

METHODIST HEALTHCARE MEMPHIS HOSPITALS AND METHODIST HEALTHCARE -OLIVE BRANCH HOSPITAL

UNIFIED MEDICAL STAFF POLICIES

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1.0 AMENDMENT AND ADOPTION OF GOVERNANCE DOCUMENTS BY THE ORGANIZED MEDICAL STAFF

- 1.1 If the Medical Executive Committee (MEC) proposes to adopt or amend a rule or regulation it first communicates this to the medical staff. The MEC will ratify this proposal not earlier than its next meeting.
- 1.2 In cases of a documented need for urgent amendment to rules and regulations, (to comply with law or regulations), the MEC may provisionally adopt and the governing body may provisionally approve. In such cases, the medical staff will be notified by the MEC and has the opportunity for review of the comment on provisional amendment. If there is no significant conflict between the organized medical staff and MEC, this provisional amendment stands and is so noted at the next appropriate MEC and governing body meetings. If there is conflict, the process for resolving conflict between the organized medical staff and MEC is implemented. If necessary, a revised amendment is submitted to the governing body for action.

1.3 The organized medical staff has the ability to amend and adopt its governance documents by proposing them directly to the governing body. The procedure for this includes first submitting the proposal to an MEC member. After review by the MEC, the MEC Board Representative will submit the proposal in an unaltered format to the governing body.

2.0 CONFLICT MANAGEMENT BETWEEN ORGANIZED MEDICAL STAFF AND MEDICAL EXECUTIVE COMMITTEE

The Conflict Management process applies to, but is not limited to, proposals to amend or adopt a rule, regulation, or policy.

- 1. The Department Chair or another elected Medical Staff leader will consider issues of conflict between the MEC and the organized Medical Staff (OMS). At least 1% of the OMS should support the issue to initiate the conflict management process.
- 2. Resolution begins with the Medical Staff executive leadership and can escalate to the MEC if resolution is not imminent. If these steps are not productive, the MEC will forward their response to the Board.
- 3. If the Board finds the MEC response satisfactory, the Board will forward to Medical Staff Services Department (MSSD) for dissemination to the OMS. If the Board finds the MEC response unsatisfactory, the matter will be sent to a special committee comprised of three OMS representatives, three MEC representatives, and one Board representative. The committee will review, discuss, and resolve.

3.0 PROCEDURAL SEDATION POLICY FOR NON-ANESTHESIA STAFF

3.1 Purpose

This policy applies to all non- Anesthesia staff who administer moderate and deep procedural sedation to patients of all ages within the MLH System based on their delineation of privileges. The purpose of this policy is to provide evidence-based guidelines to assist in the provision of safe procedural sedation during diagnostic and therapeutic procedures.

These guidelines apply to all locations where moderate or deep procedural sedation is administered. Locations include, but are not limited to:

Endoscopy Suites Critical Care areas Emergency Department Diagnostic Imaging Interventional Radiology Operating Room Cardiac Cath Lab Non-invasive Cardiology Starlight Room MEG Lab

3.2 Focus

This policy is **not** intended to apply to the following settings:

- General anesthesia
- Administration of medication intended solely to counteract anxiety
- Sedation used during the placement or maintenance of an artificial airway (e.g. mechanical ventilation).

3. 3 Definitions

A patient under sedation can convert into deep sedation and/or loss of consciousness because of the unique characteristics of the drugs as well as the clinical condition of the individual patient. The level of sedation planned will determine the level of qualified personnel and monitoring requirements.

A. Levels of Sedation and Anesthesia are defined as:

- 1. <u>Minimal Sedation (anxiolysis)</u> is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.
- 2. <u>Moderate sedation/analgesia ("conscious sedation")</u> is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- 3. <u>Deep sedation/analgesia</u> is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- 4. General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug- induced depression of neuromuscular function. Cardiovascular function may be impaired.

B. Personnel:

- 1. Physician/Proceduralist
 - An M.D. or D.O. who is credentialed to provide moderate and/or deep procedural sedation.
 - Physicians-in-training (residents) may participate in procedures under the supervision of the Attending physician, as appropriate.
 - The physician must maintain current ACLS and/or PALS (as appropriate) certification.
 - The sedating physician is responsible for ordering the medication including dose, route and understanding the complications associated with the drugs.
 - The sedating physician is responsible for managing the patient receiving moderate or deep procedural sedation and therefore must be present until the entire procedure is completed and the patient's vital signs and state of consciousness are at their baseline.
 - The sedating physician must be able to manage complications that may occur related to the

- administration of the moderate and deep procedural sedation medications.
- Competency to provide procedural sedation must be documented and reflected in the physician's privileges or scope of practice.
- 2. The physician performing the procedural sedation must be competent in establishing a patent airway and performing positive pressure ventilation of the patient when indicated.

3. Qualified Personnel

- RNs, Certified Physician Assistants and Advanced Practice Registered Nurses (nurse
 practitioners, nurse anesthetists, clinical nurse specialists) with appropriate competency
 may administer moderate procedural sedation medications under the direct supervision of a
 physician. The physician must be present at the bedside during sedation medication
 administration and have privileges to perform moderate procedural sedation.
- A trained RN who has the appropriate competency in procedural sedation, current ACLS
 and/or PALS certification, and has been trained to recognize clinical signs of hypoventilation
 as well as abnormal blood pressure, EKG, capnography, and pulse oximetry readings will
 monitor the patient throughout the procedure.

3.4 Responsibilities

The Department of Anesthesia in collaboration with the Pharmacy Department will define appropriate agents for moderate and deep procedural sedation. This information will be maintained on MOLLI.

3.5 Patient Selection Criteria

This policy is applicable to all patient ages within the MLH system. The American Society of Anesthesiologists (ASA) classification system will be used as a guideline for patient selection criteria. Patients appropriate for procedural sedation will have an ASA classification of I through III. Patients with an ASA classification of IV or greater may require evaluation by an Anesthesia provider, depending on the setting.

The physician is responsible for performing the airway assessment and assigning the patient an ASA classification.

ASA Classification:

| STATUS | DEFINITION |
|--------|--|
| I | A normal healthy patient |
| II | A normal patient with mild systemic disease |
| III | A patient with a severe systemic disease that limits activity but is not |
| | incapacitating |
| IV | A patient with an incapacitating systemic disease that is a constant threat to life. |
| V | A moribund patient not expected to survive 24 hours with or without the |
| | procedure |

3. 6 Airway Assessment

The following findings may increase the likelihood of airway obstruction during spontaneous ventilation and should be recognized:

- Habitus: significant obesity (especially involving the neck and facial features)
- Head & Neck: short neck, large neck circumference, limited neck extension, decreased

- hyoid mental distance (<3cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation
- Mouth: small mouth opening, edentulous, protruding incisors, loose or capped teeth, high arched palate, macroglossia, tonsillar hypertrophy, nonvisible uvula
- Jaw: micrognathia, retrognathia, trisumus, significant malocclusion

If any of the following findings is present by history or exam, the physician should strongly consider consultation with an anesthesia provider or other appropriate specialist prior to the administration of moderate or deep procedural sedation:

- Abnormal airway
- ASA status classification of IV, or V, with exception of intubated patients
- Previous problems with anesthesia or sedation
- Positive pressure-dependent sleep apnea
- Dysmorphic facial features (e.g. Pierre-Robin syndrome, Trisomy 21)
- Advanced Rheumatoid Arthritis
- Patients with recent oral intake (See Appendix II)
- Pregnant patients
- Severely compromised or medically unstable patients (e.g., history of severe COPD, Coronary artery disease, or CHF)

3. 7 Criteria for Administration of Moderate and Deep Procedural Sedation

- Medication to provide procedural sedation will be given on the direct order of a physician
 who has been trained to perform sedation during procedures and who is physically present
 during the initial and continued administration of sedation. (See credentialing delineations of
 privileges).
- Sedation medications administered during the procedure may be administered by the physician or by qualified personnel who have the appropriate training and clinical competencies, under the direct supervision of the physician who is present at the bedside.
- Maintenance of IV access is required for patients receiving procedural sedation, except for
 pediatric patients receiving procedural sedation via other routes, e.g., intranasal, orally, IM.
 These patients must have a person skilled in establishing venous access immediately
 available.
- An airway assessment and ASA classification must be documented prior to the administration of procedural sedation.

3. 8 Pre-Procedure Assessment Responsibilities, and Plan of Care

A. Pre-Sedation Assessment:

The pre-procedure assessment will be performed and documented prior to the administration of moderate or deep procedural sedation. The assessment and documentation must include:

- Age-specific, procedure-pertinent assessment with emphasis on heart, lungs and airway
- ASA status
- Baseline vital signs (blood pressure [may be excluded if it interferes with care of the pediatric patient], heart rate, respiratory rate, heart rhythm, oxygen saturation, temperature)
- Level of Consciousness (pediatric patients will be evaluated according to developmental and

- age appropriate responses)
- Baseline Aldrete score
- Oral intake status per guidelines (see Appendix II).
- Procedural Sedation Plan (i.e. moderate procedural sedation with monitoring or deep procedural sedation with monitoring)
- Informed consent to include risks and benefits of procedural sedation discussed with the patient and family
- Presence or absence of patent IV access
- Current medication and history of drug allergies or adverse reactions

B. Pre-Procedural Sedation Documentation Requirements

Procedures involving moderate and/or deep procedural sedation require physician documentation of their preprocedural assessment in the EHR using the appropriate templates.

The following table indicates the scope of the practitioner assessment prior to the operative and other invasive procedures. Additional physician notes as to the patient's pre-procedure condition, if any, may be recorded separately (before or after the procedure) or included in the procedure note.

| Procedure | Procedural Sedation Assessment | Anesthesia Evaluation | Н&Р |
|---|-----------------------------------|--------------------------|-----------|
| Surgical procedures in the operating room | | $\sqrt{}$ | $\sqrt{}$ |
| Interventional Procedures involving general anesthesia regardless of location | | $\sqrt{}$ | √ |
| Other procedures involving moderate or deep sedation | √ or | · √ | |

C. Pre-Sedation Reassessment

- Immediately prior to the administration of moderate and deep procedural sedation, all patients will be reassessed by the physician.
- The following shall be documented by the RN/Qualified personnel or physician administering the procedural sedation medications:
 - Vital signs obtained immediately prior to sedation (blood pressure, heart rate, respiratory rate,
 - oxygen saturation, and if indicated temperature)
 - Oxygen requirement
 - o NPO status
 - Level of consciousness
 - o Pain Score
 - o Baseline Aldrete Score

- **D. Required Equipment:** The following <u>age-specific</u> equipment should be available in all procedural sedation areas prior to the administration of moderate and/or deep procedural sedation. Ensure availability and working condition of <u>age-specific</u> emergency equipment to include:
 - Oxygen
 - Positive Pressure Ventilation System
 - Crash cart with Ambu bag
 - Laryngoscopes and blades (age and size-appropriate for the patient/population)
 - Endotracheal tubes with stylet sized appropriate for patient/population
 - Cardiac monitor, including defibrillator
 - Oxygen availability by a system with positive pressure delivery
 - Suction apparatus with Yankauer tip (ready to use)
 - Continuous pulse oximetry
 - Capnography/End Tidal CO2 monitoring
 - Reversal agents
 - Non-invasive blood pressure monitoring equipment
 - Patent IV access and appropriate equipment to administer IVFs and drugs, including blood and blood components as needed (except as noted in section 3.7, 3rd bullet point)

3. 9 Procedural Sedation Staffing Requirements

Qualified personnel trained in the recognition of apnea and airway obstruction will be present in the room throughout the performance of all cases requiring moderate and/or deep procedural sedation.

Emergency Support: Assure that at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room.

Minimum Staffing Requirements for Planned Moderate and Deep Procedural Sedations

| Procedural Sedation Type | Minimum # of Staff Required | Other Duties Allowed for RN/Qualified Personnel |
|-----------------------------|---|--|
| Moderate | Two (2) | |
| | Physician who is the proceduralist-may administer the moderate sedation medications prior to starting the procedure RN/Qualified Personnel – May administer moderate sedation medications as ordered by the physician (while monitoring the patient) and also be responsible for monitoring the patient. | The RN/qualified personnel is responsible for administering the moderate sedation medications (under the direct supervision of the physician), and for monitoring the patient. The RN may assist with interruptible tasks of short duration, provided that monitoring is maintained. |
| Deep ¹ | Three (3) | |
| | Physician/Resident who is the | The RN/qualified personnel |

| proceduralist.Physician (Sedationist) to administer the deep sedation medications AND to monitor the patient. | responsible for monitoring the patient shall have NO other duties. |
|--|---|
| • RN to monitor the patient. | |

¹⁾ Deep Sedation: Any physician who administers and monitors deep sedation must be dedicated to that task. Therefore, the non-anesthesiologist physician who administers and monitors deep sedation <u>must</u> be different from the individual performing the diagnostic or therapeutic procedure.

3.10 Procedural Sedation Monitoring Standards for RN/Qualified Personnel

Patients receiving procedural sedation are to have oxygenation, ventilation, Capnography/end-tidal CO2, circulation and cardiac rhythm continuously monitored during all procedures.

| Monitoring Standards | Periodically | Continually | Continuously |
|--|--------------|-------------|--------------|
| Level of Consciousness | | | |
| Responsiveness to verbal commands or light touch (either verbal or other indication of consciousness like "thumbs up" gesture) | X | | |
| Ventilation and Oxygenation | | | |
| Observation of changes in respiratory pattern | | X | |
| O2 Saturation | | | X |
| Capnography/End Tidal CO2 | | | X |
| Hemodynamics | | | |
| Blood pressure | | X | |
| Heart rate (ECG) | | | X |

^{*} ECG should be used in patients with significant cardiovascular disease or those undergoing procedures where dysrhythmias are anticipated.

Definitions:

Periodically – approximately every 5 minutes during the procedure

Continually – repeated regularly and frequently in steady succession (every 5 minutes)

Continuously – prolonged without any interruption at any time

3.11 Required Procedural Sedation Documentation for RN/Qualified Personnel

| Documentation Requirements Level of Consciousness | Before administration of sedation/ analgesic | After administration of sedation/ analgesic | Regular intervals during procedure (every 5 mins) | Initial Recovery | Immediately before discharge |
|--|---|--|--|---------------------|------------------------------------|
| Responsiveness to verbal commands or light touch (either verbal or other indication of consciousness like "thumbs up" gesture) | X | X | X | X | X |
| Ventilation and Oxygenation | | | | | |
| Observation of changes in respiratory pattern | X | X | X | X | X |
| O2 Saturation | X | X | X | X | X |
| Capnography/End Tidal CO2 | X | X | X | X | X |
| Hemodynamics | | | | | |
| Blood pressure | X | X | X | X | X |
| Heart rate | X | X | X | X | X |

^{*}Device alarms **must** be set to alert the care team to critical changes in patient status

3.12 Post- Procedural Sedation Responsibilities

A. Physician Documentation

The physician shall document a post-procedural sedation note electronically using the appropriate note type; and it should be entitled "Procedural Sedation Note". If an electronic note type other than a PowerNote is utilized, then the Procedural Sedation Outcomes Note (PowerNote) should be used to document the presence or absence of specific outcomes/adverse events.

B. RN/Qualified Personnel Post – Procedural Sedation Monitoring and Documentation

The patient's post procedure status will be assessed on admission to and before discharge from the post-procedural sedation or recovery area. Post-procedural sedation monitoring and documentation by the RN/Qualified Personnel shall include the following:

- Patients receiving reversal agent(s) must be monitored for a minimum of one (1) hour after last dose of reversal agent.
- Observation and monitoring of the patient's vital signs in an appropriately staffed and equipped area every 15 minutes or more frequently if the patient's condition warrants
- Monitor the patient's oxygenation continuously until the patient is near their baseline level of consciousness and no longer at increased risk for cardiorespiratory depression or hypoxia.
- Observation and documentation of any unusual events or post-procedural complications and the patient's response
- Provide a verbal and documented handoff to the individual assuming care of the patient should

[‡] Medication administration must be documented with dose and time (if medication given after procedure stop time, there must be a documented reason for administration, such as for pain).

admission to inpatient or observation status be required.

3.13 Discharge Criteria

The following criteria must be met and documented before a patient can be discharged:

- Patients will be discharged from the post-procedural sedation area upon the documented order from a qualified licensed independent practitioner or attainment of Aldrete score within two (2) points of pre- procedural sedation assessment score (see Appendix I). Patients cannot be discharged with a score of "0" in any category.
- The last dose of procedural sedation medication must have been administered 60 minutes prior to discharge.
- Two hours must have lapsed since administration of the last dose of reversal agent prior to discharge.
- The nurse responsible for the patient shall document discharge criteria has been met and the condition of the patient just prior to discharge.
- Outpatients shall be discharged in the presence of a responsible adult who will accompany them home or to a care facility and be able to report any post-procedure complications.
- Outpatients and their escorts shall be provided with written instructions, including postprocedure diet, medications, activities, and a phone number to call in case of an emergency. The instructions shall document prohibitions against driving and against important decisionmaking.
- If the patient is admitted inpatient for further care, the nurse responsible for the patient's care will provide report to the accepting nurse.

3.14 Credentialing and Competency

Privileges shall be recommended by the Credentials Committee to MEC and must be granted by the Governing Body. Privileging shall be based upon training, education and a demonstrated record of successful experience in moderate and/or deep procedural sedation.

Procedural sedation shall be administered in accordance with the current relevant clinical policies and procedures.

The following non-Anesthesia staff are eligible for deep procedural sedation privileges**:

- Class III Adult Emergency Medicine Physicians:
- Class III Pediatric Emergency Medicine Physicians;
- Board Certified/Eligible Adult Critical Care Physicians (who provide evidence that procedural sedation was part of their fellowship program); and
- Board Certified/Eligible Pediatric Critical Care physicians (who provide evidence that procedural sedation was part of their fellowship program).

^{**}The privileging process is outlined in the MH-MH & MOBH Unified Credentials Policies. Privileging criteria are detailed in the Deep Procedural Sedation for Non-Anesthesiologist Delineation of Privileges document, including any exceptions to the above criteria.

3.14 Performance Improvement

Performance improvement will be addressed as outlined in the attached appendix (Appendix III).

3.15 Appendices

Appendix I: ALDRETE SCORE

| Assessment <u>Score</u> | |
|--|---|
| Activity | |
| Able to move 4 extremities voluntarily or on command | 2 |
| Able to move 2 extremities voluntarily or on command | 1 |
| Not able to move extremities voluntarily or on command | 0 |
| | |
| Respiration | |
| Able to deep breathe and cough freely | 2 |
| Dyspnea, shallow, or limited breathing | 1 |
| Apneic | 0 |
| Circulation Alata: For hagaline automatically agains a good of 2) | |
| Circulation (Note: For baseline, automatically assign a score of 2) Blood pressure +/= 20% of pre-sedation level | 2 |
| Blood pressure +/= 20-50% of pre-sedation level | 2 |
| Blood pressure +/= 50% of pre-sedation level | 0 |
| blood pressure 17-3070 of pre-sedation level | U |
| Consciousness | |
| Fully awake | 2 |
| Arousable on calling | 1 |
| Not responding | 0 |
| O2 Saturation | |
| Able to maintain SaO2>92% on room air | 2 |
| Needs O2 to maintain SaO2>90% | 1 |
| SaO2 <90% even with O2 supplement | 0 |
| 5402 5070 even with 62 supplement | U |

Appendix II: NPO Guidelines

Pre-Procedural Sedation Oral Intake Guidelines for Adults and Pediatrics

A. Elective Procedures:

The following guidelines apply to elective procedures:

- Patients undergoing elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before the procedure. If NPO requirements have been violated, the physician will decide to proceed, delay, or cancel the procedure. This decision will be documented in the medical record.
- Adults and pediatric patients (all ages) may have solid food and dairy products until 8 hours before their scheduled arrival time at the hospital or provider-based clinic
- The minimal procedural sedation fasting period for infant formula is 6 hours and 4 hours for breast milk
- Alcoholic beverages should be avoided within 8 hours of the scheduled arrival time.

• Clear liquids - NOT milk or dairy products - are actively encouraged until 2 hours before the time the patient is scheduled to arrive at the hospital or provider-based clinic.

Clear, see-though liquids include:

- o Water
- o Clear fruit juices such as apple juice and white cranberry juice
- Plain tea or black coffee (**NO** milk or creamer)
- Clear, electrolyte-replenishing drinks such as Pedialyte, Gatorade or Powerade (NOT yogurt or pulp-containing "smoothies")
- Ensure Clear or Boost Breeze (**NOT** the milkshake varieties)

Pre-Procedural Sedation Oral Intake Guidelines:

| Stop Solid Foods | Drink Clear Liquids | Arrival Time |
|------------------|---------------------|--------------|
| 10 p.m. | 4 a.m. | 6 a.m. |
| Midnight | 6 a.m. | 8 a.m. |
| 2 a.m. | 8 a.m. | 10 a.m. |
| 4 a.m. | 10 a.m. | 12 p.m. |

B. Emergent Procedures:

In urgent or emergent situations where complete gastric emptying is not possible, the decision to administer procedural sedation should not be based on fasting time alone. The physician shall document the risks versus benefits decision and discussion with the patient.

Appendix III: Performance Improvement

Pertinent performance data will be collected, trended, and reported for review through the Medical Staff Office (MSO) and ultimately reviewed (as appropriate) by the Chair of Anesthesiology.

- Patient outcomes will be monitored, trended, and reported using the following criteria documented in the Procedural Sedation Outcomes PowerNote:
- Hypoxia: drop in oxygen saturation to <90% for ≥ 1 minute.
- Unplanned admission or transfer to a higher level of care
- Administration of reversal agents
- Hypotension: drop of \geq 20mm Hg in systolic and/or diastolic blood pressure, requiring medical intervention(s). For the pediatric population, episodes of bradycardia will be assessed instead of this parameter.
- Hemodynamically significant dysrhythmia related to the sedation in progress
- Requirement to place airway support (oral airway or ET tube).
- Requirement for assisted ventilation.
- All episodes of medical emergency (i.e. "Emory House" or "Harvey Team") related to the procedure.
- Progression of intended moderate sedation to deep sedation.

4.0 Patient Care

4.1 Guidelines for Withholding or Withdrawing of Life Sustaining Treatment

PURPOSE

To establish procedures for determining when and how to properly implement "terminal care orders", i.e. medical orders under which life support measures may be either withheld or withdrawn.

- A. Patients with decision-making capacity: A patient with decision-making capability has the right to make decisions about his/her medical care. This encompasses the right to decline any medical procedure, including procedures relating to resuscitation and/or life sustaining treatment. This includes artificially administered nutrition and hydration.
- B. Patients without decision-making capability: If a patient has executed an advance directive which addresses resuscitative services and/or life sustaining treatment methods, the treating physician or his designated consultative attending physician (DCAP) (each, as defined by hospital policy) shall attempt to comply as fully as possible with the patient's directive. For further explanation of hospital policy on advance directives, see Methodist Healthcare Policy S-05-018.
- C. Minors: A minor patient is anyone lacking decision-making capability under State law due to age.

General principles

The following principles are to be followed in decisions concerning care for critically ill patients:

- A. Every patient treated at Methodist Le Bonheur Healthcare will have maximum efforts used to maintain life and health except in those circumstances in which such efforts are not medically indicated or ethically justified. These cases include the terminally ill and/or inappropriate medical situations at the end of life. In cases where surrogate decision makers are not available, the decisions of the providers will always be made on the basis of the best interest of the patient. Surrogate decision-makers will be identified in accordance with applicable state law(s).
- B. The attending physician or his DCAP has the ultimate responsibility for medical diagnosis, prognosis and identification of medically acceptable treatment options. Consultation with the appropriate medical consultants is encouraged, but left to the judgment of the attending physician. (The attending physician is defined as the physician primarily responsible for the patient's hospital care).
- C. The attending physician or his DCAP, patient, when he/she has decision making capability, or otherwise the parent/guardian or surrogate decision maker, has the primary responsibility for making decisions concerning the medical care of the patient. It is the responsibility of the attending physician or his DCAP to see that the patient, parent/guardian, or other acceptable surrogate decision maker, has been supplied with all information necessary in the sensitive decision making process. Family members should be kept informed and their wishes taken into consideration (unless the patient chooses not to include them), but the decisionally capable patient or appropriate surrogate always has the right to make his/her own healthcare decisions.
- D. Euthanasia, i.e. intervention with affirmative measures intended to cause death of the patient, is not only illegal, but also violates the mission and core values of Methodist Le Bonheur Healthcare. Such

interventions are clinically and ethically unacceptable at Methodist Le Bonheur Healthcare.

Categories of clinical care

The following categories of clinical care will apply:

- A. Full care any patient who does not fall into categories B or C below.
- B. Full care efforts except specified interventions.
- 1. This category may be applied to patients who have a poor prognosis or terminal condition and who have had such for a period sufficiently long that the prognosis has been determined with reasonable medical certainty. The attending physician or his DCAP is responsible for communicating this prognosis to the patient/surrogate, along with medically acceptable treatment options, and for assuring their comprehension as much as possible. All attending physicians may also offer their treatment recommendations.
- 2. The decision to limit therapy by excluding specific interventions is a decision which should ordinarily be made by the patient/surrogate decision-maker, after appropriate discussions with the patient's attending physician or his DCAP, and documented by a physician's order in the patient's medical record. Annotations must be made in the progress note which detail the discussions with the surrogate decision makers or patient regarding the prognosis and specifics concerning their understanding of the treatment plan, including specific quotes if possible. This note should be signed or countersigned by the attending physician or his DCAP, and ideally by a second party such as a Nurse, Social Worker or Chaplain who is present during the discussions as a witness.
- 3. In situations where initiation of life sustaining therapy, including cardiopulmonary resuscitation, would be, in the opinion of the attending physician or his DCAP, of no benefit and/or disproportionate (of more harm than good), said therapy need not be offered as an option. In such situations, if conflict arises, it is recommended that the attending physician or his DCAP consult the Ethics Committee or similar body per hospital policy. The Ethics Committee may facilitate communication and offer recommendations. Legal Affairs/Risk Management should also be notified if there is conflict. Until the conflict is resolved, there should be no limitation of therapy. Hospital procedures should be followed in the case of irresolvable disagreements, per the guidelines on the determination of Inappropriate Medical Interventions in End of Life policy.

Discontinuation of life-sustaining therapy

- 1. This category may be applied to patients who have a terminal medical condition or for whom the conditions of existence on prolonged life sustaining therapies are not acceptable, and achieve no useful benefit for the patient.
- 2. Such condition should have existed for a time sufficiently long that the prognosis has been determined with reasonable medical certainty. The attending physician or his DCAP is responsible for communicating this prognosis to the patient/surrogate, along with medically acceptable treatment options, and for assuring their comprehension as much as possible. All attending physicians may also offer their treatment recommendations. Patients may be placed in this category only after careful discussion with the patient/surrogate and appropriate others who are involved. Medical consultation with another physician or the Ethics Advisory Committee is recommended. The decision and the factual basis for the decision must be thoroughly documented in the medical record, including the extent and general content of discussion with all concerned individuals in the form of a progress note by the attending physician or his DCAP.
- 3. In situations where initiation of life sustaining therapy including cardiopulmonary resuscitation would be, in the opinion of the attending physician or his DCAP, of no benefit and/or disproportionate (of

more harm than good) harm, said therapy need not be offered as an option. In such situations, if conflict arises, it is recommended that the attending physician or his DCAP consult the Ethics Committee.

Responsibilities Attending physician

Ethics Committee or similar body, per hospital policy. Such a Committee may facilitate communication and offer ethical recommendations. Legal Affairs/Risk Management should also be notified if conflict is problematic. Until the conflict is resolved, there should be no limitation of therapy. Hospital procedures should be followed in the case of irresolvable disagreements, per the Guidelines on the Determination of Inappropriate Medical Interventions in End of Life Care.

The decision to place a patient in Categories C and to withdraw certain ongoing therapy in the situation described must be communicated by a specific order by the attending physician or his DCAP. In the case of a designee, the attending's designee in the progress note must document this discussion at the time the order is written. The attending physician or his covering associate must countersign any such order at his/her earliest convenience.

For patients in Categories B or C presenting for operative procedures, the operative period is considered to begin upon the patient's arrival to the holding area and to end once the patient meets post-anesthesia/sedation discharge criteria. The specifics of the code status during this period will be addressed in accordance with separate hospital policy by the anesthesiologist and/or surgeon in coordination with the patient/surrogate decision-maker and the attending physician or his DCAP prior to the procedure. Documentation of this discussion will be detailed in the patient's chart.

ACTION:

- 1. Has ultimate responsibility for making diagnoses deciding of proper elements of treatment and determining and relating prognosis to the patient/surrogates.
- 2. Consults with physicians from other specialties and subspecialties as appropriate.
- 3. Ordinarily defers to the expressed wishes of the patient/surrogate. If the attending physician or his DCAP disagrees with the patient/surrogate on the category of clinical care, the attending physician or his DCAP need not be compelled to initiate or continue therapy. The Ethics Committee may be consulted to assist with resolution of any conflict. Resolution of disagreements should be undertaken in accordance with hospital policies, such as the Guidelines on the Determination of Inappropriate Medical interventions in End of Life Care.
- 4. Any physician order placing a patient in a specific category of clinical care will be reviewed by the attending physician. In addition, it can be changed at any time via patient/surrogate request, or as the result of conflict resolution procedures described above. The reason for this change should be documented in the progress record.
- 5. Change of orders must be documented on the physician order sheet and be to the appropriate parties.
- 6. A healthcare provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.
- 7. In the event there is not agreement pertaining to para. 6. above, Section 68-1708, (f), p. 8 in the TNHCDA or Section 41-41-215, (7), p. 19 in the MS Uniform Health-Care Decisions Act shall provide further guidance.

Social Worker, Nurse,

- 1. When requested, participate as a witness in the Chaplain discussions with the parent/guardian, surrogate decision maker, or patient.
- 2. Participate, within the limits of their expertise, in the process of enhancing communication between the patient/surrogate and health care provider.

4.2 Guidelines on the Determination of Inappropriate Medical Interventions in the End of Life Care

The traditional goals of medicine have been to heal and relieve suffering and pain. In recent years, it has been recognized that these goals are sometimes best served by limiting rather than by continuing medical interventions. These guidelines affirm both the traditional goals of medicine and the moral values of physician and institutional integrity in discerning the appropriate limits of medical interventions at the end of life. Respect for this integrity provides the basis for the right to refuse to provide ongoing medical interventions in a futile situation. These guidelines understand a medically inappropriate situation to be (1) one in which further treatment or intervention, except for comfort care, cannot be reasonably expected to improve or restore a quality of life that would be satisfactory to the patient as he or she has expressed personally, by means of advance directive, or through a legal surrogate; or (2) to be a situation in which further treatment or intervention does not serve a legitimate goal of medical practice. This complements the right of patient self-determination that must be given both voice and effect in any forum for medical decision making. This appeal to integrity is generally rooted in a combination of concerns such as avoiding harm to patients and avoiding provision of unsuitable care. These guidelines affirm the value of integrity so long as appropriate institutional review and evaluation support the determination of medical inappropriateness.

Caregivers will strive to understand and address the reasons regarding patient/surrogate decision maker/provider conflicts. After following the procedures set forth in this policy and after providing attention to the emotional needs and questions of the patient and/or surrogate decision maker, a medically inappropriate intervention may be withheld or withdrawn without obtaining the agreement of the patient or legal surrogate.

Procedures

- 1. The existence of this policy and procedure, as well as other policies and procedures regarding limits to treatment should be made known to the patient as determined by each institution to be appropriate.
- 2. When the attending physician or his/her designated physician (hereinafter the "responsible physician") determines that a medical intervention is inappropriate, the responsible physician should discuss carefully with the patient or legal surrogate the nature of the ailment, options for treatment including palliative and hospice care, and the prognosis and the reason(s) why the intervention is medically inappropriate. The responsible physician should explain that not providing the intervention in question does not mean abandoning appropriate medical care designed to provide comfort, dignity, pain management, and emotional and spiritual support. If the patient or legal surrogate concurs with the physician's recommendation to limit treatment, then procedures outlined in the institution's policies regarding patient treatment refusals shall be followed.
- 3. If, despite this explanation, the patient (or surrogate decision maker) insists that the medical intervention be provided, the responsible physician should address with the patient (or surrogate decision maker) the options of patient transfer to another institution and of obtaining an independent medical opinion concerning the medical inappropriateness of the intervention in question. The responsible physician should also provide the patient (or surrogate decision-maker) with a copy of these guidelines and explain the process, along with a list of institutional resources that might assist either in considering this issue further.

- 4. The assistance of institutional resources (such as nursing, patient care representatives, chaplaincy, social services or the Committee on Advance Care Planning/Bioethics, hereinafter "the Committee") shall be made available to the patient (or surrogate decision-maker) and to the responsible physician. In any deliberation, the first concern will always be the welfare of the patient.
- 5. If, after reasonable effort by the responsible physician using the available institutional resources, agreement is not reached between the responsible physician and the patient (or surrogate decision maker), the responsible physician who still wishes to limit the intervention must obtain a second medical opinion from a physician who has personally examined the patient and who is not currently involved in the care of the patient. The responsible physician must present the case for review by the Committee or other approved institutional body, and must provide to that body, clinical and scientific information pertinent to the determination that the intervention is medically inappropriate, including the results of the second opinion that was sought.
- 6. The responsible physician must notify the patient (or surrogate decision maker) that this process has been invoked, what it involves and what are its possible outcomes, when and where the review will take place, and that the options of transfer before the meeting exists, but that arranging such a transfer is the responsibility of the patient or surrogate decision maker. Absent patient or surrogate decision maker consent to an earlier time, the meeting cannot take place for at least 72 hours after the patient (or surrogate decision maker) is notified and must occur within 48 following the expiration of that 72 hour period.
- 7. During the review by the Committee or other approved institutional body, the responsible physician and the patient (or surrogate decision maker) are encouraged to be present to express their views for consideration, including alternative plans of care.
- 8. If, however, the Committee or other approved institutional body does not concur with the responsible physician's determination of medical inappropriateness, then orders to limit the medical intervention will not be recognized as valid without patient (or surrogate decision maker) agreement. In this situation, either the patient or the responsible physician may request a transfer of care to another physician and the institution will endeavor to locate another physician who is comfortable carrying out the medical intervention which the patient or surrogate decision maker requests.
- 9. If a finding of inappropriate medical intervention is affirmed by the Committee or other approved institutional body, the intervention may be disallowed and a plan of care established that addresses comfort care and the preservation of patient dignity. In this situation, intrainstitutional transfer of the care of the patient to another physician to provide palliative care is allowed. However, intrainstitutional transfers to another physician to provide the intervention that has been judged by the Committee to be medically inappropriate will not be allowed. In this case the patient and family may on their own seek care from providers outside this institution. If such case arrangements can be made, then the institution will attempt to aid in the orderly and safe transfer of the patient.
- 10. It is agreed by all caregivers that the emotional needs of the patient, family and/or surrogate decision maker will be supported throughout this process.

4.3 Medical Screening Exam

It is the policy of Methodist Healthcare – Memphis Hospitals and MHOBH that all persons presenting to the hospital for unscheduled care, procedures or evaluation shall receive a medical screening examination (MSE) within the capabilities of the facility's emergency department and the ancillary services routinely available.

Emergency Department

The emergency physician or nurse practitioner/certified physician assistant conducts, and is responsible for, the MSE. It is defined as the initial and ongoing evaluation of the unscheduled presenting patient to determine whether the patient has an emergency medical condition and/or to ensure that the patient does not have an emergency condition. The MSE is specific to age and presenting complaint. It includes the history, physical examination, appropriate testing as indicated, evaluation of the patient, documentation of findings, and use of on-call physicians as appropriate.

In the event a hospital is experiencing extraordinary Emergency Department surges, the hospital may utilize RNs who have been trained to conduct medical screening in such circumstances. This includes surges confirmed as communicable disease outbreaks that require an immediate response by the hospital to prevent spread. These RNs will have been trained in conducting MSEs and using personal protective equipment (PPE) as defined by system polices. These extraordinary situations may be declared by the facility CEO in conjunction with the Emergency Department Medical Director and are anticipated to be temporary and not to exceed a time period of 120 days unless reviewed and approved by the Medical Staff President, Chief of Staff, Vice Chief of Staff and Chief Quality and Patient Safety Officer.

Patients shall not be denied evaluation, screening, treatment, or stabilization on the basis of means or ability to pay, race, creed, color, national origin, age, sex, or actual or perceived disability.

The triage nurse may collect data required to complete the MSE, such as the initial patient assessment and any reassessment. The Emergency Department Technician (EDT) may initiate collection of vital signs and chief complaint and assign the initial triage acuity. The triage nurse shall verify the data collected by the EDT and assign the final triage acuity. However, the medical screening examination must be performed by a physician and/or nurse practitioner/certified physician assistant and is not complete until the ED physician and/or nurse practitioner/certified physician assistant has reviewed the triage assessment, the results of any necessary testing or treatment, and has examined the patient.

Obstetrical Patients

For obstetrical patients 20 weeks or greater gestation, the medical screening examination to be determined or rule out labor may be conducted by an appropriately trained and competent obstetrical registered nurse. After examination, the obstetrical nurse will communicate the findings and consult with the patient's physician or on-call physician. The physician will determine if the presenting condition is an emergency medical condition or that the patient may be discharged.

4.4 On Call Physicians And Emergency Transfers

A. On-Call Physicians

Hospital administration should determine which specialties (if any) are required to be on-call based on the reasonable needs of the Hospital. The determination shall be documented by the MEC and records of this determination should be maintained on file in MSSD. Lists of on call physicians shall be maintained in MSSD and posted on MOLLI.

The Hospital should maintain a list in the Hospital Emergency Department (ED) of individual physicians who are on-call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition, in accordance with the procedures below:

• If, after an initial medical screening exam (MSE), a physician (or other QMP) determines that the individual requires the services of an on-call physician, then the on-call physician should be contacted. Alternatively, if the on-call physician has been made aware of a transfer by the

transferring physician, the on-call physician should contact the Hospital emergency department to notify the ED of the transfer.

• On-call physicians should respond to Hospital calls/requests for emergency on-site coverage within a reasonable time. If a scheduled on-call physician fails to respond, the emergency department physician or designee should attempt to obtain the services of another appropriate physician from the Hospital's medical staff.

Unless otherwise contractually agreed, it is the general policy of the Hospital that physicians who are considered to be on-call are allowed to schedule elective surgeries and take call at other facilities. Such physicians are required to be medical staff members in good standing of Hospital, and if taking call at two facilities simultaneously, the physician must make the Hospital aware of the physician's on-call schedule so that these back up call lists or specific procedures can be developed.

Any changes to call availability shall be communicated to MSSD for corrected call coverage posting. If an unavoidable change occurs after hours or during the course of the call requirement, the physician should notify the facility ED and/or transfer center directly and also notify MSSD the next business day.

See also below for procedures for use in responding to situations in which a particular specialty is not available or the on-call physician does not respond.

B. Procedures for Responding to Situations in Which a Particular Specialty is not available or the Oncall Physician Does Not Respond

If a physician on-call is not available or does not respond, Department Chair or designee or the Chief of Staff should be contacted by the ED physician or designee. Patients should not be referred to the on-call physician's private practice office for emergency screening or treatment.

If available call coverage and capability exists at another MLH hospital, the patient may be transferred to that other facility for further care.

This procedure also applies to situations when the on-call physician is unavailable due to elective surgeries or being on call for another hospital.

C. Obligation to Accept Certain Transfers – Specialized Capabilities

To the extent that the Hospital has specialized capabilities or facilities that are not available at a facility that has requested the Hospital to accept the transfer of an individual needing those capabilities or facilities, the Hospital should accept appropriate transfers of such individual if the Hospital has the capacity to treat the individual. The Hospital may not condition the acceptance of an appropriate transfer on the use by the sending hospital of a particular transport service instead of the transport arrangements made by the attending physician at the sending hospital. A request for transfer should be documented along with the response to the request, and the basis for any denial of such a request.

ED physicians are authorized to accept and manage transfers from requesting hospitals. Only ED physicians or Pediatric ICU (NICU, PICU, CVICU) attendings should deny transfers.

D. Inappropriate Refusal of Transfers

Hospital medical staff and employees, in particular those who work in a dedicated emergency department, who have "reason to believe" that the Hospital may have inappropriately refused to accept the transfer of an individual from another facility should report the incident directly to the Compliance Officer or to the Compliance Hotline promptly for investigation.

If, based on the investigation, it is determined that there is "reason to believe" a transfer was inappropriately refused, the Compliance Officer should consult Hospital's Risk/Legal Officer regarding the Hospital's obligations and potential staff or employee sanctions (if appropriate).

E. Reporting the Receipt of Inappropriate Transfers

Hospital medical staff members and employees, in particular those who work in a dedicated emergency department, who have "reason to believe," that the Hospital received an inappropriate transfer in violation of the law, should report the incident promptly to the Hospital Compliance Officer or through the Compliance Hotline.

Factors that might give rise to "reason to believe" that an apparent receipt of inappropriate transfer may have occurred include, but are not limited to, the following:

- Transfer was made even though (i) the risks of the transfer outweighed the expected medical benefits of the medical treatment; (ii) the individual transferred did not request the transfer; and (iii) neither a physician nor a qualified medical person of the transferring facility certified that the benefit of medical treatment at the receiving Hospital outweighed the increased risks of the transfer;
- Individual was transferred with an unstable EMC from another hospital in violation of 42 C.F.R. § 489.24(e).
- Transfer was made even though the transferring facility was notified that the Hospital did not have available the capacity and/or capability/personnel for the treatment of the individual;
- Transfer was made without the provision of appropriate level of qualified personnel and/or transportation equipment and/or medically appropriate life support measures;
- Representatives of the transferring Hospital stated to the Hospital personnel that the transfer was made for financial reasons (e.g., lack of insurance/funds where the transfer was not requested by the individual);
- Hospital did not receive the appropriate medical records;
- Hospital received no advance notification of the transfer of an individual with an emergency medical condition; or
- The transfer was a lateral transfer.

The Compliance Officer should promptly investigate reports of apparent inappropriate transfers. At the conclusion of the investigation, the Compliance Officer or designee should determine whether there is "reason to believe" that an apparent inappropriate transfer occurred. If, based on the investigation, it is determined that there is "reason to believe" that an inappropriate transfer has occurred, the Chief Executive Officer and

Compliance Officer should consult with Hospital's Risk/Legal Officer regarding Hospital's obligations. The Hospital's Risk/Legal Officer should report the incident to the appropriate agencies/parties within 72 hours of its occurrence - if, in his/her judgment, an inappropriate transfer was made to the Hospital from other medical facilities in violation of EMTALA and if reporting is required by 42 C.F.R. § 489.20(m).

4.5 Guidelines for Appropriateness of Adult Transfusion

The following criteria for blood component administration are not meant to be standards of care. Rather, they represent guidelines for transfusion that would be considered reasonable, not mandatory. The criteria are for autologous as well as allogeneic transfusion.

Blood utilization based on these criteria is designed to continuously improve the use of blood and blood components.

GUIDANCE STATEMENT:

These represent <u>guidelines</u> for transfusion. Not all patients who meet the criteria set forth in these guidelines will require transfusion. In certain clinical circumstances, the provider may consider transfusion appropriate outside these guidelines. The decision to transfuse is a clinical decision based on real-time clinical assessment of the patient by the provider responsible for that patient's care. In all circumstances, the indication for transfusion, and the clinical decision and supporting data, should be documented in the medical record. Accumen recommends that all cellular blood products be leukoreduced.

Red Blood Cells (RBCs, pRBCs)

- One unit is the usual adult dose. Two units or more can be considered for hemodynamically unstable patients with large volume blood loss and ongoing hemorrhage.
- One unit of transfused packed red cells should increase hemoglobin by approximately 1 g/dL or hematocrit by approximately 3%.

Guideline by hemoglobin threshold and clinical indication:

Not all patients will need a transfusion even with hemoglobin less than 7 g/dL

Active bleeding independent of hemoglobin

- Active bleeding with greater than 1500 mL estimated blood loss, or who need more than 4-5 units of RBCs within 1 hour, and hemodynamic instability.
- Massive hemorrhage or massive transfusion protocol initiated.

Hemoglobin less than 7 g/dL (or hematocrit less than 21%) *

- Hemoglobin less than 7 g/dL and signs or symptoms of anemia unresponsive to management without transfusion.
- Hemoglobin less than 7 g/dL in a patient with STABLE ischemic heart disease and signs or symptoms of anemia unresponsive to management without transfusion.
- Hemoglobin less than 7 g/dL in a patient with acute upper gastrointestinal hemorrhage.
- Hemoglobin less than 7 g/dL in a patient with sepsis.
- Hemoglobin less than 7 g/dL in patient with marrow suppression due to chemotherapy and/or radiotherapy.

Hemoglobin less than 8 g/dL (or hematocrit less than 24%) *

- Hemoglobin less than 8 g/dL in patients with acute coronary syndrome or evidence to support the need for increased O2 delivery indicated by any of the following:
 - o Tachycardia and/or hypotension unresponsive to pharmacologic therapy
 - o New EKG changes
 - o Recurrent chest pain.
 - o Acute respiratory failure, inadequate cardiac output, or inadequate oxygenation.
- Hemoglobin less than 8 g/dL in a patient with bone marrow suppression or bone marrow failure (e.g., thalassemia, myelodysplasia, marrow aplasia) AND long-term transfusion dependency whose anemia cannot be managed with erythropoietic stimulating agents and/or intravenous iron with significant symptoms or unable to tolerate lower hemoglobin threshold

Hemoglobin less than 9 g/dL (or hematocrit less than 27%)*

• Hemoglobin less than 9-10 g/dL in a sickle cell anemia patient undergoing surgery to bring the hemoglobin to 10 g/dl.

Adult Platelets

GUIDANCE STATEMENT:

These represent guidelines for transfusion. Not all patients who meet the criteria set forth in these guidelines will require transfusion. In certain clinical circumstances the provider may consider transfusion to be appropriate outside these guidelines. The decision to transfuse is a clinical decision based on real-time assessment of the patient by the provider responsible for that patient's care. In all circumstances, the indication for transfusion, and the clinical decision and supporting data, should be documented in the medical record. Accumen recommends all cellular blood products be leukoreduced.

PLATELETS (Apheresis platelets, AcrodoseTM pre-storage pooled platelets, pooled random donor platelets) One unit of apheresis platelets contains approximately 200-400 ml of plasma and is the equivalent of approximately 4-6 units of pooled platelet concentrates. In circumstances where a patient has become alloimmunized to HLA antigens and refractory to platelet transfusions, HLA matched or cross-matched platelets may be used. Pooled platelet concentrates are prepared from platelets harvested by centrifugation from whole blood donations from multiple donors (for example, a five-unit pool is from five donors). Platelets are stored at room temperature. Platelet count thresholds for prophylactic transfusion in patients with marrow failure are based on high quality, strong evidence. Guidelines for periprocedural and therapeutic use of platelets are largely based on weak evidence and expert opinion.

A unit of apheresis platelets or a four to six-unit pool of platelet concentrates should increase the platelet count in a 70 kg recipient by approximately 40,000 per microliter.

Guideline by platelet count threshold and clinical indication:

Prophylactic use of platelets

- Platelet count less than 10,000/mm³ in a stable patient with hypoproliferative thrombocytopenia (marrow failure or suppression)
- Platelet count less than **10,000 20,000/mm³** in a stable patient with hypoproliferative thrombocytopenia (marrow failure or suppression) and presence of minor bleeding (WHO Grade 2 or higher), or additional risk factors for bleeding.
- Consider no prophylactic platelets for well patients with no evidence of bleeding who have had an autologous stem cell transplant or for patients with asymptomatic chronic bone marrow failure including those taking low dose oral chemotherapy or azacytidine particularly during times of platelet shortages.

• Platelet count < 30,000/mm³ and undergoing Extracorporeal Photoperesis.

Peri-procedural use of platelets

According to evidence, low risk invasive procedures can be safely carried out with a platelet count of <20,000. High risk procedures may be performed with a platelet count of <50,000 depending on the procedure and the patient's risk of bleeding. Please refer to the Society for Interventional Radiology guidelines (2019) for a complete list of procedures.

- Bone marrow biopsy: may be performed regardless of platelet count
- Peripherally inserted central catheters (PICC) lines: May be performed without platelet transfusion
- Patient undergoing LOW bleeding risk procedure: platelet count less than 20,000/ mm³
 - Catheter exchanges (gastrostomy, biliary, nephrostomy, abscess, including gastrostomy/gastrojejunostomy conversions)
 - Diagnostic arteriography and arterial interventions: peripheral, sheath < 6 F, embolotherapy
 - Diagnostic venography and select venous interventions: pelvis and extremities
 - Dialysis access interventions
 - Endoscopy/Bronchoscopy without expected biopsy.
 - Facet joint injections and medical branch nerve blocks (thoracic and lumbar spine)
 - IVC filter placement and removal
 - Lumbar puncture
 - Nontunneled chest tube placement for pleural effusion
 - Nontunneled venous access and removal (including PICC placement)
 - Paracentesis
 - Peripheral nerve blocks, joint, and musculoskeletal injections
 - Sacroiliac joint injection and sacral lateral branch blocks
 - Superficial abscess drainage or biopsy (palpable lesion, lymph node, soft tissue, breast, thyroid, superficial bone, e.g., extremities and bone marrow aspiration)
 - Thoracentesis
 - Transjugular liver biopsy
 - Trigger point injections including piriformis
 - Tunneled drainage catheter placement
 - Tunneled venous catheter placement/removal (including ports)

• Patient undergoing HIGH bleeding risk procedure: platelet count less than 50,000/ mm³

- Ablations: solid organs, bone, soft tissue, lung
- Arterial interventions: > 7-F sheath, aortic, pelvic, mesenteric, CNS
- Biliary interventions (including cholecystostomy tube placement)
- Catheter directed thrombolysis (DVT, PE, portal vein)
- Deep abscess drainage (e.g., spine, soft tissue in intraabdominal, retroperitoneal, pelvic compartments)
- Endoscopy/Bronchoscopy with expected biopsy.
- Gastrostomy/ gastrojejunostomy placement
- IVC filter removal complex
- Port vein interventions
- Solid organ biopsies
- Spine procedures with risk of spinal or epidural hematoma (e.g., kyphoplasty, vertebroplasty,

- epidural injections, facet blocks cervical spine)
- Transjugular intrahepatic portosystemic shunt
- Urinary tract interventions (including nephrostomy tube placement, ureteral dilation, stone removal)
- Venous interventions: intrathoracic and CNS interventions
- General surgery and Gynecological surgery (including C-sections): platelet count less than 50,000/mm³
- Epidural catheter insertion or removal: platelet count less than 80,000/ mm³
- Neurosurgery or retinal surgery: platelet count less than 100,000/ mm³ or abnormal laboratory assessment of platelet function
- **Proven significant congenital or acquired platelet functional defect**: platelet transfusion based on laboratory assessment of platelet function (note: Surgery, including majority surgery such as cardiothoracic procedures, can be safely performed in patients with mild platelet inhibition medications, e.g., aspirin, without platelet transfusion)

Therapeutic Use of Platelets

- **Post-surgical or post-procedural bleeding**: platelet count less than **50,000/mm³** or abnormal laboratory assessment of platelet function
- **Significant non-procedure related bleeding**: platelet count less than **50,000/mm³** or abnormal laboratory assessment of platelet function
- Cardiac surgery with unexpected bleeding: platelet count less than 100,000/mm³ and/or abnormal laboratory assessment of platelet function.
- Massive hemorrhage protocol or massive transfusion protocol: by protocol if actively bleeding or platelet count less than 80,000/mm³ or abnormal laboratory assessment of platelet function
- **Neuraxial bleeding**: platelet count less than **100,000/mm³** or abnormal laboratory assessment of platelet function

*Note: In patients with hemorrhage and thrombocytopenia due to hypersplenism, platelet transfusion may be indicated in an emergency, if platelet count is less than 50,000/mm

**Note: Recent data including small randomized controlled trials, suggest that platelet transfusion in the absence of thrombocytopenia in patients undergoing anti-platelet therapy does NOT improve survival or neurologic outcomes and may result in an increased risk of mortality. Platelet transfusion in this setting cannot be considered evidence-based and should be undertaken with caution.

Adult Plasma

GUIDANCE STATEMENT:

These represent <u>guidelines</u> for transfusion. Not all patients who meet the criteria set forth in these guidelines will require transfusion. In certain clinical circumstances the provider may consider transfusion to be appropriate outside these guidelines. The decision to transfuse is a clinical decision based on real-time

^{*}Note: excludes neurosurgery for intracranial hemorrhage associated with anticoagulant or anti-platelet therapy

assessment of the patient by the provider responsible for that patient's care. In all circumstances, the indication for transfusion, and the clinical decision and supporting data, should be documented in the medical record.

PLASMA

One unit of plasma contains approximately 300 ml although the volume of each unit may vary.

Multiple studies have shown the PT/INR is a poor predictor of bleeding risk and many procedures can be safely carried out when the INR is mildly to moderately elevated.

Plasma transfusion carries a significant risk of transfusion-associated circulatory overload and acute lung injury.

12-15 ml/kg is the usual adult dose for all plasma products. In a 70 kg patient this represents 3-4 units of plasma.

Prothrombin complex concentrate (4-factor PCC) is now preferred for emergent warfarin reversal along with intravenous vitamin K according to the American College of Chest Physicians Guidelines. Withholding warfarin or intravenous vitamin K alone is indicated for warfarin reversal or a return to therapeutic levels in non-emergencies. Do not use plasma for volume repletion only.

Published data shows that the PT/INR is a poor predictor of bleeding risk. Low risk invasive procedures can be safely carried out, without plasma transfusion, when the INR is mildly to moderately elevated. In many instances, pre-procedure coagulation studies are unnecessary. Low risk procedures may be performed with an INR in the range of 2.0-3.0 or less. High risk procedures may be performed with an INR in the range of 1.5-1.8 or less depending on the procedure and the patient's risk of bleeding. Please refer to the Society for Interventional Radiology Guidelines (2019) for a complete list of procedures.

Guideline by PT/INR threshold and clinical indication:

Active bleeding before coagulation studies are available

• Massive hemorrhage protocol or massive transfusion protocol initiated

Prophylactic use of plasma

Note: Vitamin K alone or 4-factor PCC with vitamin K should be used instead of plasma in patients receiving warfarin.

- INR greater than 3, patient unresponsive to Vitamin K and undergoing paracentesis
- INR in the range of 2.0-3.0, patient unresponsive to Vitamin K and undergoing low-risk procedures such as:
 - Catheter exchanges (gastrostomy, biliary, nephrostomy, abscess, including gastrostomy/gastrojejunostomy conversions)
 - o Diagnostic arteriography and arterial interventions: peripheral, sheath < 6 F, embolotherapy
 - o Diagnostic venography and select venous interventions: pelvis and extremities
 - Dialysis access interventions
 - o Facet joint injections and medical branch nerve blocks (thoracic and lumbar spine)
 - o IVC filter placement and removal

- Lumbar puncture
- o Nontunneled chest tube placement for pleural effusion
- o Nontunneled venous access and removal (including PICC placement)
- Paracentesis
- o Peripheral nerve blocks, joint, and musculoskeletal injections
- o Sacroiliac joint injection and sacral lateral branch blocks
- O Superficial abscess drainage or biopsy (palpable lesion, lymph node, soft tissue, breast, thyroid, superficial bone, e.g., extremities and bone marrow aspiration)
- Thoracentesis
- Transjugular liver biopsy
- Trigger point injections including piriformis
- o Tunneled drainage catheter placement
- o Tunneled venous catheter placement/removal (including ports)

INR greater than 2.0, patient unresponsive to Vitamin K and undergoing emergent surgical intervention

- INR in the range of 1.5 1.8, patient unresponsive to vitamin K and undergoing high-risk procedures such as:
 - o Ablations: solid organs, bone, soft tissue, lung
 - o Arterial interventions: > 7-F sheath, aortic, pelvic, mesenteric, CNS
 - o Biliary interventions (including cholecystostomy tube placement)
 - o Catheter directed thrombolysis (DVT, PE, portal vein)
 - Deep abscess drainage (e.g., spine, soft tissue in intraabdominal, retroperitoneal, pelvic compartments)
 - o Gastrostomy/ gastrojejunostomy placement
 - o IVC filter removal complex
 - o Port vein interventions
 - Solid organ biopsies
 - o Spine procedures with risk of spinal or epidural hematoma (e.g., kyphoplasty, vertebroplasty, epidural injections, facet blocks cervical spine)
 - o Transjugular intrahepatic portosystemic shunt
 - Urinary tract interventions (including nephrostomy tube placement, ureteral dilation, stone removal)
 - Venous interventions: intrathoracic and CNS interventions
- INR greater than 1.7, patient unresponsive to vitamin K and undergoing:
 - o Epidural placement or removal
 - Surgery involving the neuroaxis
 - o Large-bore Tunneled CVC Insertion in Patients with Coagulopathy

Therapeutic Use of Plasma

- Plasma exchange transfusion in thrombotic thrombocytopenic purpura
- Hemorrhage and partial thromboplastin time greater than 50 seconds due to factor deficiency for which no factor concentrate is available (rule out heparin and anti-phospholipid antibody before considering plasma transfusion)
- INR greater than 1.4 and intracranial hemorrhage; prothrombin complex concentrate unavailable or contraindicated

*Note: TIPS and transjugular liver biopsy must often be performed at an INR > 1.8 in patients with hepatic coagulopathy. Data suggest that these patients may have normal thrombin generation and may be at lower bleeding risk than indicated by the INR. For TIPS, If INR is acutely elevated from baseline or >3.0, consider checking fibrinogen and if <100mg/dL give fibrinogen replacement (cryoprecipitate or fibrinogen concentrate).

Adult Cryoprecipitate

GUIDANCE STATEMENT

These represent <u>guidelines</u> for transfusion. Not all patients who meet the criteria set forth in these guidelines will require transfusion. In certain clinical circumstances the provider may consider transfusion to be appropriate outside these guidelines. The decision to transfuse is a clinical decision based on real-time assessment of the patient by the provider responsible for that patient's care. In all circumstances, the indication for transfusion, and the clinical decision and supporting data, should be documented in the medical record. Accumen recommends all cellular blood products be leukoreduced.

CRYOPRECIPITATE

Cryoprecipitate is usually provided as pre-pooled concentrates of five or six units or as individual units for pediatric patients. Each unit from a separate donor is suspended in 10-15 ml of plasma. Each unit provides up to 350 mg of fibrinogen. A five-unit pool can be expected to raise the fibrinogen level in a 70 kg patient approximately 50 mg/dL.

Guideline by fibrinogen threshold and clinical indication:

- Fibrinogen less than 200 mg/dL and ongoing obstetrical hemorrhage
- Fibrinogen less than 200 mg/dL and ongoing large volume blood loss and coagulopathic bleeding in trauma
- Fibrinogen less than 150 mg/dL in acute leukemia
- Massive hemorrhage or massive transfusion protocol (Note: Recommend goal-directed therapy based on fibrinogen result when laboratory results are available and timely)
- Congenital fibringen deficiency and bleeding
- Factor VIII deficiency with hemorrhage when specific factor concentrates are not available*.
- vWD with bleeding or prior to urgent invasive procedure when specific concentrates are not available or DDAVP is contraindicated or unavailable*.
- Factor XIII deficiency when specific factor concentrates are not available*.
 - * Every effort should be made to obtain specific factor concentrates

4.6 Neonatal Massive Transfusion Guideline (Patients weighing > 10 kilograms)

1. PRINCIPLE:

1.1. Massive Transfusion is defined as an infusion of Packed Red Blood Cells in amounts approaching or exceeding replacement of the recipient's total blood volume within less than 24 hours or the acute administration of more than half of the patient's estimated blood volume per hour.

2. SCOPE:

2.1. This guideline applies to patients weighing less than 10 kilograms at Le Bonheur Children's Medical Center.

3. PROCEDURE:

- 3.1. The Neonatal Massive Transfusion Guideline may be initiated by either the patient's physician or by the Medical Director of Transfusions Services (or the designee Pathologist).
 - A. It is the responsibility of all technologists in the Transfusion Service to monitor patients receiving large numbers of red cell units without the addition of other blood products (i.e., Fresh Frozen Plasma (FFP), Platelets and Cryoprecipitate).
 - B. It is standard procedure for the blood bank technologist to review a patient's transfusion history before dispensing blood products.
 - C. If 6 doses (ml/kg as indicated for the patient) of Red Blood Cells have been ordered and dispensed within a 24 hour time period without FFP, Platelets and Cryoprecipitate being transfused, the Transfusion Service should call the patient's physician to see if he/she wishes to invoke the Massive Transfusion Guideline, which will include Fresh Frozen Plasma, Platelets and Cryoprecipitate in addition to Packed Red Blood Cells. The Medical Director of Transfusion Services (or the designee Pathologist) must be notified.
- 3.2. When this guideline is initiated, the blood bank staff will prepare and issue "Massive Transfusion Pack #1" according to the Massive Transfusion Guideline chart (see attached). Once the MTP Pack #1 has been issued, the blood bank technologist will prepare the next MTP Pack (MTP Pack #2). Subsequent MTP Packs (#3, #4, etc) will be prepared when the previous MTP pack is issued until the Massive Transfusion Guideline has been terminated by either the patient's physician or the Medical Director of Transfusion Services (or designee Pathologist).
 - A. If a current Type and Screen has been completed, Red Blood Cells will be assigned to patients less than four months of age, and initial-spin crossmatches with type-specific Packed Red Blood Cells will be performed on neonates greater than four months of age (whenever time permits for the crossmatch). ABO-compatible plasma components will be issued for the MTP Packs by the Transfusion Service. If the packed red blood cells are needed emergently and time does not allow a crossmatch to be performed for neonates greater than four months of age, Emergency Uncrossmatched, O Negative packed Red Blood Cells will be dispensed per current policy for these patients. The Physician will need to sign the "Release of Uncrossmatched Blood" form per current policy.
 - B. If the Type and Screen has not yet been received for testing, the Transfusion Service will dispense the appropriate volume of Emergency, Uncrossmatched, Group O, Rh Negative Packed Red Blood Cells and Group AB plasma components until the Type and Screen is completed. The ordering Physician will need to sign the "Release of Uncrossmatched Blood" form per current policy in this situation.
 - C. If the Type and Screen has been partially completed (patient's ABO and Rh has been determined, but the Antibody Screen is not yet completed) Emergency, Uncrossmatched, Type-specific Red Blood Cells can be dispensed until the Antibody Screen is completed. The ordering Physician will need to sign the "Release of Uncrossmatched Blood" form per current policy, in this situation as well.
 - D. The ordering physician should be encouraged to obtain a sample on the patient as soon as possible, to enable the blood bank to perform the Type and Screen and dispense immediate-spin crossmatch-compatible Type-specific packed Red Blood Cells.
 - E. Once an Rh-Negative patient has been transfused with ten packed Red Blood Cell units, the blood bank technologist will call the Medical Director of Transfusion Services (or designee Pathologist) for further recommendations on transfusion support for the patient.
 - F. A new specimen must be obtained for Type and Screen every 24 hours within the setting of the Massive Transfusion Guideline.

4.7 Pediatric Massive Transfusion Guideline (Patients weighing > 10 kilograms) PRINCIPLE:

Massive Transfusion is defined as an infusion of Packed Red Blood Cells in amounts approaching or exceeding replacement of the recipient's total blood volume within less than 24 hours or the acute administration of more than half of the patient's estimated blood volume per hour.

SCOPE:

This guideline applies to patients weighing greater than 10 kilograms; the patient should be treated at Le Bonheur Children's Hospital.

PROCEDURE:

- 1 The Pediatric Massive Transfusion Guideline may be initiated by either the patient's physician or by the Medical Director of Transfusions Services (or the designee Pathologist).
 - A. It is the responsibility of all technologists in the Transfusion Service to monitor patients receiving large numbers of Red Blood Cell units without the addition of other blood products (i.e., Fresh Frozen Plasma (FFP), Platelets and Cryoprecipitate).
 - B. It is standard procedure for the technologist to review a patient's transfusion history before dispensing blood products.
 - C. If 6 units of Packed Red Blood Cells have been ordered and dispensed within a 24 hour time period without FFP, Platelets and Cryoprecipitate being transfused, the Transfusion Service should call the patient's physician to see if he/she wishes to invoke the Massive Transfusion Guideline, which will include FFP, Platelets and Cryoprecipitate, in addition to Packed Red Blood Cells. The Medical Director of Transfusion Services (or the designee Pathologist) must be notified.
- 2. When the guideline is initiated, the blood bank staff will prepare and issue "Massive Transfusion Pack #1" according to the Massive Transfusion Guideline chart (see attached). Once the MTP Pack #1 has been issued, the blood bank technologist will prepare the next MTP Pack (MTP Pack #2). Subsequent MTP Packs (#3, #4, etc) will be prepared when the previous MTP pack is issued until the Massive Transfusion Guideline has been terminated by either the patient's physician or the Medical Director of Transfusion Services (or designee Pathologist).
 - A. If a current Type and Screen has been completed, immediate-spin crossmatch- compatible type-specific Packed Red Blood Cells and ABO-compatible plasma components (Platelets, FFP, Cryoprecipitate) will be issued for the MTP Packs by the Transfusion Service. If packed Red Blood Cells are needed emergently, and time does not allow for crossmatching of the RBCs, Emergency Uncrossmatched O Negative packed RBCs will be dispensed per current policy. The ordering Physician will need to sign the "Release of Uncrossmatched Blood" form per current policy.
 - B. If the Type and Screen has not been received, the Transfusion Service will dispense Emergency, Uncrossmatched, Group O, Rh Negative Packed Red Blood Cells and Group AB plasma components until the Type and Screen is completed. The ordering Physician will need to sign the "Release of Uncrossmatched Blood" form per current policy.
 - C. If the Type and Screen has been partially completed (patient's ABO and Rh has been determined, Antibody Screen not complete), Emergency, Uncrossmatched, Type-specific Red Blood Cells will be dispensed until the Antibody Screen is completed. The ordering Physician will need to sign the "Release of Uncrossmatched Blood" form per current policy.

- D. The ordering physician should be encouraged to obtain a sample on the patient as soon as possible so that the blood bank may dispense immediate-spin crossmatch- compatible, Type-specific Packed Red Blood Cells.
- E. Rh Negative Male patients may be switched to ABO-compatible, Rh Positive immediate-spin crossmatched Packed Red Blood Cells after 10 units of ABO-compatible or Group O, Rh Negative Packed Red Blood Cells have been transfused, with approval from the Medical Director of Transfusion Services (or designee Pathologist).
- F. Female Rh Negative patients should continue to receive Rh Negative Packed Red Blood Cells.
- G. In the event ABO-compatible Rh Negative Packed Red Blood Cells are not available for Rh Negative patients, the patient may be switched to ABO-compatible Rh Positive immediate-spin crossmatched Packed Red Blood Cells only with the approval of the Medical Director of Transfusion Services (or the designee Pathologist) in conjunction with the patient's physician.
- 3. Subsequent orders for blood are also dispensed as a "Massive Transfusion Pack #2, #3, etc, (which will also include Cryoprecipitate with MTP Pack #2 and forward), until further notice from either the clinical team or the Medical Director of Transfusion Services (or the designee Pathologist). A new specimen must be obtained for Type and Screen every 24 hours within the setting of the Massive Transfusion Guideline.

4.8 Clinical Effectiveness Standards

The purpose of this policy is to delineate all evidence based and best practice clinical guidelines approved for use. Use of these should occur for each patient care episode at MH-MH and MH-OBH, and as appropriate in Provider-based clinics.

Clinical Care & Best Practice Default Standards

Pneumococcal vaccine

The following acute care hospitalized in-patients will receive the Pneumococcal vaccine if no acceptable contraindication:

- Aged 65 and older
- Aged 6 years to 64 years who are considered high risk and have not received the vaccine before. High risk criteria include:
 - o Alcoholism
 - Asplenia (congenital or acquired, splenic dysfunction, or splenectomy)Asthma (only includes age 19 years to 64 years)
 - Cerebral spinal fluid leaks
 - Chronic heart disease (including CHF and excluding hypertension)
 - Chronic liver disease (including cirrhosis)
 - Chronic lung disease (including COPD, bronchitis, and emphysema)
 - Cigarette smoker (only includes ages 19 to 64 years)
 - Cochlear implant
 - Diabetes
 - Sickle Cell Disease and other

- hemoglobinopathies
- Congenital or acquired immunodeficiencies
- Chronic renal failure
- Generalized malignancy
- HIV/AIDs
- Hodgkin's disease
- Leukemia
- Long-term systemic corticosteroids
- Lymphomas
- Multiple Myeloma
- Nephrotic syndrome; nephrosis
- Solid organ transplant
- Radiation therapy
- Residents of nursing homes or longterm facilities

Acceptable Exclusions:

- Serious allergic reaction to prior pneumococcal immunization
- o Patient/caregiver refuses vaccine
- o Patient is receiving chemo/radiation during this hospital stay
- Patient has received chemo/radiation in the past 2 weeks
- o Patient has had a bone marrow transplant within the last 12 months
- Patient has received shingles vaccine in the past 4 weeks
- o Patient is 6 years of age and has received a conjugate vaccine in the past 8 weeks
- Organ transplant during this hospital stay

Smoking cessation advice

Every smoker and recently quit smoker will receive smoking cessation advice (Learning for Life)

Oxygenation Assessment

Oxygen assessment will become another vital sign that is

measured in the ED

Influenza vaccine

Every acute care hospitalized in-patient age 6 months and greater will be screened and vaccinated with the flu

vaccine during the flu season as determined by

CDC/CMS (in general, months of October – March) if

no acceptable contraindication.

Rehabilitation evaluation

Rehabilitation referral will be initiated 24 hours post

admission on all stroke patients

Hospice Evaluation

For each patient given "Do not resuscitate" status, the attending physician will be asked if a hospice evaluation is appropriate. If affirmed, the hospice evaluation will

be requested.

Ventilator Liberation Protocol Protocol will be initiated on all ventilated patients in the

adult critical care units

Sedation and Analgesia Orders

The appropriate sedation/analgesia orders will be

initiated on all ventilated patients in the adult critical

care units

4.9 Requirement to Specify Numerical Gestational Age

Numerical gestational age/estimated numerical gestational age should be documented in the mother's Hospital medical record by the obstetrician prior to or at the time of delivery.

4.10 Telemetry and Cardiac Monitoring Guidelines

Telemetry and Cardiac Monitoring orders will require designation of Class I, II, or III as represented by the American College of Cardiology guidelines for in-hospital cardiac monitoring. The medical indication will be included in the order based on the Class.

- Class I: Cardiac monitoring is indicated in most, if not all, patients in this group, typically ICU appropriate patients. This classification does not require documentation of necessity until designation is changed to Class II or Class III.
- Class II: Cardiac monitoring may be of benefit in some patients but is not considered essential for all patients. This classification should have documentation of necessity at least every 48 hours. The original order is valid until discontinued.
- Class III: Cardiac monitoring is not indicated because a patient's risk of a serious event is so low that monitoring has no therapeutic benefit. This classification should have documentation of necessity every 24 hours. The original order is valid until discontinued.

4.11 Imaging & Radiology Studies Requiring Interpretation by Radiologist

Below is a list of tests that require credentialed radiologist interpretation:

General diagnostic radiology (x-ray), diagnostic ultrasound, diagnosis and treatment using radionuclides, nuclear medicine studies including PET, diagnostic neuroradiology, diagnostic invasive procedures and diagnostic body imaging, computerized tomography, MRI, mammography, and myelography.

A full procedure list for this scope of practice can be found under the radiology DOPs and special privileges.

Exception: If granted privileges for limited diagnostic radiology interpretation, primary care providers in designated provider-based clinics may interpret the following diagnostic x-rays performed in their clinic: chest x-ray, extremities, spine, skull, and sinus.

Exception 2: If granted the privilege, maternal fetal medicine attendings may interpret targeted obstetrical ultrasound.

Exception 3: If granted the privilege, board certified cardiologists with appropriate training, education, and current clinical competency may interpret cardiac MRI.

4.12 Qualifications of Non-Medical Staff ordering Diagnostic Tests or Imaging

A provider who is neither credentialed nor privileged by MLH may order diagnostic and imaging studies when the following are verified:

- National Provider Identifier number
- valid provider license
- no sanctions through OIG (Office of the Inspector General)

5.0 Physician Professional Conduct

5.1 Physician/Associate Grievance Policy

To provide a process for Associates which allows review and documentation of problems between Associates and physicians (including house staff members). Complaints may be related to behavior, harassment, or other issues, which may not fit the Associates grievance procedure or other formal avenues. The complaint must be work related and occur within MH-MH or MH-OBH facilities, or Provider-based clinics. This process is in addition to the Occurrence Reporting Procedure or procedures provided for pursuant to the medical staff bylaws. It is preferable that Associates always attempt to solve problems informally through discussion with their supervisors. This process is for the occasion when informal discussion does not resolve the complaint.

Step 1: The Associate discusses the incident with the appropriate supervisor within five calendar days following the occurrence. The Associate and supervisor attempt to resolve the issue at this point, if appropriate. If the problem is not resolved, the supervisor notifies the MSSD which will be responsible for setting up a meeting with the physician involved in the complaint and the appropriate Medical Staff Department Chair (or Resident Program Director) and the appropriate administrative representative depending upon the location of the incident.

The Associate's supervisor will attend the meeting and the Associate may attend at his or her discretion. This meeting is to occur within 30 days. If the physician involved has no discrepant information in regard to the complaint and/or a concurrence of the complaint can be obtained between the physician and Associate, the Medical Staff Department Chair (or Resident Program Director) and the administrative representative will attempt to resolve the problem with appropriate action. This resolution must meet the approval of both the Associate and the physician. If such resolution is not, possible at this level, the process proceeds to Step 2.

Step 2: Human Resources is notified of the situation and begins data collection and then submits a complete report to the MSSD (to be forwarded to the appropriate Medical Staff Department Chair or Resident Program Director), the appropriate administrative representative, and the Associate Chief of Staff. The complaint is reviewed by this 3-member committee (appropriate Departmental Chair or Resident Program Director, administrative representative, and the Associate Chief of Staff). A unanimous vote of this committee is required to declare the complaint valid or invalid. One dissenting vote will forward the complaint to the Senior Leadership Council (SLC). If at the committee level or SLC level the complaint is deemed invalid, the issue is terminated at this point. If at the committee level or SLC level the complaint is deemed valid, steps outlined in the medical staff bylaws are initiated for appropriate action.

5.2 Physician Health Policy

Purpose

The hospital and the medical staff leadership has an obligation to protect patients from harm. In this regard, the medical staff leaders design a process that provides education about physician health, addresses prevention of physical, psychiatric, or emotional illness, and facilitates confidential diagnosis, treatment, and rehabilitation of physicians who suffer from a potentially impairing condition.

The process is to assist and rehabilitate, rather than discipline and to aid the physician in retaining or regaining optimal professional functioning, consistent with protection of patients.

Reporting and investigating

If any individual working in the hospital has a reasonable suspicion that a physician appointed to the medical staff is impaired, the following steps should be taken:

- 1. The individual who suspects the physician of being impaired must provide a written report to the Department Chair, Chief of Staff, Associate Chief of Staff, MEC or the Board of Directors. The report must be factual and shall include a description of the incident(s) that led to the belief that the physician might be impaired. The individual 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) there is enough information to warrant an investigation and/or assessment, the CEO, Medical Staff President, or Chief of Staff shall request an investigation and/or assessment. Depending on the severity of the problem or nature of the impairment the investigation and/or assessment can be performed by either:
 - a) the Medical Staff Well Being Committee; or
 - b) an outside consultant; or
 - c) another individual or individuals appropriate under the circumstances, or
 - d) the MEC
- 3. If the physician refuses to have an assessment, the assessment will be changed to the disciplinary tract according to the medical staff bylaws.
- 4. A report of the investigation and/or assessment will be presented to the MEC if the findings produce sufficient evidence that the physician might be impaired.
- 5. If the investigation and/or assessment produce sufficient evidence that the physician is impaired, the physician shall be told that the results indicate that the physician may suffer from impairment that affects his or her practice. The physician need not be told who filed the report, and does not, necessarily need to be told the specific incidents contained in the report.
- 6. A physician may make a self-referral to the Department Chair, Chief of Staff, Associate Chief of Staff, MEC or the Board of Directors.
- 7. Depending upon the severity of the problem and the nature of the impairment, the MEC and the hospital has, but is not limited to, the following options:
 - a) require the physician to undertake a rehabilitation program as a condition of continued
 - b) impose appropriate restrictions on the physician's practice; or

- c) Immediately suspend the physician's privileges in the hospital until rehabilitation/advocacy has been accomplished, if the physician does not agree to discontinue practicing voluntarily.
- 8. Any official actions must be in accordance with the medical staff bylaws, rules and regulations.
- 9. The physician's confidentiality of the self-referral, other referral and assistance will be maintained except as limited by law, ethical obligation, or when the safety of the patient is threatened.

Rehabilitation

The MEC shall not recommend reinstatement of a physician until it is established, that the physician has entered or successfully completed a rehabilitation program and maintains advocacy with the Tennessee Medical Foundation – Physicians Health Program (TMF-PHP) or Mississippi Professionals Health Program (MPHP).

Reinstatement

Upon sufficient proof that a physician who has been found to be suffering an impairment has entered or successfully completed a rehabilitation program, the MEC may recommend reinstatement of the physician to the medical staff.

When considering an impaired physician for reinstatement, the hospital and its medical staff leadership must consider patient care interests.

As proof of the physician having entered or completed a rehabilitation program, the MEC must obtain a letter from the program director or his/her designee of the rehabilitation program where the physician was treated. The physician must authorize the release of this information and it is the responsibility of the physician to obtain this letter. The letter from the program director/designee of the rehabilitation program shall state:

- a) whether the physician is participating in the program;
- b) whether the physician is in compliance with all of the terms of the program and has received advocacy
- c) whether the physician attends program meetings regularly (if appropriate);
- d) to what extent the physician's behavior and conduct are monitored;
- e) whether, in the opinion of the rehabilitation program physicians, the physician is, or has the potential to be rehabilitated;
- f) whether an after-care program has been recommended to the physician and, if so, a description of the after-care program; and
- g) whether, in the program director's opinion, the physician is capable of resuming medical practice and providing continuous, competent care to patients.

Assuming all information the hospital receives indicates the physician is in or has completed an acceptable rehabilitation program and is capable of resuming patient care, the MEC_and/or the hospital must take the following additional precautions when restoring clinical privileges:

- a) Require the physician to provide the MEC with quarterly reports from the rehabilitation program stating that the physician is continuing treatment or therapy, as appropriate, and that his or her ability to treat and care for patients in the hospital is not impaired.
- b) Failure to complete the program or the prescribed after care program will result in further action by the MEC.

- c) Failure to report loss of advocacy will result in further action by the MEC
- d) The physician will be monitored during the rehabilitation phase

All actions should be pursuant to the medical staff bylaws, rules and regulations and policies.

5.3 Conflicts of Interest Policy

Medical staff officers, department chairs, and all medical staff members serving on committees and as committee chairs are obliged to represent the interests of the Hospital's medical staff in upholding the quality of care provided at the Hospital. To meet this obligation and to enable discerning decision-making, officers, department chairs, and all medical staff members serving on committees must disclose potential conflicts of interest relevant to the position held and the circumstances. Members shall not use or disclose any information obtained as a result of his/her medical staff leadership position for any purpose other than the furtherance of quality medical care in the Hospital.

Members of the medical staff and LIPs shall disclose conflicts of interest to the medical staff leaders when he/she becomes aware that such a conflict of interest exists.

When and How Disclosures are Made:

When assuming office/position: At time of election as medical staff officer or department chair; or

At time of appointment to a medical staff committee chair

Annually: All Medical Staff Leaders, Department Chairs and Committee Chairs

How: Complete and sign the Conflict of Interest Statement Form

accompanying the appointment letter or other agreement

evidencing willingness to serve in the role(s).

As necessary: For all medical staff members serving on committees, including ad hoc

committees, when a member has a conflict of interest with any matter that is

brought before the committee for discussion and/or vote.

For all medical staff members and LIPs, when he/she becomes aware that such a

conflict of interest exists

How: Verbally at any time before the discussion begins on the matter or at the earliest

time in the discussion when a potential conflict of interest occurs.

Meeting Agenda:

All committee meeting agenda shall include, at least a reference to or reminder of the following statement by the committee chairperson at the beginning of the meeting: If a member has a conflict of interest relating to an item on the agenda, medical staff policy requires the member to excuse him/herself from vote and/or discussion; and, if appropriate, leave the room during the discussion.

5.4 Professional Conduct of Physicians

Purpose

It is the policy of Methodist Healthcare (MH) that all individuals within its facilities shall be treated courteously, respectfully and with dignity. To that end, MH requires all individuals, Associates, medical staff and other practitioners to conduct themselves in a professional and

cooperative manner in MH facilities. The purpose of this policy is to address inappropriate conduct by a medical staff member.

Policy

It is the policy of MH that all individuals within its facilities be treated with courtesy, respect, and dignity. This section establishes a mechanism whereby the conduct, condition, or action of a member of the medical staff, which could compromise delivery of quality patient care, be identified, reviewed and resolved.

The mechanism whereby incident reports addressing professional conduct of physicians will be reviewed and resolved will be through Provider Quality with reporting to the appropriate committees charged with peer review and professional conduct review. Individuals authorized by this policy to act on behalf of committees charged with peer review and professional conduct review are entitled to immunity afforded to these committees and committee members under federal and state statutes.

It is MH's intention that actions taken and data produced pursuant to this policy are confidential and privileged and subject to all applicable peer review protections under law.

Definitions

Behaviors that undermine a culture of safety may include, but may not be limited to:

- Obstruction of the operation of the hospital
- Interference with the ability of others to do their jobs
- Creation of a hostile work environment for Methodist Associates, medical staff members, affiliated staff members and clinical students
- Interference with an individual's ability to practice competently
- Professional conduct adversely affecting or impacting the community's confidence in the hospital's ability to provide quality patient care
- Attacks—verbal or physical—leveled at any medical staff, affiliated staff members, clinical students, Methodist Associates, patients, or visitors, that are personal or beyond the bounds of fair professional conduct
- Inappropriate comments (or illustrations) made in patient medical records or other official documents unfairly impugning the quality of care in the hospital, or attacking particular practitioners, nurses, or hospital policies
- Criticism that is addressed to its recipient in such a way as to intimidate, undermine confidence, belittle, or suggest stupidity or incompetence.
- Throwing of charts, medical instruments, or other objects at an associate, clinical student, or other medical staff member.
- Deliberately damaging or destroying medical instruments, equipment or facilities.

Procedure

A. Report

Any practitioner, employee, patient, or visitor may report behaviors that undermine a culture of safety. Documentation of the behavior is critical because ordinarily no one incident leads to disciplinary action; there is usually a pattern of conduct. The Occurrence Report Form shall be the mechanism whereby such conduct shall be documented and reported. The Occurrence Report should include, at a minimum, the following:

- The date and time of the incident
- A statement of whether the incident affected or involved a patient in any way, and if so, the patient's name
- The circumstances that precipitated the situation

- A factual and objective description of the behavior as it related to patient care or hospital operations
- A record of any action taken to remedy the situation, including the date, time, place, action and name(s) of those intervening.

B. Review and Evaluation of Complaint:

1. INITIAL PROCESS: Upon receipt of the Report, a member of the Provider Quality Department shall notify the Chief Medical Officer (CMO) at the facility where the incident occurred. The CMO (or designee) and Corporate Director of Provider Quality (or designee) shall verify the need for a further review of the complaint. They will coordinate a plan and process to review pertinent information, notify and interview the practitioner and interview other appropriately identified witnesses.

In evaluating the complaint, the practitioner may be asked to provide information regarding the complaint. He/she shall also be informed that retaliation, even subtle retaliation, will not be tolerated. In the event the practitioner retaliates against the complainant or the complaint is sufficiently egregious, a precautionary suspension may be invoked against the Practitioner in accordance with the medical staff bylaws, rules and regulations.

After completion of the interviews and other applicable inquiry, the elected medical staff leadership (as designated by the Medical Staff President and/or Chief of Staff), CMO or designee shall determine whether the report is credible. If the report is determined not to be credible and if the practitioner had been informed of the complaint, he/she shall be informed that the complaint was not substantiated

PLAN TO RESOLVE COMPLAINT: The Medical Staff President (or designee) and the CMO (or designee) shall confer and develop a plan for resolution of the complaint. In addition, other Medical Staff leaders (as designated by the Medical Staff President) and the Corporate Director of Provider Quality (or designee) may be involved as deemed necessary by the Medical Staff President. In developing the plan, the decision makers shall consider whether the alleged conduct may be a product of an impairment or another health problem (and therefore subject to resolution under the medical staff rules and regulations), whether the alleged conduct may constitute harassment or behaviors that undermine a culture of safety, the severity of the conduct, the impact on patient care, the nature and type of previous conduct allegations, previous actions taken by Methodist Healthcare against the practitioner, and other pertinent information. The Medical Staff President after consultation with the CMO shall determine whether informal action under this policy or formal action pursuant to the medical staff rules and regulations is warranted.

If it is believed that the alleged conduct is a result of an impairment or another health problem, the practitioner may be referred to the Tennessee Medical Foundation (TMF) or Mississippi Professionals Health Program (MPHP) for further evaluation. In cases where the behavior of the practitioner is sufficiently egregious participation in TMF or MPHP may be a condition of continued appointment.

C. Resolution of Complaint and Disciplinary Action

- 1. INFORMAL ACTION:
 - a) FIRST EVENT: If a single incident warrants informal action under this policy, the CMO and/or designee(s) shall meet with the practitioner to discuss the complaint. This policy and any other applicable policies shall be discussed with the practitioner. The conversation shall be documented in a letter to the practitioner, a copy of which shall

be filed in the Quality Improvement file.

In cases where the conduct is sufficiently egregious to warrant greater intervention, the practitioner shall be told that a single further incident of harassment or behaviors that undermine a culture of safety will result in initiation of formal disciplinary action pursuant to the medical staff rules and regulations. A letter to the practitioner describing these expectations shall be filed in the Quality Improvement File.

- b) SECOND EVENT: If additional incidents of harassment or behaviors that undermine a culture of safety are reported, they will be evaluated according to the process described above.
 - If substantiated, the Medical Staff President or designee and the Associate Chief of Staff (or other designated Medical Staff Leader) and/or the CMO (or designee) shall discuss the matter informally with the practitioner. At the request of the physician, the Department Chair and/or the Department Peer Review Body will be included in the process. The conversation shall be documented in a letter to the practitioner, a copy of which shall be filed in the Quality Improvement file. The letter shall state that the practitioner is required to correct the inappropriate behavior and cooperate with the resolution of the problem that his/her behavior caused.
- c) THIRD EVENT: If additional incidents of harassment or behaviors that undermine a culture of safety are reported, they will be evaluated according to the process described above.
 - If confirmed, the Medical Staff President or the CMO (or designee) may discuss the matter with Chairperson of the PROC. The Medical Staff President, CMO (or designee), Associate Chief of Staff (or designee) and a Medical Staff Leader shall meet with and advise the practitioner that such conduct is intolerable and must stop. At the request of the physician, the Department Chair and/or the Department Peer Review Body will be included in the process. This shall be followed with a letter reiterating the conditions applicable to continued appointment, a copy of which shall be filed in the Quality Improvement file. The MEC shall be informed.
- d) SUBSEQUENT EVENT: A single additional confirmed incident shall result in initiation of formal disciplinary action pursuant to the medical staff rules and regulations.
- 2. FORMAL ACTION: If formal action is deemed to be warranted by the Medical Staff President after consultation with the CMO at any time, the matter shall be referred to the MEC for action pursuant to the medical staff bylaws and Governing Documents. Suspension of the offender may be appropriate if warranted under the medical staff bylaws and Governing Documents.

6.0 Resident Oversight Exceptions

6.1 Resident Oversight During Surgical Cases

- A. If a resident or fellow is performing the procedure, the following must apply:
 - 1. The departmental attending must be notified prior to the scheduling of the procedure
 - 2. The departmental attending physician must physically be present, within the facility where the procedure occurs, for the major components of the procedure and degree of involvement documented.
 - 3. The anesthesiologist or any member of the surgical team may, at any time, request the presence of the departmental attending in the OR.
 - 4. In Emergent cases where immediate care is initiated to preserve life or prevent impairment, the procedure is initiated with the departmental attending contacted and in route.

- 5. Resident surgical cases will be tracked monthly for type, service, acuity, attending presence at any time during the procedure and clinical outcomes. These will be forwarded to the graduate medical education office, the appropriate division heads and the quality management committee.
- B. The Departments of Orthopedics and Plastic Surgery have MEC approved exceptions to the above and are as follows:
 - 1. Orthopedic PGY 4 and 5 residents may perform emergency surgery for fractures and infections under general supervision (under the attending staff member's overall direction and control but the attending physician's presence is not required at the time of care).
 - 2. Plastic Surgery PGY 6 and 7 residents may perform specific emergency trauma surgeries under general supervision nasal bone fracture, facial laceration soft tissue acute repair, and mandible alveolar ridge fracture (PGY 7 only).
- C. The University of Tennessee, College of Medicine Graduate Medical Education Resident Supervision Policy will be followed in all cases.

6.2 Resident Oversight Exception Policy

When an exception (as outlined above) is invoked, any occurrences of adverse outcomes will be referred to the Peer Review Oversight Committee (PROC) for review. The PROC may take any/all of the following actions:

- 1. Refer to department for peer review
- 2. In the event of an unanticipated complication, mortality, or a trend of complications the PROC may recommend to the Chief of Staff that a precautionary suspension (including loss of privileges) be issued to the supervising physician. The supervising physician may attend the next MEC Executive Session to discuss the case. The MEC may make recommendations to the supervising physician and/or revisions to the resident oversight exceptions as a result of their review.

7.0 Graduate Medical Education Policies

7.1 Supervision of Residents

Definitions:

Supervising Credentialed Physician (SCP) is a member of the medical staff who has appropriate credentials and privileges to deliver medical services at the hospital or in a Provider-based clinic, plus a teaching appointment in the graduate medical educational program.

General Supervision means that the care or procedure is conducted under the SCP's overall direction and control but the SCP's presence is not required at the time of care.

Direct Supervision requires that the SCP must be immediately available to furnish assistance and direction. **Personal Supervision** means that the SCP must be in attendance in the room during the procedure.

- I. **Supervision by Medical Staff:** The MH-MH medical staff assures supervision of graduate medical education residents by a Supervising Credentialed Physician (SCP) with appropriate clinical privileges for the medical care that is being supervised. Patient care responsibilities are not delegated to residents without proper supervision and meeting the medical staff responsibilities of the SCP.
- II. **Committee Structure:** The Graduate Medical Education Committee (GMEC) at the University of Tennessee will have representatives from Methodist. The Graduate Medical Education Operations

Committee (GMEOC) is responsible for providing effective communication between professional graduate education programs and the medical staff and Governing Body of Methodist Healthcare.

- Ш. Supervision of Patient Care: The management of each patient's care (including patients under the care of participants in professional graduate education programs) is the responsibility of a SCP. The medical staff assures that each participant in a professional graduate education program is supervised in his/her patient care responsibilities and by the activities of the GMEC under Methodist's affiliation with the University of Tennessee. Written descriptions of the role, responsibilities, and patient care activities of participants in professional graduate education programs are provided to the medical staff by the Office of Graduate Medical Education. These descriptions include identification of the mechanisms by which the participant's supervisor(s) and graduate education program director make decisions about each participant's progressive involvement and independence in specific patient care activities. Medical staff rules and regulations and policies also delineate those participants in professional education programs who may document patient care orders, the circumstances under which they may do so (without prohibiting SCPs from documenting orders), and what entries, if any, must be countersigned by an SCP. In the State of Tennessee, residents are Institutionally Licensed Physicians according to Tennessee Annotated Section 63-6-201. Thus, under Tennessee law, residents may document orders. No resident's order requires SCP's signature unless the medical staff rules stipulate otherwise.
- IV **Communication:** The GMEC of the University of Tennessee and MH-MH medical staff regularly communicate about the safety and quality of patient care provided by, and the related educational and supervisory needs of, the participants in professional graduate education programs. The GMEC and the MH-MH Governing Body (Board of Directors) periodically communicate about the educational needs and performance of the participants in the program. Graduate education programs will be accredited by the Accreditation Council on Graduate Medical Education, the American Osteopathic Association, or the American Dental Association's Commission on Dental Accreditation.
- V. **Supervision of Residents:** An appropriate level of supervision is required of all residents during all clinically relevant educational activities by the SCP.
 - A. Residents will receive supervision in accordance with the respective ACGME RRC requirements. These must include the following key principles:
 - 1. Clinical responsibilities must be conducted in a carefully supervised and graduated manner, tempered by progressive levels of independence to enhance clinical judgment and skill. Although attending physicians who are SCP's remain ultimately responsible for overseeing management decisions, it is the resident's responsibility to communicate significant clinical information to the attending physician or a senior level resident. In the event of a critical clinical situation in which the attending physician cannot be notified, the resident should communicate with a member of the full-time teaching faculty (who are available 24 hours/day, 7 days/week) for advice and assistance. At all times, patient safety and care is the highest priority. Residents should document their communications with the attendings concerning management decisions.
 - 2. This supervision must provide timely and appropriate feedback about the resident's performance, including instructive feedback, which describes deficiencies and provides specific instructions about how to correct these deficiencies.
 - 3. Resident supervision must support each program's written educational curriculum.

- 4. Resident supervision should foster humanistic values by demonstrating concern for each resident's well-being and professional development.
- B. Residents are supervised by teaching staff in accordance with established written guidelines.
- C. Faculty call schedules are structured to assure that support and supervision are readily available to residents on duty.
- D. The quality of resident supervision and adherence to above guidelines are monitored through annual review of the resident's evaluations of their faculty and rotations by Residency Committees and the GMEC of the University of Tennessee under its affiliation with Methodist Healthcare.
- E. For any significant concerns regarding resident supervision, the appropriate Residency Program Director will submit a plan for its remediation to the GMEC for approval. This will be reported to the MEC and governing body by the Chair of GMEOC for any concerns that involve MH.
- F. The appropriate Residency Program Director will submit progress reports to the GMEC until the situation or issue is resolved. This will be reported to the MEC and governing body as outlined above.
- G. Any quality question concerning patient care in which a resident's clinical activities are involved will be addressed to the SCP responsible for directing the patient care. In addition, the SCP will notify the resident and the residency program concerning the quality question. The SCP's response to the quality question will include resolving any question about the actions of a resident. In addition, the SCP will report to the PROC the action of the residency program concerning the quality question. Appropriate actions may be individual counseling, individual educational remediation, a conference using the quality concern as a case study, or a "Morbidity and Mortality" conference that will address the quality question in detail. The residency program is given the responsibility of determining the most effective manner of addressing the quality concern and reporting it via the SCP. In the event the SCP lapses in the reporting of the response of the residency program, the PROC will ask the Site Director of the residency program to report the response of the program. If needed, the Chair of GMEOC for MLH will use the GMEC of the University of Tennessee affiliation and the budget process of the Office of Medical Education to assure that residency programs respond to the PROC.
- VI. **Resident Responsibilities:** Responsibility on teaching service will begin with the first year resident, who is responsible for obtaining and recording the history and physical examination and documenting admission orders. On teaching services with an educational team, the first year resident is supervised by an upper level resident, who is also responsible for obtaining a history and performing a physical examination and documenting a summary of these findings. The final responsibility on all teaching services rests with the SCP, who is responsible for making management rounds seven days per week and being accessible, or delegating that responsibility to another SCP at all times.

With each year of training, the degree of responsibility accorded to a resident, both professional and administrative, will be increased progressively. This includes responsibility in such areas as patient care, leadership, teaching organization and administration. This goal is achieved by having senior residents supervise junior residents or act as consultants to junior residents, particularly in the subspecialty areas. Although SCPs remain ultimately responsible for overseeing management decisions, it is the resident's responsibility to communicate significant clinical information to the SCP or a senior level resident. In the event of a critical clinical situation in which the SCP cannot be notified, the resident should communicate with a member of the full-time teaching faculty (who are

available 24 hours/day, 7 days/week) for advice and assistance. At all times, patient safety and care is the highest priority. Residents should document their communications with the SCPs concerning management decisions.

Decisions regarding increasing clinical responsibility are made on the basis of written evaluations (monthly, CEX's) by SCPs and senior residents.

Procedures must be directly supervised by the SCP or senior resident who is certified to perform the procedure. Certification is dependent on the documented supervised performance of a minimum number of procedures as outlined in the Procedure Documentation Logs of the respective programs and listed on the Program's UT Website.

VII. **General Policy:** The program director of the resident and the chair of the department to whom the resident is assigned are responsible for monitoring of the resident's educational progress. Responsibility for specific monitoring of an educational rotation may be assigned to the SCP supervising the resident on an academic rotation.

All patients receiving care at Methodist are assigned to a member of the active staff as the Attending Physician. The SCP responsible for the care of the patient will provide the appropriate level of supervision based on the nature of the patient's condition, the likelihood of major changes in the management plan, the complexity of care, and the experience and judgment demonstrated by the residents being supervised. If quality concerns about patient care arise, those quality concerns will be addressed and assigned to the Attending Physician or the SCP supervising a specific component of management.

As part of the training program, residents should be given progressive responsibility for the care of patients and to act in a teaching capacity and provide supervision to less experienced residents and students. It is the decision of the SCP, with advice from the program director, as to which activities the resident will be allowed to perform within the context of the assigned levels of responsibility. The overriding consideration must be the safe and effective care of the patient.

VIII. Inpatient Areas: Approved Teaching Services will be designated by the Medical Executive Committee (MEC). Teaching Services will consist of organized physician teams led by a supervising credentialed physician (SCP). Teaching Services will meet all guidelines for the Supervision of Resident Activities as approved by the MEC and the medical staff rules and regulations. Each Teaching Service will designate a Senior Resident who is qualified by clinical experience and progression in the educational program to evaluate patients, communicate with attending physicians, and supervise junior residents. The Senior Resident on the Teaching Service will document his/her direct involvement by evaluating an admission or consultation and signing the admission or consultation note within 24 hours. Interaction with the SCP is required within the first 24 hours as evidenced by a note documented in the patient record by the SCP. Every hospital inpatient on an Approved Teaching Service will be visited by a resident assigned to the Approved Teaching Service directing the patient care at least once a day and progress of patient care will be documented daily.

The SCP will see the admitted inpatient at a minimum of every calendar day and document his/her visit in the medical record. The SCP will see consults within 24 hours and then every 72 hours at a minimum or daily if in ICU. The SCP will document his/her visit in the medical record. In addition, the SCP will sign all admission history and physicals, operative notes, initial consultation notes, and discharge summaries.

Approved Teaching Services at Methodist University Hospital are:

Cardiology Consultative Dermatology General Internal Medicine

General Surgery Gynecology Endocrinology

Hematology/Oncology Infectious Disease Plastic Surgery

Nephrology Neurology Neurosurgery Orthopedic Surgery Ophthalmology Otolaryngology Pathology Plastic Surgery

Pulmonary/Critical Care Medicine

Radiology Thoracic Surgery

Urology

Approved Teaching Services may be added or deleted by action of the MEC.

- **IX. Outpatient Clinic:** Residents seeing patients in an outpatient clinic, including provider-based clinics, will receive appropriate supervision. Management plans for new patients or revision of management plans will be reviewed before the patients have left the clinic.
- X. Emergency Department: Residents assigned to the emergency room service will receive Direct or Personal Supervision, depending on the severity of the problem and experience of the resident. Residents providing consultation or care to patients followed by their respective services receive General Supervision by the staff of the ED or of their service. Supervision will be documented by the SCP, who may be a member of the ED staff. Dispositions of these patients may be discussed by phone with the appropriate staff member and/or reviewed on return to an outpatient facility.
- XI. Operating Room or Special Procedure Facility: Residents performing operative, therapeutic or special diagnostic procedures will receive General, Direct, or Personal supervision by an SCP, depending on the experience and proficiency previously demonstrated by the resident, certification by the Approved Teaching Service as documented on the Website, and as determined by the SCP. That supervision will be documented by signing the operative note or note from a special procedure area.
- XII. Emergency Care: In an emergency, defined as a situation where immediate care is necessary to preserve life or prevent serious impairment of health, residents are permitted to perform everything possible to save a patient from serious harm pending arrival of more qualified staff. The appropriate medical staff practitioner will be notified as soon as possible.
- XIII. Affiliation with University of Tennessee College of Medicine: MH has an Affiliation Agreement with the University of Tennessee. This affiliation stipulates that the University of Tennessee is responsible for overall educational administration of the affiliated professional graduate medical education programs that exist at MH. The University of Tennessee is also responsible for obtaining and maintaining ACGME accreditation of all programs. However, Methodist medical staff and governing body retain the right and responsibility to develop and enforce any rule or regulation appropriate for patient care and quality assurance.
- **XIV.** Resident Supervision Policy

The following are minimum standards for resident supervision and documentation in patient care settings. They are designed to promote patient safety, provide educational excellence but maintain autonomy based on demonstrated education competence. These requirements are effective in all training sites without regard to patient insurance status or time of day. Residents and Faculty members in training programs under the auspices of ACGME will abide by the supervision and documentation schema as noted below:

| Supervision Setting/Clinical | Required Supervision Level/Description | *Minimum Level of |
|---|---|-----------------------------------|
| Activity | 20,022000.ption | Supervision |
| | | Documentation |
| A. Operating/Delivery Room | • Direct Supervision by Attending Physician The departmental attending must be physically present, within the facility where the procedure occurs and immediately available to the resident and patient, for the major components of the procedure. The departmental attending physician must be notified prior to the scheduling of the procedure And must be aware of the document competency level of the resident. | Degree of involvement documented |
| B. Non-Routine, Non-Bedside, Non-OR Procedures (e.g. Cardiac Cath, Endoscopy, Interventional Radiology, etc.) | Direct Supervision by Attending Physician The departmental attending must be physically present, within the facility where the procedure occurs and immediately available to the resident and patient, for the major components of the procedure. The departmental attending must be notified prior to the scheduling of the procedure and must be aware of the documented competency level of the resident. | Degree of involvement documented |
| C. Emergency Department | Direct Supervision by Attending Physician Departmental attending must be physically present in the facility where the procedure occurs and immediately available to the resident and patient, for the major components of the procedure. The departmental attending must be notified prior to the scheduling of the procedure and must be aware of the documented competency level of the resident. | Level 4 |
| D. Emergency Care – Immediate care is initiated to preserve life or prevent impairment. The procedure is initiated when the departmental attending physician is contacted | The departmental attending must be notified prior to the scheduling of the procedure. | Degree of involvement documented. |
| E. Inpatient Care/ New Admissions | Indirect Supervision with Direct Supervision Available. Oversight | Level 2 |

| Supervision Setting/Clinical Activity | Required Supervision Level/Description | *Minimum Level of Supervision Documentation |
|---|--|---|
| | The departmental attending physician will see and evaluate the patient within 24 hours of admission. | |
| Inpatient Care/ Continuing Care | • Oversight | Level 4 |
| Inpatient Care/ Intensive Care | Indirect with Direct Supervision immediately available | Level 4 |
| Inpatient Care/ Hospital Discharge and Transfers | Oversight The attending must be involved in decision to discharge or transfer patient. | Level 3 |
| F. Outpatient Care / New Patient Visit | Indirect with Direct Supervision immediately available | Level 2, |
| Outpatient Care / Return Patient Visit | • Oversight | Level 5 |
| Outpatient Care / Clinical Discharge | • Oversight | Level 5 |
| G. Consultations Inpatient, outpatient and Emergency Department | Oversight Post-hoc review with feedback by supervising faculty/resident physician | Level 4 |
| H. Radiology/Pathology | Oversight Post-hoc review with feedback by supervising faculty/resident physician | All reports verified by departmental attending physician prior to release |
| I. Routine Bedside and Clinic Procedures | Indirect Supervision with Direct Supervision available | Level 4 |

| *Levels of Supervision Documentation: | *Levels of Supervision Documentation: |
|--|--|
| Level 1. Departmental attending Physician Note | Level 1. Departmental attending physician Note |
| Level 2. Department attending Physician Addendum to the resident's note (not a co-signature) | Level 2. Departmental attending physician Addendum to the resident's note (not a co-signature) |
| Level 3. Departmental attending physician Co-signature implies that the departmental attending physician has | Level 3. Departmental attending physician Co-signature implies that the departmental attending physician has |

| reviewed the resident's note, and absent an addendum to the contrary, concurs with the content of the resident's note. | reviewed the resident's note, and absent an addendum to the contrary, concurs with the content of the resident's note. |
|--|--|
| Level 4. Resident documentation of departmental attending physician supervision (e.g., "I have seen and/or discussed the patient with my departmental attending physician, Dr, who agrees with my assessment and plan.") | Level 4. Resident Documentation of departmental attending physician supervision. (e.g., "I have seen and/or discussed the patient with my departmental attending physician, Dr. "X," who agrees with my assessment and plan.") |
| Level 5. Documentation to be determined by individual program director | Level 5. Documentation to be determined by individual program director |

8.0 New Medical Technology

8.1 Introduction and Approval Process

Objective

To outline the structure for a systematic review process that is designed to:

- -Assess emerging technologies
- -Approve only appropriate and proven technologies
- Promote resource management
- Support clinically effective care
- Support and drive standardization

Definitions

"Clinical Standards Committee (CSC)/ New Technology" means the multidisciplinary committee charged with the initial review of all requests for New Medical Technology and is responsible for presenting its recommendations for approval or rejection thereof to the MEC.

"Clinically Effective Care" means the application of interventions which have been shown to be safe and efficacious to appropriate patients in a timely fashion to improve health and secure the greatest value for the use of resources.

"New Medical Technology (NMT)" means a new drug or medication*, a new invasive procedure or technique or new device or medical equipment that: (a) has final approval for prescribed use from the applicable regulatory body; (b) has not previously been reviewed and approved for use within the Institution; and (c) will be used in offering a treatment modality or service type previously unavailable or promoted for a different delivery venue. New Medical Technology includes devices that are determined to be Substantially Equivalent Devices by the Food and Drug Administration (FDA).

"Medical Devices Management Committee (MDMC)" means the multidisciplinary committee charged with the oversight and management of new and existing medical devices utilized within the Hospital and the review and follow-up of medical device incidents, recalls and communication thereof to all affected departments and end users.

All New Medical Technology must be approved by the Hospital in accordance with the procedures outlined below prior to its introduction and use within the Hospital.

*New drugs and medications are reviewed by the Pharmacy and Therapeutics Committee and will not be subject to the review process outlined in this Policy.

"Substantially Equivalent Devices" means devices that are substantially equivalent to legally marketed devices with respect to the device's intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, bio-compatibility, standards and other applicable characteristics and has FDA final approval through the 510(k) process.

Policy

All New Medical Technology must be approved by the Hospital in accordance with the procedures outlined below prior to its introduction and use within the Hospital. Any medical technology that does not have full and final approval by the applicable regulatory body must be reviewed and approved by the MH Institutional Review Board in accordance with its established policies and procedures.

Approval Process

- 1. All applications and supporting documentation for approval of New Medical Technology shall be submitted to the MSSD on the Request Form attached hereto as Exhibit A within 6 weeks prior to the next scheduled meeting of the CSC. All NMT that is not a Substantially Similar Device must be brought to the Medical Staff Department for approval prior to the application process. Following such approval, Practitioners shall submit their applications on complete and accurate forms, accompanied by relevant and well-recognized scientific information and literature. The material should include a summary of analyses regarding the NMT's safety, effectiveness and effect on health outcomes in sufficient detail and volume, to allow the CSC to conduct a clinical assessment of the NMT in accordance with the criteria outlined in Item 5 below. If the NMT is deemed a Substantially Equivalent Device by the FDA, then the only supporting documentation required is a copy of the 510k approval letter from the FDA and the CSC shall defer review and recommendations for approval or rejection of such device to the MDMC.
- 2. The MSSD shall distribute copies of the Request Form and supporting documentation to the CSC and a copy of the Request Form only to the MDMC, as applicable for applications requesting approval of new medical devices and/or medical equipment.
- 3. The CSC and MDMC shall review the application at the next scheduled meeting of each such Committee.
- 4. The MDMC shall perform its review of the application for approval of new medical devices and/or medical equipment in accordance with the policy and procedures set forth in the Medical Device Management Committee Policy and shall report its findings and present its recommendations to the CSC.
- 5. The CSC shall review the NMT in accordance with the following assessment criteria:
 - a. The NMT must have final approval from the appropriate government regulatory bodies. This criterion applies to biological products, devices and diagnostics;
 - b. The scientific evidence submitted with the application should permit conclusions concerning the effect of the NMT on patient health outcomes. Such evidence should:
 - (1) consist of well-designed and conducted investigations published in peer-reviewed journals. Scientific evidence and expert opinion provide the basis for assessing the potential net patient health outcome.
 - (2) demonstrate that the NMT can measure or alter the physiological changes related to a disease, injury, illness or condition. There should be evidence that

- such measurement or alteration positively affects patient health outcomes.

 (3) include opinions and evaluations by national medical associations, consensus panels or other technology evaluation bodies.
- c. The NMT must improve the net health outcome—the NMT should outweigh any harmful effects on health outcomes;
- d. The NMT must be as beneficial as any established alternatives;
- e. The improvement must be attainable outside the investigational settings;
- f. The NMT should not negatively impact the management of available resources disproportionately to the net health outcome gained by the introduction of the NMT. The findings and recommendations from the MDMC regarding capital requirements, reimbursement approval from third party payors and hospital staff training requirements shall be considered in such assessment.
- 6. All applicants must be available to present the NMT before the CSC and when requested, before the MEC. Other non-members may be invited by the CSC to the assessment meeting for advisory purposes.
- 7. CSC shall recommend to the MEC to either approve or reject the NMT. If the NMT is rejected, the applicant may appeal such decision to the MEC.
- 8. NMT that requires physician privileging will require notification to the Credentials Committee.
- 9. The CSC reserves the right to recommend provisional approval only for certain NMT based upon certain facts and circumstances that would warrant a second review and approval of the NMT following a conditional period of use.
- 10. All approvals for NMT are subject to approval by the governing body in accordance with established Hospital policy and practice.

9.0 HIPAA Privacy Compliance – Joint Notice of Privacy Practices

MH-MH, MHOBH, its medical staff and other licensed independent practitioners granted any privileges at such Hospitals (collectively, "Hospitals and LIPs") support the rights of all patients to have their protected health information secure from unauthorized viewing, use and disclosure.

Hospitals and LIPs shall comply with all applicable federal and/or state laws, rules and regulations that govern the use and disclosure of such information, including, but not limited to the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R.Parts 160 and 164 which requires compliance therewith effective April 14, 2003 ("HIPAA Privacy Standards").

In non-emergent situations, the HIPAA Privacy Standards require the provision of a Notice of Privacy Practices by Healthcare Providers to patients with whom such providers have direct treatment relationships on the date of first service following the April 14, 2003 compliance date. Pursuant to such requirement, MH-MH & MHOBH will provide a Notice of its Privacy Practices ("NPP") to each individual patient presenting on and after the compliance date.

Hospitals and LIPs are considered an Organized Health Care Arrangement in accordance with the applicable provisions outlined in the HIPAA Privacy Standards. In order to streamline the provision of the NPP and preclude the necessity for each medical staff member rendering direct patient care to issue a separate NPP to his/her patient for delivery of care rendered in the hospital on and after the April 14th date, the Hospitals and LIPs shall issue a joint NPP which will be provided to patients by staff designated by MH-MH and MHOBH. Hospitals and LIPs agree to comply with the provisions contained in such joint NPP, including amendments thereof, as approved by the Medical Staff Executive Committee.

The joint NPP only covers the provision of care rendered by a LIP for patients attended in a MH-MH hospital, MHOBH and/or its outpatient departments, clinics and facilities.

10.0 Scopes of Practice

Registered Dietitian Scope of Practice

In accordance with the Mississippi Regulations Governing Licensure of Dietitians and the Tennessee Rules of The Board of Dietitian/Nutritionist Examiners, a Registered, Licensed Dietitian/Nutritionist may provide medical nutrition therapy that includes standardized order choices approved by the Methodist Le Bonheur Healthcare Medical Staff, nursing leadership, and pharmacy leadership (including the Nutrition Care Committee). Such orders are based on guidelines of the American Dietetic Association and Academy of Nutrition and Dietetics.

Registered/Certified Respiratory Therapist Scope of Practice

Respiratory Care is the allied health profession responsible for treatment, management, diagnostic testing, and care of patients with deficiencies and abnormalities associated with the cardiopulmonary system pursuant to the orders of a physician licensed in the state. (T.C.A. 63-27-102, Miss. Code Ann. 73-57-5)

The practice of respiratory care includes direct and indirect services such as the administration of pharmacological, diagnostic, therapeutic agents and medical gases necessary to implement treatment; promote disease prevention; provide pulmonary rehabilitation or diagnostics prescribed by a physician (MD,DO) or advance practice professional (APN, PA). It includes implementation of orders pertaining to respiratory care; observing and monitoring signs, symptoms and responses to determine whether such signs and symptoms warrant implementation of appropriate reporting, referrals, respiratory care protocols or change in treatment for the patient. (T.C.A. 63-27-102, Miss. Code Ann. 73-57-5)

The practice of respiratory care includes establishment and maintenance of airways, initiation of emergency procedures, bronchopulmonary hygiene, cardiopulmonary resuscitation, as well as cardiac and respiratory life support, education on such things as: respiratory disease processes, use of respiratory modalities including but not limited to medication and treatment; and the development and implementation of care plans and protocols as pertains to respiratory care. All can be performed in an inpatient and outpatient setting, clinic, hospital, nursing home, private dwelling or any other place deemed appropriate and necessary pursuant to orders of a physician (MD,DO) or advance practice professional (APN, NP) licensed in the state. (T.C.A. 63-27-102, Miss. Code Ann. 73-57-5)

Under the supervision of a physician (MD, DO), advanced practice professional (APN, PA), a respiratory care practitioner will exercise clinical judgement in the care of patients with respiratory related illnesses. Respiratory care practitioners can execute therapy as outline in physician (MD, DO) and advance practice professional (ANP, PA) orders and system policy and procedures. Respiratory practitioners can serve as a resource to the physician (MD, DO), and advance practice professional (APN, PA) in relation to the technical aspects of respiratory care as to safe and effective method for administering respiratory care modalities. (T. C. A. 63-27-106, Miss Code Ann. 73-57-13)

11.0 Observership Program

Purpose

To provide guidelines for the establishment of an observation program, which would permit qualified licensed practicing physicians and qualified international applicant physicians to visitt MH-MH, MHOBH or Provider-based Clinics for the purpose of observing certain activities at MH-MH on a temporary, restricted basis.

Policy

In keeping with its commitment to global exchange, MH-MH and MHOBH establish an Observership Program. Such program shall be open to any qualified licensed practicing physician or qualified international applicant physician trained in a specialty represented at MH-MH or MHOBH who wishes to visit MH-MH or MHOBH for a short period of time to observe the activities of a particular department, division, center or institute at MH-MH or MHOBH. Upon recommendation by the Department Chair and with the approval of the Credentials Committee, a qualified licensed practicing physician or qualified international applicant physician at the postdoctoral level who is not a member of the medical staff can apply for an observership experience under the supervision of a current medical staff member for educational purposes as an Approved Observer. Because Approved Observers are not members of the medical staff, they may not participate in direct or indirect patient care or management. As the name implies, an Observership is an informal observational experience and does not constitute training. Approved Observers do not receive any form of certification from MHMH or MHOBH

Observership Guidelines

- 1. Applicants should submit a letter to the MSSD indicating the goals of the applicant, as well as the time period when the applicant would like to come, a current curriculum vitae indicating training, and an official letter from the applicant's school of medicine certifying receipt of a medical degree.
- 2. Applicants will be contacted by a credentialing liaison from the MSSD to complete other forms as necessary to complete the certification process to verify education, training and professional qualifications.

Additional Observership Guidelines for International Applicants

- 1. B-1/B-2 Visa or Visa Waiver Program Status: A foreign national wishing to participate in the Observership Program (hereinafter referred to as "Participant") shall be responsible for obtaining a B-1 (Visitor for Business) or B-2 (Visitor for Tourism) non-immigrant visa from the appropriate authorities or for entering the United States under the VWB (Visa Waiver for Business) or VWT (Visa Waiver for Tourism) Program, and for maintaining and complying with all legal requirements of such status during the entire duration of a Participant's observation. Any and all costs incurred in obtaining or maintaining a Participant's visa status shall be borne by the Participant. A Participant may use the invitation letter or other materials regarding the Observership Program given to the Participant by the Department in support of the Participant's application for a B-1/B-2 visa or to enter in VWB/VWT status, but MH-MH and MHOBH shall not be required to sponsor or otherwise support the application of a Participant for such visa or status.
- 2. <u>Other Non-Immigrant Visas</u>: Other foreign nationals who are in the United States in non-immigrant status obtained through or dependent on their spouses' non-immigrant status (e.g., H-4, L-2, F-2, etc.) shall be eligible to participate in the Observership Program under the same

terms and conditions as a foreign national participating in the Observership Program on a B-1/B-2 visa or through the VWB/VWT Program, as set forth in this policy and procedure.

3. <u>Length of Observership</u>: The length of time for a Participant's observership shall depend upon the particular activities the Participant shall be observing at MH-MH or MHOBH, but an observership shall not last longer than three (3) months unless an extension or renewal of an observership in previously approved by MSSD. Upon the expiration of a Participant's observership, he/she will no longer be permitted access to MH-MH & MHOBH facilities. An observership is strictly a voluntary program and can be terminated at any time by either a Participant or Facility, with or without cause.

4. <u>Observership Activities</u>:

- a. Observation only. An observership shall be strictly an observational tutorial program. Accordingly, each Participant shall only be permitted to observe the activities for which they have applied to observe and to discuss his/her observations with applicable MLH medical staff members. A Participant shall in no way be permitted to actively participate care or contact, examination, research or other work during his/her observership. A Participant shall at all times be treated by MH-MH or MHOBH as a visitor and any medical staff member that allows a Participant to do more than observe may be denied the privilege of having observership Participants in the future.
- b. <u>Compensation</u>. At no time should a Participant be considered or held out to be an agent, servant or employee of MH-MH or MHOBH. Any and all expenses incurred by a Participant during his/her observership shall be borne by the Participant.
- c. <u>Confidentiality</u>. Each Department shall ensure that a Participant maintains the confidentiality of records and files of MH-MH and MHOBH and observe all confidentiality policies of the Facility during a Participant's observership.
- d. <u>Expiration of Observership</u>. Each Department will be responsible for ensuring that the Participant's observership ceases at that time.
- 5. Medical Insurance. A Participant whose observership will last longer than two (2) weeks shall be required to show proof, upon arrival at the Facility, of medical insurance adequate to cover the Participant's expenses in the event the Participant becomes ill or is injured in the United States during his or her observership, including expenses of repatriation should it become necessary. If the Participant does not have such insurance in his or her home country, the Participant will be required to purchase such insurance in the United States, in order to participate in an observership. Each Department will be responsible for forwarding proof of such insurance to for insertion in the Participant's file.

Observation Only Authorization

Observation only authorization may be granted to a licensed physician, dentist or allied health professional who is not a member of the medical staff but requests to observe a specified diagnostic or therapeutic event(s) or process(es).

Observation authorization shall be granted only at the request of a member who shall assume full responsibility for the actions of the physician, dentist or allied health professional during the course of the observation period. An individual granted observation authorization may not admit, treat, examine, consult, document or give verbal orders, perform or assist with procedures, document in the

medical record, or otherwise participate directly or indirectly in the care of any patient. Such individuals shall not be a member of the medical staff, shall not have access to any of the rights or prerogatives of membership, and shall agree to abide by all rules, policies and conditions required for observation participation.

Requests for observation only authorization must be submitted to MSSD on the designated form prior to the desired observation date. Observation authorization may be granted by the President of the Medical Staff, Chief of Staff or Credentials Committee Chair. Such limited authorization may be extended for a period of up to ninety days.

Procedure

PART 1 – BEFORE THE OBSERVER ARRIVES IN THE US

If a medical staff member is interested in inviting a foreign national to participate in the Observership Program, the medical staff member should contact the MSSD for a letter of invitation to the Participant, which will be substantially the form as attached hereto as Attachment 1. The letter should be signed by the medical staff member inviting the Participant and the Department Chair.

PART 2 – AFTER THE OBSERVER ARRIVES IN THE US

Upon arrival, the medical staff member should have the Participant complete the Agreement and Release Form, Participant Contact Information, and Participant's Documents form. The sponsoring medical staff member should fax these forms to the MSSD along with copies of the Participant's passport biographical information page, passport expiration date page, B-1/B-2 visa (where applicable), front and back of Form I-94 (small white or green card usually located in the passport), and proof of medical insurance specifying beginning and ending dates of coverage if observership will last longer than two weeks. If the Participant's documents are in order, MSSD will notify the Department that the Participant may engage in the MH-MH or MHOBH Observership Program.

Upon the expiration date of the Participant's observership, the sponsoring medical staff member should inform the MSSD of the Participant's departure from the Facility.

12.0 Medical Student Documentation

Third and fourth year medical students from approved programs, who are involved in patient care, may document in the electronic medical. Students must use their own username and password to make entries into the electronic medical record.

The attending or supervising physician is responsible for timely and accurate record completion by medical students working under his/her supervision. Documentation should substantiate the active participation in and supervision of the patient's care by the attending or supervising physician, as evidenced by attestation and co-signature.

13.0 Copy and Paste Policy

Purpose:

This policy provides guidance on the use of the copy and paste function in the electronic health record to ensure quality documentation. For the purpose of this policy, the term copy means any one of the

following synonyms: copy and paste, cloning, copy forward, reuse, carry forward, and save note as a template and any intent to move documentation from one part of the record to another. Quality documentation supports patient care, continuity of care, record integrity, and accurate professional fee and facility billing.

Risks associated with the misuse of copy and paste functionality:

- 1. Inaccurate, contradictory, duplicative, inapplicable, erroneous, or misleading information
- 2. Over-documentation with clinically irrelevant facts
- 3. Questions regarding the validity of entries
- 4. Potential for inaccurate billing claims due to billing for a different level of service than was provided
- 5. Lack of individuality of entries from one visit to the next creating questions regarding medical necessity

Policy:

- 1. Providers are responsible for the total content of their documentation, whether the content is original, copied, pasted, imported, or reused.
- 2. Progress notes shall provide an accurate depiction of treatment surrounding a specific date of service. Any information that is copied and pasted shall be updated with current information. Copy and paste into the record only that information needed to support clinical decisions or illustrate direct impact on care. Notes should be succinct to make them more readable and prevent loss of pertinent information. Notes created for different encounters should not be identical.
- 3. Providers are responsible for correcting any errors identified within the copied documentation. Contact Health Information Management if it is necessary to delete an incorrect note (i.e. entered under the wrong patient) or regarding any error(s) in the source note.
- 4. Do not copy and paste between different patient's records.
- 5. If the provider references a prior section within the record (IE. review of systems) he/she must reference the note with sufficient detail to uniquely identify the source. Example: "For review of systems, see note dated 1/11/14."
- 6. Material copied from a note authored by another provider should be attributed to the author and reference the date and note type from which the information was copied. Consider use of a different font, italics, or quotation marks to help identify the copied information. Never copy data or information that falsely identifies a provider as involved in that patient's care.
- 7. Providers are responsible for summarizing applicable lab data, pathology, and radiology reports rather than copying such reports in their entirety into the note.
- 8. Reviewers of the record, including but not limited to Health Information Management and Quality Management Staff, are responsible for referring any cases of inappropriate copying and pasting to the

Medical Records Committee for review. The Medical Record Committee will refer violations to the Compliance Officer for possible review by the Peer Review Oversight Committee.

14.0 Influenza Vaccination

Medical Staff Members, Allied Health Practitioners, and Allied Health Caregivers are required annually to receive the influenza vaccination unless they provide a documented medical or religious declination. If the vaccination is not administered, individuals will be required to wear a mask in all patient care settings during the flu season. If an individual does not comply, the provider's privileges/authorization will be deemed voluntarily relinquished until documentation of vaccination or appearance before MEC occurs.

15.0 Pertussis Vaccination for Le Bonheur Hospitals & Provider-based Clinics

All medical staff Members, Allied Health Practitioners, and Allied Health Caregivers, that provide care to pediatric patients in Le Bonheur Hospitals or Provider-based Clinics are required to provide proof of Pertussis vaccination prior to any direct contact with patients 12 years or under unless they provide a documented medical or religious declination. If the vaccination is not administered, individuals will be required to wear a mask in all patient care settings. If an individual does not comply, the provider's privileges/authorization will be deemed voluntarily relinquished until documentation of vaccination or appearance before MEC occurs.

16.0 High Reliability Organization (HRO)

Red Rules focus attention on acts that are critical to patient safety and reducing preventable harm to patients and associates. A Red Rule is an act that has the highest level of risk or consequence to patients or associate safety if not performed exactly, each time. "Red" designates the highest priority for exact compliance, to stop all action if compliance cannot be achieved. Red Rules are:

- Check and match 2 patient identifiers prior to acting
- Perform independent double-checks for designated high risk medications
- Complete time outs prior to invasive procedures, as part of MLH Universal Protocol

Referrals to Provider Quality for red rule violations/concerns will be addressed through staged collegial interventions and corrective action as noted in Unified Medical Staff By-laws.

Revision Log

| Revision # | Document | Reference | Subject of Revision | Board Approval |
|------------|-------------|-----------|---|-----------------------|
| 1 | MS Policies | 4.4 C, | Revisions to conform with the Ouality and Safety Plan | August 2008 |
| | | G | Quality and Salety Flan | |

| | | 6.1 | | |
|----|--|--------------------|---|--------------------|
| 2 | UT Resident Oversight Policy | 5.1, XIII | UT Policy was adopted for use at MLH with clarification for new admission supervision that the attending physician must evaluate the patient within 24 hours | September 2008 |
| 3 | Moderate & Deep Sedation policy / Location for Administration | 1.1, 2.7 | The MEG area at Le Bonheur has been added as an appropriate procedural area for both moderate and deep sedation | December 2008 |
| 4 | Observation Only Authorization | 8.0 | Delineates requirements for authorizing "observation only" status for physicians licensed in the US and Canada. The application form supporting those requirements was also approved. | March 26, 2009 |
| 5 | Guidelines for Appropriateness of Adult Transfusion | 3.4 | Addition – this policy delineates guidelines for appropriateness of blood products transfusions for adults. Notable is lowering of Hgb/Hct levels to 7/21 for less acutely ill or younger patients. | May 28, 2009 |
| 6 | Return to Practice | 4.5 & Attachment 7 | Addition – Guidelines for granting /renewing privileges for practitioners returning to practice after a period of absence from clinical activity. | August 27, 2009 |
| 7 | Medical Screening Exam | 3.3 | This policy modification allows trained RN's to conduct medical screening exams in particular emergency situations based upon temporary surges in volume. | September 24, 2009 |
| 8 | MS Policies | 5.1 | Maintenance changes | March 12, 2010 |
| 9 | Conflicts of Interest Policy | 4.3 | Clarification or reflect practice | March 25, 2010 |
| 10 | Neonatal & Pediatric Massive Transfusion Guidelines | 3.5& 3.6 Addition | Guidelines for transfusion | April 29, 2010 |
| 11 | Supervision of Residents: Inpatient Areas | 5.1, VIII | Modified the requirement that the SCP will see patients every 24 hours instead of 72 hours. | June 16, 2010 |
| 12 | Maintenance | 6.1 | Formatting to mirror the policy. | September 9,2010 |
| 13 | Addition | 1.0 & 2.0 | MS.01.01.01, a new Joint Commission (TJC) standard, requires several modifications to our medical staff policies. 1.0 Amendment and adoption of governance documents by the organized medical staff 2.0 Conflict management between organized medical | 11.2010 |

| | | | staff and MEC | |
|----|-------------------------------|--|--|---|
| 14 | Renumber document | | Due to insertion of 1.0 and 2.0 Medical Staff Policies has been renumbered. | 11.2010 |
| 15 | 5.4 | Addition of 5.4 renumbered document | Addition of on call physicians and emergency transfers | Provisional Board date: July 28, 2011 Board date: August18, 2011 |
| 16 | 5.8 | Revision to Clinical Effectiveness | Updated immunization protocols to reflect patient age changes per CMS guidelines. | August 18, 2011 |
| 17 | 7.0 | Graduate Medical Education Policies | Since there is no longer a Vice President of Medical Education position, the policy verbiage is updated to GMEOC. | October 19, 2011 |
| 18 | 6.4 | Professional Conduct of Physicians | To comply with TJC standards the words "disruptive behavior/conduct" were replaced with behavior or behaviors that undermine culture of safety | December 15, 2011 |
| 19 | 5.8 | Pneumococcal vaccine | Clinical care and best practice standards as well as acceptable exclusions for Pneumococcal Vaccine have been updated per CMS guidelines | March 21, 2012 |
| 20 | 3.12, 4.13, 5.1, 7.1, 10.0 | Maintenance | Revised write, written, writing with document documented, documenting to align with the electronic environment | June 20, 2012 |
| 21 | 7.1 XIV | Resident Oversight Policy | Revised policy to mirror the UT GME policy. | February 20, 2013 |
| 22 | 11.0 | Addition | Medical Student Documentation This defines the role and process for 3 rd & 4 th year Medical Student documentation. | March 20, 2013 |
| 23 | 6.3 | Conflict of Interest | Policy notes the medical staff members and other LIPs should disclose a conflict of interest to a medical staff leader when he/she becomes aware that such a conflict exists | March 28, 2013 |
| 24 | 3.12 & 4.13 | Sedation Protocol | Removed "unless pre- procedure Aldrete is zero in both sections. Per Anesthesia | May 16, 2013 |
| 25 | Observation forms | | Removed all of the observation forms in the document | May 30, 2013 |
| 26 | Resident Oversight Policy | 7.0 | Addition to the Policies – a process for any occurrences of adverse outcomes when the exception for Orthopedics & plastics Surgery is invoked. | June 19, 2013 |
| 29 | | | Renumbered document after 7.0 additions. | June 19, 2013 |
| 30 | Resident Oversight | Addition 7.1 | Moved from Rules & Regulations section 4.5 | July 19, 2013 |

| 31 | Return to Practice & Attachment 1 | Attachment 1 | This grid was updated to clarify requirements for CME, concurrent proctoring and retrospective review. | August 20, 2014 |
|--------------------------|--|----------------------|---|------------------------------------|
| 32 | Copy & Paste Policy | 13.0 | Addition – This policy provides educational guidance on the use of the copy and paste function in the HER to ensure quality documentation. | August 20, 2014 |
| 33 | Influenza Vaccination | Addition 14.0 | Addition – Vaccination requirements for the medical staff | September 17, 2014 |
| 34 | Return to Practice | 6.5 and Attachment 1 | Relocated to the Consolidated Credentials Policies | September 17, 2014 |
| Unification Revisions | Throughout the document | | Added "and MHOBH" when MHMH is referenced | November 19,2014 |
| Unification Revisions | 2.0 Conflict Management Between Medical Staff and MEC 3.7 Criteria for Administration | | Reconcile what is currently stated in the MHMH Medical Staff Policies. (See below) MHOBH states 10% The Conflict Management process applies to, but is not limited to, proposals to amend or adopt a rule, regulation, or policy. The Department Chair or another elected Medical Staff leader will consider issues of conflict between the MEC and the organized Medical Staff (OMS). At least 1% of the OMS should support the issue to initiate the conflict management process Grammatical Corrections — the word "policies" left out. (see credentialing policies). | November 19,2014 November 19,2014 |
| Unification Revisions | 3.13 Credentialing and Competency | | Added this statement "Privileging criteria are delineated in the credentials policies/DOPs" to the following paragraph: Privileging should be based upon a demonstrated record of successful experience in procedures requiring moderate sedation. Privileging criteria are delineated in the credentials policies/DOPs. Sedation should be administered in accordance with the current relevant clinical policies and procedures. | November 19,2014 |
| Unification Revisions | 3.13 Credentialing and Competency A. Physician | | In addition to a record of experience in <u>successfully</u> administering sedation during | November 19,2014 |

| | Qualifications – Credentialing and Competency | | procedures (minimum of 10 per year), the physician shall: | |
|--------------------------|---|-----------|--|-------------------|
| Unification Revisions | 5.0 Patient Care General Principles D. | | 7. In the event there is not agreement pertaining to para. 6. above, Section 68-1708, (f), p. 8 in the TNHCDA or Section 41-41-215, (7), p. 19 in the MS Uniform Health-Care Decisions Act shall provide further guidance | November 19,2014 |
| Unification Revisions | 5.9 Requirement to Specify Numerical Gestational Age | | Numerical gestational age/estimated numerical gestational agestational | November 19,2014 |
| 1 | 10.0 HIPAA Privacy Compliance | Revision | This revision identifies all LIPs with privileges as comprising the OHCA | February 17, 2016 |
| 2 | 11.0 Scopes of Practice (renumbered sequential sections) | Addition | These Scopes of Practice enable Dietitians, Respiratory Therapists, Pharmacists to make orderset choices based on approved protocols; standing orders otherwise cannot contain choices | February 17, 2016 |
| 3 | Entire Document | Revisions | These revisions to the Medical Staff Policies comply with CMS requirements for provider-based clinics licensed under the hospital. | November16, 2016 |
| 4 | 5.10 Imaging & Radiology Studies requiring Interpretation by Radiologist | Addition | A list of tests that require a credentialed radiologist interpretation | December 21, 2016 |
| 5 | 5.11 Qualifications of non-Medical Staff ordering Diagnostic Tests or Imaging | Addition | A provider who is neither credentialed nor privileged by MLH may order diagnostic and imaging studies when qualifications are verified. | December 21, 2016 |
| 6 | 5.10 | addition | Attendings granted maternal fetal medicine privileges may interpret targeted obstetrical ultrasound. This addition is an exception to the list of radiologic, nuclear, and | February 15,2017 |

| | | | ultrasound images requiring interpretation by Radiologists. | |
|----|--------------------------------|--|---|--------------------|
| 7 | 5.10 | Addition | Exception for board certified cardiologist with appropriate training and education and CCC may interpret cardiac MRI | December 20, 2017 |
| 8 | 15.0 | Revision | Revised Influenza Vaccine verbiage from "placed in abeyance" to "deemed voluntarily relinquished: | September 20,2018 |
| 9 | 16.0 | Addition | Added requirements for Pertussis Vaccination for Le Bonheur Hospitals & Provider-based Clinics | September 20, 2018 |
| 10 | 5.3 | Revision | Revised the MSE policy that clarifies that an appropriately trained and competent obstetrical nurse may perform a medical screening examination to determine or rule out labor. | September 20, 2018 |
| 11 | 5.10 & renumbered 5.11 & 5.12. | Addition | Telemetry and Cardiac monitoring guidelines were added. This will require designation of Class I,II,III for in –hospital cardiac monitoring | September 20,2018 |
| 12 | 13.0 | Revision | CMS now allows medical student documentation to be used in the medical record for E&M purposes. Our Medical Staff policies have been updated to reflect this change. The attending or supervising physician is responsible for timely and accurate record completion by medical students working under his/her supervision. | December 19,2018 |
| 13 | 17.0 | Addition | An addition to the Medical Staff policies. Should a violation occur it will be addressed through staged collegial interventions and corrective action as noted in Unified Medical Staff By-laws. | November 20, 2019 |
| 14 | 3.0 & 4.0 | Addition to 3.0 and deletion of 4.0 Deep | Procedural Sedation Policy (Section 3.0). This policy | November 20, 2019 |

| | | Sedation Renumber entire document | applies to all non- Anesthesia staff who administer moderate and deep sedation. | |
|----|------|---|--|---|
| 20 | 4.3 | Medical Screening Exam | Revisions to address the need for trained personnel to conduct MSEs | MEC Virtual Vote 3/12/2020 April 15, 2020 |
| 21 | 4.5 | Guidelines for Appropriateness of Adult Transfusion | Revised guidelines to reflect best practices | March 17, 2021 |
| 22 | 10.0 | Registered/Certified Respiratory Therapist Scope of Practice | Revised to update and reflect the scope of practice for respiratory therapists. | December 20, 2023 |