and Neglect and Violent Crime Policy

a) Signs of physical abuse
b) Unexplained bruises, welts or marks forming a pattern should be evaluated. Face, lips, mouth, torso, back, buttocks and thighs are common abuse areas. Various states of healing, clustered markings or regular patterns reflecting a shape of an article used to inflict injury such as a belt buckle or other object.

c) Unexplained lacerations or abrasions.
d) Unexplained burns, cigarette burns, immersion burns or other suspicious burns.
e) Unexplained fractures or fractures in various stages of healing. Multiple long bone or spiral fractures. Injuries to the grown center of bone structure.

2) Behavioral Indicators of child physical abuse – Not all inclusive.
   a) Wary of adult contact
   b) Behavioral extremes
   c) Overly aggressive, demanding, rageful
   d) Overly compliant, passive, withdrawn
   e) Frightened of caretaker
   f) Cringes or jumps at sudden movement or sound
   g) Developmental lags
   h) Apprehensive when other children cry
   i) Role reversal
   j) Child acts adult-like
   k) Wears long sleeve shirt/pants in hot weather
   l) Overly eager to please
   m) Verbally reports abuse/neglect

3) Caretaker behavioral indicators of physical abuse – not all inclusive
   a) Verbalizes harsh discipline not appropriate for the child's age or behavior
   b) Consistently describes the child's behavior as negative (bad, stupid, dumb)
   c) Explains child's injuries that are not consistent with child's age, development stage or behavior
   d) Becomes defensive or refusal to allow medical treatment to child
   e) Attempts to conceal child's injuries
   f) Apparent use of alcohol or drugs

4) Physical indicators of physical neglect of a child – not all inclusive
   a) Lack of supervision – young children left unattended, children inadequately unsupervised for long periods of time, lack of meeting basic necessity of child care.
   b) Nutrition – Lack of proper quantity of food intake. Children who fall three to four standard deviations below normal height/weight for age range.
Title: Abuse and Neglect and Violent Crime Policy

c) Basic needs – lack of adequate clothing. Children dressed inappropriately for the weather. Consistently dressed dirty or inappropriate torn clothing. Severe diaper rash, lack of medical or dental care, unbathed.

5) Behavior indicators of physical neglect of a child – not all inclusive.
   a) Begging or stealing food, constantly complaining of hunger
   b) Constant fatigue
   c) Alcohol or drug abuse
   d) Delinquency, frequent absences from school
   e) Reports of being left alone or abandoned

6) Caretaker behavioral indicators of physical neglect – not all inclusive
   a) Misuse of alcohol or drugs
   b) Chaotic home life
   c) Expects child to care for self at inappropriate age

7) Physical Indicators of sexual abuse – not all inclusive
   a) Pregnancy in girl under 16 years of age
   b) Pelvic inflammatory disease in girl under 16 years of age
   c) Venereal disease of the throat, genitals or rectum
   d) Bruised or dilated genitals or rectum
   e) Foreign matter in bladder, rectum or vagina
   f) Recurrent urinary tract infection without a physiological basis
   g) Difficulty or pain in walking or sitting without a physiological basis
   h) Torn, stained or bloody underclothing

8) Behavioral indicators of sexual abuse of a child – not all inclusive
   a) Seductive behavior, advanced sexual knowledge for age, precocious sex play
   b) Drawing pictures of genitals
   c) Exhibiting extreme behaviors
   d) Sexually abusing another child
   e) Sleep disorders, nightmares
   f) Notable changes in behavior such as regressing, withdrawing, fear
   g) Taking frequent baths – particularly after seeing one specific person
   h) Reporting the abuse – expressing fear of a particular person or place

9) Caretaker Behavioral indicators of sexual abuse - not all inclusive
   a) Extremely protective or jealous of child and child's relationships
   b) Encouraging child to be involved in prostitution or sexual acts
   c) Misuse of alcohol or drugs

10) Behavioral indicators of Emotional Maltreatment of a child – not all inclusive
   a) Rocking, head-banging or thumb sucking in an older child
   b) Developmental lag
   c) Daytime anxiety and unrealistic fears
   d) Withdrawal or antisocial behavior
   e) Sleep disorders, nightmares
   f) Apathetic, indifferent, listless
   g) Extreme aggression or passiveness. Inappropriate adult or infantile behavior
   h) Defiant behavior
   i) Enjoyment out of hurting other children or animals

11) Caretaker Behavioral indicators of Emotional Maltreatment – not all inclusive
Title: Abuse and Neglect and Violent Crime Policy

a) Rejecting or belittling the child.
b) Harsh Criticizing and not showing affection
c) Treating the child different than others in the family
d) Terrorizing the child. Blaming the child for things in which the child has no control. Threatening the child's safety and or possessions (toys, dolls, pets)
e) Isolation of the child from social experiences or friendships
f) Ignoring or having little interest in the child
g) Teaching the child socially deviant behavior

12) Abuse/Neglect of an endangered Adult – not all inclusive

An endangered adult is someone 18 years of age or older that is incapable of making their own decisions due to mental illness, challenged mental capacity, dementia, habitual drunkenness, excessive use of drugs, age, infirmity or other physical or mental incapacity – inability to care for self, make decisions or manage property or activities of daily living. Anyone who stands in a position of trust with an endangered adult is responsible to provide a safe environment.

a) Neglect – leaving the adult alone for extended periods of time without providing appropriate care.
b) Physical abuse
c) Misuse of the adult's funds, personal property or services

13) Physical indicators of Endangered Adult physical abuse – not all inclusive

a) An injury that has not been properly cared for
b) An injury that does not match the history given by the caretaker
c) Unexplained bruises, welts or marks forming a pattern should be evaluated. Face, lips mouth, torso, back, buttocks and thighs are common abuse areas. Various states of healing, clustered markings or regular patterns reflecting a shape of an article used to inflict injury such as a belt buckle or other object
d) Cuts, lacerations or puncture wounds without explanation
e) Dehydration and or malnourishment without illness related cause
f) Extreme weight loss without illness related cause
g) Sunken eyes, cheeks without illness related cause
h) Evidence of inadequate or inappropriate medication administration
i) Signs of confinement (ligature marks on wrists, ankles, trunk)
j) Soiled, dirty, unbathed, fecal/urine smell
k) Rash, lice, sores
l) Animal infested living quarters
m) Poor skin hygiene
n) Unexplained burns, cigarette burns, immersion burns or other suspicious burns
o) Unexplained injuries under the breasts or areas normally covered by clothing
p) Frequent use of the emergency department or "physician shopping"
q) Willful infliction of mental suffering
r) Abandonment

14) Behavioral indicators of Endangered Adult abuse – not all inclusive

a) fear
b) Withdrawal and non-responsiveness
c) Depression without underlying illness
d) Agitation/anxiety
e) Implausible reasons for injuries or situations
Title: Abuse and Neglect and Violent Crime Policy

f) Hesitant to speak openly

g) Anger not due to mental capacity

h) Ambivalence to injuries or situations

i) Making excuses for caretaker

15) Caretaker behavioral indicators of Endangered Adult abuse – not all inclusive

a) Caretaker not allowing the adult to speak for themselves

b) Absence of assistance, poor attitude or indifference toward the adult.

c) Blaming of the adult for the injuries or situation.

d) Aggressive behavior toward the adult, threats, insults, harassing

e) History of abuse to other endangered adults

f) Misuse of alcohol or drugs

g) Flirtation as indicator of possible inappropriate sexual relationship

h) Social isolation or restriction of activities

i) Conflicting accounts of situations by different family, supporters, caretakers

j) Unwilling to comply with safety plans for the adult

k) Withholding funds, property or other services that belong to the adult.

l) Indicators of financial abuse of the endangered adult – unusual or inappropriate banking

m) Power of attorney changes when the adult is incompetent of making the changes

n) Concerns by the caretaker of the money being taken away from the adult they are caring for

o) Unpaid bills, collections

p) Lack of necessary personal belonging for grooming, clothing, nutrition

q) Missing personal belongings, art, jewelry, items of value

r) Deliberate isolation from friends or family. Not allowing anyone to visit adult.

16) Rights of Endangered adults/Elders

a) The adult has the right to determine their affairs to the full extent of their ability

b) The adult has the right to receive protective services in the least restrictive environment

c) The adult has the right to make decisions regarding their care to the full extent of their ability

D. Child Abuse and Neglect Reporting/Examination.

1) Any SJHS employee who has reason to believe a child under the age of 18 is a victim of abuse or neglect (including non-accidental injury, sexual assault, physical neglect, emotional maltreatment and unexplained failure to thrive) is obligated to make a report with the Department of Child Services (DCS) and notify local law enforcement agencies.

2) The employee must also notify case management/social worker and the administrative supervisor.

3) Photographs of any visual trauma areas are to be taken. Consent not required by State Statute.

4) Radiological examinations may be used if ordered by the physician.

5) All photographic and summaries related to the exam of the alleged abuse/neglect must be documented in the EMR.

6) DCS has the right to have a copy of the EMR, photographs and other relevant medical information according to law. No consent is necessary.

E. Reporting of Violent Crimes

a) Victims of violent accidents or crimes must be registered in the Emergency Department.

The local police must be notified of the patient. No information is used to register the victim.
Title: Abuse and Neglect and Violent Crime Policy

b) If a person is treated for the following, the police of jurisdiction must be notified: (Not all inclusive – if in doubt call the police)
   - Bullet wound
   - Gunshot wound
   - Powder burn
   - Any wound from a firearm or taser
   - Stabbing - knife, ice pick, axe or any other sharp object that was used to inflict harm
   - Dog bites – follow dog bite policy
   - Suspicious burns inconsistent with reason stated for burn
   - A burn that resulted from attempt at bodily injury
   - Assaults – with or without weapons

F. Possible victims of Domestic Abuse
   Certain types of injuries are typical of abusive relationships and the consideration of battery is to be reported when the explanation of how an injury occurs does not seem logical or possible.

G. Common types of Domestic Abuse injuries – not all inclusive
   a) Contusions, abrasions, lacerations, fractures, strains and sprains – inconsistent with reporting method of injury
   b) Injuries to head, breasts, neck or abdomen – inconsistent with reporting method of injury
   c) Injuries during pregnancy – breast, abdomen or genital area
   d) Poor nutrition or depression during pregnancy – miscarriage inconsistent with reporting
   e) Multiple sites of injury, or same area injured multiple times
   f) Inconsistent or suspicious reporting of headaches, difficulty sleeping, choking, abnormal breathing, frightened.
   g) Appearing anxious with partner in room
   h) Appearing shameful, helpless, evasive or social inapt
   i) Fearful when questioned about injuries

SITE SPECIFIC:

1.
   A.
Title: Abuse and Neglect and Violent Crime Policy

RELATED DOCUMENTS/INFORMATION:

DEFINITIONS:

REFERENCES/STANDARDS:
Title: Patient Safety Evaluation System (PSES)

POLICY:

SJHS, operating within Trinity Health, has an established Patient Safety Evaluation System (PSES) and participates in patient safety activities with a federally designated Patient Safety Organization (PSO). Such participation includes privileged and confidential collection, creation, maintenance, analysis, deliberation of Patient Safety Work Product (PSWP), and the submission to and receipt of PSWP from the PSO. These activities are undertaken to improve the safety and quality of patient care and to support a culture of safety at SJHS. The PSES exists anywhere SJHS conducts patient safety activities in accordance with this policy and procedure.

POLICY STATEMENT:

SJHS, operating within Trinity Health, has an established PSES, through which healthcare providers can conduct patient safety activities, as defined in, but not limited to, those named in the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and subsequent rulemaking.

The Patient Safety Act created PSOs, the PSES, and PSWP as pillars of the privileged, confidential environment to protect the patient safety activities of SJHS and Trinity Health from fear of litigation, professional sanctions, injury to professional reputation, in the form of demands for disclosure of these activities, including documents, communications, deliberations, and analyses of such (e.g., by means of level discovery proceedings, court orders, subpoena, or certain regulatory demands), in accordance with the provisions of the Act.

The PSES is established, consistent with the intent of the Patient Safety Act, to create the conditions of a culture of safety and learning at SJHS in a way that fosters and does not inhibit the free flow of information, hypothesis, criticism, self-critical analysis and unguarded commentary. The PSES is a learning system and includes all providers that are affiliated with SJHS including the Healthcare Provider’s corporate offices. References throughout this Policy to Healthcare Provider shall include all affiliated providers and entities. The PSES exists anywhere the Healthcare Provider conducts patient safety activities in accordance with this Policy.

SJHS, operating within Trinity Health, is a contracted member/client of Press Ganey PSO, a federally credentialed patient safety organization, effective from: July 1, 2021 to January 1, 2025.

SCOPE/APPLICABILITY:

SJHS is a not-for-profit multi-hospital health system located in North Central Indiana including two acute care hospitals, more than 150 providers in the Saint Joseph Medical Group, community health centers and additional points of access. In addition to acute-based hospital care, SJHS provides a range of community and health services, from primary care to specialized services, to meet the needs of the community.
Title: Patient Safety Evaluation System (PSES)

based and post-acute services including community wellness, physical rehabilitation, physician clinics, and outpatient services. SJHS is a Regional Ministry Organization of Trinity Health.

This Policy applies to the facilities that comprise the legally defined corporate Healthcare Provider entity. See Appendix I for a list of facilities and entities within SJHS that are included in the PSES.

This Policy applies to any staff member, employed or contracted licensed healthcare provider, and any staff member or contractor participating in patient safety, quality improvement, and outcomes improvement activities within SJHS. Such workforce members shall be construed to be doing so within the PSES of SJHS.

This Policy is a local policy that “mirrors” the Trinity Health System Office PSES Policy.

PROCEDURES:

A. Patient Safety Activities

It is the intent of SJHS to conduct patient safety activities, as defined by the Patient Safety and Quality Improvement Act of 2005. As enumerated by the Patient Safety Act, these activities include:

- Efforts to improve patient safety and the quality of health care delivery;
- The collection and analysis of PSWP;
- The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- The utilization of PSWP for purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
- The maintenance of procedures to preserve confidentiality with respect to PSWP;
- The provision of appropriate security measures with respect to PSWP;
- The utilization of qualified staff; and
- Activities related to the operation of a PSES and to the provision of feedback to participants in a PSES.

Patient safety activities within the PSES include, but are not limited to, the activities named above, such as quality improvement reviews, projects, discussions, meetings, huddles, data collection, adverse event reporting and review, care delivery evaluation, and analyses of these in standing committee, service line, department, or ad hoc team, unit, or group at Trinity Health. Examples include:

- Risk Management Event Reporting System Data;
- Safety Event Classification (SEC);
- Serious Adverse Events (SAE) Daily Report;
- SAE Communication Process and Documentation;
- SAE SBARs and SBAR + Action Plan;
- SEC Reliability and Shared Learning Team documents;
- Safety Alerts (Excludes a manufacturer product recall alert);
- Liability Claims Settlement Authority Risk Modification Memo.

All activities of employees and contractors of SJHS to collect or process information to improve patient outcomes and reduce patient risk are defined as existing within the PSES unless otherwise determined by qualified personnel responsible for PSES operations.

Expiration Date: 06/07/2026
Title: Patient Safety Evaluation System (PSES)

SJHS shall designate the following roles and departments as key stakeholders, that is, qualified personnel, with the responsibility for maintaining the operations of the PSES: PSES Steering Team: RHM President, Chief Medical Officer, Chief Nursing Officer, President of Saint Joseph Medical Group, Plymouth Hospital Administrator, Legal Services, Integrated Clinical Services, Insurance and Risk Management Services.

Patient safety activities may be conducted by any individual, committee or body that has responsibility for any such activities (i.e., the PSES workforce). The PSES workforce includes all SJHS employees, medical staff members, students, volunteers, and/or contractors who perform work under the direct control of the organization. If the work performed is related to clinical quality, patient safety, risk reduction, or healthcare outcomes improvement, the work and materials, communications, meetings, documents, etc. generated by the work shall be designated by PSWP.

B. Patient Safety Work Product

It is the intent of SJHS to provide for the collection, creation, maintenance, analysis, use, and disclosure of PSWP, including reporting to a PSO.

<table>
<thead>
<tr>
<th>PSWP</th>
<th>Assessment</th>
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<tbody>
<tr>
<td>Risk Management Event Reporting System Data</td>
<td>Submitted to the PSO</td>
</tr>
<tr>
<td>SEC Classification</td>
<td>Submitted to the PSO</td>
</tr>
<tr>
<td>SAE Daily Report</td>
<td>Deliberations or Analysis</td>
</tr>
<tr>
<td>SAE Communication Documentation</td>
<td>Deliberations or Analysis</td>
</tr>
<tr>
<td>SAE SBARs and SBAR + Action Plan</td>
<td>Deliberations or Analysis</td>
</tr>
<tr>
<td>Causal Analysis Investigation and Action Plan</td>
<td>Deliberations or Analysis</td>
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<tr>
<td>SAE Shared Learnings</td>
<td>Deliberations or Analysis</td>
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<td>Deliberations or Analysis</td>
</tr>
</tbody>
</table>

C. Confidentiality of Patient Safety Work Product

It is the intent of SJHS to provide for the confidentiality of PSWP.

SJHS shall ensure that PSWP collected and analyzed by SJHS remains confidential in accordance with the Patient Safety Act and applicable Health Insurance Portability and Accountability Act (HIPAA) requirements, and hereby adopts procedures to this end. The use of PSWP collected and analyzed by Trinity Health to create a culture of safety, within which PSWP may be shared within the PSES among any applicable component of SJHS in activities designed to improve healthcare delivery quality, safety, and outcomes, shall not be limited by these procedures except to maintain the confidentiality and security of PSWP, as indicated below. Employees, medical staff, contractors, students, volunteers, and others participating in the PSES have an obligation to protect PSWP and identifiable information from unauthorized disclosure via physical, electronic, or verbal communication. If applicable, SJSH shall provide documentation such as a
Title: Patient Safety Evaluation System (PSES)

Confidentiality agreement that enumerates responsibilities of such workforce, contractors, volunteers, and others. PSWP used within SJHS for patient safety activities by authorized workforce may be shared, reported, discussed, etc. during the conduct of these activities, but may not be further disclosed. If a workforce member discloses PSWP to the PSO, SJHS shall not pursue disciplinary action against that member.

Continued protection of information after disclosure: PSWP retains its privilege and confidentiality protections after disclosure, even in the case of an intentional or inadvertent disclosure.

PSWP is privileged and confidential at all times and is not:

- Subject to federal, state, local, tribal, civic, criminal or administrative subpoena or order;
- Subject to discovery in connection with a federal, state, or local civil, criminal, or administrative proceeding;
- Subject to disclosure pursuant to a Freedom of Information Act request;
- Admissible as evidence in any federal, state, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider;
- Admissible in a professional disciplinary proceeding of a professional disciplinary board established or specifically authorized under state law.

Key stakeholders in the PSES operations workgroup shall provide appropriate physical and electronic space for storage, deliberations, and analyses of PSWP.

D. Security of Patient Safety Work Product

APPENDIX II. DEFINITIONS

The foregoing Policy contains certain terms that have specific meanings governed by the Patient Safety Act and the regulations that implemented it. The Patient Safety Act, or “the Act,” refers to the Patient Safety and Quality Improvement Act of 2005 (PSQIA). As stated in the final rule of the Act found at 42 CFR 3.10, “The purpose of this part is to implement the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41), which amended Title IX of the Public Health Service Act (42 USC 299 et seq.,) by adding sections 921 through 926, 42 USC 299b-21 through 299b-26, codified at 42 CFR § 3.20.” Implementation of the Act is governed by the Agency for Healthcare Research and Quality (AHRQ) and enforced by the Office of Civil Rights.

The definitions provided below may be incorporated into a policy verbatim, or with additional language to provide operational interpretation. Examples of both are given below. It may be useful to consult legal counsel regarding additional explanatory language as part of a policy document. A healthcare provider organization’s legal counsel may also wish to review the reference in the Act regarding its construction and interpretation of privilege and confidentiality, found at 42 CFR § 3.20.

A. THE BASICS

1. PATIENT SAFETY ACT

The Act created patient safety organizations (PSOs), the concept of a patient safety evaluation system (PSES), and the designation of particular information generated by healthcare organizations as patient safety work product (PSWP), which, under the conditions established in the Act, confers a high level of legal
Title: Patient Safety Evaluation System (PSES)

confidentiality and privilege protection from external disclosure of such information. The legal protection, in
turn, permits healthcare organizations to conduct “patient safety activities” such as quality improvement
investigations, analyses, programs, and corrective actions to improve healthcare delivery and patient
outcomes by protecting certain kinds of disclosures (i.e., sharing) of such information within a healthcare
organization, and externally to PSOs. PSOs, by aggregating and obtaining data and PSWP from many
healthcare organizations, may advise their contracted members about improving their specific challenges or
problems by providing feedback about evidence-based and best practices. The conditions established by the
Act provide an incentive for healthcare organizations to be open about pursuing quality improvement efforts
internally, thereby contributing to the development of a culture of safety, rather than a culture of blame,
punishment, and fear of legal action for bringing problems in care delivery to light.
Therefore, the intent of the Act is to provide a legal framework to permit the exchange of information
between healthcare organizations and federally certified PSOs to identify the causes of preventable
healthcare errors and patient injury, and to collaborate on improvements to patient safety.

2. PATIENT SAFETY ORGANIZATION

According to 42 CFR § 3.20, “the term ‘patient safety organization’ “means a private or public entity or
component thereof that is listed as a PSO by the Secretary in accordance with subpart B. A health insurance
issuer or a component organization of a health insurance issuer may not be a PSO. See also the exclusions in
§3.102 of this part.” A PSO may be an independent entity or component of another organization that is listed
by AHRQ as an organization that has the goal of improving the quality and safety of healthcare delivery by
conducting patient safety activities. The Act approved the creation of PSOs designed to improve the quality
and safety of healthcare by reducing the number of adverse events through the voluntary reporting of patient
safety events and activities, followed by the analysis of this information in a secure, privileged, and
confidential environment.

To this end, PSOs are authorized to collect voluntarily reported information from its member provider
organizations by confidential and legally privileged means (i.e., the PSES). The PSO, by aggregating and
analyzing patient-safety adverse-event and quality-improvement information, shall use it to identify areas of
hazard and risk to patient safety, and to provide evidence-based recommendations for mitigation and
improvement.

3. PATIENT SAFETY EVALUATION SYSTEM

According to the Act: “The term ‘patient safety evaluation system’ means the collection, management, or
analysis of information for reporting to or by a patient safety organization.” (42 CFR § 3.20). A PSES is an
internal administrative mechanism for collecting, managing, and
analyzing information for reporting to, or by, a PSO. The PSES creates a protected environment for candid
consideration and analysis of quality and safety information and is flexible and scalable to meet the needs of
the healthcare provider organization. The Final Rule implementing the Act

4. PATIENT SAFETY WORK PRODUCT

The Act defines patient safety work product as follows: “(A) In general, except as provided in subparagraph
(B), the term ‘patient safety work product’ means any data, reports, records, memoranda, analyses (such as
root cause analyses), or written or oral statements—(i) which—(I) are assembled or developed by a provider
for reporting to a patient safety organization and are reported to a patient safety organization; or (II) are
Title: Patient Safety Evaluation System (PSES)

developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.” (42 CFR § 3.20)

The Act further describes PSWP by clarifying what it is not: “(B) Clarification (i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record. (ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product. (iii) Nothing in this part shall be construed to limit—(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding; (II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or (III) a provider’s recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.” (42 CFR § 3.20)

The important thing for healthcare provider organizations to keep in mind is that the definition of PSWP can be as broad or narrow, in accordance with the first paragraph above, as the organization wishes it to be. A provider organization can choose to define its PSWP as only that which is held in the PSES for reporting to a PSO, or extend its definition to include any such information that “constitute[s] the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system,” in other words, patient safety and quality information that is reviewed and considered in accordance with the PSES itself, as part of its patient safety activities and operations. For the purpose of a policy, the scope of PSWP should best be defined by those in the organization who are most familiar with quality and risk reporting, legal and regulatory reporting, and the information systems that generate and store data pertaining to patient safety. recommends as best practice, but does not require, documentation of how this particular kind of information, to be designated as patient safety work product, enters the PSES, who has access to it, and what procedures are involved. In addition, the Act does not require that all information collected, managed, or analyzed within a healthcare provider organization's PSES is to be reported to a PSO.

5. PATIENT SAFETY ACTIVITIES

According to the Act: “The term ‘patient safety activities’ means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.
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(F) The provision of appropriate security measures with respect to patient safety work product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.” (42 CFR § 3.20)

The description of patient safety activities pertains equally to healthcare provider organizations and to PSOs.

Acceptable interpretive language to define patient safety activities may be more succinct and practical, describing the operational scope of such activities within the member’s organization, e.g., “activities including but not limited to efforts to improve the collection and analysis of PSWP; the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices; the utilization of PSWP for the purposes of encouraging a culture of safety as well as providing feedback and assistance to effectively minimize patient risk; the maintenance of procedures to preserve confidentiality with respect to PSWP; the utilization of qualified staff; activities related to the operation of the PSES and to the provision of feedback to participants in the PSES.” Defining patient safety activities as closely as possible to the statutory language, such as the explanation provided above, along with some description of the operational reality of the PSES within a provider organization, is an appropriate way to ensure that the PSES policy language is written in a way that follows the statute’s requirements. Language used in the policy should also reflect the actual patient safety work being done, in terms of both the activities of the organization and compliance with its policies. In the statutory definition of patient safety activities given above, for example, sections A-D describe processes related to the delivery of healthcare, and sections E-H describe the administration of the PSES itself. Note that both kinds of work are part of the definition of “patient safety activities.” Again, the activities embraced within the PSES are meant to be “flexible and scalable” according to the organization’s needs.

B. THE LEGAL DETAILS

1. CONFIDENTIALITY PROVISIONS

The legal text reads: “Confidentiality provisions means for purposes of subparts C and D, any requirement or prohibition concerning confidentiality established by sections 921 and 922-(d), (g) and (i) of the Public Health Service Act, 42 U.S.C. 299b-21, 299b-22(b)-(d), (g) and (i) and the provisions, at 3.206 and 3.208, that implement the statutory prohibition on disclosure of identifiable patient safety work product.” (42 CFR § 3.20)

“Confidentiality” is a legal protection that attaches to PSWP, provided that the PSWP is not disclosed except as required or permitted by law. PSWP that is impermissibly disclosed may, in some circumstances, lose this federal legal confidentiality protection. Federal regulations provide for 10 types of disclosures that, if made, will not result in loss of confidentiality protection (see Appendix II).

Confidentiality is an issue pertaining to two types of PSWP—identifiable and nonidentifiable. This distinction is important because the legal protections of privilege and confidentiality attach only to identifiable PSWP.

2. IDENTIFIABLE PATIENT SAFETY WORK PRODUCT
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The Act states “the term ‘identifiable patient safety work product’ means patient safety work product that—

(A) Is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

(B) Constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

(C) Is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 299b–22(e) of this title.” (42 CFR § 3.20).

3. HIPAA CONFIDENTIALITY REGULATIONS

The Act states: “The term ‘HIPAA confidentiality regulations’ means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).” (42 CFR § 3.20) Protection from identification of any healthcare providers mentioned or named within PSWP that may include information about errors or adverse events is a key component of the confidentiality provisions of the Act. The identity of those reporting adverse safety information within the PSES is also protected by this part of the Act. Maintaining this confidentiality is the duty of any member of a provider or PSO workforce or business associate who may have access to such PSWP that identifies providers, reporters, or patients. To emphasize this point, the Act makes reference to the HIPAA Privacy Rule and uses the identifiers named in that rule to describe the significance of PSWP confidentiality, and how that confidentiality is to be preserved.

4. NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT

According to the Act: “The term ‘nonidentifiable patient safety work product’ means patient safety work product that is not identifiable patient safety work product,” that is, PSWP that does not meet the foregoing definition of identifiable patient safety work product such that it does not enable the identification of anyone named in the PSWP, nor of the person who reported the PSWP, or that the PSWP has had any applicable identifiers, consistent with the HIPAA confidentiality regulations (i.e., HIPAA Privacy Rule), removed from the PSWP in question. (42 CFR § 3.20)

5. SAFE HARBOR

According to the Act, the concept of “safe harbor” refers to a provider or responsible person in the workforce of a healthcare provider organization (but not a PSO) who may have violated the confidentiality provisions of the Act—that is, if a member of a healthcare provider workforce makes external disclosure of PSWP for some kind of quality improvement purpose, or discloses accidentally. The safe harbor provision applies only if such a disclosure did not assess the actions, failure or act, or the quality of care of an identifiable provider. (42 CFR § 3.20(c))

6. DISCLOSURE

The Act states that “Disclosure means the release, transfer, provision of access to, or divulging in any other manner of patient safety work product by: (1) An entity or natural person holding the patient safety work product to another legally separate entity or natural person, other than a workforce member of, or a health
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care provider holding privileges with, the entity holding the patient safety work product; or (2) A component PSO to another entity or natural person outside the component PSO and within the legal entity of which the component PSO is a part.” (42 CFR § 3.20)

For practical purposes, “disclosure” means sharing PSWP outside of the healthcare provider organization. Within the entities and facilities of the healthcare provider organization, such sharing, especially for improving safety and quality, is not deemed to be a disclosure, but rather is considered the legitimate “use” of that PSWP. The distinction matters because of the duty to maintain the confidentiality and privilege protections afforded by the Act to this sensitive information.
The Act permits external disclosure of PSWP in 10 types of circumstances, commonly known as “permissible disclosures” (see Appendix II).

Use may be defined as the sharing of PSWP within a Healthcare Provider Organization, such as among clinicians, risk managers or other workforce members. It may also include certain internal business operations and patient safety activities.

7. PRIVILEGE

The Act grants a statutory “privilege” to PSWP, as follows: “Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be:

(1) Subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(2) Subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(3) Subject to disclosure pursuant to section 552 of title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

(4) Admitted as evidence in any Federal, State, or local 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 established or specifically authorized under State law.” (42 CFR § 3.204)

Privilege means that there is a legal rule that prevents information that is deemed “privileged” from being disclosed or admitted into evidence at trial, e.g., attorney-client privilege. For PSWP, this privilege means workforce members or their healthcare institutions are not legally required to disclose PSWP on demand in a claim or malpractice case, or other legal proceeding, or in a federal court, or by subpoena. The PSQIA privilege of PSWP cannot be waived.

The concept of privilege, when applied to PSWP, is a powerful tool to incentivize the use of such information in an honest and candid manner to inform licensed providers within an organization what they need to know or do to improve safety practices, since the information cannot legally be used against them. It
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also incentivizes healthcare organizations to report PSWP to a PSO, which extends learning opportunities across multiple organizations that may be challenged by similar issues.

C. THE AFFECTED PARTIES

1. PROVIDER OR PROVIDER ORGANIZATION

According to the Act, “The term ‘provider’ means—(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner’s office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or (ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or (B) any other individual or entity specified in regulations promulgated by the Secretary.” (42 CFR § 3.20)

In terms of the Act, “provider” more often refers to a healthcare organization rather than a licensed individual, but the definition comprises both concepts. The term may also refer to a parent organization of one or more entities licensed or otherwise authorized to provide healthcare services (see “Affiliated Provider” below).

2. AFFILIATED PROVIDER

An “affiliated provider” is defined in the Final Rule as “with respect to a provider, a legally separate provider that is the parent organization of the provider, is under common ownership, management, or control with the provider, or is owned, managed, or controlled by the provider.” (42 CFR § 3.20)

This would include components of a clinically integrated network, for example, or multiple hospitals, outpatient services, and medical offices within a network or components of the same healthcare corporate (public, private, nonprofit or for profit) entity.

3. RESPONSIBLE PERSON

The Act defines a “responsible person” as “a person, other than a provider or a PSO, who has possession or custody of identifiable patient safety work product and is subject to the confidentiality provisions [of the Patient Safety Act].” (42 CFR § 3.20)

This term refers to persons who may receive or have access to identifiable PSWP during the course of their business affairs in connection with a provider organization or a PSO, such as accountants, lawyers, information technology staff, or contractors. Such associates are responsible to the duties described in the confidentiality provisions defined in the Act.

4. WORKFORCE

According to the Act, “workforce means employees, volunteers, trainees, contractors, or other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of
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such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person.” (42 CFR § 3.20)

The term “workforce” pertains to those working for or on behalf of a healthcare provider organization or a PSO, including business associates considered to be “responsible persons” as defined in the Act. Such employees and associates must be “qualified” for their roles and responsibilities for handling patient safety work product in accordance with the provisions of the Act.

APPENDIX III: PERMISSIBLE DISCLOSURES OF PATIENT SAFETY WORK PRODUCT

Permissible Disclosures, or “Exceptions to Confidentiality” of Patient Safety Work Product in the Patient Safety and Quality Improvement Act.

The Patient Safety and Quality Improvement Act (PSQIA) provides for the confidentiality of patient safety work product (PSWP), prohibiting its disclosure to external parties. There are certain exceptions, however, in which PSWP may be disclosed, without risking noncompliance with the PSQIA’s requirements. The following 10 “exceptions to confidentiality” found at 42CFR § 3.206(b) are commonly referred to as the “permissible disclosures” of PSWP and exist within the patient safety evaluation system of the healthcare provider organization.

1. DISCLOSURE IN CRIMINAL PROCEEDINGS

2. DISCLOSURE TO PERMIT EQUITABLE RELIEF FOR REPORTERS

The first two of the permissible disclosures require a judge or court to make determinations and provide assurances of confidentiality of any relevant PSWP that is disclosed in these situations. Both are situations in which legal processes are taking place: (1) a criminal court case and its attendant hearings and proceedings; and (2) for equitable relief (i.e., fairness of access to confidential information by all parties) during employment of legal action. For disclosures in criminal proceedings, a judge needs to make certain determinations about the type and quality of the proposed PSWP to be disclosed, for example, the material cannot be obtained by any other means, and will otherwise remain confidential. For equitable relief disclosures, a court must issue a protective order prohibiting further disclosures other than for the purpose of the relief being sought.

3. DISCLOSURE AUTHORIZED BY IDENTIFIED PROVIDERS

The third situation allows disclosure of identifiable PSWP, but only if any licensed provider named within the identifiable PSWP provides written authorization to do so. Other conditions include the obligation to inform the named providers of the scope and context of the disclosure(s), and to retain a record of the disclosure(s) for six years.

4. DISCLOSURE FOR PATIENT SAFETY ACTIVITIES

The situation described as “patient safety activities” permits sharing of PSWP between a healthcare provider organization and its PSO (i.e., any reporting to a PSO); disclosures to contractors of the provider
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organization or a PSO (i.e., to a vendor operating a health system’s risk management information system); among the affiliated entities of a healthcare provider organization, such as its parent company or component hospitals, medical practices, contractors, etc.; and certain disclosures that PSOs may make, either to other providers organizations or to other PSOs, if specific identifying information about the original PSWP is removed from the PSWP before disclosure (e.g., for educational purposes).

5. DISCLOSURE FOR NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT

This type of disclosure becomes permissible when particular identifiers are removed from the PSWP. The identifiers are consistent with those stipulated in the HIPAA Privacy Rule. Once any such identifying information is removed from PSWP, it is no longer PSWP and may be disclosed in any manner as deemed necessary by the healthcare provider organization. ECRI also provides guidance on the HIPAA Privacy Rule.

6. DISCLOSURE FOR RESEARCH

It is possible during the course of research using human subjects’ medical information, biological and genetic materials, or conducting public health and social sciences research, that some PSWP could be collected. Such research is permitted; however, since research is required to be reported externally (e.g., to funding sponsors, federal regulatory agencies, institutional review boards (IRBs) of record [which may be external], published websites) additional stipulations apply if PSWP is part of the research record. The PSQIA requires research organizations that are also HIPAA covered entities to follow the steps required by the HIPAA Privacy Rule when disclosing any PSWP that also contains protected health information (PHI)—i.e., those conducting the research using PSWP that is also PHI must follow the HIPAA regulatory requirements for research (e.g., IRB and privacy board review/approval, informed consent, or removal of identifiers, if applicable) when reporting any PHI identifiers, as part of any research-related disclosures of information that are also considered PSWP.

7. DISCLOSURE TO THE FOOD AND DRUG ADMINISTRATION (FDA) AND ENTITIES REQUIRED TO REPORT TO THE FDA

The FDA regulates pharmaceuticals, biologic and disease-modifying (genetically active) drugs, medical devices and equipment, food, and cosmetics marketed in the United States. FDA also conducts post-approval surveillance evaluations and regulates sponsored research of these products or their similars. Any information that contains PSWP reported to the FDA about these products or activities may be disclosed to the FDA as part of voluntary or required reporting (e.g., failure of a medical device or reports submitted during 510(k) device testing; suspected contamination of a pharmaceutical product; post marketing surveillance of the effectiveness of an approved drug or biologic). Regulators receiving information that contains PSWP may not further disclose it.

8. VOLUNTARY DISCLOSURE TO AN ACCREDITING BODY

PSWP pertaining to certain clinical quality processes and retrospective events may be useful during the course of an institutional accrediting process for a healthcare provider organization. PSQIA permits the provider organization to volunteer PSWP for this purpose, but the accrediting body may not require or demand access to it. If any licensed individuals are named, either their authorization is required for the voluntary disclosure by the organization, or the identifiers stipulated at 42 CFR § 3.206(b)(4)(iv)(A) must be removed. In addition, the accrediting body cannot further disclose PSWP shared by the provider.
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organization, nor require or demand information that the healthcare provider organization has shared with a PSO.

9. DISCLOSURE FOR BUSINESS OPERATIONS

Healthcare provider organizations and PSOs are allowed to disclose PSWP to “attorneys, accountants, and other professionals” if necessary, for business operations. Further disclosure by those professionals is prohibited. However, this provision leaves the door open for the U.S. Department of Health and Human Services (HHS) to further expand or define “business operations,” which would likely appear in subsequent federal regulations or guidance documents.

10. DISCLOSURE TO LAW ENFORCEMENT

If a healthcare provider organization or member of its workforce reports PSWP to any law enforcement agency in connection with an actual or reasonably suspected criminal act, this disclosure is permitted under PSQIA. Law enforcement may not further disclose the information other than for the purposes of continued legal action regarding the criminal act under investigation/prosecution. For example, a patient commits a felonious assault against someone while admitted to a healthcare provider organization facility, and the facility decides to file criminal charges. The PSWP associated with the event could include for example, the incident report, patient and victim identifiers, diagnostic and treatment information, and the internal investigation, mitigation, and prevention activities if deemed relevant to the criminal case.

FURTHER CONDITIONS, CONSIDERATIONS, AND COMPLIANCE

42 CFR § 3.206(c) also protects healthcare provider organizations from penalties for accidental disclosures of PSWP by members of its workforce in its Safe Harbor provision. This may seem to allow any claim of a disclosure of confidential PSWP by a provider organization as “accidental,” but conditions apply. “Accidental” sharing of PSWP information that identifies or evaluates a provider organization or a person, that is, externally discloses the quality of care, or a provider’s action or failure to act, is still prohibited, because such PSWP is meant to be, and to remain, confidential to the originating healthcare provider organization, unless it directly pertains to one of the 10 exceptions above.

Healthcare provider organizations should be aware that HHS may make such PSWP disclosures as it deems necessary to enforce PSQIA, for compliance with PSQIA and with the HIPAA Privacy Rule, to determine penalties or other regulatory actions, including the listing of PSOs.

Finally, in another apparent broad permission, healthcare provider organizations and PSOs are permitted by PSQIA to delegate the authority to make disclosures or uses of PSWP on their behalf; moreover, they may also require greater confidentiality limitations by contract with business entities or professionals. This seems to recognize the business environment in which vendors, insurers, attorneys, etc. may be delegated or contracted to use PSWP in the course of their business duties. For such situations, consultation with legal counsel and/or defense counsel of a healthcare provider organizations is advisable.
Title: Patient Safety Evaluation System (PSES)
Title: Patient Rights and Responsibilities

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Location: Saint Joseph Regional Medical Center, INC (SJRMC)
Mishawaka, Plymouth, Saint Joseph Physician Network

Departments: Administration, Nursing, Saint Joseph Physician Network, Mission Integration, Legal, Registration

POLICY:

1. Saint Joseph Regional Medical Center (SJRMC) demonstrates its support of patient rights through various processes in which staff members interact with and care for patients. It is through this process that we recognize and respect all patient rights and responsibilities and work collaboratively to support ethical decision-making for all of our patients.

2. SJRMC establishes and maintains structures to support patient rights and does so in a collaborative manner that involves leaders as well as all relevant others. The structures are based on policies, procedures, and their philosophical basis, which make up the framework to address both patient care and organizational ethical issues including the following:

   A. The patient’s right to reasonable access to care.
   B. The patient’s right to care that is considerate and respectful of his or her personal values and beliefs.
   C. The patient’s right to be informed about and participate in decisions regarding his/her care.
   D. The patient’s right to participate in ethical questions that arise in the course of his/her care including issues of conflict resolution, withholding resuscitative services, foregoing or withdrawal of life-sustaining treatment, and participation in investigational studies or clinical trials.
   E. The patient’s right to security and personal privacy and confidentiality of information.
   F. The issue of proactively designating a decision maker (Healthcare Representative) in case the patient becomes incapable of understanding a proposed treatment or is unable to communicate his or her wishes regarding care.
   G. The patient’s right to access protective services.
   H. The patient’s right to appropriate assessment and management of pain.
   I. The patient’s right to choose who may visit them during their inpatient stay, regardless of whether the visitor is a family member, a spouse, a domestic partner (including same-sex domestic partner), or other type of visitor, as well as the right to withdraw such consent to visitation at any time.
   J. To receive treatment without discrimination based on age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation and gender identity or expression.
   K. Medicare patients have the right to appeal a premature discharge through the Quality Improvement Organization (QIO).
Title: Patient Rights and Responsibilities

3. The patient has certain responsibilities which ensure that medical staff can do everything possible to provide thorough, quality care. These responsibilities include, but are not limited to the following:
   A. Being considerate of the needs of other patients, staff and the hospital/physician practice; to respect others' privacy and property and to follow hospital/physician practice rules.
   B. Providing information that facilitates medical care, treatment and services.
   C. Cooperating with his/her doctor and medical team to develop treatment and pain management plans.
   D. Asking questions or acknowledging when he/she does not understand the treatment course or care decision.
   E. Following instructions, policies, rules and regulations in place to support quality care for patients and a safe environment for all individuals in the hospital/physician practice.
   F. Supporting mutual consideration and respect by maintaining civil language and conduct in interactions with staff, providers, and licensed independent practitioners.
   G. Telling his/her doctor if he/she is unable to follow through with treatment or keep appointments. If the patient refuses treatment or does not follow the practitioner's instructions, he/she is responsible for the consequences of those actions.
   H. Meeting financial commitments
      I. Advising the health care team if he/she has an Advance Directive and to provide a copy.

4. Patient’s psychosocial, spiritual, and cultural values affect how they respond to their care. The hospital/physician practice is considerate of and allows patients and their families to express their spiritual beliefs and cultural practices, as long as these do not harm others or interfere with their care of others.

5. The hospital/physician practice provides care in response to a patient’s request and need, so long as the care is within the hospital’s/physician's capacity, its stated mission and philosophy, and relevant laws and regulations. When the hospital/physician practice cannot provide the care a patient requests, staff fully informs the patient of his/ her alternatives for care. If it is necessary and medically advisable, the hospital transfers the patient to another organization, providing the transfer is acceptable to the receiving organization.

6. The hospital/physician practice promotes patient and family involvement in all aspects of their care through implementation of policies and procedures that are compatible with the hospital’s/physician practice's mission and resources, have diverse input, and guarantee communication across the organization. Patients are involved in at least, but not limited to, the following aspects of their care:
   A. Giving informed consent;
   B. Resolving dilemmas about care decisions;
   C. Formulating Advance Directives;
   D. Withholding resuscitative services;
   E. Foregoing or withdrawing life-sustaining treatment;
   F. Care at the end of life;
   G. Care decisions relevant to pre-admission, admission, treatment during the course of care, transfer, discharge planning, and discharge processes.
7. With these in mind, structures and processes are developed, approved, and maintained through supportive collaboration among hospital leaders and all relevant others.

PROCEDURE:

A. At the time of registration in the hospital/physician practice, each patient will be provided a copy of the pamphlet titled “A Guide to Patient Rights, Responsibilities, and Advance Directives”. The patient will be asked to review the document.

B. The Registrar will explain to the patient that his/her signature on the electronic or paper (when an electronic form is unavailable) patient consent form, acknowledges their receipt of the document.

C. If a patient has special language needs, the forms will either be given to them in their own language (i.e. Spanish) or the information will be interpreted to them as appropriate. When written communication is not effective, for example, the patient cannot read or the patient’s language is rare in the population served, the patient is informed of his or her rights shortly after admission, in a manner that he or she can understand. The 24-hour Cyramcom language line/ signers/ and/or interpreters are available to assist as appropriate when communication barriers exist or special needs are identified.

D. Any alleged violation of a patient’s rights is subject to disciplinary action through the reporting process of SJRMC.

E. Staff education regarding patient rights and their role supporting those rights occurs during new colleague orientation, education processes as well as on an ongoing yearly and “as needed “basis.

Related Documents:
- See “A Guide to Patient Rights, Responsibilities & Advance Directives”
Title: ADVANCE DIRECTIVES

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Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Policy:
1. Saint Joseph Health System (SJHS) holds **Reverence and Integrity** as Core Values and honors the sacredness and dignity of every person and their right to make decisions directing their clinical care. The presence or lack of advance directives does not determine the patient’s right to access of care, treatment and other services. SJHS encourages adult patients, Colleagues, and the communities we serve to consider Advance Care Planning by completing Advance Directives. SJHS will approach decisions regarding Advance Directives within the context of its Mission, Ethical and Religious Directives for Catholic Health Care Services (ERD), and the law.

2. Under federal law, adult/emancipated minor inpatients and observation patients must be offered written information about their rights under state law to formulate Advance Directives.

3. During the admission/registration process, **A Guide to Patient Rights, Responsibilities and Advance Directives** brochure will be available to adult/emancipated minor outpatients. The brochure refers patients for assistance with formulating Advance Directives upon request.

4. SJRMC staff will involve appropriate parties in considering a patient’s Advance Directives. In the event of a perceived conflict between a patient’s Advance Directive and the ERDs or state/federal laws, SJRMC staff will involve the Center for Spiritual Care and/or the Ethics Committee.

5. SJRMC staff will document the presence or absence of written Advance Directives in the medical record, and request a copy of the Advance Directives, if the patient has one or more, but did not supply a copy for his/her medical record.

6. The patient may review, modify or rescind the Advance Directives at any time. If a patient modifies/rescinds any part of or the entire document, such changes are to be noted in the patient’s medical record.

Purpose:
To establish the process for inquiring, consulting, and completing Advance Directives by providing education and instruction for Colleagues and Medical Staff.

Procedure:
Definitions
1. **Adult**
   a. Person who is at least 18 years old; or
   b. An emancipated minor with court documentation
Title: ADVANCE DIRECTIVES

2. Advance Directive (AD)
   a. Documents that direct the clinical care of a patient in the event they are unable to communicate or are unable to make medical decisions as determined by the Attending Physician.¹
   
   b. SJHS will assist and facilitate the following AD documents:
      i. Provider’s Orders for Scope of Treatment (POST)
      ii. Health Care Representative (HCR)
   
   c. A Power of Attorney document can be witnessed by a SJHS notary and /or two Colleague witnesses. SJHS will not initiate the completion of a non-healthcare related document.
   
   d. If patient produces a non-healthcare document, e.g. “POA Property,” without designation of a Health Care Representative, this document will not be uploaded to the electronic medical record (EMR).

3. Decision-making capacity
   a. The ability to understand the nature and consequences of a decision about treatment options and the ability to make and communicate a decision based on that understanding for the current situation
   
   b. Decisional capacity is presumed unless otherwise documented by the Attending Physician in the EMR²
   
   c. An adult is unable to participate in their treatment decisions if, for the current situation, they cannot:
      i. Understand the nature of their illness and proposed treatment or;
      ii. Understand the potential consequences of accepting or refusing the treatment or;
      iii. Make decisions or communicate them

4. Living Will
   a. A written statement prepared by a person with decision-making capacity directing forms of medical treatment that the individual wishes to receive or forego/decline if:
      i. The patient has an incurable injury, disease or illness,
      ii. Will die within a short time; and
      iii. The use of life prolonging procedures would serve only to artificially prolong the dying process

   b. IC 16-36-4-8
      i. “A living will declaration...:

¹ IC 16-36-1-4, Indiana Code 2019 - Indiana General Assembly, 2022ss1 Session, August 2022.
² Ibid. IC 16-36-1-4
Title: ADVANCE DIRECTIVES

1. Does not require the physician to use, withhold, or withdraw life
   prolonging procedures but is presumptive evidence of the patient’s desires
   concerning the use, withholding or withdrawal of life prolonging
   procedures under this chapter; and
2. Shall be given great weight by the physician in determining the intent of
   the patient who is mentally incompetent”

5. Physician Appointed Surrogate (See attachment for form)
   a. If a patient does not have a legally appointed guardian or has not completed a Health
      Care Representative prior to the loss of decision-making capacity, the Attending
      Physician must complete the “Physician Appointed Surrogate” form (see attachment)

   b. This form must then be uploaded to EMR

   c. The Attending Physician may request the assistance of Case Management for the names,
      relationships and phone numbers of the authorized persons pursuant to IC 16-36-1-5:
      i. Spouse
      ii. Adult children
      iii. Parent
      iv. Adult sibling
      v. Grandparent
      vi. Adult grandchildren
      vii. Nearest other adult relative
      viii. A friend who:
           1. is an adult
           2. Has maintained regular contact with the patient; and
           3. Is familiar with the patient’s activities, health and religious and moral
              beliefs.
      ix. The patient’s religious superior if the patient is a member of a religious order

   d. If there are multiple individuals at the same priority level under this section, those
      individuals shall make a reasonable effort to reach a consensus as to the health care
      decisions on behalf of the individual who is unable to provide health care consent. If the
      individuals at the same priority level disagree as to the health care decisions on behalf of
      the individual who is unable to provide health care consent, a majority of the available
      individuals at the same priority level controls.
Title: ADVANCE DIRECTIVES

e. This appointment does not constitute an AD or HCR. If the patient regains decision-making capacity, the Attending Physician will assess and document that the patient is decisional.

   i. The patient is then to be informed about the necessity of this form and given the opportunity to nominate an individual as an HCR by contacting Pastoral Care

f. If the patient does not complete an AD or HCR and returns to the hospital, the Physician Appointed Surrogate process must be repeated and newly completed form uploaded to the patient’s EMR each hospitalization even if the authorized person that is named has not changed

g. If there are complications or questions in the Physician Appointed Surrogate process, you are encouraged to initiate an Ethics Consult.

   i. Access SJHS Sharepoint/Daily Dose, go to: Useful Links, click on: Ethics On-Call Calendar, find today’s date, phone identified Chaplain On-Call.

   ii. Access MDsyncNet through: Zenworks app OR hotline on SJHS Sharepoint/Daily Dose. Go to: “Group Call (Ethics Call) Epic Haiku.” Call Chaplain listed for today.

6. Physician/Provider’s Orders for Scope of Treatment (POST)

   a. Once created, hyperlink: “Physician/Provider’s Orders for Scope of Treatment”
   b. This voluntary form is a medical order based on the patient’s current medical condition and preferences. The POST should be reviewed at each admission and whenever the patient’s condition changes.
   c. A patient with capacity or their legally appointed representative may void a POST at any time

      i. In order to revoke a POST, [POST-Revocation-checklist-2018.pdf](https://indianapost.org)
   d. If Sections A,B,C,D have no selection, it does not invalidate the form and implies full treatment for that section
   e. Signatures - Sections E and H (if applicable, F) - are required to be completed entirely

      i. Failure to complete signatures invalidates the form
   f. HIPAA Permits disclosure of POST forms to other health care professionals as necessary for treatment
Title: ADVANCE DIRECTIVES

g. POST form is to be printed on AstroBright pink cardstock and this original form is the
   personal property of the patient and will discharge with them
   i. SJHS may use facsimiles, paper or electronic copies for communication between
      other health care professionals

7. Legally Appointed Guardian
   a. A guardian is person or entity (e.g. Real Services) appointed by a court that is responsible
      for the care and supervision of a person’s wellbeing, property, and healthcare
   b. SJHS must contact guardian to obtain consent to treat, informed consent and
      communicate course of treatment

8. Catholic Identity and Conscience
   a. ERD 24: In compliance with federal law, a Catholic health care institution will make
      available information regarding their rights and responsibilities according to the state of
      Indiana and the opportunity to make an AD for their medical treatment. SJHS, however,
      will not honor an AD that is contrary to Catholic teaching. If the AD conflicts with
      Catholic teaching, explanation should be provided as to why the directive cannot be
      honored.
      i. Contact Pastoral Care or Ethics Committee
   b. ERD 25: Each patient may identify in advance a representative to make health care
      decisions in the event that the patient loses the capacity to make health care decisions.
      i. If a patient loses decision-making capacity without any known AD, a Physician
         Appointed Surrogate form must be completed.
   c. ERD 25: Decisions by either the legally appointed representative or the Physician
      Appointed Surrogate should be faithful to Catholic moral principles and to the person’s
      intentions and values, or if the person’s intentions are unknown, to the person’s best
      interests

9. Health Care Representative (HCR)
   a. This document is a patient’s written designation of another person (called an agent) to
      make decisions about their medical treatment if the patient loses decision-making
      capacity.
   b. An HCR is legally recognized in the State of Indiana
   c. The patient must be at least 18 years old to complete an advance directive
   d. An HCR’s powers become effective only while an individual is unable to make medical
      treatment decisions.
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e. An HCR may decide to withhold or withdraw life-sustaining treatment if the patient has expressly authorized this in a clear and convincing manner and has acknowledged that death may result.

f. An HCR’s decision to withhold or withdraw life-sustaining treatments that will likely result in the death of a pregnant woman must initiate an Ethics Consult
   i. Access SJHS Sharepoint/Daily Dose, go to: Useful Links, click on: Ethics On-Call Calendar, find today’s date, phone identified Chaplain On-Call.
   ii. Access MDsyncNet through: Zenworks app OR hotlink on SJHS Sharepoint/Daily Dose. Go to: “Group Call (Ethics Call) Epic Haiku.” Call Chaplain listed for today.

g. A patient who has designated an HCR can revoke the designation at any time and may do so in any manner that they are able to communicate their intent to revoke.

10. Power of Attorney (POA)
   a. Indiana recognizes a POA with various titles such as Durable POA, POA for Property, POA for Finance, etc.
   b. If patient presents with a completed POA such as these, it must be reviewed appropriately
      i. Initiate a Pastoral Care consult via Epic chat, “SJMW SJHS Chaplain On Call”

RESPONSIBILITIES
Pastoral Care is responsible for maintaining this policy

PROCEDURE
1. It is the responsibility of the patient to communicate decisions in writing through AD so that their wishes may be followed by their Attending Physician and other healthcare professionals in accordance with state law and the Ethical and Religious Directives for Catholic Health Services.
2. During the Registration process and at Admission, Registration and RN will ask patients if they have an AD.

3. If the patient indicates they have an AD,
   a. Request a copy of the advance directive from the patient.
   b. Nurse and Case Management will follow up with the patient regarding the request for a copy of the advance directive. This can be discussed at Inter-Disciplinary Round. Do this prior to the patient’s discharge.
      i. Document follow-up efforts to obtain a copy of the patient’s advance directive in the medical record. Include the following details:
Title: ADVANCE DIRECTIVES

1. Description of the follow-up activities that were performed (for example, “contacted by telephone the patient’s primary care physician, under patient authorization and at patient’s request, to request a copy of the advance directive”)
2. Date and time the follow-up activities were performed
3. Results of the follow-up activities (for example, “patient’s primary care physician sent a copy of the advance directive following telephone call”)
4. If the patient does not have an AD, the following must occur:
   a. The Guide to Patient Rights and Responsibilities will be provided and staff can offer the assistance of Pastoral Care.
      i. If patient is agreeable, contact Pastoral Care via Epic chat:
         “SJMW SJHS Chaplain On Call”

General Procedures for Advance Directives

Colleagues do the following:

1. Review every patient’s EMR for AD

2. Upon admission and change of level of care, Code Status and POST form will be reviewed with every patient or their Health Care Representative
   a. If patient does have a POST form, the Attending Physician will verify for validity and current patient wishes
   b. If patient does not have POST form and has a qualifying condition, submit consult to Palliative Care for review and completion of POST form

3. Decision-making capacity is presumed unless an Attending Physician assesses and documents within EMR the patient’s lack of capacity.3
   a. Decision-making capacity is determined by the Attending Physician; there is no need for a psychiatric consult unless there are additional psychological/psychiatric needs.
   b. Though the patient’s condition may be complex, the documentation of decision-making capacity must be specific. For example, “this patient has decision-making capacity.”

4. In accordance with the ERD, staff will respect the patient and family’s wishes about foregoing or withdrawing life-sustaining care, treatment, and services. Life-sustaining care, treatment and services include but is not limited to:
   a. CPR
   b. Ventilation support
   c. Artificial nutrition provision (for example, feeding tubes)
   d. Surgeries or other procedures that are intended to address life-threatening conditions
   e. Kidney dialysis

3 Ibid., IC 16-36-1-4
Title: ADVANCE DIRECTIVES

5. Colleagues will refer to the SJHS policies regarding Organ Donation protocol

Determination for Decision-Making Capacity
1. The Attending Physician approaches the patient as if they have decision-making capacity unless there is a reasonable degree of medical certainty otherwise

2. The Attending Physician documents the lack of decision-making capacity in the EMR. This should include the following elements:
   a. Nature of the patient’s incapacity
   b. Cause of the patient’s incapacity
   c. Extent of the patient’s incapacity
   d. Probable duration of the patient incapacity

3. Once capacity has been determined, the Attending Physician will promptly notify the following individuals:
   a. Patient - if there is any indication that the patient can comprehend the notice
   b. Legally Appointed Guardian
   c. HCR / POAHC
   d. Physician Appointed Surrogate (if patient does not have a known AD)
   e. Updates the Care Team by documenting in the EMR

Reference:
Title: Clinical Conflict Resolution (Medically Futile Treatment)

Policy:
1. The purpose of this policy is to assist Saint Joseph Regional Medical Center (SJRMC) clinicians, patients, and families in addressing complex, medical issues and to provide a framework for resolution of conflicts in clinical decision-making.

2. SJRMC and its care-giving teams are committed to providing quality, humane, ethical and appropriate care of patients in a transparent manner. The Ethical and Religious Directives for Catholic Health Care Services (ERDs) instruct us that, “above all, as a witness to its faith, a Catholic health care institution will be a community of respect, love, and support to patients or residents and their families as they face the reality of death.”

3. The following ethical principles from bioethics and Catholic moral teaching are fundamental to this policy:
   A. Respect for Patient Autonomy – the goals and values of the patient must be both respected and considered. “The free and informed judgment made by a competent adult patient concerning the use or withdrawal of life-sustaining procedures should always be respected and normally complied with, unless it is contrary to Catholic moral teaching.” (ERDs 59) “The faith that inspires Catholic health care guides medical decisions in ways that fully respect the dignity of the person and the relationship with the health care professional.” (ERDs, p. 16)

   B. Beneficence and Non-maleficence – To heal and reduce suffering are the goals of medicine. To offer treatments that will not achieve these two goals subverts both the imperative of concern for the best interest of the patient and the first principle of medicine from the Hippocratic Oath – “First of all, do no harm.” “The well-being of the whole person must be taken into account in deciding about any therapeutic intervention or use of technology. Therapeutic procedures that are likely to cause harm or undesirable side-effects can be justified only by a proportionate benefit to the patient.” (ERDs 33)

   C. Professional Integrity
      1) Clinicians are professionally obligated to patients and their families to provide medical information and clinical opinions of the likelihood of therapeutic effectiveness and/or benefit/burden of various treatments and procedures.
      2) Offering ineffective treatments deviates from professional standards, places undue burdens on patients, and betrays the public’s trust.
      3) Clinicians are justified in risking harm to patients only when there is a proportionate chance of benefit. Forcing clinicians to risk harm to patients, without what the clinician in
Title: Clinical Conflict Resolution (Medically Futile Treatment)

good conscience believes to be potential and proportionate benefit makes him/her an agent of harm.

4. **Negative and Positive Rights** – Medical professionals must accept the refusal of treatments made by a competent adult patient with decisional capacity. The refusal may be in person or through an Advance Directive or Living Will or the legal appointment of a healthcare representative. The refusal may also be made by the patient’s healthcare representative. However, there is no ethical or legal obligation to deliver a treatment simply because the patient or his/her legal guardian or appointed healthcare representative demands it.

5. **Transparency** – SJRMC and its caregivers will communicate care plans with all legally interested parties, in full compliance with HIPAA regulations.

PROCEDURE:
A. See attached flow charts:
   1) Concern Starts with the Attending Physician
   2) Concern Starts with a Member of the Clinical Care Team
   3) Concern Starts with the Patient, Proxy/Surrogate, or Family Member

ROLES OF INDIVIDUALS AND GROUPS:
- **Patient** – Ultimate responsibility for decisions regarding his/her medical care with the caveat that he/she cannot determine medical appropriateness.
- **Patient-appointed healthcare representative** – Has responsibility only when the patient is incapable of making decisions. When this occurs, he/she has the same responsibilities as the patient.
- **Legal Guardian** – **Court-appointed guardian** that has responsibility for making decisions on behalf of an individual who is incapable of making decisions due to age, mental status, or other infirmity.
- **Attending physician** – Holds the ultimate responsibility for determining the medical appropriateness of patient treatment(s). The only way to be overruled is to no longer be the attending physician. This may be accomplished by transferring the patient to another physician and/or facility, either at the attending physician’s request, the patient’s request, or as required by the Chair of the Department, Chief of Staff, or Chief Medical Officer.
- **Medical consultants** – Provide professional opinions regarding medical appropriateness when requested.
- **Nurses, ancillary staff** – Responsible for facilitating communication. May initiate the question of appropriateness and offer opinions within their scope of practice.
- **Chair of the Department, President of the Medical Staff, Chief Medical Officer** – Responsible for providing medical opinion(s) when requested and/or asking for consultation, and to assist in facilitating change of attending physician when necessary.
- **Clinical Ethics Committee (CEC)** – Clinical Ethics Committee representative is responsible for assisting in the facilitation of communication, being present at meetings among principals, reviewing
Title: Clinical Conflict Resolution (Medically Futile Treatment)

the case, and presenting the case at the Clinical Ethics Committee meeting. The Clinical Ethics Committee representative will not express an opinion regarding the medical appropriateness of the treatment in question even if he/she is a physician.

- **Clinical Care Team (CCT)** – Provides patient care. In addition to medical and nursing professionals, the CCT may include representatives of the following disciplines: Spiritual Care, Clinical Ethics, Palliative Care, Social Work, Case Management, Risk Management, Pharmacy, Legal, Rehab Services, and Dietetics.

- **Clinical Administrators** – leaders of clinical areas that have administrative oversight and responsibility for clinical decision-making.

**References/Standards:**
- JCAHO
- Ethical and Religious Directives for Catholic Health Care Services – ERDs
- Patient-Self Determination Act, 42 USC 1395cc(f)
- Indiana Health Care Consent Act, Indiana Code 16-36-1 et seq.
- Indiana Living Wills and Life-Prolonging Procedures Act, Indiana Code 16-36-4-1
**Title: Clinical Conflict Resolution (Medically Futile Treatment)**

**Concern Starts with Attending Physician**

Attending Physician voices a concern due to the fact that patient/surrogate are not in agreement with medical plan

Obtain consultation to confirm impression if indicated/deemed necessary.

The attending and/or consulting physician meets with patient or surrogate to explain recommended medical decision. Patient’s nurse should be present. Spiritual Care Associate and/or CEC member may also be present.

Agreed upon course of action instituted.

Agreement is reached between attending and patient/surrogate/proxy/family/significant other

Yes

No

Nurse Manager contacts Clinical Administrator

Clinical Administrator representative reviews chart and speaks with Clinical Care Team

Clinical Administrator notifies attending physician of findings of Clinical Care Team review

Yes

Agreement is reached

No

Clinical Administrator moderates a meeting of the Clinical Care Team including a Spiritual Care Associate and/or CEC member with the patient/patient’s surrogate/representative.

Yes

Agreement is reached

No

Attending physician/hospital will offer to assist in transferring the patient to another appropriate physician and/or hospital after the patient/proxy/surrogate finds one willing to accept the patient.
**Title: Clinical Conflict Resolution (Medically Futile Treatment)**

**Concern starts with the Patient, Proxy/Surrogate, or Family Member**

Patient, proxy/surrogate, or family member voices a concern

Direct person to discuss concerns with Attending Physician

Yes → Patient/patient’s representative hesitant to discuss concerns with Attending Physician

Person with concern brings it to the attention of the Nurse Manager who in turn contacts the Clinical Administrator.

Clinical Administrator reviews the chart and speaks with the Clinical Care Team.

Clinical Administrator notifies attending physician and the patient/proxy/surrogate/family member of the findings of the Clinical Care Team review

Attending Physician agrees with concern and findings of the Clinical Care Team

Yes → Attending Physician agrees with attending physician

Clinical Administrator discusses matter with an administrative physician e.g. department chair or Chief Medical Officer and a Spiritual Care Associate and/or CEC member.

Administrative Physician agrees with Attending Physician

Yes → Administrative Physician with assistance of colleagues may suggest or require further consultation.

The Administrative and Attending Physicians meet with the patient/proxy/surrogate/family member and discusses findings and options.

If no resolution is reached, Attending physician/hospital will offer to assist in transferring the patient to another appropriate physician and/or hospital after the patient/proxy/surrogate finds one willing to accept the patient.

Expiration Date: 05/24/2022
Title: Fall Risk Assessment and Prevention

POLICY STATEMENT:
Colleagues assess each patient for his or her fall risk and implement appropriate safety interventions in the least restrictive environment possible.

PURPOSE:
To guide decisions regarding the management of patients at risk for falls with appropriate risk assessment, interventions, and follow up to achieve a reduction in the number of patient falls and injuries for an end goal of Zero Harm.

SCOPE:
Applies to all clinical and medical colleagues.
Applies to inpatients and outpatients.

DEFINITIONS:
Fall- Any unplanned descent to the floor or next lower surface, excluding falls resulting from violent blows or other purposeful actions. This will include all assisted falls and exclude fall near misses.

Assisted Fall- When a colleague attempts to minimize the impact of a fall.

Fall Near Miss- Any situation in which the patient is at risk for a fall, but a fall does not occur.
Examples include:
  o Bed rail left down
  o Patient without gait belt when required or bed/chair alarm appropriately armed
  o Patient transferring or ambulating without required assistance

Witnessed/Unwitnessed Fall- It is assumed the patient has fallen when a patient is found on the ground regardless if there was a witness unless other explanation provided.

Level of Injury
  o 0 – No apparent injury
  o 1 – Minor injury (abrasion, bruise, minor laceration requiring application of a dressing, ice, cleaning of the wound, limb elevation, or topical medication)
  o 2 – Moderate injury (laceration requiring stitches/steri-strips, fracture that does not require surgery, casting, or traction, or may be splinted)
  o 3- Major injury (resulted in surgery, casting, traction, required neurological consultation {e.g. basilar skull fracture or small subdural hematoma} or internal injury {e.g. rib fracture, small liver laceration} or patient with any type of fracture regardless of treatment or patients who have coagulopathy who receive blood products as a result of a fall)
Title: Fall Risk Assessment and Prevention

- 4-Death (Patient died as a result of injuries sustained from the fall, not from physiological events causing the fall)

Patient Safety Attendant- Colleague who provides 1:1 monitoring of patient.

Tele Sitter- Continuous virtual monitoring (CVM) via the AvaSys robot.

RESPONSIBILITIES:
Conducting the fall risk assessment is the responsibility of qualified nursing staff members who have completed relevant training and education. Adult Fall Risk Assessment will be completed on all patients and will be completed as part of the initial nursing assessment within four (4) hours of admission to the unit.

PROCEDURES:
1. Fall risk re-assessment will be done:
   a) Twice daily (each shift)
   b) Upon transfer to a new unit.
   c) Post fall
   d) Change of status; defined to include:
      - Surgery
      - Anesthesia
      - Procedure
      - Change in patient condition warranting a call to the physician

2. Patient populations:
   A. Adult inpatients entering Saint Joseph Health System (SJHS) will be considered at risk for falls and will have Universal Fall Precautions implemented. Additional fall risk precautions will be implemented for patients with a Hester Davis score greater than/equal to 7 or with a last known fall within the last month/during current hospitalization.

   1) Hester Davis Scale
      a) Last known fall
         - With the last year
         - Within the last six months
         - Within the last month
         - During the current hospitalization
      b. Mobility
         - Dizziness/generalized weakness
         - Immobilized/requires assist of one person
         - Use of assistive device/requires assist of two people
         - Hemiplegic, paraplegia, or quadriplegia
      c. Medications
         - Cardiovascular or central nervous system meds
Title: Fall Risk Assessment and Prevention

- Cardiovascular and central nervous system meds
- Diuretics
- Chemotherapy in the last month

d. Mental Status/LOC/Awareness
- Awake, alert and oriented to date, place and person
- Oriented to person and place
- Lethargic/oriented to person only
- Memory loss/confusion and requires reorienting
- Unresponsive/noncompliance with instructions

e. Toileting needs
- No needs
- Use of catheters or diversion devices
- Use of assistive device (bedside commode, bedpan, urinal)
- Incontinence
- Diarrhea/frequency/urgency

f. Volume/Electrolyte Status
- No problem
- NPO greater than 24 hours
- Nausea/vomiting
- Low blood sugar/electrolyte imbalances

g. Communication/Sensory
- No deficits
- Visual (glasses)/hearing deficit
- Non-English speaking patient/unable to speak/slurred speech
- Neuropathy
- Blindness or recent visual change

h. Behavior
- Appropriate behavior
- Depression/anxiety
- Behavioral noncompliance with instruction
- Ethanol/substance abuse
- Impulsiveness

1) Universal Fall Precautions: Precautions to be implemented for all adult patients admitted to SJHS

a) Orient patient to surroundings
b) Ensure patient footwear is adequate; if no footwear is available, provide non-skid socks
c) Keep bed in low position and locked
d) Lock all wheels on all wheelchairs, beds, commodes, and stretchers.

Expiration Date: 01/04/2026
Title: Fall Risk Assessment and Prevention

e) Ensure adequate lighting, patient room is free of clutter and trip hazards.
f) Call light is within easy reach of the patient.
g) Keep telephone (hospital phone and cell phone) and patient personal items within reach of the patient.
h) Perform purposeful hourly rounding with extra focus on addressing the “5 P’s” including:
   • “Potty” (toileting)
   • Pain assessment
   • Positioning
   • Possessions (ensuring that personal items and phones (hospital and cell phone) are within reach)
   • Protection (ensuring bed is low and locked, bed or chair alarm on, consideration of virtual monitoring, side rails up appropriately, removal of clutter, non-slip socks are on, and call light is within reach).
i) Consider additional rounding surrounding the following times:
   • Upon awakening
   • One hour after diuretics
   • Before analgesics
   • After meals
   • Before bedtime
j) Standardized patient/family education has been completed utilizing the Patient Safety through Fall Prevention trifold.
k) Provide patient/family with age-appropriate education on ways to prevent a fall from occurring such as: use of eyeglasses, appropriate footwear, hearing aids and any personal assistive devices as needed.
l) Call for assistance to transfer, ambulate, toilet or retrieve hard to reach items.
m) Inform the nurse of any symptoms (e.g. dizziness or lightheadedness) with postural changes.

2) Additional fall risk precautions will be implemented for patients with a Hester Davis score greater than/equal to 7 or with a last known fall within the last month/during current hospitalization. Nursing may implement additional precautions beyond a patient’s fall score but should not use less precautions than the fall score in any category warrants.
   a) Place a yellow wrist band on patient
   b) Initiate yellow light indicating fall risk within Hill Rom call system if patient had a previous fall during current hospitalization.
   c) Bed or chair alarm activated
   d) Consider requesting family to stay with patient
   e) Re-orient to environment, time, person, place, as frequently as needed and/or use behavior management techniques.
Title: Fall Risk Assessment and Prevention

f) Consider the use of telesitter or 1:1 Patient Safety Attendant.
g) Use gait belt for ambulation
h) Initiate a Fall Care Plan which addresses:
   - Medications (pain, antidepressants, anti-epileptics, diuretics, anti-psychotics, sedatives/hypnotics, and/or opiates/narcotics)
   - Cognitive function
   - Gait and/or balance
   - Other issues that may be contributing to patient's risk for falls
i) Recommend referral or consults as needed to address individually assessed problems (e.g. physical therapy, occupational therapy, pharmacy, speech, social worker, pain management)

3) Patients who are at high risk for falls and who meet one or more of the following IMPOSE criteria will be considered as 'Stay with Me' patients. Colleagues will remain within arm's reach (approximately 3 feet) of the patient and maintain visualization of the patient during toileting for prompt intervention and fall prevention.
   - Impulsive
   - Meds – Anticoagulants, Diuretics, Antihypertensives, Analgesics (Pain meds)
   - Past fall
   - Osteoporosis
   - Surgery
   - Eighty-five or older

B. Adult outpatients entering SJHS will be considered at risk for falls and will have Universal Fall Precautions (see above) implemented in addition to any other fall precautions or specialized interventions appropriate for that location in accordance with department assessment protocols in the Assessment and Reassessment policy.
   1) Colleagues will demonstrate an awareness of the patient's status and communicate any concerns to the clinical staff.
   2) Colleagues will assess the patient's ability to ambulate to the treatment area or exam room and provide appropriate assistive devices/assistance as needed.
   3) Colleagues will perform a clinical assessment of the patient's ability to sit, stand, lie and participate in the various positions needed for treatment.
   4) If a patient is determined to be at high risk for falls, the patient should remain visible to colleagues during the outpatient visit.

C. Newborn patients will be considered at risk for falls and will have Universal Newborn Fall Precautions implemented.
   1) Universal Newborn Fall Precautions: Precautions implemented for patient birth to age 28 days. Reference Neonatal Safe Sleep and Fall Prevention Policy for more in-depth information
a) Newborns are at fall risk all the time.
b) Infants are in a crib, warmer or isolette when not being held. Other approved
Title: Fall Risk Assessment and Prevention

devices can be used, provided the infant is supervised.
c) Cribs or warmers are used for transporting infants from place to place. Head of
the bed is flat during transport.
d) At all times when infant is unattended, ensure crib rails are fully raised, warmer
sides are up, and isolette doors are closed.
e) Ensure that children are closely supervised while weighing or conducting
procedures.
f) Mother needs to call for assistance when handling infant until the mother is
ambulatory.
g) Infant should not sleep in bed with mother.
h) When mother is breastfeeding in bed, bed rails x2 should be up and pillows use
for propping infant.
i) At all times, an adult must supervise minors who are allowed to hold the infant.
j) Family will be educated on fall prevention strategies as stated above.

D. Pediatric Patients entering SJHS will be considered at risk for falls and will have Universal
Pediatric Fall Precautions implemented.

1) Universal Pediatric Fall Precautions: Precautions implemented for pediatric patients.
This list of fall precautions will be used as age and developmentally appropriate for
pediatric patients in addition to the Universal Fall Precautions for adult patients.

2) Determine appropriate bed type and position. Typically, children age 3 and under will
use a crib but will depend on patient size and developmental status.

3) Keep objects and toys away from latches on cribs to make sure they are locked.

4) Use bubble tops on cribs for children who can pull to a standing position.

5) Keep bed/crib rails up and isolette doors closed when child is unattended.

6) Keep the floors and hallways clutter/obstacle free.

7) Ensure the children are closely supervised while weighing or conducting procedures.

8) All infants and developmentally young children are transported in the appropriate device
(e.g., crib, wagon, isolette)

Family will be educated on fall prevention strategies as stated in above precautions. Post Fall
Assessment and Follow-up

1) Nurse will immediately assess a patient who has sustained a fall, including assessment for
trauma and assessment of vital signs prior to moving the patient when possible. For pregnant
patients, notify OB provider, consider assessment of fetal heart tones. A physician will be
notified immediately after the initial assessment. The patient's physician, physician on-call
for the practice, Emergency Department physician, or resident physician will assess the
patient within two (2) hours of the occurrence based on the nature and severity of any injuries
to determine the need for additional interventions.

2) A Fall Huddle will convene following the assessment. The team members are to include
(depending on availability) nurses, physicians, PCPs, rehabilitation, nursing management,
risk management, administrative supervisor and Patient Safety Officer. The Post Fall Huddle
Form will be completed forwarded to the unit manager and risk manager.

3) The family will be notified of the fall as soon as possible with patient permission.

4) A significant event form will be documented in Epic immediately following the event.
Title: Fall Risk Assessment and Prevention

5) A VOICE report will be submitted

REFERENCES/STANDARDS:
- Post Fall Huddle Form (# 6010-30) available on Daily Dose under Clinical Forms.
Title: Pain Management

Policy:

1. Patients in all settings will be assessed/screened for presence, absence and history of pain at point of service.
2. Assessment of pain (Pain Scales):
   A. Patient’s self-report is the primary indicator of pain reporting:
      1) Verbal (0 – 10) Pain Scale with 0 being no pain and 10 being worst pain.
         a) Mild (1-3), Moderate (4-6), Severe (7-10)
      2) Adults and Children who can understand number concept
         a) Faces Scale: Children (age 3 and older) and Adults
         b) Other self-reporting methods include; Visual Analog Scale (VAS); Categorical Scales: patient rates pain using verbal or visual descriptor (mild, unbearable, crushing, etc.)

3. Assessment of Pain in Patients with Barriers to Communication
   A. Infants and children
   B. Individuals with advanced age (e.g. older than 85 years)
   C. Adults with emotional or cognitive disturbances
   D. Patients with cultural, educational, or language barriers to communication
   E. Intubated patients
   F. Patients who are seriously ill

4. General Approach to Pain Assessment of Patients with Barriers to Communication
   A. Allow sufficient time for the assessment
   B. Allow opportunity to use a rating scale or other tool appropriate for that population (i.e. intubated patient may nod, point to a number on a scale, etc)
   C. Use of Hierarchy of Pain Assessment:
      1) Self-report whenever possible
      2) Search for Potential Causes of Pain – Pathologic Conditions (e.g. surgery, wound care, rehab activities, positioning/turning, blood draws, heel sticks, history of persistent or chronic pain)
      3) Observe Patient Behaviors that may indicate pain such as grimacing, crying, agitation.
      4) Use of behavioral pain assessment scales
Title: Pain Management

a) For patients who are cognitively impaired or unable to verbalize pain intensity on verbal pain scale, use age or population appropriate pain rating scale in the electronic medical record (EMR).
b) Pain intensity using objective judgment may not be an accurate reflection of the severity of pain in these patients. A multifaceted approach is recommended (observation, family/caregiver and evaluation of response to treatment).
c) Surrogate Reporting (family members, parents, caregivers)
d) Attempt an Analgesic Trial based on estimated pain intensity (mild, moderate, severe), patient’s pathology and analgesic history.

5. Initial patient history will include: Screening question about pain based on patient self-report.
6. When self-report is not obtainable the nurse will utilize Hierarchy of Pain Assessment as above. A positive finding for pain on admission will initiate further questioning, which includes, but is not limited to the following:
   A. Description
   B. Intensity
   C. Location
   D. Aggravating and alleviating factors
   E. Associated signs and symptoms
   F. Impact on functional ability
   G. Methods of pain management (current and past regimens and effectiveness)
   H. Patient’s personal goal for pain relief
   I. Physical exam/observation of the pain site

7. Initial assessment of learning includes pain management and becomes a part of the plan of care.
8. Pain assessment (intensity and/or pain relief) will be assessed/screened and documented at a minimum:
   A. On admission/presentation to Emergency Department
   B. Routine: based on assessment/reassessment policy, physician orders, and patients’ status.
   C. After any known pain producing event
   D. With each new report or behavioral indication of pain
   E. After each pain intervention once sufficient time has lapsed for the treatment to reach peak effect (pharmacologic and nonpharmacologic).
      1) Within 30 Minutes for IV Medications
      2) Within 60 Minutes for PO Medications or other Non-Pharmacologic interventions
      3) Intensity (reported verbal pain level 0-10 or corresponding pain level if objective pain scale utilized) of pain should be documented at time of Intervention and post intervention as above.
         a) If verbal rating scale utilized and patient resting or cannot rate intensity of pain at minimum document the following
            (1) Pain relieved with Medication? Yes or No (If unable to determine – i.e. patient sleeping then complete is pain level acceptable)?
            (2) Is pain level acceptable? Yes, No, Unable to Determine, or Other. If Unable to determine or other (add comment – i.e. sleeping).

9. Parents/legal guardians will be involved in pain management decisions regarding their child
Title: Pain Management

10. Methods to decrease pain in neonates, infants, and children include but are not limited to:
   A. Providing information and preparing the parent and child.
   B. Involving the parent.
   C. Maintaining a quiet, calm environment.
   D. Allowing comfort items such as favorite stuffed animals or blankets.
   E. Giving the child choices to increase the perception of control.
   F. Planning ahead and drawing all blood samples at once if possible.
   G. Sucrose Pacifier

11. All terminally ill patients will be kept as comfortable as possible to allow them to die comfortably and with dignity. It is understood that medications may be given to the dying patient, even if this therapy may indirectly shorten patient’s life, as long as the intent is not to hasten death.

PROCEDURE:

Pain Assessment
A. Admitting nurse questions patient for current pain and a history of pain. If patient complains of pain or behavioral indicators are present, appropriate approved scale should be used for intensity and the remainder of comfort section completed.
B. Process of interventions should be initiated and documented with modifications based on patient self-report and ongoing assessments. Patient preferences for pain management strategies (pharmacologic and/or nonpharmacologic) should be utilized when possible. Personal, cultural, spiritual, and/or ethnic beliefs will be considered in decisions regarding pain management.
C. Prescribed analgesics should be administered in a timely, logical, and coordinated manner.
D. There are certain circumstances when an LIP may write PRN medication orders that allow variation in administration based on patient preference.

   1) A patient may request to receive a medication ordered for a lesser pain scale. It is NEVER acceptable to administer a medication intended for a higher pain scale based on patient preference.

   a) For example, if a patient has on their profile Tylenol 650 mg every 4-6 hours PRN for Mild Pain and Norco-5 1 tablet every 4-6 hours PRN for Moderate pain then:

1. If the patient reports their pain is Mild, they can receive the Tylenol because it is indicated for Mild Pain
2. If the patient reports their pain as Moderate, they can receive the Norco for Moderate pain or the Tylenol because it is ordered for a lesser pain scale
3. If the patient reports their pain as Mild, they can NEVER receive the Norco, as it is intended for a higher pain scale

   2) The medical record must accurately reflect that the medication used for a lesser pain scale was based on patient preference.

E. As an adjunct to analgesia, nonpharmacologic approaches may be utilized (e.g. distraction therapy, positioning).
F. If a patient continues to complain of unrelieved pain following interventions, the physician should be contacted. Additionally, new pain, change in location, quality or intensity, and side effects should be documented and reported.
G. Patient and family education should include rights and responsibilities, information to allay fears and correct misconceptions about pain medications, pain treatment, and expected response.
Title: Pain Management

H. A proactive approach should be utilized re: anticipated pain-producing events, e.g. exercise, wound care, diagnostic/therapeutic procedures.
11. Pain management should be included in the discharge planning process.
12. Staff education regarding pain management should be provided, and staff competency should be evaluated during orientation and on an on-going basis.
13. Pain management issues will be included in topics for discussions during interdisciplinary care planning/conferences.
14. Patient’s preference for pain rating scale will be determined at first report of pain, and will be utilized for subsequent pain assessments. Change in the patients’ condition may require utilization of a different pain scale or method.

Related Documents/Information:
• See Range Order policy for medication administration requirements based on patient pain rating (mild, moderate, severe) and rules regarding patient preference when requesting medication ordered for lower rating.

References/Standards:
• Gelinas C., Fillion L., Puntillo K., et al: Validation of the Critical Care Pain Observation Tool (CPOT) in adult patients, Presented at the IASP 11th World Congress on Pain, Sydney Australia, August 12, 2005
• Krechel S W, Bildner J: CRIES: a new neonatal postoperative pain measurement score, Initial testing and validity and reliability. Paediatric Anaesthesiology, 5(1), 53-61
Title: Restraints and Seclusion

<table>
<thead>
<tr>
<th>Document Owner: Gregor Staniszewski</th>
<th>PI Team: POC</th>
<th>Date Created: 06/01/08</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approver(s): LeAnn Springman, Loretta Schmidt</td>
<td>Date Approved with no Changes: 05/26/2021</td>
<td>Date Approved: 05/26/2021</td>
</tr>
<tr>
<td>Location: Saint Joseph Regional Medical Center (SJRMC)</td>
<td>Department: Nursing Admin (14030_10005)</td>
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</table>

Policy:

Policy Statement
Use of restraint and seclusion is limited to situations in which it is necessary to ensure the immediate physical safety of the patient, staff members, or others. Restraint and seclusion are used only with appropriate and adequate clinical justification when less restrictive interventions are ineffective and the least restrictive means of restraint or seclusion to ensure safety is applied. It is not used as a means of coercion, discipline, convenience, or staff retaliation. Discontinuation of restraint and seclusion occurs as soon as possible, based on an individualized patient assessment and reevaluation, regardless of the scheduled expiration of the order.

Purpose
To establish standardized decision-making criteria and practical procedures for the use and discontinuation of restraint and seclusion to protect the patient’s health and safety and the safety of others, as well as to preserve the patient’s dignity, rights, and well-being.

Scope
Applies to staff members who provide patient care, who may assist with the application of restraints, and who monitor patients in restraints and/or during seclusion.

Definitions
Authorized physician or other licensed independent practitioner – An individual primarily responsible for the patient’s ongoing care who is legally authorized to practice by the state in which this organization is located and who is acting within the scope of his or her license when he or she orders restraint or seclusion.

Restrain – 1. Any method (chemical or physical) of restricting an individual’s freedom of movement, including seclusion, physical activity, or normal access to his or her body that
   (1) is not a usual and customary part of a medical diagnostic or treatment procedure to which the individual or his or her legal representative has consented,
   (2) is not indicated to treat the individual’s medical condition or symptoms, or
   (3) does not promote the individual’s independent functioning.

2. Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or

   A drug or medication when it is used as a restriction to manage the patient’s behavior or restrict the patient’s freedom of movement and is not a standard treatment or dosage for the patient’s condition.
Title: Restraints and Seclusion

3. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

Seclusion – Seclusion occurs on the Plymouth campus only in the ED safe room.
1. The involuntary confinement of an individual in a room alone, for any period of time, from which the individual is physically prevented from leaving. Seclusion may be used only for the management of violent or self-destructive behavior.

Seclusion does not include involuntary confinement for legally mandated but nonclinical purposes, such as the confinement of a person who is facing serious criminal charges or who is serving a criminal sentence. Forensic patients require the presence of law enforcement.

Responsibilities
Ordering restraint and/or seclusion is the responsibility of a physician or another licensed independent practitioner primarily responsible for the patient’s ongoing care.

<table>
<thead>
<tr>
<th>Restraints Non-Violent (Non-Violent or Non-Self-Destructive)</th>
<th>Restraints Violent (Violent or Self-Destructive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical restraints used to limit the mobility of a patient related to a medical/post-surgical need. The reason for use is to directly support medical healing by preventing interference with treatment or unsafe behavior by the patient.</td>
<td>Physical restraint used in emergency situations where the patient's behavior is violent, aggressive, or assaultive, and the least restrictive measure that will assure the patient or others safety is a restraint or seclusion. This is behavior that presents an immediate and serious danger to the safety of the patient, other patients, or staff. Medications used for behavior management are medications used in addition to or in replacement of the patient's regular drug regimen to control extreme behavior during an emergency.</td>
</tr>
</tbody>
</table>

PROCEDURE:

Only an authorized physician or another licensed independent practitioner does the following:
1. Orders the use of restraint or seclusion when determined to be clinically necessary.
   • Determines that all alternative interventions have been considered or have failed.
   • Assess the risks and benefits of restraint or seclusion use.
2. Includes the following details in all orders for restraint or seclusion:
   • Type of restraint or seclusion
   • Start time of restraint initiation
   • Anticipated ending time as soon as possible, based on an individualized patient assessment and reevaluation
Title: Restraints and Seclusion

- All non-violent restraints are ordered daily; violent restraints are to be reordered
- Indications and reasons for use
- Behavioral criteria for release

Emergency Situations Without an Available, Authorized Physician, or Licensed Independent Practitioner
A registered nurse (RN) who is competent in restraint or seclusion usage does the following:
1. Directs that the patient be restrained or secluded.
2. Notifies the authorized physician, or licensed independent practitioner immediately and obtains an order. Immediately, either during the restraint application or after restraints applied, ideally 15 minutes or less.
3. For Violent restraints/seclusion the patient is under constant supervision until the physician, or licensed independent practitioner arrives. The physician /LIP completes the face-to-face assessment either before or within an hour after the application of the violent restraint/seclusion.
4. Documents the following:
   - Name of the authorized physician or licensed independent practitioner who was notified
   - Time the physician, clinical psychologist, or licensed independent practitioner was notified
   - Alternative measures that were considered or attempted
   - Rationale for the restraint or seclusion method used
   - Steps taken to ensure that the patient’s needs, comfort, and safety were appropriately considered

The notified physician or licensed independent practitioner will do the following:
1. Write an order for the restraint during the emergency application of the restraint or seclusion.
OR
2. Write an order for the restraint immediately after the restraint or seclusion is applied, if it is not possible to write the order during the emergency application of the restraint or seclusion.
3. Will evaluate the patient within one hour of Violent restraint application if not present during the application.

Applying the Restraint or Initiating Seclusion
Staff members do the following:
1. Use the least restrictive device.
2. Apply the restraint or initiate seclusion in a manner that respects the patient’s rights, confidentiality, dignity, privacy, and individuality.
3. As needed, gather staff to safely apply the restraint or initiate seclusion and explain why the restraint/seclusion is being initiated and any comorbidities of the patient.
4. Explain the following to the patient and/or his or her family, as appropriate:
   - Procedure to be used
   - Reason for procedure
   - Criteria for release
   - Notify family if not present and document in EMR
5. Allow the patient and/or family to participate in the patient’s care, as appropriate.
6. Maintain the patient’s modesty at all times.
7. Maintain a clean, safe, and comfortable environment.
**Title: Restraints and Seclusion**

**Monitoring:**
1. Provide a means of communication with the patient at all times
2. Evaluate the patient for safety and comfort at the initiation of restraint or seclusion. The evaluation includes any of the following, as appropriate to the patient and the type of restraint or seclusion:
   - The type of restraint applied
   - Nutrition and hydration
   - Circulation and range of motion in the extremities (unless the patient is asleep)
   - Vital signs
   - Hygiene and elimination
   - Physical and psychological status and comfort
   - Readiness for discontinuation of restraint or seclusion
3. Take and record vital signs, as ordered or per Assessment/Re-Assessment policy

**Continued Use of Restraint or Seclusion**
Only an authorized physician or another licensed independent practitioner does the following:
1. Determines the clinical justification for continued use of restraint or seclusion at the time of the order's renewal.
2. Issues a new order of restraint only when clinically justified.
3. A physician's order is required daily for the continued use of non-violent restraint.
4. For violent/self-destructive behavior, renewal of the order is within the following limits,
   - 4 hours for adults 18 years of age or older and emancipated minors
   - 2 hours for children and adolescents 9 to 17 years of age
   - 1 hour for children under 9 years of age

**Release from Restraint or Seclusion**
RN does the following:
1. Assesses the patient for readiness to discontinue restraint or seclusion at regular intervals that ensure the patient’s safety.
2. Documents the restraint assessments in the patient’s medical record.
3. Uses the criteria for discontinuation included in the order of restraint or seclusion to determine the patient’s readiness for release.
4. Prohibits the use of PRN (“as needed”) orders for restraints.
5. Restraints may be removed during providing care to a patient as long as nurse remains at the bedside.
6. If a restraint is removed for any duration or a lesser restraint is appropriate the nurse will need to obtain a new order from for restraining the patient.
**Title: Restraints and Seclusion**

Restrain ordering process:

<table>
<thead>
<tr>
<th>Non-Violent Restraint</th>
<th>Violent Restraint</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Non-Violent or Non-Self-Destructive)</td>
<td>(Violent or Self-Destructive)</td>
</tr>
<tr>
<td>a) For patients who are exhibiting behavior that is interfering with patient care such as the patient is attempting to pull out tubes.</td>
<td>a) For aggressive, violent patient who present immediate and serious danger to self or others</td>
</tr>
<tr>
<td>b) EMR fires task to the nurse to renew order in 20 hours</td>
<td>b) EMR does not fire tasks</td>
</tr>
<tr>
<td>Restraint Order Review Pending</td>
<td>c) Document on Violent Restraint Form</td>
</tr>
<tr>
<td>ii) After review of need for renewal, complete on Activities/Interventions</td>
<td>d) Restraints are used to control assaultive, combative behavior</td>
</tr>
<tr>
<td>c) EMR fires tasks for the Nonviolent Restraint Form q 2 hours</td>
<td>e) The order must be obtained prior to application or as restraints are being applied or within minutes of the application. Physician must complete a face-to-face assessment either before or within one hour of application of the restraints.</td>
</tr>
<tr>
<td>i. Initiation – must be completed when initiating restraint(s)</td>
<td>f) The initial order cannot exceed four hours for adults, two hours for adolescents (age 9-17) or one hour for children under 9. The order may be renewed every four hours (for adults) by phone if necessary, for a total of 24 hours. Orders for adolescents and children cannot be renewed without a face-to-face and reassessment by the physician.</td>
</tr>
<tr>
<td>ii. Subsequent assessments: complete the assessment</td>
<td>g) Orders must include:</td>
</tr>
<tr>
<td>iii. Discontinue – complete when restraint no longer needed</td>
<td>i. Date and time of order</td>
</tr>
<tr>
<td>iv. Must ad hoc the first form (the EMR will fire the task on the next even hour from the time the restraint was ordered)</td>
<td>ii. Less restrictive alternated tried</td>
</tr>
<tr>
<td>d) An order must be obtained as restraints are being placed or within minutes of being applied.</td>
<td>iii. Clinical justification/Indication for restraint</td>
</tr>
<tr>
<td>e) A physician’s order is required daily for the continued use of restraints</td>
<td>iv. Type of restraint</td>
</tr>
<tr>
<td>f) Orders must include:</td>
<td>v. End restraint when no longer required</td>
</tr>
<tr>
<td>i. Date and time of order</td>
<td>vi. Physician’s signature</td>
</tr>
<tr>
<td>ii. Less restrictive alternated tried</td>
<td><strong>PRN orders are not permitted</strong></td>
</tr>
<tr>
<td>iii. Clinical justification/Indication for restraint</td>
<td></td>
</tr>
<tr>
<td>iv. Type of restraint</td>
<td></td>
</tr>
<tr>
<td>v. End restraint when no longer needed</td>
<td></td>
</tr>
<tr>
<td>vi. Physician’s signature</td>
<td></td>
</tr>
<tr>
<td><strong>PRN orders are not permitted</strong></td>
<td></td>
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</tbody>
</table>

A. Re-assessment (Nursing)
## Title: Restraints and Seclusion

<table>
<thead>
<tr>
<th>Restraints Non-Violent Restraint Form</th>
<th>Restraints Violent Restraint Form</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Non-Violent or Non-Self-Destructive)</strong></td>
<td><strong>(Violent or Self-Destructive)</strong></td>
</tr>
<tr>
<td>1) RN reassesses every two hours for:</td>
<td>1) At the end of the initial 4-hour order if the</td>
</tr>
<tr>
<td>a) Behavior indicating continued need</td>
<td>continued use of restraint to manage violent or</td>
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<tr>
<td>b) Appropriate application</td>
<td>self-destructive behavior is deemed necessary</td>
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<tr>
<td>c) Least restrictive method used</td>
<td>based on an individualized patient assessment,</td>
</tr>
<tr>
<td>d) Physical and emotional well-being</td>
<td>another order is required.</td>
</tr>
<tr>
<td>e) Rights, dignity and safety maintained</td>
<td></td>
</tr>
<tr>
<td>2) Observation routine rounding schedule</td>
<td>2) Prior to the expiration of the original order the</td>
</tr>
<tr>
<td>3) Vital signs every 4 hours if clinically indicated</td>
<td>RN, must contact a physician or other LIP, report</td>
</tr>
<tr>
<td>4) Circulation and skin check every 2 hours</td>
<td>the results of his/her most recent assessment and</td>
</tr>
<tr>
<td>5) Release of restraint, range of motion and</td>
<td>request that the original order be renewed, if</td>
</tr>
<tr>
<td>repositioning every 2 hours</td>
<td>restraints are still indicated.</td>
</tr>
<tr>
<td>6) Offering fluids and toileting every 2 hours</td>
<td>3) The original restraint order may be renewed</td>
</tr>
<tr>
<td>7) Provision for nutrition</td>
<td>within the limits for up to a total of 24 hours. The</td>
</tr>
<tr>
<td>8) Provision for regular hygiene and personal</td>
<td>physician/LIP must assess the patient at the end of</td>
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<tr>
<td>care</td>
<td>the 24-hour period to renew the restraints.</td>
</tr>
<tr>
<td>9) Documentation is recorded in EMR</td>
<td>4) Whether or not an onsite assessment is</td>
</tr>
<tr>
<td>Restraint form every 2 hours</td>
<td>necessary prior to renewing the order is left at the</td>
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<td></td>
<td>discretion of the physician or LIP in conjunction</td>
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<td>with the discussion with the RN who is overseeing the</td>
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<td></td>
<td>care of the patient.</td>
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<tr>
<td>5) RN reassesses at least every 15 minutes for:</td>
<td>5) RN reassesses at least every 15 minutes for:</td>
</tr>
<tr>
<td>a) Behavior indicating continued need</td>
<td>a) Behavior indicating continued need</td>
</tr>
<tr>
<td>b) Appropriate application</td>
<td>b) Appropriate application</td>
</tr>
<tr>
<td>c) Least restrictive method used</td>
<td>c) Least restrictive method used</td>
</tr>
<tr>
<td>d) Physical and emotional well-being</td>
<td>d) Physical and emotional well-being</td>
</tr>
<tr>
<td>e) Rights, dignity and safety maintained</td>
<td>e) Rights, dignity and safety maintained</td>
</tr>
<tr>
<td>f) Effects of medication if used as restraint</td>
<td>f) Effects of medication if used as restraint</td>
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<tr>
<td>6) Continuous observation by caregiver and</td>
<td>6) Continuous observation by caregiver and</td>
</tr>
<tr>
<td>complete observation records every 15 minutes</td>
<td>complete observation records every 15 minutes</td>
</tr>
<tr>
<td>7) Vital signs as dependent upon the patient's needs and situational factors</td>
<td>7) Vital signs as dependent upon the patient's needs and situational factors</td>
</tr>
<tr>
<td>8) Circulation and skin check every 15 minutes</td>
<td>8) Circulation and skin check every 15 minutes</td>
</tr>
<tr>
<td>9) Release of restraint, range of motion and repositioning every 2 hours/pm</td>
<td>9) Release of restraint, range of motion and repositioning every 2 hours/pm</td>
</tr>
<tr>
<td>10) Provision for nutrition</td>
<td>10) Provision for nutrition</td>
</tr>
<tr>
<td>11) Provisions for regular hygiene and personal care</td>
<td>11) Provisions for regular hygiene and personal care</td>
</tr>
<tr>
<td>12) Documentation is recorded in EMR</td>
<td>12) Documentation is recorded in EMR</td>
</tr>
<tr>
<td>Restraint forms every 15 minutes</td>
<td>Restraint forms every 15 minutes</td>
</tr>
</tbody>
</table>

1. Education/Training of Associates/LIPs
Title: Restraints and Seclusion

A. Education regarding use of restraints will be included in orientation as appropriate for patient care associates, prior to participating in the application of restraints, the monitoring, assessment, or care of a patient in restraints.

B. Additional competencies will be provided for appropriate patient care associate, based on the associate's needs, changes in policy, and trends in restraint data.

C. Physician/LIP - Upon orientation and based on the Physician/LIP needs, changes in policy, and trends in restraint data.

2. Reporting of Deaths Related to Restraint/Seclusion Usage

A. The hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient’s death:
   a. Each death that occurs while a patient is in restraint or seclusion.
   b. Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
   c. Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. “Reasonable to assume” in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation…
   d. The staff must document in the patient’s medical record the date and time the death.

B. The hospital must report to its CMS Regional Office each death that occurs, the only exception is when no seclusion has been used and the only restraint used was a soft, cloth-like two-point wrist restraints;
   • Within 24 hours after the patient has been removed from restraint or seclusion, except when no seclusion has been used and the only restraint used was a soft, two-point wrist restraint; or,
   • Within 1 week after use of restraint or seclusion where the death is known to the hospital and it is reasonable to assume that the use of restraint or seclusion contributed directly or indirectly to the patient’s death, regardless of the type(s) of restraint used on the patient during this time.
     • “Reasonable to assume” applies only to those deaths that occur on days 2-7 after restraint or seclusion has been discontinued.
     • This criterion applies regardless of the type of restraint that was used on the patient. In other words, it applies to all uses of restraint or seclusion where the patient has died on days 2-7 after the restraint or seclusion was discontinued, and it is reasonable to assume the use of the restraint or seclusion contributed to the patient’s death.
     • In a case where only two-point soft wrist restraints were used and there was no seclusion, it may reasonably be presumed that the patient’s death was not caused by the use of restraints.
     • In cases involving death within one week after use of restraint or seclusion where the intervention may have contributed to the patient’s death it is possible that the patient’s death might occur outside the hospital and that the hospital might not
Title: Restraints and Seclusion

Risk Management will document in the patient’s medical record the date and time the death was reported to CMS. When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient’s wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, Risk Management must record in an internal log the following information:

(i) Any death that occurs while a patient is in such restraints.
(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

D. Document in the patient’s medical record the date and time the death was recorded in the internal log for deaths

E. For deaths entered in to the log must be documented as follows:
   (i) Each entry must be made not later than seven days after the date of death of the patient.
   (ii) Each entry must document the patient’s name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient medical record number, and primary diagnosis(es).
   (iii) The log information must be made available in either written or electronic form to CMS immediately upon request.

F. Hospitals must maintain an internal log or other type of tracking system for recording information on each death that occurs:
   - While a patient is in only 2-point soft, cloth-like non-rigid wrist restraints and there is no use of seclusion; and
   - Within 24 hours of the patient being removed from 2-point soft, cloth-like non-rigid wrist restraints where there was no use of any other type of restraint or seclusion.

G. Use of the log is limited only to patient deaths meeting one of these two criteria. Examples of patient deaths associated with restraints that must still be reported to CMS include:
   - Deaths occurring during or within 24 hours of discontinuation of 2-point soft, cloth-like non-rigid wrist restraints used in combination with any other restraint device or with seclusion; or
   - Deaths associated with the use of other types of wrist restraints, such as 2-point rigid or leather wrist restraints.

H. These cases would not be included in this internal log or tracking system and would require reporting the death to CMS using telephone, fax, or electronically.

I. The two-point soft wrist restraint death report must be entered into the internal log or tracking system within 7 days of the patient’s death.

J. The death report log or tracking system entry must include:
   - The patient’s name;
   - Patient’s date of birth;
   - Patient’s date of death;
     - Name of the attending physician or other licensed practitioner who is responsible for the care or the patient;
   - Patient’s medical record number; and
Title: Restraints and Seclusion

- Primary diagnosis(es), cause of death (preliminary, in case a final, official cause of death is not yet available),
- types of restraint of seclusion used.

K. There is a CMS form used by Risk Management to complete and submit to CMS
L. The information must be made available in either written or electronic form to CMS immediately upon request.

M. The Indiana State Department of Health regulations require any patient death or serious disability associated with the use of restraints or bed rails while being cared for in the hospital must be reported. The report must be submitted to the State Department of Health no later than 15 working days after the reportable event is determined to have occurred by the hospital; and a potential reportable event once identified by the hospital must be submitted no later than 4 months to the State Department of Health. The System CNO is responsible for reporting the incident in cooperation with the risk manager.

N. The hospital must report to the Food and Drug Administration (FDA), and to the device manufacturer—if the manufacturer’s identity is known—within 10 working days of becoming aware of information that reasonably suggests that a device has caused or may have caused or contributed to a death. The hospital must report to the manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has caused or may have caused or contributed to a serious injury. Such reports shall be submitted to the FDA if the device manufacturer is not known. The System CNO or designee is responsible for reporting the incident in cooperation with the risk manager and the safety officer.

References/Standards:
- TJC RESTRAINT/SECLUSION STANDARDS.
- CMS RESTRAINT REGULATIONS.
POLICY:

1) A comprehensive approach in the care and treatment of patients with the following psychopathology and require acute care hospitalization will be used to ensure safety.
   a. Drug overdose
   b. Current intoxication or history of alcohol or drug abuse
   c. Mental/emotional disturbances with diagnosis/instability
   d. Patients with an Emergency Detention Order (EDO)

2) A suicide-screening tool (Columbia-Suicide Severity Rating Scale – C-SSRS) will be performed on patients who are being treated for or present with a complaint of an emotional or behavioral disorder to provide early identification of suicidal ideation or intent.

3) The suicide-screening tool will be completed by a Registered Nurse.

4) A patient is considered at risk for suicidal ideation if they answer "yes" to any questions on
   a. the Columbia-Suicide Severity rating Scale (C-SSRS). A patient is considered low, moderate, or high risk based on how the patient answers questions on the Adult Self-Harm Screening Tool/Columbia-Suicide Severity rating Scale (C-SSRS). The EHR will automatically determine the calculated risk level at the bottom of the Suicide Assessment based on the following questions:
      i. A patient is considered LOW RISK if the answer is "yes" to either of these screening questions and "no" to the other screening questions
         1. Wish to be dead (past 1 month)
         2. Non-specific active suicidal thoughts (past 1 month)
      ii. A patient is considered MODERATE RISK if the answer is "yes" to any of the above screening questions and yes to either of these questions:
          1. Active suicidal ideation with any methods (not plan) without intent to act (Past 1 month)
          2. Suicidal Behavior (lifetime)
      iii. A patient is considered HIGH RISK if they are placed on involuntary hold due to being at risk of harm to self. A patient is also considered HIGH RISK if the answer is "yes" to any of these screening questions in addition to any of the questions
          1. Active suicidal ideation with some intent to act, without specific plan (past 1 month)
          2. Active suicidal ideation with specific plan and intent (past 1 month)
          3. Suicidal behavior (3 months)
Title: Suicide/Mental Health Precautions, Suicide Assessment

5) All patients who suddenly have a change to a primary diagnosis that is behavioral or emotional will have a suicide screening tool completed within two hours. Suicide precautions will be implemented as appropriate, and a case management referral should be completed. If the screening has 3 or more positive responses, the physician will complete a suicide risk assessment.

6) If the physician's assessment indicates that the patient is at risk for suicide or mental health crisis, a referral to case management or Oaklawn will be made at Mishawaka campus. A referral to Bowen Center will be made in Plymouth.
   a. All transfers will occur by qualified transport services.
   b. Detained patients requiring a judge's signature for transportation to an inpatient psychiatric facility will be transported or escorted by county police.

7) The environment will be managed using the environmental checklist.

8) The level or risk and plan to mitigate the risk must be documented in the medical record.
   a. The plan to mitigate the risk must include the observation interventions (e.g., 1:1 or 1:2 monitoring, video monitoring).

9) Direct Observation of patients with suicidal ideations who are considered high risk
   a. consists of 1:1 continuous, unobstructed, undistracted monitoring, observations allowing
   b. for 360-degree viewing at a position to immediately intervene Immediately intervene is
   c. defined as being positioned unobstructed and close enough to prevent an action that
   d. may cause harm to the patient.
   e. For high-risk suicidal patients that also exhibit violent behaviors, security may be
      i. consulted to determine safe positioning of the observer to maintain direct
      ii. observation, while ensuring colleague safety. Observers must use caution, be
         iii. aware of surroundings, and respect personal boundaries.

10) The Administrative Supervisor and Charge Nurse must be notified of the need for a
   a. Patient Safety Attendant as soon as possible.

11) The RN will collaborate with the clinical social worker to determine a safety plan for the
   a. patient who is an acute threat to themselves (suicidal or awaiting involuntary psychiatric
   b. hospitalization). The physician may be involved in this process as needed; however, a
   c. physician order is not required for observation. Physician involvement is necessary if
   d. patient meets the criteria for emergency hold as dictated in EDO Policy

12) Patients admitted for medical care following a suicide attempt will be considered high-risk
   a. and remain on direct observation with 1:1 monitoring at a position to immediately
   b. intervene.

13) If a patient is sedated in a critical care unit requiring frequent clinical monitoring, he or
   a. she is at low risk of successful self-harm; therefore, the use of a Patient Safety
   b. Attendant is not clinically indicated.
   c. As soon as the patient is awake and becomes more alert or is transferred from
      i. critical care, a Patient Safety Attendant is required based on assessed risk.

14) Video monitoring without a patient observer is not permitted for any high-risk suicide
   a. patient. Video monitoring alone may be used for patients considered low or possibly
      moderate risk for suicide

PROCEDURE:
A. Admission Process:
Title: Suicide/Mental Health Precautions, Suicide Assessment

1) Emergency Department admission process/Attending physician responsibilities:
   a) The Emergency Department physician on duty will see patients in need of psychiatric care coming to the Emergency Department. He/she will determine the proper treatment. If the patient needs psychiatric hospital care the patient will be transferred, according to the hospitals transfer policy, to a facility caring for psychiatric patients. In all cases, the hospital will be responsible for the administration and continuity of patient care until transfer arrangements to an appropriate psychiatric care facility have been completed.
   b) Saint Joseph Regional Medical Center will only admit patients who are medically unstable for transfer to a psychiatric/substance abuse facility.
   c) When a patient is medically unstable for transfer, the Emergency Department physician, in consultation with the attending physician determines the appropriate care based on the patient’s physiological/mental status needs.
   d) Patients with secondary diagnosis of psycho-neurotic disorders, e.g., anxiety, mild depression associated with a physical disorder, will be admitted, and cared for at the discretion of the attending physician according to the established hospital and medical staff policies. The admitting unit will implement the SUICIDE/MENTAL HEALTH PRECAUTIONS as outlined below.

2) Patients who, during hospitalization, become emotionally ill and/or suffer from the effects of alcoholism or drug abuse, are treated and cared for under the direction of the attending physician.

3) Decision for care
   a) Mishawaka
      (1) Patient’s condition is stabilized and/or assessed in ED.
      (2) Notify case management/Oaklawn and request consult/evaluation when patient medically stable for transfer.
      (3) If a patient threatens and or the patient is deemed to be at risk of leaving, the physician may initiate an Emergency Detention Order see Medical Detention policy.
   b) Plymouth
      (1) Patient’s condition is stabilized in ED.
      (2) If a patient threatens to leave, see Medical Detention policy.
      (3) Notify Bowen Center of intent to transfer when medically stable.

B. Suicide/Mental Health Precautions: To reduce the risk of harm to self and/or others for the patient in crisis or severe depression.

1) Informational
   a) Interventions for safety are of primary importance for patients whose behavior may be destructive to themselves or others. The goal is to provide protection for the patient in the least restrictive environment that allows for necessary level of observation and/or physiologic monitoring. When a patient screens positive for suicide and order for suicide precautions is placed. A physician may also order suicide precautions for mental health crisis.
Title: Suicide/Mental Health Precautions, Suicide Assessment

b) 1:1 observation must be provided by aPCP (patient care provider, EDT (emergency department technician), or PA (patient attendant) under the direct supervision of an RN. An RN may also provide 1:1 observation.

c) The need for suicide/mental health precautions remains active until the attending physician discontinues the suicide precautions order.

d) Psychiatric consultation will be requested on all patients requiring suicide precautions.

C. Assess risk for suicide on a continual basis & document when changes are noted

D. Report to physician/other care team members the effectiveness of interventions such as but not limited to the following: (behavior/mood changes, any increase or decrease in suicidal ideation).

E. Interventions

1) Nursing supervisor is called for PSA as soon as the patient is screened/identified as at risk for suicide or in mental health crisis.

2) Call charge nurse to notify physician of patients

3) RN, PCP, or EDT will remain with patient until PSA arrives

4) Initiate continuous observation documentation

5) In the ED, undress patient, place in paper scrubs, place clothing and belongings in plastic tub, remove plastic tub from room, and place at nurse’s station.

6) Call security to secure any valuables and/or contraband.

7) If the patient refuses to undress, call security for assistance.

8) RN will complete environmental checklist and will assure identified ligature risks from room are removed.

9) In the ED, place removed items in a plastic tub and secure outside the patient room.

10) In the ED, the public patient restroom can be used as long as 1:1 observation is maintained. When necessary, the patient will be provided a bedside commode with constant 1:1 observation.

11) In the in-patient units the adjoining bathroom will be locked at all times. When necessary, the patient will be provided at bedside commode with constant 1:1 observation.

12) For privacy, curtains may be closed when using the bedside commode, bathing, or dressing. A PSA, PCP, EDT, or PA will remain with the patient at all times.

13) When a patient is taking medications, observe use of plastic cup and that the cup is returned to the nurse and removed from the room. Ensure all medication is swallowed.

14) Visitors should be monitored so that they do not bring materials and/or drugs into the patient room. Security and/or RN to search any object or packages brought in by visitors. Visitors refusing will not be allowed in the room with objects of packages.

15) No food or drink may be brought in by visitors.

16) Allow only cordless electric razors.

17) Meals will be served on paper plates, using only plastic/paper containers and plastic spoons.

18) The patient will remain in the room at all times with a sitter. If a medical condition warrant leaving the department for care, treatment, or services the sitter must accompany and/or the RN and security as needed.
Title: Suicide/Mental Health Precautions, Suicide Assessment

19) If a patient becomes resistant or belligerent call "Code Armstrong".

20) Offer to contact spiritual care for guidance. Assist patient to identify network of supportive persons and resources.

21) Facilitate support of patient by family and friends as allowed by the patient. Involve patient/family (if the patient allows) in availability of Behavioral Health Services and discharge planning (e.g. illness and medication education, recognition of increasing suicidal risk, patients plan for dealing with thoughts of harming self, community resources).

F. Teaching
1) Explain precautions, associated restrictions, and rationale to patient and family.
2) Inform family/visitors that potentially harmful items (glass, scissors, etc) are not to be given to the patient.
3) Encourage support of patient by family/friends.
4) Instruct family about possible warning signs.
5) If the patient is discharged provide appropriate discharge, follow up, and NATIONAL SUICIDE PREVENTION LIFELINE 1-800-273-TALK (8255) number.

G. Document
1) Assessment findings.
2) Suicide precautions maintained; observation intervals; effectiveness of interventions.
3) Physician notification.
4) Items removed from patient or environment.

Related Documents:
- Sitter Policy
- Self-Harm Environmental Checklist (form # 6908) (See above)
- Medical Detention Policy

References/Standards:
- The Joint Commission Standards
- Compass Group Inc. Suicide Screening Tool
**Title:** UNIVERSAL PROTOCOL FOR PREVENTING WRONG SITE, WRONG PROCEDURE, AND WRONG PERSON SURGERY

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**Printed copies are for reference only. Please refer to the electronic copy for the latest version.**

**POLICY:**

1. The Universal Protocol focuses on the safety for all procedures (that is, all surgical and nonsurgical invasive procedures that expose patients to more than minimal risk). Patient Safety can be enhanced by correctly identifying the patient, making a correct diagnosis, selecting the appropriate procedure, identifying the correct site of the procedure, positioning the patient properly before surgery, and providing all necessary equipment.

2. Saint Joseph Health System is committed to providing quality care to the patients of our community and strives to prevent undesired patient outcomes or occurrences. This commitment is reflected in the SJRMC patient care processes where the patient care team are committed to following the “universal protocol” for preventing wrong site, wrong procedure and wrong person surgery based on the following principles:
   
   A. A robust approach using multiple, complementary strategies is necessary to achieve the goal of eliminating all wrong-person, wrong-site, wrong-procedure events.
   
   B. Active involvement and use of effective methods to improve communication among all members of the procedure team are important for success.
   
   C. To the extent possible, the patient and as needed, the family, are involved in the process.
   
   D. Consistent implementation of a standardized protocol is most effective in achieving safety.
   
   E. The Universal Protocol applies to all procedures that expose patients to more than minimal risk, including procedures done in settings other than the operating room.
   
   F. Pre-procedure verification, site marking, and the time-out procedures should be as consistent as possible throughout the hospital, including the operating room and other locations where invasive procedures are performed. In the event of life threatening emergencies only, steps may be abbreviated or skipped.
   
   G. Saint Joseph Health System will have zero tolerance for not adhering to the site marking policy.

**PROCEDURE:**

**Pre-Operative Verification Procedure:**

The operative/procedural team ensures that all the relevant documents and studies are available prior to the start of the procedure and that they have been reviewed and are consistent with each other, with the patient’s expectations and with the team’s understanding of the intended patient, procedure, site and, as applicable any implants. The team must address missing information or discrepancies before starting any procedure.

A. Verification of the correct person, procedure and site will occur at the following times:
   
   1) at the time the surgery/procedure is scheduled by surgical scheduler

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2) at the time of pre-admission screening
3) at the time of admission or entry into the facility for a procedure – elective or emergent
4) during the signing of consent and prior to taking patient into operating room or procedural area (or at bedside if bedside procedure)

B. Verification will be done by staff completing the following processes:
1) Patient’s identification wristband is visually checked by staff member and verified verbally with patient or legal designee.
2) Patient or legal designee states patient’s name, birth date, procedure, procedure site and physician performing procedure to staff member.
3) Site and procedure verification with the order for consent, the consent itself, the history and physical, the surgical or procedural schedule, pre-anesthesia assessment and ancillary/diagnostic tests for films. The site must be marked prior to the surgical incision or the initiation of any procedure. Relevant images and results are properly labeled and able to be appropriately displayed.
4) Any time the responsibility for care of the patient is transferred to another caregiver, including the anesthesia providers at the time of and during the procedure.
5) With the patient involved, awake and aware, if possible or with their legal designee.
6) If patient is unable to participate in this process (i.e., comatose, incompetent, etc.), the patient’s legal guardian or healthcare representative should participate in the process.

C. Marking the operative site: The team, including the patient [if possible], identifies unambiguously the intended site of incision or insertion.
1) Site marking is required for surgical procedures involving right/left distinction, multiple structures (such as fingers, toes, and/or lesions) or levels in spinal surgery.
2) The mark must be made using a marker that is sufficiently permanent to remain visible after completion of the skin prep.
3) The mark must be positioned to be visible after the patient is skin is prepped, the patient is positioned, and sterile draping is completed. If the site marking is covered during the draping process, the site must be remarked by the LIP as outlined below in Item E.
4) Final verification of the site mark must take place during the “Time Out.”

D. DO NOT MARK any non-operative site.

E. The procedure site must be marked with the initials of the licensed independent practitioner or other provider who is privileged or permitted by the hospital to perform the intended surgical or non-surgical invasive procedure. This individual will be involved directly in the procedure and will be present at the time the procedure is performed. This cannot be delegated to an RN.
1) Make the mark at or near the incision site.
   a) Mark all cases involving incision, percutaneous instrumentation or placement of instruments through a natural orifice with specific attention to laterality, surface (flexor, extensor) level (spine) or specific digit or lesion to be treated.
   b) For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side is indicated by a mark at or
near the insertion site indicating laterality and remains visible after completion of the skin prep and sterile draping.

c) Mark the skin at or near the proposed incision/insertion site to indicate the correct side of the proposed procedure, even when the proposed incision insertion site is in the mid-line or through a natural body orifice.

d) The mark must be positioned to be visible after the patient is prepped and draped, unless it is technically or anatomically impossible or impractical to do so.

e) Any portions of the procedure listed on the consent as “possible” involving laterality will not be marked.

2) Spinal procedure marking is completed in two steps: a) Initial marking of the general spinal region and unilaterality if not stated bilateral, with surgeon initials prior to the patient going into the operating room. b) Intra-operative radiographic techniques must be used to mark the exact vertebral level(s)

3) Craniotomies will be site confirmed by intra-operative radiographic techniques to confirm the side and site. The surgeon will identify the site by clipping the hair or by parting the hair at the incision site.

4) For cystoscopy procedures, with laterality for stent placement or removal, the site will be determined using radiographic imaging.

5) An alternative process is in place for patients who cannot easily be marked under the following conditions:

a) Cases in which it is technically or anatomically impossible or impractical to mark the site, such as mucosal surfaces, perineum and premature infants (for whom marking may cause permanent tattooing), an alternative method for visually identifying the correct side and site is used. Possible alternatives include:

(1) Marking on intact skin adjacent to the mucosa to designate laterality.
(2) Use of armbands, stickers or temporary site marking tattoos.

b) For interventional procedure cases for which the catheter/instrument insertion site is not predetermined (for example, cardiac catheterization, pacemaker insertion).

c) For teeth, the operative tooth name(s) and number are indicated on documentation or the operative tooth (teeth) is marked on the dental radiographs or dental diagram. The documentation, images, and/or diagrams are available in the procedure room before the start of the procedure.

d) For premature infants, for whom the mark may cause a permanent tattoo.

e) Any radiological procedure due to prior imaging before a procedure is started, the breast will not be marked until the image is done. Then the radiologist performing the procedure will mark the breast with their initials and a timeout will occur prior to any invasive aspect of the procedure. The placement of the needle will suffice for the OR site marking.

6) Site marking is not required when the individual doing the procedure is continuously with the patient from the time of the decision to do the procedure through to the performance of the procedure. However, the requirement for final time-out verification still applies.

7) If patient refuses to allow site to be marked, staff member should document the refusal on the Surgical Safety Checklist (see attached) and complete a Refusal of Care or Treatment form.
Title: **UNIVERSAL PROTOCOL FOR PREVENTING WRONG SITE, WRONG PROCEDURE, AND WRONG PERSON SURGERY**

with reason for refusal and patient signature. Procedure may be cancelled after additional discussion if site marking refusal remains.

F. “Time Out” immediately before starting the surgical procedure

1) This final procedure verification step is conducted prior to starting the actual procedure but after draping is complete, in the location where the surgical procedure will be done, and with the patient properly positioned for the procedure.

2) It must involve the entire patient care team using active communication. During the “time out,” other activities are suspended to the extent possible without compromising the safety of the patient, so that team members are focused on the active verification of the correct patient, procedure, site and other critical elements. No music will be playing in the procedural room until the time out is completed and the time out must be documented in the Surgical Safety Checklist.

3) In the event there is only one person performing the procedure, a brief pause to confirm the “Time Out” criterion is appropriate.

4) Immediately prior to the start of the surgery/procedure, a time out is performed as follows and the team verbally verifies:

   a) There is a pause in all activities in the room
   b) There is an introduction of team members
   c) The following is confirmed:
      (1) Patient identification
      (2) Procedure
      (3) Site
      (4) Consents
   d) Site marking is visible through draping
   e) There is a review of critical or unexpected steps and procedural duration
   f) Anticipated blood loss is reviewed
   g) The following is reviewed:
      (1) Sterility
      (2) Any implants
      (3) Any special equipment
   h) It is reviewed whether antibiotics were given in the past 60 minutes
   i) Administration of the antibiotics is confirmed and the potential need for re-dosing is addressed
   j) Essential imaging and lab data is available and displayed if necessary
   k) When flammable germicides or antiseptics are used during surgery utilizing electrosurgery, cautery, or lasers, the following are reviewed:
      (1) Application site is dry prior to draping and use of surgical equipment
      (2) Pooling of solution has not occurred or has been corrected
Title: **UNIVERSAL PROTOCOL FOR PREVENTING WRONG SITE, WRONG PROCEDURE, AND WRONG PERSON SURGERY**

(3) Solution-soaked materials have been removed from the operating room prior to draping and use of surgical devices

1) When a regional block is indicated for the patient, the anesthesiologist shares the status of the block during timeout indicating if complete or if it will be completed post-op.

5) If any member of the surgical/procedural team has any questions or concerns regarding the correct patient, side and site, surgery/procedure to be done, positioning, availability of correct implants, or special equipment or requirements the procedure is not started until all questions and concerns are resolved.

6) If the physician leaves the room after the time out, but prior to the incision, another time out must occur prior to the initiation of the procedure.

7) In procedural sedation location the initial order for sedation may be obtained as part of the time out or immediately following.

G. The appropriate Director or administrative designee will be notified of any concerns or issues that were encountered and appropriate action taken.

H. When two or more procedures are being performed on the same patient, a “time out” is performed to verify each subsequent procedure before it is initiated.

1) When the second procedure is a distinct and separate procedure.

2) When a second surgeon is performing the second procedure.

3) An intra-operative consult involving a second surgeon does not require a timeout unless a separate procedure is started.

I. Procedures for non-operating room settings, including bedside procedure:

1) Site marking must be done for any procedure that involves laterality, multiple structures or levels, even if the procedure takes place outside the operating room.

2) Verification, site marking, and “time out” procedures will be consistent throughout the organization, including the Operating Room, Ambulatory Surgery, ADU, Emergency Room, Endoscopy, Cath Lab, IR, OB, and other locations where procedures are performed.

**Management of Wrong Site Surgery/Procedure/Wrong Person:**

If during the course of the surgery/procedure, or, after the surgery/procedure has been completed, it is determined that the surgery/procedure is being performed or has been performed on the wrong surgical site or person, the physician will:

A. Notify the appropriate department director when the event occurred and Risk Management.

B. Act in accord with the patient's best interests to promote the patient's well-being.

C. Take necessary/appropriate steps to return the patient, as nearly as possible, to the patient's preoperative condition.

D. Perform the planned surgery/procedure on the correct site, unless there are medical reasons not to proceed in this manner. For example, if proceeding with the planned surgery/procedure on the correct site would increase the risk associated with extending the length of the surgery/procedure or if the correct site surgery/procedure would likely result in an additional and unacceptable disability.

E. Advise the patient or the patient's legal representative, and the patient's family: (as outlined in the Responding Justly to Adverse Outcomes Policy)
Title: UNIVERSAL PROTOCOL FOR PREVENTING WRONG SITE, WRONG PROCEDURE, AND WRONG PERSON SURGERY

1) of what occurred and of the likely consequences, if any, of the wrong site surgery/procedure;
2) of any recommendations to the patient/family of what, in the physician's best judgment, is the appropriate course for the patient to follow under the circumstances
3) of the physician's judgments in response to questions posed by the patient/family. Such consultation will take place as soon as reasonably possible following the occurrence.

F. If appropriate/necessary, the physician will proceed with immediate patient care interventions as consented to by the patient/family.

G. Record the events in the patient's medical record.

H. Provide necessary/appropriate information to the RN, who, in turn, will immediately complete a Midas Occurrence Report for physician related occurrences and a Voice for staff related occurrences.

I. An investigation will take place per the Sentinel Event Policy & Procedure
The Saint Joseph Health System Diabetes Education Center offers a full range of services that sets the standard for diabetes care in Northern Indiana. Our program is led by an interdisciplinary team, including Registered Nurses and Dietitians, who are committed to the total well-being of every patient. The Diabetes Education Center is designed to give those with diabetes the knowledge and confidence they need to manage their disease on a day-to-day basis. Our services are available at Mishawaka and Plymouth Medical Centers.

**Our Services**
- Taking Charge of Your Diabetes education classes
- Individual education
- Diabetes and Pregnancy education
- Medical interpretation services available

Saint Joseph Health System has been recognized by the American Diabetes Association for Quality Self-Management Education. A physician’s order is required to attend these classes.

To register call **574.335.2372**

**Taking Charge of Your Diabetes**
Taking Charge of Your Diabetes are classes designed to provide education and self-management skills. The classes are recommended for individuals newly diagnosed with diabetes and those not previously educated in diabetes care. The fee for classes are covered by most insurance and Medicare.

**Class Topics**
- What is diabetes
- Self-monitoring
- Role of exercise
- Medications
- Sick-day management
- Meal planning & daily dining challenges
- How to avoid complications
- Healthy coping
- Skills training
- Goal setting and problem-solving
When ordering outpatient Diabetes education for someone that has Diabetes, use the Ambulatory referral to Diabetic Education. If you use the incorrect order, the order will not route to the correct department.

Try It Out

1. Place the order for Ambulatory referral to Diabetic Education.

2. Below is the order prior to making any specific changes.
Diabetes Education Referral Orders

SJPL = St. Joseph Plymouth
SJMW = St. Joseph Mishawaka

3. The following steps MUST be completed in the order below:
   a. In the To dept: type MHMHC Hackley Nutritional Therapy (or specific department in your region)
   b. If necessary, change the To dept spec: to Nutrition
   c. Complete the rest of the order, making sure the order expires after 1 year

4. Click Accept, associate a DIABETES diagnosis and sign order.

You Can Also...
Favorite this order by selecting the ‘star’ icon if you commonly refer to a specific location. Then this order can be "shared" or "copied" by other users.
16. Diabetes Care in the Hospital: Standards of Care in Diabetes—2023

The American Diabetes Association (ADA) “Standards of Care in Diabetes” includes the ADA’s current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care. Members of the ADA Professional Practice Committee, a multidisciplinary expert committee, are responsible for updating the Standards of Care annually, or more frequently as warranted. For a detailed description of ADA standards, statements, and reports, as well as the evidence-grading system for ADA’s clinical practice recommendations and a full list of Professional Practice Committee members, please refer to Introduction and Methodology. Readers who wish to comment on the Standards of Care are invited to do so at professional.diabetes.org/SOC.

Among hospitalized patients, hyperglycemia, hypoglycemia, and glucose variability are associated with adverse outcomes, including increased morbidity and mortality (1). Careful management of people with diabetes during hospitalization has direct and immediate benefits. Diabetes management in the inpatient setting is facilitated by preadmission treatment of hyperglycemia in people with diabetes, having elective procedures, a dedicated inpatient diabetes service applying well-developed and validated standards of care, and careful transition to prearranged outpatient management. These steps can shorten hospital stays, reduce the need for readmission and emergency department visits, and improve outcomes. Some in-depth reviews of in-hospital care and care transitions for adults with diabetes have been published (2–4). For older hospitalized patients or for patients in long-term care facilities, please see Section 13, “Older Adults.”

**HOSPITAL CARE DELIVERY STANDARDS**

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<td><strong>16.1</strong></td>
<td>Perform an A1C test on all people with diabetes or hyperglycemia (blood glucose &gt;140 mg/dL [7.8 mmol/L]) admitted to the hospital if not performed in the prior 3 months. <strong>B</strong></td>
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<tr>
<td><strong>16.2</strong></td>
<td>Insulin should be administered using validated written or computerized protocols that allow for predefined adjustments in the insulin dosage based on glycemic fluctuations. <strong>B</strong></td>
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**Considerations on Admission**

High-quality hospital care for diabetes requires standards for care delivery, which are best implemented using structured order sets and quality improvement strategies for process improvement. Unfortunately, “best practice” protocols, reviews, and guidelines (2,4) are inconsistently implemented within hospitals. To correct this, medical centers striving for optimal inpatient diabetes treatment should establish protocols and structured order sets, which include computerized provider order entry (CPOE).
Initial orders should state the type of diabetes (i.e., type 1, type 2, gestational diabetes mellitus, pancreatogenic diabetes) when it is known. Because inpatient treatment and discharge planning are more effective if based on preadmission glycemia, A1C should be measured for all people with diabetes or hyperglycemia admitted to the hospital if an A1C test has not been performed in the previous 3 months (5–8). In addition, diabetes self-management knowledge and behaviors should be assessed on admission, and diabetes self-management education provided, especially if a new treatment plan is being considered. Diabetes self-management education should include appropriate skills needed after discharge, such as medication dosing and administration, glucose monitoring, and recognition and treatment of hypoglycemia (9,10). Evidence supports preadmission treatment of hyperglycemia in people scheduled for elective surgery as an effective means of reducing adverse outcomes (11–14).

The National Academy of Medicine recommends CPOE to prevent medication-related errors and increase medication administration efficiency (15). Systematic reviews of randomized controlled trials using computerized advice to improve glycemic outcomes in the hospital found significant improvement in the percentage of time individuals spent in the target glucose range, lower mean blood glucose levels, and no increase in hypoglycemia (16,17). Where feasible, there should be structured order sets that provide computerized guidance for glycemic management. Electronic insulin order templates also improve mean glucose levels without increasing hypoglycemia in people with type 2 diabetes, so structured insulin order sets incorporated into the CPOE can facilitate glycemic management (18,19). Insulin dosing algorithms using machine learning and data in the electronic health record (EHR) currently in development show great promise for more accurately predict insulin requirements during hospitalization compared with existing clinical practices (20).

Appropriately trained specialists or specialty teams may reduce the length of stay and improve glycemic and other clinical outcomes (21–23). In addition, the increased risk of 30-day readmission following hospitalization that has been attributed to diabetes can be reduced, and costs saved when inpatient care is provided by a specialized diabetes management team (21,24,25). In a cross-sectional study comparing usual care to specialists reviewing diabetes cases and making recommendations virtually through the EHR, rates of both hyperglycemia and hypoglycemia were reduced by 30–40% (26). Providing inpatient diabetes education and developing a diabetes discharge plan that includes continued access to diabetes medications and supplies and ongoing education and support are key strategies to improve outcomes (27–29). Details of diabetes care team composition are available in the Joint Commission standards for programs and from the Society of Hospital Medicine (30,31).

Even the most efficacious orders may not be carried out in a way that improves quality, nor are they automatically updated when new evidence arises. The Joint Commission accreditation program for the hospital care of diabetes (31), the Society of Hospital Medicine workbook for program development (30), and the Joint British Diabetes Societies (JBDS) for Inpatient Care Group (32) are valuable resources.

**GLYCEMIC TARGETS IN HOSPITALIZED ADULTS**

**Recommendations**

16.4 Insulin therapy should be initiated for the treatment of persistent hyperglycemia starting at a threshold ≥180 mg/dL (10.0 mmol/L) (checked on two occasions). Once insulin therapy is started, a target glucose range of 140–180 mg/dL (7.8–10.0 mmol/L) is recommended for most critically ill and noncritically ill patients. A More stringent goals, such as 110–140 mg/dL (6.1–7.8 mmol/L) or 100–180 mg/dL (5.6–10.0 mmol/L), may be appropriate for selected patients and are acceptable if they can be achieved without significant hypoglycemia. C

**Standard Definitions of Glucose Abnormalities**

Hyperglycemia in hospitalized patients is defined as blood glucose levels >140 mg/dL (7.8 mmol/L) (33). Blood glucose levels persistently above this level warrant prompt interventions, such as alterations in nutrition or changes to medications that cause hyperglycemia. An admission A1C value ≥6.5% (48 mmol/mol) suggests that the onset of diabetes preceded hospitalization (see Section 2, “Classification and Diagnosis of Diabetes”) (33,34). Hypoglycemia in hospitalized patients is categorized by blood glucose concentration and clinical correlates (Table 6.4) (35). Level 1 hypoglycemia is defined as a glucose concentration of 54–70 mg/dL (3.0–3.9 mmol/L). Level 2 hypoglycemia is defined as a blood glucose concentration <54 mg/dL (3.0 mmol/L), which is typically the threshold for neuroglycopenic symptoms. Level 3 hypoglycemia is defined as a clinical event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery. Levels 2 and 3 require immediate correction of low blood glucose. Prompt treatment of level 1 hypoglycemia can prevent progression to more significant level 2 and level 3 hypoglycemia.

**Glycemic Targets**

In a landmark clinical trial conducted in a surgical intensive care unit, Van den Berghe et al. (36) demonstrated that an intensive intravenous insulin protocol with a target glycemic range of 80–110 mg/dL (4.4–6.1 mmol/L) reduced mortality by 40% compared with a standard approach targeting blood glucose of 180–215 mg/dL (10–12 mmol/L) in critically ill hospitalized patients with recent surgery. This study provided robust evidence that active treatment to lower blood glucose in hospitalized patients could have immediate benefits. However, a large, multicenter follow-up study in critically ill hospitalized patients, the Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation (NICE-SUGAR) trial (37), led to a reconsideration of the optimal target range for glucose lowering in critical illness. In this trial, critically ill patients randomized to intensive glycemic management (80–110 mg/dL) derived no significant treatment advantage compared with a group with more moderate glycemic targets (140–180 mg/dL [7.8–10.0 mmol/L]) and had slightly but
significantly higher mortality (27.5% vs. 25%). The intensively treated group had 10- to 15-fold greater rates of hypoglycemia, which may have contributed to the adverse outcomes noted. The findings from NICE-SUGAR are supported by several meta-analyses and a randomized controlled trial, some of which suggest that tight glycemic management increases mortality compared with more moderate glycemic targets and generally causes higher rates of hypoglycemia (38–40).

Based on these results, insulin therapy should be initiated for the treatment of persistent hyperglycemia ≥180 mg/dL (10.0 mmol/L) and targeted to a glucose range of 140–180 mg/dL (7.8–10.0 mmol/L) for the majority of critically ill patients. Although not as well supported by data from randomized controlled trials, these recommendations have been extended to hospitalized patients without critical illness. More stringent goals, such as 110–140 mg/dL (6.1–7.8 mmol/L), may be appropriate for selected patients (e.g., critically ill postsurgical patients or patients with cardiac surgery) as long as they can be achieved without significant hypoglycemia (41–43). For inpatient management of hyperglycemia in noncritical care, the expert consensus recommends a target range of 100–180 mg/dL (5.6–10.0 mmol/L) for noncritically ill patients with “new” hyperglycemia as well as people with known diabetes prior to admission. It has been found that fasting glucose levels <100 mg/dL are predictors of hypoglycemia within the next 24 h (44). Glycemic levels >250 mg/dL (13.9 mmol/L) may be acceptable in terminally ill patients with short life expectancy. In these individuals, less aggressive insulin regimens to minimize glucosuria, dehydration, and electrolyte disturbances are often more appropriate. Clinical judgment combined with ongoing assessment of clinical status, including changes in the trajectory of glucose measures, illness severity, nutritional status, or concomitant medications that might affect glucose levels (e.g., glucocorticoids), may be incorporated into the day-to-day decisions regarding insulin dosing (42).

**BLOOD GLUCOSE MONITORING**

In hospitalized individuals with diabetes who are eating, point-of-care (POC) glucose monitoring should be performed before meals; in those not eating, glucose monitoring is advised every 4–6 h (33). More frequent POC blood glucose monitoring ranging from every 30 min to every 2 h is the required standard for safe use of intravenous insulin. Safety standards for blood glucose monitoring that prohibit sharing lanceting devices, other testing materials, and needles are mandatory (45).

The vast majority of hospital glucose monitoring is performed with FDA-approved prescription POC glucose monitoring systems with and capillary blood taken from finger sticks, similar to the process performed by outpatients for home blood glucose monitoring (46). POC blood glucose meters are not as accurate or as precise as laboratory glucose analyzers, and capillary blood glucose readings are subject to artifacts due to perfusion, edema, anemia/erythrocytosis, and several medications commonly used in the hospital (47) (Table 7.1). The U.S. Food and Drug Administration (FDA) has established standards for capillary (finger-stick) blood glucose meters used in the ambulatory setting, as well as standards to be applied for POC measures in the hospital (47). The balance between analytic requirements (e.g., accuracy, precision, interference) and clinical requirements (rapidity, simplicity, point of care) has not been uniformly resolved (46,48), and most hospitals have arrived at their own policies to balance these parameters. It is critically important that devices selected for in-hospital use, and the workflow through which they are applied, have careful analysis of performance and reliability and ongoing quality assessments. Recent studies indicate that POC measures provide adequate information for usual practice, with only rare instances where care has been compromised (49,50). Best practice dictates that any glucose result that does not correlate with the patient’s clinical status should be confirmed by measuring a serum sample in the clinical laboratory.

**Continuous Glucose Monitoring**

Real-time continuous glucose monitoring (CGM) provides frequent measurements of interstitial glucose levels and the direction and magnitude of glucose trends. Even though CGM has theoretical advantages over POC glucose monitoring in detecting and reducing the incidence of hypoglycemia, it has not been approved by the FDA for inpatient use. Some hospitals with established glucose management teams allow the use of CGM in selected people with diabetes on an individual basis, mostly in noncritical care settings, provided both the individual and the glucose management team are well educated in the use of this technology. CGM is not currently approved for intensive care unit use due to accuracy concerns such as hypoglycemia, hypoperfusion, and use of therapies such as vasopressor agents.

During the coronavirus disease 2019 (COVID-19) pandemic, many institutions were able to use CGM to minimize contact between health care professionals and people with diabetes, especially those in the intensive care unit under an FDA policy of enforcement discretion during the pandemic (51–59). This approach has been helpful in that regard, as well as in minimizing the use of personal protective equipment. The availability of data about the safe and effective use of CGM in the inpatient setting is evolving. Preliminary data suggest that CGM can significantly improve glycemic management and other hospital outcomes (57,60–63).

For more information on CGM, see Section 7, “Diabetes Technology.”

### GLUCOSE-LOWERING TREATMENT IN HOSPITALIZED PATIENTS

**Recommendations**

**16.6** Basal insulin or a basal plus bolus correction insulin regimen is the preferred treatment for noncritically ill hospitalized patients with poor oral intake or those who are taking nothing by mouth. A

**16.7** An insulin regimen with basal, prandial, and correction components is the preferred treatment for most noncritically ill hospitalized patients with adequate nutritional intake. A

**16.8** Use of a correction or supplemental insulin without basal insulin (often referred to as a sliding scale) in the inpatient setting is discouraged. A

**Insulin Therapy**

**Critical Care Setting**

Continuous intravenous insulin infusion is the most effective method for achieving glycemic targets in the critical care setting. Intravenous insulin infusions should be administered based on validated...
written or computerized protocols that allow for predefined adjustments in the infusion rate, accounting for glycemic fluctuations and insulin dose (64).

Noncritical Care Setting
In most instances, insulin is the preferred treatment for hyperglycemia in hospitalized patients. However, in certain circumstances, it may be appropriate to continue home therapies, including oral glucose-lowering medications (64,65). If oral medications are held in the hospital but will be reinstated after discharge, there should be a protocol for guiding resumption of home medications 1–2 days prior to discharge. For people taking insulin, several reports indicate that inpatient use of insulin pens is safe and may be associated with improved nurse satisfaction compared with the use of insulin vials and syringes with safety protocols in place (66–68). Insulin pens have been the subject of an FDA warning because of potential blood-borne diseases if inadvertently shared with more than one person; the warning “For single patient use only” should be rigorously followed using strict safety measures such as barcoding to prevent errors (69,70).

Outside of critical care units, scheduled insulin orders are recommended to manage hyperglycemia in people with diabetes. Orders for insulin analogs or human insulin result in similar glycemic outcomes in the hospital setting (71). The use of subcutaneous rapid- or short-acting insulin before meals, or every 4–6 h if no meals are given or if the individual is receiving continuous enteral/parenteral nutrition, is indicated to correct or prevent hyperglycemia. Basal insulin, or a basal plus bolus correction schedule, is the preferred treatment for noncritically ill hospitalized patients with adequate oral intake or those restricted from oral intake. An insulin schedule with basal, prandial, and correction components is the preferred treatment for most noncritically ill hospitalized people with diabetes with adequate nutritional intake (72). In people with diabetes with blood glucose <240 mg/dL, consider alternatives to basal-bolus therapy as discussed below (72,73).

For individuals who are eating, insulin injections should align with meals. In such instances, POC glucose monitoring should be performed immediately before meals. If oral intake is inadequate, a safer procedure is administering prandial insulin immediately after eating, with the dose adjusted to be appropriate for the amount of carbohydrates ingested (71).

A randomized controlled trial has shown that basal-bolus treatment improved glycemic outcomes and reduced hospital complications compared with a correction or supplemental insulin without basal insulin (formerly known as sliding scale) in general surgery for people with type 2 diabetes (74). Prolonged use of correction or supplemental insulin without basal insulin as the sole treatment of hyperglycemia is strongly discouraged in the inpatient setting, with the exception of people with type 2 diabetes in noncritical care with mild hyperglycemia (23,75,76).

While there is evidence for using premixed insulin formulations in the outpatient setting (77), an inpatient study of 70/30 NPH/regular insulin versus basal-bolus therapy showed comparable glycemic outcomes but significantly increased hypoglycemia in the group receiving insulin mixtures (78). Therefore, insulin mixtures such as 75/25 or 70/30 insulins are not routinely recommended for in-hospital use.

Type 1 Diabetes
For people with type 1 diabetes, dosing insulin based solely on premeal glucose levels does not account for basal insulin requirements or caloric intake, increasing the risk of both hypoglycemia and hyperglycemia. Typically, basal insulin dosing is based on body weight, with some evidence that people with renal insufficiency should be treated with lower doses (79,80). An insulin schedule with basal and correction components is necessary for all hospitalized individuals with type 1 diabetes, even when taking nothing by mouth, with the addition of prandial insulin when eating.

Transitioning From Intravenous to Subcutaneous Insulin
When discontinuing intravenous insulin, a transition protocol is associated with less morbidity and lower costs of care (81,82) and is therefore recommended. A person with type 1 or type 2 diabetes being transitioned to a subcutaneous regimen should receive a dose of subcutaneous basal insulin 2 h before the intravenous infusion is discontinued. Prior to discontinuing an insulin infusion, initiation of subcutaneous basal insulin may help minimize hyperglycemia and avoid rebound hypoglycemia (83,84). The dose of basal insulin is best calculated on the basis of the insulin infusion rate during the last 6 h when stable glycemic goals were achieved (85). For people being transitioned to concentrated insulin (U-200, U-300, or U-500) in the inpatient setting, it is important to ensure correct dosing by utilizing an individual pen or cartridge for each person and by meticulous pharmacy and nursing supervision of the dose administered (85,86).

Noninsulin Therapies
The safety and efficacy of noninsulin glucose-lowering therapies in the hospital setting is an area of active research (73,87–89). Several recent randomized trials have demonstrated the potential effectiveness of glucagon-like peptide 1 receptor agonists and dipeptidyl peptidase 4 inhibitors in specific groups of hospitalized people with diabetes (90–93). However, an FDA bulletin states that health care professionals should consider discontinuing saxagliptin and alogliptin in people who develop heart failure (94).

Sodium–glucose cotransporter 2 (SGLT2) inhibitors should be avoided in cases of severe illness, in people with ketonemia or ketonuria, and during prolonged fasting and surgical procedures (4). Until safety and efficacy are established, SGLT2 inhibitors are not recommended for routine in-hospital use for diabetes management, although they may be considered for the treatment of people with type 2 diabetes who have or are at risk for heart failure (95). Furthermore, the FDA has warned that SGLT2 inhibitors should be stopped 3 days before scheduled surgeries (4 days in the case of ertugliflozin) (96).

HYPOGLYCEMIA

Recommendations

16.9 A hypoglycemia management protocol should be adopted and implemented by each hospital or hospital system. A plan for preventing and treating hypoglycemia should be established for each individual. Episodes of hypoglycemia in the hospital should be documented in the medical record and tracked for quality improvement/quality assessment.
People with or without diabetes may experience hypoglycemia in the hospital setting. While hypoglycemia is associated with increased mortality (97), in many cases, it is a marker of an underlying disease rather than the cause of fatality. However, hypoglycemia is a severe consequence of dysregulated metabolism and/or diabetes treatment, and it is imperative that it be minimized during hospitalization. Many episodes of inpatient hypoglycemia are preventable. Therefore, a hypoglycemia prevention and management protocol should be adopted and implemented by each hospital or hospital system. A standardized hospital-wide, nurse-initiated hypoglycemia treatment protocol should be in place to immediately address blood glucose levels of <70 mg/dL (3.9 mmol/L) (98,99). In addition, individualized plans for preventing and treating hypoglycemia for each individual should also be developed. An American Diabetes Association consensus statement recommends that an individual’s treatment plan be reviewed any time a blood glucose value of <70 mg/dL (3.9 mmol/L) occurs, as such readings often predict subsequent level 3 hypoglycemia. Episodes of hypoglycemia in the hospital should be documented in the medical record and tracked (1,2).

**Triggering Events and Prevention of Hypoglycemia**

Insulin is one of the most common drugs causing adverse events in hospitalized patients, and errors in insulin dosing and/or administration occur relatively frequently (97,100,101). Beyond insulin dosing errors, common preventable sources of iatrogenic hypoglycemia are improper prescribing of other glucose-lowering medications, inappropriate management of the first episode of hypoglycemia, and nutrition–insulin mismatch, often related to an unexpected interruption of nutrition (102). A recent study describes acute kidney injury as an important risk factor for hypoglycemia in the hospital (103), possibly as a result of decreased insulin clearance. Studies of “bundled” preventive therapies, including proactive surveillance of glycemic outliers and an interdisciplinary data-driven approach to glycemic management, showed that hypoglycemic episodes in the hospital could be prevented. Compared with baseline, two such studies found that hypoglycemic events fell by 56–80% (99,104,105). The Joint Commission recommends that all hypoglycemic episodes be evaluated for a root cause and the episodes be aggregated and reviewed to address systemic issues (31).

In addition to errors with insulin treatment, iatrogenic hypoglycemia may be induced by a sudden reduction of corticosteroid dose, reduced oral intake, emesis, inappropriate timing of short- or rapid-acting insulin in relation to meals, reduced infusion rate of intravenous dextrose, unexpected interruption of enteral or parenteral feedings, delayed or missed blood glucose checks, and altered ability of the individual to report symptoms (106).

Recent inpatient CGM studies show promise for CGM as an early warning system to alert of impending hypoglycemia, offering an opportunity to mitigate it before it happens (60–63). The use of personal CGM and automated insulin delivery devices, such as insulin pumps that can automatically deliver correction doses and change basal delivery rates in real time, should be supported for ongoing use during hospitalization for individuals who are capable of using devices safely and independently when proper supervision is available. Hospitals should be encouraged to develop policies and protocols to support inpatient use of individual- and hospital-owned diabetes technology and have expert staff available for safe implementation. Hospital information technology teams are beginning to integrate CGM data into the electronic health record. The ability to download and interpret diabetes device data during hospitalization can inform insulin dosing during hospitalization and care transitions (107).

For more information on CGM, see Section 7, “Diabetes Technology.”

**Predictors of Hypoglycemia**

In people with diabetes in the ambulatory setting, it is well established that an episode of severe hypoglycemia increases the risk for a subsequent event, partly because of impaired counterregulation (108,109). This relationship also holds true for people with diabetes in the inpatient setting. For example, in a study of hospitalized individuals treated for hyperglycemia, 84% who had an episode of “severe hypoglycemia” (defined in the study as <40 mg/dL [2.2 mmol/L]) had a preceding episode of hypoglycemia (<70 mg/dL [3.9 mmol/L]) during the same admission (110). In another study of hypoglycemic episodes (defined in the study as <50 mg/dL [2.8 mmol/L]), 78% of patients were using basal insulin, with the incidence of hypoglycemia peaking between midnight and 6:00 A.M. Despite recognition of hypoglycemia, 75% of individuals did not have their dose of basal insulin changed before the next insulin administration (111).

Recently, several groups have developed algorithms to predict episodes of hypoglycemia in the inpatient setting (112,113). Models such as these are potentially important and, once validated for general use, could provide a valuable tool to reduce rates of hypoglycemia in the hospital. In one retrospective cohort study data, a fasting blood glucose of <100 mg/dL was shown to be a predictor of next-day hypoglycemia (44).

**MEDICAL NUTRITION THERAPY IN THE HOSPITAL**

The goals of medical nutrition therapy in the hospital are to provide adequate calories to meet metabolic demands, optimize glycemic outcomes, address personal food preferences, and facilitate the creation of a discharge plan. The American Diabetes Association does not endorse any single meal plan or specified percentages of macronutrients. Current nutrition recommendations advise individualization based on treatment goals, physiological parameters, and medication use. Consistent carbohydrate meal plans are preferred by many hospitals as they facilitate matching the prandial insulin dose to the amount of carbohydrate given (114). Orders should also indicate that the meal delivery and nutritional insulin coverage should be coordinated, as their variability often creates the possibility of hyperglycemic and hypoglycemic events (28). Many hospitals offer “meals on demand,” where individuals may order meals from
the menu at any time during the day. This option improves patient satisfaction but complicates meal-insulin coordination. Finally, if the hospital food service supports carbohydrate counting, this option should be made available to people with diabetes counting carbohydrates at home (115,116).

SELF-MANAGEMENT IN THE HOSPITAL

Diabetes self-management in the hospital may be appropriate for specific individuals who wish to continue to perform self-care while acutely ill (117,118). Candidates include children with parental supervision, adolescents, and adults who successfully perform diabetes self-management at home and whose cognitive and physical skills needed to successfully self-administer insulin and perform glucose monitoring are not compromised (9,119). In addition, they should have adequate oral intake, be proficient in carbohydrate estimation, take multiple daily insulin injections or use insulin pumps, have stable insulin requirements, and understand sick-day management. If self-management is supported, a policy should include a requirement that people with diabetes and the care team agree that self-management is appropriate on a daily basis during hospitalization. Hospital personal medication policies may include guidance for people with diabetes who wish to take their own or hospital-dispensed diabetes medications during their hospital stay. A hospital policy for personal medication may consider a pharmacy exception on a case-by-case basis along with the care team. Pharmacy must verify any home medication and require a prescriber order for the individual to self-administer home or hospital-dispensed medication under the supervision of the registered nurse. If an insulin pump or CGM is worn, hospital policy and procedures delineating guidelines for wearing an insulin pump and/or CGM device should be developed according to consensus guidelines, including the changing of infusion sites and glucose sensors (107,120,121). As outlined in Recommendation 7.30, people with diabetes wearing diabetes devices should be supported to continue them in an inpatient setting when they are competent to perform self-care and proper supervision is available.

STANDARDS FOR SPECIAL SITUATIONS

Enteral/Parenteral Feedings

For individuals receiving enteral or parenteral feedings who require insulin, the insulin orders should include coverage of basal, prandial, and correctional needs (115,122,123). It is essential that people with type 1 diabetes continue to receive basal insulin even if feedings are discontinued.

Most adults receiving basal insulin should continue with their basal dose, while the insulin dose for the total daily nutritional component may be calculated as 1 unit of insulin for every 10–15 g carbohydrate in the enteral and parenteral formulas. Commercially available cans of enteral nutrition contain variable amounts of carbohydrates and may be infused at different rates. All of this must be considered while calculating insulin doses to cover the nutritional component of enteral nutrition (116). Giving NPH insulin two or three times daily (every 8 or 12 h) to cover individual requirements is a reasonable option. Adjustments in insulin doses should be made frequently. Correctional insulin should also be administered subcutaneously every 6 h with human regular insulin or every 4 h with a rapid-acting insulin analog. If enteral nutrition is interrupted, a 10% dextrose infusion should be started immediately to prevent hypoglycemia and to allow time to select more appropriate insulin doses.

For adults receiving enteral bolus feedings, approximately 1 unit of regular human insulin or rapid-acting insulin per 10–15 g carbohydrate should be given subcutaneously before each feeding. Correctional insulin coverage should be added as needed before each feeding.

In individuals receiving nocturnal tube feeding, NPH insulin administered with the initiation of the feeding represents a reasonable approach to cover this nutritional load.

For individuals receiving continuous peripheral or central parenteral nutrition, human regular insulin may be added to the solution, particularly if >20 units of correctional insulin have been required in the past 24 h. A starting dose of 1 unit of human regular insulin for every 10 g dextrose has been recommended (115) and should be adjusted daily in the solution. Adding insulin to the parenteral nutrition bag is the safest way to prevent hypoglycemia if the parenteral nutrition is stopped or interrupted. Correctional insulin should be administered subcutaneously to address any hyperglycemia. For full enteral/parenteral feeding guidance, please refer to review articles detailing this topic (122,124,125).

Because continuous enteral or parenteral nutrition results in a continuous postprandial state, efforts to bring blood glucose levels to below 140 mg/dL (7.8 mmol/L) substantially increase the risk of hypoglycemia in these patients.

Glucocorticoid Therapy

The prevalence of consistent use of glucocorticoid therapy in hospitalized patients can approach 10%, and these medications can induce hyperglycemia in 56–86% of these individuals with and without preexisting diabetes (126,127). If left untreated, this hyperglycemia increases mortality and morbidity risk, e.g., infections and cardiovascular events. Glucocorticoid type and duration of action must be considered in determining appropriate insulin treatments. Daily ingested intermediate-acting glucocorticoids such as prednisone reach peak plasma levels in 4–6 h (128) but have pharmacologic actions that can last through the day. Individuals placed on morning steroid therapy have disproportionate hyperglycemia during the day but frequently reach target blood glucose levels overnight regardless of treatment (126). In subjects on once- or twice-daily steroids, administering intermediate-acting (NPH) insulin is a standard approach. NPH is usually administered in addition to daily basal-bolus insulin or in addition to oral glucose-lowering medications. Because NPH action peaks at 4–6 h after administration, it is recommended to administer it concomitantly with intermediate-acting steroids (129). For long-acting glucocorticoids such as dexamethasone and multidose or continuous glucocorticoid use, long-acting basal insulin may be required to manage fasting blood glucose levels (65,130). For higher doses of glucocorticoids, increasing doses of prandial (if eating) and correctional insulin, sometimes as much as 40–60% or more, are often needed in addition to basal insulin (72,131,132). A single-center retrospective study found that increasing the ratio of insulin to steroids was positively associated with...
improved time in range (70–180 mg/dL); however, there was an increase in hypoglycemia (133). Whatever insulin orders are initiated, daily adjustments based on levels of glycemia and anticipated changes in type, doses, and duration of glucocorticoids, along with POC blood glucose monitoring, are critical to reducing rates of hypoglycemia and hyperglycemia.

**Perioperative Care**
It is estimated that up to 20% of general surgery patients have diabetes, and 23–60% have prediabetes or undiagnosed diabetes. Surgical stress and counterregulatory hormone release increase the risk of hyperglycemia as well as mortality, infection, and length of stay (134). There is little data available to guide care of people with diabetes through the perioperative period. To reduce surgical risk in people with diabetes, some institutions have A1C cutoffs for elective surgeries, and some have developed optimization programs to lower A1C before surgery (135).

The following approach (136–138) may be considered:

1. A preoperative risk assessment should be performed for people with diabetes who are at high risk for ischemic heart disease and those with autonomic neuropathy or renal failure.
2. The A1C target for elective surgeries should be <8% (63.9 mmol/L) whenever possible (139,140).
3. The target range for blood glucose in the perioperative period should be 100–180 mg/dL (5.6–10.0 mmol/L) (139) within 4 h of the surgery (1).
4. Metformin should be held on the day of surgery.
5. SGLT2 inhibitors must be discontinued 3–4 days before surgery.
6. Hold any other oral glucose-lowering agents the morning of surgery or procedure and give half of NPH dose or 75–80% doses of long-acting analog or insulin pump basal insulin based on the type of diabetes and clinical judgment.
7. Monitor blood glucose at least every 2–4 h while the individual takes nothing by mouth and dose with short- or rapid-acting insulin as needed.
8. There are no data on the use and/or influence of glucagon-like peptide 1 receptor agonists or ultra-long-acting insulin analogs on glycemia in perioperative care.

A recent review concluded that perioperative glycemic targets tighter than 80–180 mg/dL (4.4–10.0 mmol/L) did not improve outcomes and was associated with more hypoglycemia (137); therefore, in general, stricter glycemic targets are not advised. Evidence from a recent study indicates that compared with usual dosing, a reduction of insulin given the evening before surgery by ~25% was more likely to achieve perioperative blood glucose levels in the target range with a lower risk for hypoglycemia (141).

In noncardiac general surgery patients, basal insulin plus premeal short- or rapid-acting insulin (basal-bolus) coverage has been associated with improved glycemic outcomes and lower rates of perioperative complications compared with the reactive, correction-only short- or rapid-acting insulin coverage alone with no basal insulin dosing (74,134,142).

**Diabetic Ketoacidosis and Hyperosmolar Hyperglycemic State**
There is considerable variability in the presentation of diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic states, ranging from euglycemia or mild hyperglycemia and acidosis to severe hyperglycemia, dehydration, and coma; therefore, individualization of treatment based on a careful clinical and laboratory assessment is needed (83,143–145).

Management goals include restoration of circulatory volume and tissue perfusion, resolution of hyperglycemia, and correction of electrolyte imbalance and acidosis. It is also essential to treat any correctable underlying cause of DKA, such as sepsis, myocardial infarction, or stroke. In critically ill and mentally obtunded individuals with DKA or hyperosmolar hyperglycemia, continuous intravenous insulin is the standard of care. Successful transition from intravenous to subcutaneous insulin requires administration of basal insulin 2–4 h before the intravenous insulin is stopped to prevent recurrence of ketoacidosis and rebound hyperglycemia (143). There is no significant difference in outcomes for intravenous human regular insulin versus subcutaneous rapid-acting analogs when combined with aggressive fluid management for treating mild or moderate DKA (146). Individuals with uncomplicated DKA may sometimes be treated with subcutaneous insulin in the emergency department or step-down units (147). This approach may be safer and more cost-effective than treatment with intravenous insulin. If subcutaneous insulin administration is used, it is important to provide an adequate fluid replacement, frequent POC blood glucose monitoring, treatment of any concurrent infections, and appropriate follow-up to avoid recurrent DKA. Several studies have shown that the use of bicarbonate in patients with DKA made no difference in the resolution of acidosis or time to discharge, and its use is generally not recommended (148). For further treatment information, refer to recent in-depth reviews (4,106,149).

**Transition from the Hospital to the Ambulatory Setting**

**Recommendation 16.11** A structured discharge plan should be tailored to the individual with diabetes. B

A structured discharge plan tailored to the individual may reduce the length of hospital stay and readmission rates and increase satisfaction with the hospital experience (150). Multiple strategies are key, including diabetes education prior to discharge, diabetes medication reconciliation with attention to access, and scheduled virtual and/or face-to-face follow-up visits after discharge. Discharge planning should begin at admission and be updated as individual needs change (3,151).

The transition from the acute care setting presents risks for all people with diabetes. Individuals may be discharged to varied settings, including home (with or without visiting nurse services), assisted living, rehabilitation, or skilled nursing facilities. For individuals discharged to home or assisted living, the optimal discharge plan will need to consider diabetes type and severity, effects of the illness on blood glucose levels, and the individual’s capabilities and preferences (29,152,153). See Section 13, “Older Adults,” for more information.

An outpatient follow-up visit with the primary care clinician, endocrinologist, or diabetes care and education specialist
within 1 month of discharge is advised for all individuals experiencing hyperglycemia in the hospital. If glycemic medications are changed or glucose management is not optimal at discharge, an earlier appointment (in 1–2 weeks) is preferred, and frequent contact may be needed to avoid hyperglycemia and hypoglycemia. A discharge algorithm for glycemic medication adjustment based on admission A1C, diabetes medications before admission, and insulin usage during hospitalization was found useful to guide treatment decisions and significantly improved A1C after discharge (6). If an A1C from the prior 3 months is unavailable, measuring the A1C in all people with diabetes or hyperglycemia admitted to the hospital is recommended upon admission.

Clear communication with outpatient health care professionals directly or via hospital discharge summaries facilitates safe transitions to outpatient care. Providing information regarding the root cause of hyperglycemia (or the plan for determining the cause), related complications and comorbidities, and recommended treatments can assist outpatient health care professionals as they assume ongoing care.

The Agency for Healthcare Research and Quality recommends that, at a minimum, discharge plans include the following (154):

**Medication Reconciliation**
- Home and hospital medications must be cross-checked to ensure that no chronic medications are stopped and to ensure the safety of new and old prescriptions.
- Prescriptions for new or changed medication should be filled and reviewed with the individual and care partners at or before discharge.

**Structured Discharge Communication**
- Information on medication changes, pending tests and studies, and follow-up needs must be accurately and promptly communicated to outpatient health care professionals.
- Discharge summaries should be transmitted to the primary care clinician as soon as possible after discharge.
- Scheduling follow-up appointments prior to discharge with people with diabetes agreeing to the time and place increases the likelihood that they will attend.

It is recommended that the following areas of knowledge be reviewed and addressed before hospital discharge:
- Identification of the health care professionals who will provide diabetes care after discharge.
- Level of understanding related to the diabetes diagnosis, glucose monitoring, home glucose goals, and when to call the health care professionals.
- Definition, recognition, treatment, and prevention of hyperglycemia and hypoglycemia.
- Information on making healthy food choices at home and referral to an outpatient registered dietitian nutritionist or diabetes care and education specialist to guide individualization of the meal plan, if needed.
- When and how to take blood glucose-lowering medications, including insulin administration.
- Sick-day management (29,153).
- Proper use and disposal of diabetes supplies, e.g., insulin pen, pen needles, syringes, and lancets.

People with diabetes must be provided with appropriate durable medical equipment, medications, supplies (e.g., blood glucose test strips or CGM sensors), prescriptions, and appropriate education at the time of discharge to avoid a potentially dangerous hiatus in care.

**PREVENTING ADMISSIONS AND READMISSIONS**

In people with diabetes, the hospital readmission rate is between 14 and 20%, nearly twice that in people without diabetes (151,155). This may result in increased diabetes distress and has significant financial implications. Of people with diabetes who are hospitalized, 30% have two or more hospital stays, and these admissions account for over 50% of hospital costs for diabetes (156). Factors contributing to readmission include male sex, longer duration of prior hospitalization, number of previous hospitalizations, number and severity of comorbidities, and lower socioeconomic and/or educational status; scheduled home health visits and timely ambulatory follow-up care reduce readmission rates (151,155). While there is no standard to prevent readmissions, several successful strategies have been reported (151). These include targeting ketosis-prone people with type 1 diabetes (157), insulin treatment of individuals with admission A1C >9% (75 mmol/mol) (158), and the use of a transitional care model (159). For people with diabetic kidney disease, collaborative patient-centered medical homes may decrease risk-adjusted re-admission rates (160). A 2018 published algorithm based on demographic and clinical characteristics of people with diabetes had only moderate predictive power but identified a promising future strategy (161).

Age is also an important risk factor in hospitalization and readmission among people with diabetes (refer to Section 13, “Older Adults,” for detailed criteria).

**References**

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109. Rickers MR. Hypoglycemia-associated autonomic failure, counterregulatory responses, and therapy. 2015:5;http://annals.org/annals.org/content/117/2/353.long
11. Miscellaneous Websites/Resources

a. SJHS Physician Websites
b. Indiana Inspect Website
c. Indiana Death Registry Website
d. Links to Miscellaneous Websites
e. Accreditation Websites
Website: For Physicians, Saint Joseph Health System (sjmed.com)
Website: Bylaws, Policies, Rules and Regulations, Saint Joseph Health System (sjmed.com)
Physician Orientation and Ongoing Education Manual

Website:  orientation-manual-9-2023.pdf (sjmed.com)

1. SJRMC Code of Conduct
2. Medical Staff Information
3. Available Clinical Services Resource
4. SJRMC Emergency Preparedness & Codes
5. Mission Statement/Patient Rights & Responsibilities
6. Overview SJRMC Policy/Procedures
7. Infection Control
8. Visiting Nurses Association

Medical Staff Policies & Procedures

Website:  Medical Staff Policies and Procedures, Saint Joseph Health System (sjmed.com)
State of Indiana –

The Indiana Prescription Monitoring Program

PLA: INSPECT: Home (click link to the left)

Welcome to INSPECT

The Indiana Prescription Monitoring Program (PDMP)

To register for the PDMP and to perform patient look-up requests please use the following link: [https://indiana.prescreening.net/oppp/](https://indiana.prescreening.net/oppp/)

Prescription data submissions must be submitted through the PMP Clearinghouse. Please use the following link: [https://tmdsagenda.house.gov](https://tmdsagenda.house.gov)

If you had an account on the original Indiana Prescription Monitoring Program system prior to October 11, 2017, do not submit a new application. You may access your account by clicking [here](https://tmdsagenda.house.gov) and selecting “Reset Password.” A link to reset your password will be sent to the email address listed in your profile.

If you require technical assistance please contact support at 844-446-4767 or submit your request to inspect@pla.in.gov and someone will assist with account updates and password resets within 24 hours.

The following information will be required to process your request:

First Name:
Last Name:
DOB:
Individual email address (only the practitioner has access to):
DEA #:
Professional License #:
Driver’s License #:

**Statewide Integration Announcement**

Effective August 24, 2017 Indiana will begin steps to implement a statewide, comprehensive platform for healthcare professionals to review patients’ controlled substance prescription history more quickly and efficiently. This platform supports Indiana’s Prescription Drug Monitoring Program (INSPECT) and transfers data into electronic health records and pharmacy management systems. Statewide integration of the INSPECT platform is a key component of Indiana’s ongoing efforts to attack the opioid crisis. For more information or to learn more about INSPECT integration please fill out the form below.
Indiana Website to Register for Death Registry

Health: Vital Records: Database Registration of Indiana’s Vital Events (DRIVE) (click link to left)

Database Registration of Indiana’s Vital Events (DRIVE)

DRIVE is live!

The Indiana Department of Health is excited to announce that phase II of the DRIVE (Database for Registering Indiana’s Vital Events) vital records system implementation went live on Monday, June 6th. The update to our vital records system, DRIVE now includes the fetal death and terminated pregnancy (FTDP) modules.

To access the birth and death registration system you will need to register for an Access Indiana account at https://www.in.gov/access/. Once you have a registered Access Indiana account, you can register your DRIVE account. To register, click on the DRIVE icon/title posted within Access Indiana to submit an e-request to link your active Genesis/DRIVE user profile to your Access Indiana account. This is a two-step process.

If you have not already done so, register now to access DRIVE.
Links, Saint Joseph Health System (sjmed.com) (click on link to the left)

Links

- National Provider Identifier (NPI): Learn more about NPI and how to apply by visiting The Centers for Medicare & Medicaid Services, CMS, [website](https://www.cms.gov).  
- Indiana License & Indiana Controlled Substance Registration (CSR): Online Renewal Renew your Indiana license and Indiana controlled substance registration by visiting the [Indiana Licensing website](https://www.in.gov/pls/psmicrosite.jsp).  
- DEA License: Online Renewal Renew your DEA online by [visiting the DEA website](https://www.deadiversion.usdoj.gov).  
- CAQH: Credentialing Providers The standardized credentialing on-line application known as the CAQH form must be completed, [complete form](https://www.caqh.org).
Welcome to the Regulatory and Accreditation Resource Page:

You will find key links and Documentation to Regulatory and Accreditation Bodies here. More information will also follow as it is updated.

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410_IAC_15-1.pdf (in.gov) – Indiana Dept of Health Title 410 Administrative Code