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Rules & Regulations

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

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"Member" means any physician, dentist, or podiatrist who has been granted Medical Staff appointment and / or any allied health practitioner who has been appointed to the Allied Health Staff, by the Board.

100. PROFESSIONALISM

These rules and regulations are intended to provide comprehensive information to members of the Indiana University Health Fort Wayne Hospital Medical Staff in order for them to fulfill their commitment and responsibility to provide quality and safe patient care. In addition, members are obliged to carry themselves in a manner, which

exemplifies the utmost respect and professionalism toward patients, families, visitors, staff and employees of Indiana University Health Fort Wayne Hospital.

200. CONFIDENTIALITY

In keeping with state and federal laws as well as IU Health Fort Wayne Hospital policy, all medical records, patient- specific information, peer review materials, risk management materials, credentialing records and files, minutes of relevant medical staff and hospital meetings, are the property of IU Health Fort Wayne Hospital.

All involved parties, including hospital personnel, members, board members and any external parties and/or community members that are involved, appointed, or otherwise authorized to participate in business of the health system, will respect the confidentiality of all information obtained in connection with their responsibilities. This confidentiality extends not only to information documented but to discussions and deliberations that take place in the conduction of these activities. Breach of confidentiality by any member related to credentialing or peer review information will result in disciplinary action and may lead to termination.

Access to confidential materials by a member is permissible only when the person seeking access is involved in the care of the patient or is engaged in peer review, risk management, credentialing or other authorized activity. This requirement applies to information in electronically stored or hard copy format.

Unless otherwise authorized, access to information, files and records are limited to the representatives listed below and to the extent necessary to perform the functions and responsibilities of their role:

- Medical Staff Services Manager and Credentialing Specialists
- Medical Staff President and Officers
- Chief Quality and Safety Officer
- Chief Medical Director
- Chief Executive Officer or his/her Designee
- Medical Director of Quality and Safety
- Board Members
- Committee Chairs (Credentials, Sections Standards, MSQC, MEC)

A member may review his/her own credentials file under the following circumstances:

- IU Health Fort Wayne President, medical staff President, or credentials / section standards Chairman approval;
- A representative from Medical Staff Services or a medical staff officer is present during the review; and
- The physician practitioner understands that removal of items from the file

is prohibited Upon approval, only the following items from the file may be

reviewed:

- Information from the practitioner member
- Correspondence to the practitioner member
- Clinical privilege forms
- Applications

Requests for any other information not noted above must be made in writing and may require consultation and approval from legal counsel before it can be reviewed by the requesting member.

300. ADHERENCE TO POLICIES AND PROCEDURES

All members are expected to adhere to established policies and procedures for IU Health Fort Wayne Hospital. This

includes adherence to all health care regulatory and accreditation requirements. Breach of policies, standards

regulations by individual members will be handled through peer review mechanisms of the IU Health Fort Wayne Hospital Medical Staff.

400. QUALITY IMPROVEMENT AND PATIENT SAFETY

Participation in quality activities of the clinical service for which the member practices is required. Trending of aggregate data on clinical processes and outcomes, professionalism, administrative and utilization data is to occur through each clinical service of the medical staff. Members are expected to examine their individual performance as compared to peers among their service in order to identify opportunities for improvement in their clinical practice. Members may be asked to participate on improvement teams.

The Medical Staff participates in organization-wide performance improvement, through various established and ad-hoc committees, and is responsible for the measurement, assessment and improvement of patient care, treatment and services.

Examples include:

- The clinical assessment and treatment of patients
- Adverse privileging
- Medication therapy
- Infection Control
- Blood and blood component utilization
- Operative and other procedures, including cases with moderate sedation
- Appropriateness of diagnostic procedures
- Outcomes of therapeutic interventions
- Appropriateness of clinical practice patterns
- Significant departures from established patterns of clinical practice
- The use of developed criteria for autopsies
- Patient safety / sentinel event data
- Medical record pertinence and timeliness
- Utilization review and discharge planning
- Restraint utilization
- Mortality review
- Patient satisfaction / complaints involving medical staff related issues

500. RISK MANAGEMENT ACTIVITIES

Members are encouraged to promptly report actual / potential medical errors and patient safety concerns via the event reporting process or by contacting a member of the risk management team. Significant medical errors or serious harm events should be communicated immediately to the Administrator-On-Call.
Root causes analysis (RCAs) will be conducted following significant events and individuals are expected to make attendance at such meetings a priority.

Members may be requested to participate in activities to promote patient safety, reduce risk to patients and improve processes.

600. PATIENT CARE

601. Admission of Patients

Active, Associate, and Temporary Medical Staff members may be privileged to admit patients to the hospitals. The member who admits the patient will be designated as the attending and will provide a provisional clinical diagnosis. The admitting member will be considered the attending unless an order is written to transfer care to another member who has agreed to accept responsibility for the patient's care management. Licensed Independent Practitioners and Advanced Practice Providers may co-admit and co-manage patients and may contribute to history and physicals, patient care, treatment, and services, as delineated by the privileges granted.

Patients will be assigned priority for admission based on the following:

- Emergency – an immediate threat to life
- Urgent – potential for irreparable harm without immediate treatment
- Pre-Operative – previously scheduled for surgery
- Routine – elective admissions involving all clinical services

602. Attending Requirements

Patients admitted to the hospital shall be seen by a member within a timeframe reflective of the clinical needs of the patient.

- Patients designated as emergency and those admitted directly to the ICU or transferred into the ICU must be evaluated within 4 hours of arrival
- Patients admitted to general care areas must be evaluated, as indicated by the patient's condition, within 12 hours, unless the patient was evaluated by a physician immediately prior to admission
- Elective admissions must be evaluated within 18 hours of arrival

The attending member is in charge of the patient's overall care management, including but not limited to review of orders, request of necessary consultations, determination of the patient's resuscitation status, planning for discharge, completion and signing of medical records documentation.

Hospitalized patients shall be seen daily by the attending / designee.

603. Delegation of Member Responsibilities

In order to insure quality health care to all patients, certain responsibilities must be performed by members and are not to be delegated to allied health practitioners without proper oversight. These responsibilities are as follows:

1. Admission of patients to the hospitals.
2. Obtain and review the history of the present illness and perform the initial physical examination.
3. Dictation of operative notes.
4. Completion of discharge summary and/or death notes.
5. Completion of pre/post anesthesia notes.
6. Performance of surgery
7. Signatures of reports, orders or other medical record entries.

604. Consultations

Consultations should be considered on critically ill patients; patients who are poor surgical risks; those whose diagnosis is obscure; where doubt exists as to best therapeutic measures; and / or in cases where the disorder

or complications are not in the field of the attending member's field of practice or approved privileges. Requests for consultation should involve an order for the consultation and include the reason, extent and involvement expected from the consultant.

Recommended categories for consultation include:

- Consultation only;
- Consultation and management of a specific entity or procedure;
- Participation in management; and
- Consultant to assume management.

The consultation should be documented in the medical record and include discussion of background information and specific questions about the patient. The consultant must make and sign a report of findings, opinions, and recommendations that reflect an actual examination of the patient and review of the patient's medical record. The consultant's report of findings will become part of the medical record.

To promote effective consultation among members of various specialties involved in the treatment of patients, it is recommended that the attending / designee directly discuss with a consultant the need to examine, discuss, or otherwise provide an opinion regarding a patient's care management.

605. Transfer of Care

The admitting member shall remain admitting until an order is written to transfer care to another member who has accepted responsibility. Such transfer is to occur only after discussion of the patient's care and status of the patient's clinical needs.

606. Care Management

Care Management is a hospital-wide, interdisciplinary process that plans, organizes and provides health care services in a timely, cost-effective manner while maintaining quality patient care consistent with the mission of IU Health Fort Wayne Hospital. As an integral member of the team process, members support effective and efficient utilization of hospital facilities and services through the following actions:

1. Communicate with care managers and member leaders to help improve inefficiencies in care and safely move the patients to a lower level of care when medically appropriate.
2. Obtain specialty consultation early and frequently.
3. Support evidence based medicine such as in the treatment of DVT, pneumonia, surgical care, AMI, stroke and CHF patients.
4. Review medicines and orders daily:
    a. Discontinue interventions that are not medically necessary (examples: telemetry and Foley catheter)
    b. Change medicines from IV to oral when appropriate (examples: antibiotics and pain meds)
    c. Advance diet and activity when appropriate.

5. Discuss daily with your patients (and families) those objectives that will need to be accomplished before discharge is possible.
6. Keep your patient, the family and the interdisciplinary team informed of potential discharge plans and the expected date of discharge.
7. When patient medically meets criteria for discharge and further testing is needed, discharge patient and finish workup as an outpatient
8. Consider end of life issues where palliative care, hospice or geriatric services may be appropriate for the patient.
9. Compare your utilization, LOS and cost performance to your peers.
10. Participate in communication between case managers to help resolve concurrent verbal denials for continued hospital stay.

The Utilization Review and Compliance Committees are responsible for the review of care including utilization management functions. Utilization management issues will be reported at least quarterly or more frequently as deemed appropriate to these committees. These committees may appoint members outside of the committees to perform concurrent or retrospective chart reviews for utilization management. The member will be available to assist and counsel personnel responsible for utilization functions and to consult with peers to resolve issues. Peer review protection applies in accordance with Indiana Peer Review Statue I.C. 34-4-12.6.1.

The Hospital complies with the Emergency Medical Treatment and Labor Act (EMTALA) and applicable Hospital EMTALA polices. The following are qualified medical professionals authorized to conduct a medical screening exam and related responsibilities as more particularly described in the Hospital EMTALA Policy: physician member of the Medical Staff with clinical privileges granted by the Board, nurse practitioner member of the Allied Health Staff with clinical privileges granted by the Board, and physician assistant member of the Allied Health Staff with clinical privileges granted by the Board.

607. Discharge of Patients

Patients are to be discharged only by order of the attending / designee. Telephone orders for discharge may be utilized at the discretion of the attending/ designee. In the event that patient is being transferred to another agency or institution, the member is to ensure the same information is documented on approved discharge/ transfer forms and an immediate discharge summary is dictated.

Whenever possible, as part of the discharge process, the attending / designee is to identify the practitioner who will provide follow-up care after discharge from IU Health Fort Wayne Hospital and provide comprehensive communication to include the patient's hospital course, medications upon discharge, and need for continuing care.

It is the responsibility of the attending to ensure discharge of patients in a timely fashion. Discharge planning is multidisciplinary and attending / designees are to engage nursing, care management, and other health care disciplines as needed in the process. Care conferences may be necessary to address challenging patient or family issues that could negatively affect discharge. Members are expected to participate in such conferences or give input when needed.

700. MEDICAL RECORDS

701. Handwritten Entries and Use of Abbreviations

All handwritten entries in the medical record must be legible and in black or blue ink. Pencil entries are not

permitted. Entries are to be dated and timed. The date and time of the note will be the date and time of the entry, regardless of whether the content of the note relates to a previous date or time. Documentation throughout the medical record regarding medication orders must be written without the use of unsafe abbreviations.

702. Authentication of Entries

All entries in the medical record must be confirmed by written signature or computer signature, identifying the credentials of the author.

Reports dictated and transcribed through Health Information Management require authentication by electronically editing and signing reports within appropriate clinical systems.

Entries by medical students require countersignature by a supervising member.

Verbal and telephone orders may be signed by any member who provided care to the patient or has knowledge of the patient's care if the ordering practitioner is unavailable and authentication should be completed within forty-eight (48) hours of the order. Authentication of verbal orders by the attending physician will automatically occur as part of discharge planning physician documentation (EDI) and/or discharge summary completion.

703. History & Physicals

A complete history and physical examination must be completed within twenty-four (24) hours after admission or prior to a surgery or procedure by an eligible member of the Medical Staff or Allied Health Staff. A legible original or copy of a medical history and physical obtained in the physician/dentist's office completed within thirty (30) days prior to date of admission is acceptable if the patient's clinical status information is updated within twenty-four (24) hours after admission or prior to a surgery or procedure if occurring within the first twenty-four (24) hours. In an emergency situation, the responsible physician/dentist must make a comprehensive entry regarding the condition of the patient prior to the start of the procedure. A complete history and physical examination is then to be recorded immediately following the emergency procedure. A comprehensive history and physical examination report is to include the chief complaint, details of the present illness, all relevant past medical, social and family histories, inventory of body systems, current physical examination, allergies / medications / dosage / reactions, conclusions, and plan of action. For further details, please reference Hospital policies on completion of medical records and content of medical records.

704. Orders

Initial admission, diagnostic, treatment and discharge orders may be written by the attending / designee. Admission status order (inpatient, observation, or outpatient in a bed) shall be entered for each patient receiving care on a nursing unit. Orders may be given verbally to authorized professionals when the medical record or electronic order system is not readily accessible, in emergencies, or by telephone from another location. Verbal orders are to be reserved as much as possible for emergent situations.

Orders occurring prior to a procedure will *not* be automatically resumed after the procedure. To ensure patient safety, orders must be rewritten after major procedures to ensure changes to the patient clinical status are taken into full consideration.

705. Progress Notes

Progress notes shall give a pertinent chronological report of the patient's course in the hospital and reflect any change in condition, the results of treatment, and discharge planning.

Progress notes must be recorded at the time of observation and be sufficient to permit continuity of care and transferability of the patient. Whenever possible, each of the patient's clinical problems must be clearly identified in the progress notes and correlated with specific orders as well as results of tests and treatments.

Progress notes must be written daily and be authenticated by the practitioner making the note. When medical students are involved in patient care, sufficient evidence is documented in the medical record to substantiate the active participation in, and supervision of, the patient's care by the attending /designee.

706. Operative/Procedure Notes

Operative reports must be dictated immediately following any operative or other high-risk procedures. The reports must contain the preoperative diagnosis, the postoperative diagnosis, name of the primary surgeon and any assistants, detail the technical procedures used, the description of findings, blood loss, specimens

removed, and the condition of the patient at the conclusion of the procedure. For procedures performed under conscious sedation or local anesthesia, the report may be handwritten or electronically generated

The practitioner must enter an operative progress note in the medical record immediately after the procedure, providing sufficient and pertinent information for any practitioner required to attend to the patient until the operative report is available.

The complete report must be completed or dictated within forty-eight (48) hours following the procedure and signed by the practitioner.

707. Tissue and Examinations Reports

Tissue removal procedures shall be as directed through the Hospital's surgical pathology reporting policy.

Cases of concern will be channeled to the appropriate peer review committee.

708. Discharge Summary

The discharge summary is the responsibility of the attending. The discharge summary must be completed upon discharge of the patient from the hospital, not to exceed (7) days. The discharge summary must include documentation of the provisional diagnosis or reason(s) for admission, the principal and additional or associated diagnoses established by the time of discharge, significant findings, procedures performed and treatment rendered, condition of the patient on discharge, and specific instructions given to the patient and/or family (especially relating to physical activity, diet, medications, and follow-up care.

709. Autopsy and Coroner

Members may request an autopsy or notify the coroner in any instance of death. Authorization for autopsy must be obtained from an authorized person. Expenses for non-coroner autopsies are assumed by IU Health Fort Wayne, in collaboration with the IU Health Pathology Laboratory, and not passed on to families.

Members should make a concerted effort to secure autopsy authorization when one or more of the following criteria are present:

a. unanticipated death – all sudden deaths and all deaths in which the admission diagnosis suggests death was not expected;
b. intraoperative or intra-procedural death;

c. death occurring within 48 hours after surgery or an invasive diagnostic procedure;
d. death in an outpatient setting (may not be applicable to the Emergency Section);
e. death associated with a drug reaction or an adverse event;
f. death occurring while the patient is being treated under a new therapeutic trial regime (defined as therapies/procedures requiring IRB approval);
g. maternal death incident to pregnancy or within seven days following delivery;
h. stillbirth;
i. death in infants/children when congenital malformations and conditions with possible genetic implications; or
j. death where the cause is sufficiently obscure to delay completion of the death certificate.

The following **deaths must also be reported to the coroner**; however, a coroner's forensic autopsy will not necessarily be performed:

a. any medically unexpected death
    1. occurring coincident with a therapeutic or diagnostic procedure,
    2. of a child (possible SIDS), or
    3. involving unexplained coma;
b. death of a child or adult where abuse, neglect or trauma is a possibility;
c. death following disease or injury in the workplace;
d. death of an inmate or a person in official custody;
e. death involving the suspicion of criminal abortion;
f. all homicides; suicides and accidents; or
g. any suspicious, unusual or unnatural death.

800. PATIENT RIGHTS

801. Patient/Family Complaint Procedures

Hospital patients shall be provided with appropriate channels to communicate dissatisfaction with medical care and treatment, safety and security, and be provided with in a timely and appropriate response upon conclusion of the investigation into the concern. Members must fully cooperate in such investigations.

802. Informed Consent

A separate Consent for Procedure form should be completed for all operative and other invasive procedures that expose patients to more than minimal risk, including procedures done in settings other than the operating room such as a special procedure unit, endoscopy unit, interventional radiology suite, hospital-based clinics, other outpatient areas of the hospital, or at the bedside.

Invasive procedures generally are classified as those procedures that involve puncture or incision of the skin, or insertion of an instrument or foreign material into the body. Specific examples of the types of procedures subject to the requirement for completion of a written consent are listed in policy *Patient Consent for Clinical Services*.

In addition to discussing the proposed procedures with the patient or surrogate and completing the written consent, the treating member should include a note in the patient's medical record to the effect that the member spoke with and advised the patient or surrogate of the nature of the proposed care, treatment, services, medications, interventions, or procedures; potential benefits, risks, or side effects including potential problems related to recuperation; likelihood of achieving care, treatment and service goals; reasonable alternatives to the proposed care, treatment and service; relevant risks, benefits and side effects related to alternatives, including the possible results of not receiving care, treatment and services; and when indicated, any limitations of the confidentiality of information learned from the patient. An authorized attestation statement on the consent form may serve as the treating practitioner's written note.

803. Adult / Child Abuse

The mandatory reporting of suspected child abuse or neglect and mandatory reporting of suspected endangered adult shall be as directed through the Hospital's applicable reporting policies.

803. Advance Directives

An Advance Directive is a document or verbal statement in which an individual states choices for medical treatment or designates who should make treatment choices if the individual should lose decision making capacity. IU Health Fort Wayne recognizes the right of all competent adults to participate in decisions about their medical care, including the right to accept or refuse treatment and to formulate advance directives.

Advance directives may be changed or revoked at any time. Verbally expressed directives generally have priority over written directives as long as the patient has the ability to make decisions and communicate his or her wishes. If a patient wishes to revoke an advance directive while hospitalized, the patient's attending physician should be notified.

In situations where a individual's advance directive may not be honored, consider an Ethics Consult. It is the responsibility of the physician to discuss such situations with the patient / authorized individual and document the results of the discussion in the medical record.

804. Protective Measures

For the protection of the patient, staff and hospital, the admitting / attending member is responsible for providing information to assure protection of the patient from self-harm and the protection of others when the patient might be a source of danger. Any patient with known or suspected suicidal intent shall be transferred to a facility with suitable accommodations to protect the patient. Temporary protective measures will be initiated until an appropriate transfer can be completed.

Psychiatric, suicidal or threatening patients, who have a medical emergency or require urgent medical care, may be admitted for appropriate medical stabilization prior to transfer to an appropriate facility.

805. Restraint Utilization and Orders

Use of restraints for violent or non-violent behavior requires an order. PRN orders for restraints are not permitted.

Restraints for **non-violent behavior** require an order within (4) hours of application and a renewal order every (24) hours.

Restraints for **violent behavior** require an immediate order and a face-to-face evaluation within (60) minutes

of application. Restraints for violent behavior are renewable up to (24) hours, based on the following:

- Adult 18+ (every 4 hours)
- Ages 9-17 (every 2 hours)
- < age 9 (every 1 hour)

900. GENERAL RULES, RESPONSIBILITIES, AND EXPECTATIONS

901. Reporting Requirements

In addition to reporting requirements at the time of initial application and reapplication to the IU Health Fort Wayne Hospital Medical Staff, all members are to immediately report to the President of the Medical Staff (or his/her designee) any circumstances involving the following:

- suspension or any action (censure, reprimand, and/or fine) regarding their professional license
- loss, suspension or other actions (excludes routine renewal) regarding state or federal prescribing of controlled substances
- loss, suspension or limitation (excludes routine non-renewal) of clinical privileges at another health care facility
- filing of notice of exclusion/debarment from any federal health care program including Medicare/Medicaid
- filing of any criminal charge by state or federal authorities (excludes minor motor vehicle accident)

902. Emergency On-Call

Reference Policy *Medical Staff Emergency On-Call* for delineation of responsibilities associated with Emergency and Unassigned Call

903. Response to Urgent Situations

It is the responsibility of all members who provide patient care at IU Health Fort Wayne Hospital to quickly and accurately resolve immediate and urgent clinical concerns. If a clinical concern is not resolved, the healthcare professional will follow the chain of command until the issue is resolved. If circumstances surrounding the inability to reach a member merit, the case will then be forwarded the appropriate section chair for peer review.

904. Chain of Command for Patient Care Concerns

Basic responsibilities of the IU Health Fort Wayne Medical Staff include working collaboratively with staff, administration and others to provide safe, quality care by making appropriate arrangements for patient coverage and quickly resolve clinical concerns.

In the event a physician is unable or unwilling to respond to clinical concerns, the RN caring for the patient will follow the chain of command to resolve the concerns. If the patient status is life threatening, the rapid response team shall be called. The chain of command is as follows:

- The physician will be notified of urgent clinical concerns
- Unresolved clinical concerns will be discussed and validated with the Charge RN / Clinical Supervisor and the physician will be re-notified
- Continued unresolved clinical concerns will be communicated to the administrator-on-call, who will contact the physician and discuss the necessity of immediate mitigation of the concern
- Should the clinical concern remain unresolved, the administrator will notify an alternate provider to

address the concerns and notify the appropriate physician leader

The incident may be referred to the peer review committee for appropriate review and action.

905. Universal Protocol

The Universal Protocol will be utilized in all operative and other invasive procedures at IU Health Fort Wayne facilities. As the overall responsibility for the patient resides with the physician performing the procedure, members of the medical staff are expected to be active participants in the Universal Protocol process, to include verifications and site marking.

906. Peer Review Activities

Assessment of individual episodes of patient care management is triggered through various mechanisms, such as routine quality reviews, care management, medical staff committee activities and risk management activities. Peer review will be conducted as part of quality improvement efforts of the medical staff. Members are to respond promptly to queries from peer committees.

907. Continuing Medical Education

Member participation in Continuing Medical Education (CME) will be considered during reappointment and privilege renewal decisions.

Members are responsible for completing the educational activities necessary to maintain their specialty board certification(s), licensure, and any other requirements for Medical Staff or Allied Health Practitioner membership and clinical privileges.

Practitioners who participate in a specialty board's Maintenance of Certification (MOC) program and remain current with all board-required continuing education activities will be deemed to have satisfied the Medical Staff CME requirement. Documentation demonstrating compliance with MOC requirements may be requested as part of the reappointment process.

Practitioners who do not participate or are current in a board-sponsored MOC program must complete a minimum of **50 CME hours during each two-year reappointment cycle**. CME activities should include education relevant, in part, to the clinical privileges granted.

CME information must be submitted with the reappointment application. Required CME hours may be prorated for reappointments occurring in a period of less than two years. Passing examinations for licensure or specialty board certification may not be claimed for CME credit; however, preparation activities for such examinations may be eligible if they meet applicable CME criteria.

Proof of CME participation, including attendance records and program content, must be provided upon request.

908. Staff Dues

Annual dues, in amounts determined by the Medical Staff Executive Committee, shall include but not be limited to supporting medical staff / allied health care provider activities, educational offerings, elected officers, and external peer review. Non-refundable dues are payable in the Medical Staff Office by April 15th of each year for each member who is a member as of that date. Non-payment of dues shall result in termination from the Medical Staff.

Current annual dues as determined by the Medical Staff Executive Committee are as follows:

- Application Fee
  - No fee will be charged to IU Health Medical Group practitioners
  - No fee for allied health practitioners
  - $200 non-refundable application fee will be charged for all other physicians, dentists, and podiatrists
- Reappointment Fee
  - No reappointment fees are assessed
- Annual Dues
  - $200 annual dues physicians, dentists, and podiatrists (except Honorary)
  - $100 annual dues for allied health practitioners

909. Treatment of Family Members and Self-Treatment

Members of the IU Health Fort Wayne Medical Staff are not permitted to provide treatment for themselves, members of their immediate families, or with whom they have a significant emotional relationship except for life- threatening emergencies.

Activities *not* permitted include but are not limited to: participation / performance of any operation, diagnostic or therapeutic procedure. Members are *not* allowed in operating or procedure rooms to observe, and are *not* allowed to admit or provide care.

Members *are* allowed to be in attendance during labor and delivery.

910. Use of Medical Devices

Only FDA approved medical devices are used in IU Health Fort Wayne facilities and such devices are to be used only in the manner approved by the FDA. The **Chief Medical Officer** (or designee) may authorize an exception to this policy with appropriate documentation. The specific use of a medical device, approved in advance by the Institutional Review Board is an exception.

REVISIONS

This document may be revised as outlined in Article 8 Section B (4) of the IU Health Fort Wayne Bylaws.

ORIGINAL APPROVAL DATE:

Board of Directors: October 27, 2026