ORGANIZATION AND FUNCTIONS MANUAL

Medical Staff
Fort Hamilton Hospital
Hamilton, Ohio

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FUNCTIONS OF THE MEDICAL STAFF

SECTION 1.1. GENERAL

The Medical Staff is non-departmentalized. Clinical Department shall be organized according to the Medical Staff Bylaws.

This Organization Manual adopts and incorporates by reference the definitions contained in the Medical Staff Bylaws unless otherwise provided herein.

SECTION 1.2. POSITION DESCRIPTIONS

1.2.1. Medical Staff Officers

(a) Chief of Staff

Reports to: Board of Directors and Medical Executive Committee, as needed to the Hospital President.

Position Purpose: The purpose of this position is to provide overall leadership and guidance to the Medical Staff. Additionally, the Chief of Staff must promote effective communication among the Medical Staff, Medical Executive Committee, Hospital administration, and the Board. The Appointee occupying this position will serve as the elected representative of the Medical Staff and will be responsible for Bylaws implementation, Medical Staff involvement in securing and maintaining accreditation, providing information to the Board concerning matters that pertain to the care and treatment of patients and generally facilitating positive relationships among administration, the Medical Staff and other support services of the Hospital.

Clinical policies and procedures must be written in accordance with acceptable standards of medical practice and patient care. Such are reviewed and revised to reflect required changes consistent with current practice, problem resolution and standards changes. The process for review, revisions, approvals, implementation, and monitoring of compliance of such are as established in the medical staff bylaws and governing documents; clinical quality and performance improvement plans, policies and/or manuals; and/or hospital and medical staff policies, flowcharts, etc. The Chief of Staff shall sign off clinical policies and procedures as needed, but at least every three years, or as otherwise required by state regulations, hospital or medical staff policy, and/or accreditation standards.

Accountabilities and Functions: Coordinates the activities and concerns of Hospital administration, nursing service and other patient care services with those of the Medical Staff.

- Communicates and represents the opinions, policies, concerns, needs and grievances of the Medical Staff to the Board, the President of the Hospital and other officials of the Medical Staff.

- Calls, presides at, and is responsible for the agenda of all general and special meetings of the Medical Staff.

- Serves as chair of the Medical Executive Committee, a member of the Professional Practice Committee of the Board, an *Ex-Officio* attendee to the Board of Directors meetings, and an *Ex-Officio* invitee of all other Medical Staff committees.

- Consults with the Chief Medical Officer on matters of special concern to Medical Staff Appointees and maintains medical liaison with the Chief Medical Officer to assist in settling grievances and problems of the Medical Staff.

Responsibilities: Responsible for the enforcement of the Medical Staff Bylaws, Organization and Functions Manual, and Credentials Manual, for implementation of sanctions where indicated, and for the Medical Staff's compliance with procedural safeguards in all instances where corrective action has been recommended against a Practitioner.

Responsible for all administratively related activities of the Medical Staff, unless otherwise provided for by the Hospital.

Responsible, in conjunction with the Medical Executive Committee, for assessing and recommending to the relevant Hospital authority off-site sources for needed patient care services not provided by the Medical Staff or the Hospital.

Responsible, in conjunction with the Medical Executive Committee, for the development and implementation of policies and procedures that guide and support the provision of services.

Responsible, in conjunction with the Clinical Department Chair for the recommendations for a sufficient number of qualified and competent persons to provide care or service.

Responsible, in conjunction with the Clinical Department Chair, for the determination of the qualifications and competence of Clinical personnel who are not licensed independent practitioners and who provide patient care services.

Responsible for participating in the evaluation of existing programs, services, and facilities of the Hospital and Medical Staff and recommending continuation, expansion, abridgment or termination of each.

Responsible, in conjunction with the Medical Executive Committee, for participating in evaluating financial, personnel, and other resource needs for beginning a new program or service, for constructing new facilities, or for acquiring new or replacement capital equipment, and for assessing the relative priorities of services and needs and allocation of present and future resources.

Responsible for appointing Medical Staff Appointees to the following committees: Credentials (excluding the chair), Utilization Review Committee, Clinical Quality Review Committee, Quality Assurance and Performance Improvement Committee (except co-chair and its Hospital appointees), Pharmacy & Therapeutics, Medical Records and Wellness Committees.

Position Requirements: The Appointee occupying this position is recommended to meet the Qualifications of Officers. Prior experience within our hospital system as a Clinical Department Chair, Credentials Committee member, Board member, Medical Executive Committee member or other similar Medical Staff leadership position is required. The Appointee occupying this position should have received education and training concerning medical administrative activities and Medical Staff leadership.

(b) Vice Chief of Staff

Reports to: Chief of Staff and Medical Executive Committee

Position Purpose: The purpose of this position is to provide continuity in leadership during times when the Chief of Staff is absent or otherwise unable to perform his/her assigned functions and to provide the appointee with experience prior to assuming the Chief of Staff position. The Vice Chief of Staff will be expected to remain knowledgeable about all Medical Staff issues of current Medical Staff interest. At the conclusion of the term of the Chief of Staff, the Vice Chief of Staff will succeed as Chief of Staff.

Accountabilities and Functions: Assists the Chief of Staff with any functions specified by the Chief of Staff and the Medical Executive Committee. Is a member of the Medical Executive Committee. .

Responsibilities: Responsible, in conjunction with the Medical Executive Committee, for continuing surveillance of the

professional performance of all Practitioners and AHPs who have delineated Clinical Privileges.

Responsible, in conjunction with the Medical Executive Committee for the continuous assessment and improvement of the quality of care, treatment, and services provided, and for the maintenance of quality assessment and performance improvement programs as appropriate.

Chairs the Bylaws Committee, when enacted to foster open communication of Bylaws changes between the Hospital Board, administration and Medical Staff proper.

Position Requirements: The Appointee occupying this position is recommended to meet the Qualifications of Officers. Prior successful service as a Clinical Department Chair, Credentials Committee member, Board member, Medical Executive Committee member or other similar Medical Staff leadership position is required. Individuals occupying this position should have received education and training concerning medical administrative activities and Medical Staff leadership

(c) (c) Credentials Committee Chair

Reports to: Chief of Staff and Medical Executive Committee. Recommendations from the Credentials Committee are carried forward by the Credentials Committee Chair to the MEC. Recommendations from the MEC are carried forward by the Chief of Staff to the Professional Practice Committee or the Board of Directors for final approval.

Position Purpose: To provide oversight for the Credentials Program of the Hospital and direction to the Hospital Board of Directors in the credentialing, appointment and privileging of Medical Staff Appointees and AHPs. To maintain compliance with the credentialing policies of the Hospital, the Hospital's accrediting agency standards, and applicable law.

The goal of the Credentials Program is to minimize potential liability, clearly define granted Privileges, ascertain the provider's qualifications for Medical Staff appointment and/or to perform requested Privileges, periodically review information from legal and ethical sources and performance data that impact the provider's appointment and/or Privileges, and minimize the effect of social, economic, political and other non-medical factors on credentialing.

Accountabilities and Functions: Together with the CMO will develop, edit and maintain, on behalf of the Board, a fully

documented Credentials Policy Manual, criteria for appointment/reappointment and granting/re-granting of Clinical Privileges and associated policies and procedures that are utilized in the credentials process.

Appointment/reappointment and Clinical Privileges for the purpose of assuring that existing Medical Staff policies, accreditation standards, and state requirements are followed.

Will oversee processing of requests for all appointments to the Medical Staff and/or Privileges, and will specifically review those applications that fall outside of guidelines for a completed application.

The Credentials Committee Chair in conjunction with the Medical Staff Services department is responsible for the maintenance of accurate and complete documentation concerning the entire credentialing process. This includes the maintenance, security, storage and retrieval of credential files, minutes and other documents pertaining to the overall Credentials Program within the Hospital and the processing of individual applications for appointment and clinical privileges.

Position Requirements: Appointees occupying this position is recommended to meet the Qualifications of Officers. Prior service as a Clinical Department Chair, Board member, Medical Executive Committee member, or other similar Medical Staff leadership position is required. Past participation on the Credentials Committee is highly recommended. Specific training is necessary for performance and will be recommended by the immediate past Credentials Committee chair.

1.2.2 Medical Staff Clinical Department Chairs

Reports to: Chief of Staff

Position Purpose: The purpose of this position is to provide leadership to those organized Clinical Departments to discuss policies, service needs, programs, and other issues affecting the provision of patient care by providers in the Clinical Service.

Reporting Relationship: Clinical Department Chairs report directly to the Chief of Staff, Medical Executive Committee and, through written communication, to the Credentials Committee.

Accountabilities and Functions: Are members of the Medical Executive Committee and provide formal and informal positions on issues affecting the provision of patient care by providers in the Clinical Department. The

Clinical Department Chair is elected by the Clinical Department to serve a two-year term. May serve additional terms if interested.

Requirements / Responsibilities: As outlined in the Medical Staff Bylaws.

1.2.3 Assistant Chair - Medical Staff Clinical Department

Reports to: Medical Staff Clinical Department Chair

Position Purpose: If the Department chooses to name the purpose of this position is to assist the respective Clinical Department Chair to meet the needs of the department in his or her absence. Reporting Relationship: The assistant Clinical Department Chair reports directly to the respective Clinical Department Chair and, if so directed, to the Chief of Staff, Medical Executive Committee, and/or other appropriate committees.

Accountabilities and Functions: Regularly attends the Clinical Quality Review Committee and other committees as appointed in order to provide formal and informal positions on issues affecting the provision of patient care by providers in the Clinical Service. The assistant Clinical Department Chief is selected by the active members of the respective Clinical Department to serve a two-year term. May serve additional terms if interested.

May represent the Clinical Department Chair at the Medical Executive Committee in his/her absence with vote.

Requirements / Responsibilities: As outlined in the Medical Staff Bylaws.

ARTICLE 2.
PROFESSIONAL MEDICAL STAFF COMMITTEES

2.1 DESIGNATION

There will be a Medical Executive Committee (MEC). The following standing committees/councils report and provide minutes to the Medical Executive Committee:

- Credentials Committee
- Wellness Committee
- Quality Assurance and Performance Improvement Committee
- Utilization Review Committee
- Clinical Quality Review Committee
- Pharmacy and Therapeutics Committee (Network)
- Perioperative Services Governance Council
- Osteopathic Methods and Concepts Committee
- Medical Records Committee
- Medical Staff Administration Committee (Joint Conference Committee)

The Chief of Staff shall provide Medical Staff oversight for these committees and/or functions and will report to the MEC on an as needed basis regarding issues identified, which directly affect the Medical Staff. The Chief of Staff shall appoint the chair (except for Credentials Committee, which is an elected position) and members of Medical Staff committees/councils and recommend Medical Staff members for membership in Hospital and joint Medical Staff/Hospital committees/councils. Nothing in this Manual shall preclude joint meetings of Affiliate Hospitals Medical Staff committees to the extent that such meetings will assist in assuring quality patient care and effective peer review.

2.2 MEDICAL EXECUTIVE COMMITTEE

The composition and duties of the Medical Executive Committee are as set forth in the Bylaws Article 8. The Medical Executive Committee supervises overall Medical Staff compliance with accreditation and other regulatory requirements applicable to the Medical Staff or any of its clinical units as well as conducts periodic review of Medical Staff Bylaws, Organization Manual, Credentials Policy Manual and Medical Staff policies, and makes recommendations for changes to the Medical Staff and to the Board of Directors as outlined in the Medical Staff Bylaws.

It is the responsibility of the Medical Executive Committee to initiate, investigate, review, and report on corrective action, and on any other matters involving clinical, ethical, or professional conduct of any individual Practitioner. This responsibility may be delegated to the Clinical Quality Review Committee (CQRC) or a focused professional practice quality improvement panel selected by the Chief of Staff with the intent to improve the Practitioner's performance. The panel shall conduct the review as peers following the time frames set for that focused review by the MEC.

2.3 CREDENTIALS COMMITTEE

2.3.1 Composition

The credentials committee shall consist of members of the active staff selected to effectively represent the major clinical specialties of the medical staff departments. Membership is appointed by the Chief of Staff and approved annually by MEC.

2.3.2 Duties

The Credentials Committee shall investigate the qualifications of all applicants for appointment and/or Privileges, and shall review the Clinical Department assignment and the Medical Staff category and/or Privileges requested.

At an interval no greater than every twenty-four (24) months, the committee shall review all information available on each Practitioner and privileged AHP, including recommendation from the Clinical Department Chair. This information shall be used for the purpose of determining recommendations for reappointment to the Medical Staff, reassignment to the Clinical Department and for the regranting of Clinical Privileges. The Committee shall transmit its recommendations in writing, which may be reflected by its minutes, to the Medical Executive Committee. Where non-reappointment/regrant of Privileges, or a change in appointment category, Privileges is recommended, the reason(s) for such recommendation shall be stated and documented.

The Credentials Committee shall review qualifications of all privileged Allied Health Professionals, subject to recommendation Clinical Department Chair prior to their being permitted access to patients and their medical records, and the committee shall establish processes as necessary to accomplish this review.

The Credentials Committee shall establish criteria for new procedures, provided such procedures are approved to be performed at the Hospital and evaluate the qualifications of any Practitioner applying for these Privileges.

The Credentials Committee, Chair and/or designee, shall be available to meet with the Board or its applicable committee on all recommendations that the Credentials Committee may make. The Credentials Committee may also create an *ad hoc* committee to deal with specific concerns.

2.3.3 Meetings, Reports and Recommendations

The Credentials Committee shall meet as often as necessary to accomplish its duties but at least six (6) times a year. The committee shall maintain a permanent record of proceedings and actions, and report recommendations to the Medical Executive Committee with a copy to the President and the Board.

SECTION 2.4 WELLNESS COMMITTEE

2.4.1 Purpose

The Wellness Committee is a Medical Staff oversight committee whose primary purpose is to identify, assist and foster wellness or, if needed, rehabilitation of impaired Medical Staff Appointees and AHPs with Clinical Privileges and/or scope of practices. The Wellness Committee's processes are separate from the Medical Staff corrective action function. An impaired individual is one who is unable, or potentially unable, to exercise his/her Privileges with reasonable skill and safety to patients because of physical or mental illness, including deterioration through the aging process or loss of motor skills, or excessive use or abuse of drugs including alcohol.

The Committee serves to educate the Medical Staff and other Hospital staff about health, addressing prevention of physical, psychiatric or emotional illness, and impairment recognition issues specific to Physicians and others with Privileges at the Hospital including facilitation of confidential diagnosis, treatment and rehabilitation from potentially impairing conditions.

The Committee will encourage self-referral and referral by other Practitioners, AHPs, and Hospital staff.

The Committee will examine the evidence for impairment of Medical Staff Appointees and others with Privileges at the Hospital including evaluation of the credibility of a complaint, allegation or concern;

The Committee will facilitate referral of the affected person, if indicated, to the appropriate professional internal or external resources for diagnosis and treatment of the condition or concern;

Committee members will seek to maintain confidentiality of the person seeking referral or referred for assistance, except as limited by law, ethical obligation, or when safety of a patient or staff is threatened;

The Committee will provide support to Medical Staff Appointees and other privileged Practitioners/AHPs with impairment while monitoring recovery, including safety of patients until the rehabilitation or corrective action process is completed, and maintaining confidentiality;

The Committee will report to the Medical Staff leadership instances in which a recovering person is providing unsafe treatment to patients.

The functions of the Committee include: (i) reviewing concerns in an orderly and expeditious fashion that have been received by the Chief of Staff or otherwise referred to this committee in accordance with the Practitioner Wellness Policy and (ii) monitoring current cases of impairment of individuals with Privileges at the Hospital and (iii) fulfilling its responsibilities under the Practitioner Wellness

Policy which is fully incorporated herein. Concerns about impairment of individuals with Privileges at the Hospital will be taken to the next scheduled meeting or addressed sooner at the discretion of the chair or otherwise stated in the Practitioner Wellness Policy. When problems are presented, documentation will be obtained in a timely fashion. Suggestions or allegations of impairment of individuals with Privileges at the Hospital will be investigated in a thorough manner;

When the Committee finds that a formal, professional evaluation is necessary to determine whether a problem truly exists, the Committee will carry out an intervention in confidence, encouraging the suspected impaired individual with Privileges at the Hospital to voluntarily submit to the evaluation. If necessary, the Committee may seek the help of the Butler County Medical Society Physician's Effectiveness Committee and/or the Ohio State Medical Association Physician's Effectiveness Program with an intervention plan. Any intervention will be attended by the Chief of Staff, or his/her designee, who will deliver executive decision for definitive action, (i.e., requirement of a formal evaluation). The impaired individual will be encouraged to take a voluntary leave of absence or face suspension of Hospital Privileges. Immediacy of response for evaluation will depend on the magnitude of the perceived problem. If there is still inability to obtain compliance, the impaired privileged individual will be reported to the Ohio State Medical Board, or other applicable licensing entity, and to the Medical Executive Committee.

When an individual with Privileges comes to the Hospital acutely impaired, the Chief of Staff, Clinical Department Chair or designee, will be notified promptly and, if appropriate, will take the necessary actions to prevent risk to patient safety or care. The Wellness Committee will be notified of this action and shall investigate and determine whether additional action is required.

The Committee is delegated the responsibility of establishing protocols for the evaluation and treatment of Medical Staff Appointees, and others with Hospital Privileges, whose physical or mental capacity is questioned. Any physical or mental condition, which would reasonably be expected to impair the Practitioner/privileged AHP, could subject the Practitioner/privileged AHP to investigation. Such investigations are to be conducted in a confidential and impartial manner.

2.4.2 Composition

The membership of the committee shall consist of interested Medical Staff as appointed by the Chief of Staff and approved annually by MEC. There are two (2) additional members - the Chief Medical Officer and the Chief of Staff.

2.4.3 Meetings, Reports and Recommendations

The Wellness Committee shall meet as often as necessary to accomplish its duties. The committee shall maintain a permanent record of proceedings / actions and report its recommendations to the Medical Executive Committee.

SECTION 2.5 QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT COMMITTEE

2.5.1 Purpose

The Quality Assurance and Performance Improvement Committee (QAPI) is a joint committee of the Hospital and Medical Staff that establishes the quality assessment and performance improvement (QAPI) priorities and receives and provides formal information sharing between the Clinical Quality Department and the leadership of the Hospital and Medical Staff. The QAPI has the responsibility to charter, oversee and regularly evaluate QAPI programs and activities of the Hospital and its medical staff. The Committee receives and acts on summary reports from clinical and administrative committees as well as functions which track and trend information is applicable based on clinical and other monitoring activities. The committee makes recommendations for quality assessment and performance improvement and effectively communicates those recommendations to the professional staff and Hospital groups with related responsibilities as specified in the Performance Improvement Plan.

QAPI oversees organizational efforts to measure, assess and improve clinical activities outcomes, the quality and appropriateness of selected service, and identify problem in care and performance at the various levels of organizational leadership, functional area and Clinical Service and is responsible for coordinating efforts to evaluate and monitor resource consumption and utilization management. Clinical review activities include appropriateness of selected services/activities and management of the same in the following processes: (i) medication therapy; (ii) infection prevention and control; (iii) surgical management; (iv) blood products; (v) data management; (vi) discharge planning and utilization review; (vii) utilization management; (viii) complaints regarding medical staff related issues; (ix) restraint/seclusion usage; (x) mortality review; and (xi) "Never" events promulgated by CMS. Clinical review activities may be delegated to other committees and subcommittees that report through QAPI.

QAPI coordinates, prioritizes and monitors the Medical Staff, Hospital and medical education data gathering and analysis components of the quality review program, of QAPI activities using Plan, Do, Check Act ("PDCA") methodology, and coordinates the Medical Staff activities in these areas with those of the other professional and support services in the Hospital. Individualized Practitioner data identified through PI processes will be delegated for handling to the Chief of Staff and/or CQRC as needed for further evaluation according to Medical Staff peer review process.

QAPI annually evaluates the Hospital's overall PI program for its comprehensiveness, integration, effectiveness and cost efficiency, and revises the PI Plan as needed. The PI Plan includes evaluation mechanisms for every contracted patient care service and ensures that the list of all contracted services is maintained inclusive of the scope and nature of the services provided.

QAPI reviews clinical risk management events, including root cause analyses of never events, morbidity concerns and aggregate data on significant high risk events to identify possible patterns and communicate that information to the professional staff and Hospital groups with related responsibilities.

QAPI periodically oversees the development and implementation of Hospital safety programs and an emergency preparedness plan that addresses disasters, both Hospital and community.

QAPI annually reviews the Hospital Hazard Vulnerability Analysis (HVA) objectives and scope of the Emergency Operations Plan, Environment of Care, Staffing Effectiveness, Plan for Patient Care, Patient Safety Plan and the PI Plan.

QAPI establishes formats for the aggregation, display and reporting of data and findings, as well as a system of follow-up to determine that recommended actions are implemented. The committee formats and schedules submissions of data and findings, committee minutes and special reports such that the entire clinical performance of the organization is monitored, the data is reported in a structured and comprehensive manner, and appropriate recommendations can be made based on that data to provide care within the Hospital of the highest quality.

QAPI oversees quality assessment, performance improvement and peer review functions.

2.5.2 Composition

The membership of the QAPI will equally represent Medical Staff and Hospital administration including the following:

Medical Director for Clinical Quality will serve as Chair; Chief Medical Officer, Fort Hamilton Hospital- Co-chair; Hospital President; Hospital Vice President; and Chief of Staff.

2.5.3 Meetings, Reports and Recommendations

The Quality Assurance and Performance Improvement Committee shall meet as often as necessary to accomplish its duties but at least quarterly. Medical Staff QAPI reviews are reported at least semi-annually that focus on clinical assessments, diagnostic procedures, and therapeutic interventions. The committee shall maintain a permanent record of proceedings / actions, and report recommendations and findings to the Medical Executive Committee and the hospital board as deemed appropriate. QAPI data and findings are used to develop continuing education

activities, provide annual evaluations of improvement in clinical care and used in the credentialing process.

SECTION 2.6 UTILIZATION REVIEW COMMITTEE

2.6.1 Purpose

To insure high quality medical care and effective utilization of resources though review of ongoing issues, including case-specific utilization, physician and physician group profiling, and department and service line trending.

a. The Utilization Review Committee is a joint medical/administration committee which develops and amends annually a Utilization Review plan for approval by the QAPI Committee, Medical Executive Committee, Hospital Executive Council, and ultimately the Board of Trustees. The plan applies to all patients regardless of payment source, outlines the confidentiality and conflict of interest policy, and includes provision for:

(1) Reviewing admissions and medical necessity of admissions, continued hospitalization and extended stays;
(2) Discharge planning, including referral for appropriate post hospitalization care and physician follow-up;
(3) Reviewing medical necessity of professional services, such as, but not limited to, high cost procedures, drugs and biologicals.
(4) Data collection and reporting requirements;
(5) Identifying physician/case variations from evidence-based care;

b. Assist the organization with decision making and tracking of high volume, high risk, high cost and/or problem prone diseases or DRG's and recommending measures to improve outcomes. Reviewing cost and quality trends on a continuous basis, will improve clinical effectiveness and resource allocation.

c. Review, approve and recommend to the Medical Executive Committee all new physician order sets and protocols and significant revisions to existing orders/protocols, as the need arises.

2.6.2 Composition

The Utilization Review Committee will be chaired by the Medical Director for Clinical Quality.
The Committee shall consist of no less than four (4) members of the active Medical Staff, appointed annually by the Chief of Staff with reappointment of adequate members of incumbents to ensure continuity of philosophy and experience.

Due to conflict of interest, no committee member shall participate in the review of

any case with personal involvement in the care of the patient. No person serving on the Committee of this hospital may hold any financial interest in any hospital.

2.6.3 Meetings, Reports and Recommendations

The Utilization Review Committee shall meet as often as necessary to accomplish its duties but at least quarterly. The committee shall maintain a permanent record of its proceedings and actions, and report its recommendations to the Medical Executive Committee and the QAPI Committee and as deemed appropriate.

SECTION 2.7 CLINICAL QUALITY REVIEW COMMITTEE

2.7.1 Purpose

The Clinical Quality Review Committee ("CQRC") is a multidisciplinary peer review committee that is responsible to: (i) receive and/or identify, review, evaluate, and make recommendations or determinations regarding peer review issues; (ii) coordinate, track and trend clinical quality patterns and/or concerns as well as death reviews at the Hospital; (iii) engage in other peer review processes that promote clinical performance improvement and achieve quality outcomes; and (v) may receive reports and recommendations of other professional Medical Staff committees as designated by the Bylaws and its governing documents. Clinical services, subsections and/or other committees may be designated by CQRC or the MEC to conduct peer review activities and report their activities, findings, and/or recommendations to CQRC. The activities, proceedings, records, and information gathered for and/or used within the scope, evaluation and review of the committee are confidential and privileged under Ohio's Peer Review Statute (Ohio Rev. Code 2305.24, 2305.252, 2305.253); therefore, members of this committee shall agree to hold all activities, information, records, and proceedings of the committee in strictest confidence. References in this section to "chair" also includes either/or any co-chair of this committee.

The CQRC will:

a. Conduct review of surgical/invasive and manipulative procedures including tissue and non-tissue producing cases, with and without anesthesia and/or moderate sedation and cases which fail to meet predetermined criteria. These criteria may include: documentation, tissue examination, indications for surgery and post-operative care. Define the scope and types of cases to be reviewed and provide tissue and audit review with including cases with minimum or no pathology to determine the justification for all surgical procedures performed, scrutinize the relationship between preoperative diagnosis and the final postoperative diagnoses.

b. Review and evaluate internal and external data is necessary to understand the care that is being examined by the committee.

c. Monitor mortality review and complaints with quality concerns regarding medical staff related issues. Mortality review will consider the awareness of the critical nature of the cases, will analyze opportunities for early recognition of clinical deterioration, correct diagnosis and educational reporting of interesting cases for potential instructional use of the attending and house staff for purposes of improving patient safety and patient care across systems of care. As part of the peer review and quality improvement process, the morbidity and mortality review discussions are considered privileged and confidential.

d. Review physician focused data and reports related to professional and/or quality review activities involving the quality of care. The chairs of the Medical Staff committees may or shall present summary reports of certain peer review activities to CQRC as needed at the discretion of such committee chair, or by invitation or direction of the CQRC chair(s).

e. Initiate and/or conduct any attendant inquiry or other peer review process as a result of CQRC's recommendation or actions.

2.7.2 Composition

The Medical Director for Clinical Quality will serve as Chair. The Chief of Staff shall appoint interdisciplinary clinical specialty members to serve on the CQRC, including, among others, appropriate Clinical Department Chairs. Ex officio members, without vote on physician peer review issues, shall consist of the following senior Hospital management: Chief Medical Officer, and Director of Quality Department.

The committee may appoint subcommittees and/or ad hoc committees as needed, and the chair of such appointed committees may invite non-members to attend and/or present information as needed.

In the interest of objective peer review, members of the committees will not review their own cases. When possible, members should not review those of their practice associates, relatives, direct economic competitors, or others where there is a potential conflict of interest.

2.7.3 Meetings, Reports and Recommendations

The Clinical Quality Review Committee shall meet as often as necessary to accomplish its duties but at least quarterly at a time and place as designated by the Chair(s), and the expectation is that each committee member will attend these meetings. The committee shall maintain a permanent record of its proceedings and actions, and report its recommendations to either the appropriate surgical clinical service, QAPI Committee and the Medical Executive Committee as deemed appropriate.

SECTION 2.8 PHARMACY & THERAPEUTICS COMMITTEE

2.8.1 Purpose

The Pharmacy and Therapeutics (P&T) Committee:

a. Serves as a regulatory and advisory committee to the Medical Staff and Hospital administration in all matters pertaining to the evaluation, selection and utilization of medications, including equipment used to prepare and administer medications;

b. Recommends or assists in the formulation of educational programs designed to meet the needs of Practitioners, nurses, pharmacists or other health care providers on matters related to the selection, administration and monitoring of medication use;

c. Develops and maintains a formulary of drugs accepted for use in the Hospital and provides for its appropriate revisions. The selection and review of these drugs will be based on objective evaluation of their relative merit, safety and cost;

d. Establishes programs and procedures that help ensure cost effective drug therapy using indicators of patient outcome in their assessment;

e. Reviews adverse drug reactions and errors and develop programs and policies to minimize their occurrence and formulate procedures for reporting such reactions and errors; and assists the Staff in investigating such issues and implementing corrective actions;

f. Collects data, monitors and recommends process improvement to the Hospital and the Medical Staff, regarding procurement, storage and distribution; prescribing or ordering; preparing and dispensing; administering; and monitoring the effects on patients of medications used in the Hospital and enteral nutrition products in the Hospital;

g. Reviews medication errors and determine actions which should be taken to minimize their occurrence;

h. Develops a medication safety program for the Hospital that promotes safe medication administration and reduces preventable medication errors;

i. Recommends to the Medical Staff and Hospital policies regarding nutrition care issues;

j. Establishes priorities for ongoing assessment of medication used in the Hospital;

k. Monitors the anticoagulation management program for efficiency and effectiveness;

l. Recommends drugs that are stocked on nursing units;

m. Evaluates clinical data concerning new drugs requested for use in the Hospital, and advises the Staff and pharmacists on the choice of use of drugs;

n. Review Pharmacy and Therapeutics related policies at least every three (3) years and updates more frequently as necessary;

2.8.2 Composition

The P&T Committee is a network joint Medical Staff/Hospital committee with membership consisting of representatives from the Medical Staff, nursing, pharmacy, nutrition services and other health care providers.

The committee may appoint subcommittees as needed and the chair or director of pharmacy may invite non-members to attend as needed.

2.8.3 Meetings, Reports and Recommendations

The Pharmacy and Therapeutics Committee shall meet as often as necessary to accomplish its duties but at least quarterly. The committee shall maintain a permanent record of its proceedings and actions, and report its recommendations to the Quality Assurance and Performance Improvement Committee and the Medical Executive Committee as deemed appropriate.

SECTION 2.9 PERIOPERATIVE SERVICES GOVERNANCE COMMITTEE

2.9.1 Purpose

The Perioperative Services Governance is a joint medical staff and hospital committee and shall be responsible for the following: the Operating Rooms (OR), the Post Anesthesia Care Units (PACU), the Ambulatory Surgery Center (ASC) (pre and post-operative care), and the Pre-Admission Testing (PAT) services including the Pre-Operative Clinic, Endoscopy Services (GI) Outpatient Surgery Center and Central Sterile Processing. The Perioperative Services Governance Committee will:

a. Review, revise and develop policies and procedures for Perioperative Services;

b. Recommend policy revisions to the Medical Executive Committee for approval;

c. Monitor compliance with Perioperative Services policies;

d. Monitor and evaluate effectiveness of Perioperative Services, including patient safety issues and performance improvement activities.

e. Upon request, provide comments to the Credentials Committee regarding Practitioners' use of Perioperative Services;

f. Review and prioritize requests for capital equipment, instruments and medical supplies;

g. Review and comply with regulatory and accrediting agency requirements;

h. The co-chairs of the Perioperative Services Committee may in urgent situations;

i. Discuss team interactions;

j. Interpret and enforce Perioperative Services policies, if necessary, between meetings of the Perioperative Services Committee;

2.9.2 Composition

The Perioperative Services Committee is a network joint Medical Staff/Hospital committee with membership consisting of adequate representation from both Medical Staff and Hospital administration.

The committee may appoint subcommittees as needed and the chair may invite non-members to attend as needed.

2.9.3 Meetings, Reports and Recommendations

The Committee shall meet as often as necessary to accomplish its duties but at least quarterly. The committee shall maintain a permanent record of its proceedings and actions, and report its recommendations to the Performance Improvement Committee Hospital Executive Council and to the Medical Executive Committee as deemed appropriate.

SECTION 2.11 MEDICAL RECORDS COMMITTEE

2.11.1 Purpose

Provide a uniform and network-wide approach (one best practice) to the development of definitions and processes to insure an accurate, complete and regulatory compliant medical record with EPIC and the regulatory/accreditation requirements. Examples of issues that would be under review would include but not be limited to the following:

- Definition of a complete medical record
- Elements of history and physical
- Elements and requirements for immediate post op notes, op notes, progress notes and discharge summaries
- Establish time frames for completion

- Compliance with regulatory and accreditation requirements
- Completion of audits to document acceptable compliance

2.11.2 Composition

The Medical Records Committee is a network joint Medical Staff/Hospital committee with membership consisting of:

- CMIO, Chair
- Network Director, HIMS, Co-chair
- Medical staff representatives, one from each network facility/system with intent to provide representatives from multiple disciplines
- CMO of facilities
- Physician Representative appointed from KPN's Physician Leadership Group
- Finance representative
- HIMS support staff
- IS support staff
- Nursing representative appointed by Chief Nursing Officer
- Other individuals as invited by the chairs

2.11.3 Meetings, Reports and Recommendations

- The Medical Records Committee shall meet as often as necessary to accomplish its duties but at least quarterly. The committee shall maintain a permanent record of its proceedings and actions, and report its recommendations
  Reports to the Executive Finance Group and to the respective facility/system medical executive committee.

as deemed appropriate.

SECTION 2.12 MEDICAL STAFF ADMINISTRATION COMMITTEE (JOINT CONFERENCE COMMITTEE)

2.12.1 Purpose

The Medical Staff Administration (MSA) Committee is a joint committee to between Medical Staff and Hospital Leadership that creates a constructive and systematic forum to assist in policy and planning processes. The committee will discuss agenda items for the Medical Executive Committee including quality of care and professional competency, conduct issues, and process improvement issues that impact quality of care.

2.12.2 Composition

MSA may be comprised of the Chief of Staff, Vice Chief of Staff, Chief Operating Officer, Chief Nursing Officer Chief Medical Officer, Vice President Patient Services, and Hospital President

2.12.3 Meetings

The Medical Staff Administration Committee will meet monthly, typically prior to MEC, at least six (6) times a year.

ARTICLE 3.
RULES AND REGULATIONS

SECTION 3.1 OUTPATIENT (AMBULATORY), OBSERVATION AND ADMISSION STATUS

Provisional Diagnosis and Status: No patient shall be admitted to the Hospital until a provisional diagnosis has been documented in the medical record and an admission order from the admitting Practitioner, or his/her alternate, secured. Justification for the assignment of status shall reflect Medical Staff approved criteria.

Patients: The Hospital shall accept patients suffering from all types of diseases except those whose medical needs are beyond the scope of care provided at a Hospital facility. Patients presenting to a Hospital facility for treatment outside the Hospital's scope of service will be stabilized and transferred to another appropriate facility.

Protection of Other Persons: Practitioners admitting patients shall be held responsible for giving such information as may be necessary to assure the protection of other patients and personnel from those who are a source of danger from any cause whatever or to assure the protection of the patient from self-harm.

This Hospital has the obligation of minimizing the risk of hazards and safeguarding all patients, visitors and personnel. Therefore, when any patient whose mental or physical condition causes him/her to be disturbing and/or unsafe to himself/herself, other patients, and personnel of this Hospital, the patient may be transferred to a private room. This transfer will be discussed with and approved by the attending Practitioner. In case of disagreement, the appropriate Clinical Department Chair will be contacted, and if a mutual decision with the attending Practitioner cannot be reached, a Medical Staff officer or designee, shall be consulted to make a final disposition made by such an officer or designee.

Transfer of Service: Patient transfer from the admitting Practitioner's/AHP care to another Practitioner is arranged by agreement of the current attending Practitioner and receiving Practitioner whether the transfer is requested by the patient or patient's appropriate legal representative or by the attending Practitioner.

To complete a patient transfer of service the attending Practitioner must order a transfer of service with appropriate documentation of reasons for transfer in the Practitioner's progress notes as well as the receiving─Practitioner documenting acceptance of the patient transfer in the Practitioner's progress notes and orders.

Assignment of Cases:

(1) Unattached patients shall be attended by Medical Staff Appointees with appropriate Privileges and shall be assigned by the Clinical Service concerned in the treatment of the disease which necessitated admission.

(2) It is expected that private patients shall be attended by their own Practitioner. All Practitioners with Clinical Privileges are required to provide continuity of care to all patients in their practice for whom they are responsible, and to provide care that is effective, safe, patient and family centered, efficient, timely and within the parameters of granted Privileges. In the event that a Practitioner plans to be away from the Hospital for a scheduled absence (*e.g.* vacation or absences for personal reasons, but not including a leave of absence as defined in the Credentials Policy Manual), such Practitioner shall make adequate arrangements prior to departure for coverage for his/her private patients that are inpatients or who may present to the Emergency Department while the Practitioner is away on such planned absence. The Practitioner, unless in a group practice in which all Practitioners have common Privileges or in a designated call coverage group made known in advance to the Medical Staff Services Department, shall notify the Medical Staff Services Department and the Emergency Department of such period of scheduled absence, and shall identify the covering Practitioner who shall have similar Medical Staff Privileges, have agreed in writing to provide this coverage, and be located within the Hospital's geographic service area and close enough to provide timely care for the private Practitioner's inpatients and/or Emergency Department patients. If the Practitioner is also scheduled to be on-call during the scheduled absence, the practitioner must also arrange for backup on-call coverage with another Practitioner who meets the above criteria, and shall notify the departments identified above and other Hospital-areas/departments as may be required in the Manuals, and/or Medical Staff/Hospital policies. In the case of the patient requiring admission who has no attending Practitioner on the Medical Staff and does not elect or is unable to choose one, the patient shall be referred to the appropriate Clinical Service on-call Practitioner.

(3) Practitioners to whom unattached patients are referred have a responsibility to provide care to the patient at least once for the problem for which the patient was referred, regardless of ability to pay and to provide continued care or secure referral to another proper available care provider.

(4) Practitioners, who assume responsibility for unattached patients, are expected to respond to a request from the Emergency Department to provide consultative or in Hospital care in a timely fashion to meet patient care needs.

(5) All patients who are placed in a Hospital bed as an inpatient or observation status are required to be seen by the admitting or consulting Practitioner (who is permitted by the State and Hospital to admit patients to a hospital) in a timely fashion with documentation of that visit in the medical record. Medicare patients must be under the care of a MD/DO. Patients transferred or admitted to an ICU shall be seen by the attending or consulting Physician within a time frame consistent with the clinical condition of the patient, usually no longer than twelve (12) hours. Patients placed in a non-ICU bed as an outpatient (ambulatory), observation status or admission shall be seen by the admitting or consulting Practitioner within a time frame consistent with the clinical condition of the patient, but within twenty-four (24) hours. All patients, with the exception of normal newborns or patients awaiting nursing home placement who shall been seen at least weekly require daily patient visits by the attending Practitioner with privileges or his/her covering Practitioner and these visits must be documented in the progress notes as a part of usual care. To provide appropriate continuity of care for patients who are hospitalized by Practitioners other than the patient's primary care Physician, the attending is responsible to communicate, when appropriate, with the primary care Physician regarding the patient's Hospital course and the plan of care post hospitalization.

Definition of Attached Patient: A patient who a provider (or his/her group) has rendered professional services to within the past three years.

Definition of an Unattached Patient: A patient who does not have a primary care doctor or has a primary care doctor that does not come to this institution.

Exceptions:

1. 1. A patient may choose a different provider from the one who previously rendered care to that patient.

32 The primary care doctor of the patient requests a different provider for the patient.

3. The patient has been discharged from a provider's practice and is therefore no longer attached to that particular provider.

SECTION 3.2 PATIENT SAFETY

The Hospital and Medical Staff have a responsibility to promote patient safety and medical error reduction. This is accomplished through the identification and prevention of medical errors through the prospective analysis and re-design of vulnerable patient systems, the promotion of a culture of non-punitive reporting, and the responsibility to tell a patient if he or she has been harmed by the care provided. Each Practitioner is expected to participate in the patient

safety program at the hospital by actively supporting and following the Hospital policies and procedures related to providing safe medical care, including the Hospital's Patient Safety Performance Improvement initiatives and Patient Safety Culture Survey approved by the Medical Executive Committee, and informing patients and their families about unanticipated outcomes of care.

SECTION 3.3 UTILIZATION

The history and physical and progress notes must document the patient's clinical course in sufficient detail to provide a reasonable understanding of the patient's evolving condition, diagnoses, treatment, and plan of care. In addition, the notes must provide sufficient information regarding the severity of illness and/or intensity of service that requires continued use of Hospital resources.

Medical Staff Practitioners are required to provide appropriate diagnoses or clinical indications to justify diagnostic tests and therapeutic interventions performed by Hospital Departments.

Admissions prior to the day of surgery will be permitted if the medical condition warrants Hospital admission criteria. If prior approval for non-emergency surgery or admission is required by the payor, the Medical Staff Practitioner is responsible (whenever possible) for obtaining such approval prior to surgery or admission.

If approval for performance of any non-emergency procedures is required by the third party payor, such approval must be obtained prior to performance of that procedure.

It is the Practitioner's responsibility to abide by the stipulations made by the payor for patient services as long as these requirements are consistent with the Bylaws and Organization Manual of the Medical Staff and consistent with appropriate standards of care.

Periodic review of the appropriateness of patient care may be made by the staff of clinical quality department. Deviations from Medical Staff approved criteria will be referred to the utilization Physician reviewer.

SECTION 3.4 PEER REVIEW

The peer review function for Practitioners and AHPs with delineated Clinical Privileges will be performed with intention to safeguard Practitioner confidentiality to the greatest extent and to promote objective and unbiased considerations. The purpose of all peer review is to promote excellent clinical outcomes and the safety of patients and staff. Peer review is to be done with the intention to identify and improve processes which may impair the ideal delivery of clinical care with the intent of performance improvement and not

indictment of individuals. Issues of disruptive behavior are not addressed via peer review (refer to Disruptive Medical Staff Member Section of this Manual).

3.4.1 CQRC Review

Peer review is a necessary element of professionalism and all Appointees of the Medical Staff are expected to actively participate in the process, when requested.

Identification of potential variance in care may come from:

- Patient complaints
- Patient Relations referral
- Written complaints by the Hospital or Medical Staff
- Medical Director of Quality
- Vice President Medical Affairs / Chief Medical Officer
- Member of the Medical Executive Committee
- Routine chart review by appropriate Hospital Staff and/or committees, including the Hospital Quality department
- Routine review of clinical outcomes / documentation statistics
- Focused Professional Practice Evaluation as requested by a Department Chair, Medical Executive Committee, or Professional Practice Committee of the Board

Peer review issues will ultimately be classified as follows:

1. No Quality Variance: Care rendered was appropriate. Cases will be tracked for trends.

2. Minor variance from expected practice: Care rendered deemed to be outside of benchmarks/established standards/standard of care. The variance was minor or standards of care are controversial.

3. Major variance from expected practice: Care rendered is deemed to be substantially outside of benchmarks/established standards/standards of care.

The aggregate data from minor variance or major variance will be reviewed as indicated and during the biennial reappointment/regrant of Privileges and recredentialing process of the Medical Staff.

A practitioner who has received a minor variance or major variance determination will be notified in writing by Special Notice within 30 (thirty) days and given the opportunity to appeal the decision. This appeal may be in writing or in person. Appeals shall be directed to the chair of the Clinical Quality Review Committee, the Clinical Service Chair or the Chief of Staff.

CQRC will review the appeal and make a determination to rescind or uphold the variance. If the majority of the committee upholds the assignment after meeting with the Practitioner, CQRC can refer the appeal and the complete file to the Medical Executive Committee for final determination. The Medical Executive Committee will then assign a determination, recommend a subcommittee for further review / recommendation or send the file to an outside reviewer.

If a subcommittee is appointed to investigate a peer review matter by the Medical Executive Committee or the Chief of Staff, the subcommittee members will follow the following guidelines:

1. Any predetermined review by which criteria are established to evaluate a diagnosis, treatment outcome, procedure or other parameter must not be exclusively directed at one Practitioner and shall include all Practitioners involved in the same. This procedure does not preclude an investigation of an individual Practitioner based upon a specific complaint.
2. Once the initial chart review indicates further inquiry is necessary, the Practitioner involved should be notified in writing by Special Notice that a review will take place.
3. The Medical Executive Committee will maintain a file for each investigation containing the written complaint if any and all relevant correspondence, clinical records, and committee minutes. The Practitioner who is the subject of investigation will be provided a summary of the complaint and the nature of the supporting evidence. The file documents are confidential and are subject to the privileges from disclosure to the persons outside the review proceedings (Ohio Rev. Code Section 2305.251).
4. Minutes shall be maintained by the investigating subcommittee and shall identify any deviation from the appropriate standard of care or violation of Hospital and/or Medical Staff Bylaws, policies, rules and/or regulations. When such is the case, the Practitioner will be notified by Special Notice, and asked to respond. When a Practitioner's response satisfies the subcommittee or if for other reasons the subcommittee feels that no action is appropriate, the investigation will be terminated with a positive comment, MEC notified and an appropriate letter shall be sent by Special Notice to the Practitioner.
5. When the investigation reveals a significant deviation or violation as described above, or, if for other reasons the investigating subcommittee feels that further action is necessary, the affected Practitioner shall be invited to meet with the subcommittee to discuss the case(s). The chair of the subcommittee shall make efforts to see that each member of the committee reviews the complete file before the meeting. This shall include comparing any internal reviewer's report with any patient charts in question. If the matter is resolved at this level, the review will be

terminated with a positive comment, MEC notified and a letter to that effect shall be sent by Special Notice to the Practitioner.

6. If the majority of the subcommittee is still not satisfied after meeting with the Practitioner, CQRC can refer the matter and the complete file back to the Medical Executive Committee with or without recommendation. The Medical Executive Committee will act at that point, based on the recommendation, or otherwise send the file to an outside reviewer.

   External peer review shall be initiated by request, if approved by the Medical Executive Committee, from any one of the following:
   - Department Peer Review Committee
   - Department Chief
   - Chairman of Clinical Quality Review Committee
   - Chief of Staff
   - President of the Hospital
   - Board of Directors

3.4.2 External Review

Situations may arise when Practitioners outside the Medical Staff may be asked to participate in the peer review process. Indications for an external review include, but are not limited to, the following:

1. Ambiguity when dealing with vague or conflicting recommendations from committee review(s) where conclusions from the review could impact a Practitioner's appointment or Privileges;
2. Lack of internal expertise, when no one on the Medical Staff has adequate expertise in the clinical procedure or area under review;
3. When the Medical Staff needs an expert witness for a fair hearing, for evaluation of a credentials file, or for assistance in developing a benchmark for quality monitoring;
4. To promote impartiality in peer review. The Medical Executive Committee or Board of Directors may require external peer review in any circumstance deemed appropriate by either of the bodies. If referred to an outside reviewer, upon receipt of the reviewer's report, if the Medical Executive Committee is satisfied, the review will be terminated with a positive comment and an appropriate letter ~~is~~ shall be sent by Special Notice to the Practitioner (unless the Board has required such review in which event the Board will act on the reviewer's report. If not satisfied, the Medical Executive Committee will decide on an appropriate action as set forth in the Bylaws and make its recommendation to the Board for final action.

The Practitioner subject to external peer review will be apprised of this need and will be invited to nominate unbiased external Practitioners for

consideration. The decision as to whether to utilize the services of any such nominated Practitioner will be at the committee's sole discretion.

When a determination is made by the appointed peer review committee of a significant issue, the Practitioner will be given written notification by Special Notice within thirty (30) days. When a determination is made by CQRC of variance in care, the Practitioner will be given written notification by Special Notice within thirty (30) days.

SECTION 3.5 ORDERS

3.5.1 Admission Orders: All inpatients must have orders upon admission provided by an Appointee in good standing with admitting privileges granted in accordance with the Bylaws, or by an eligible House Staff physician. Non-Appointees shall not have authority to admit or co-admit patients to the Hospital, except to the extent provided by Ohio Law, Medicare Conditions of Participation, standards of the applicable accrediting body such as the Healthcare Facilities Accreditation Program, other applicable law and regulations, and the Bylaws and governing documents.

3.5.2 Written, Telephone and Verbal Orders: See hospital policy- MS-KHN Orders Management for Verbal, Telephone, Written, and fax order giving, receiving and authenticating- CPOM

SECTION 3.6 RECORDS

See most recent hospital policies related to Medical Record compliance which shall supercede requirements of this document.

3.6.1 Content, Review and Evaluation

a) Content: The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. A complete medical record of a patient in admission, observation or ambulatory status shall, as applicable, identification data; chief complaint(s); history of present illness; relevant past history; social history; family history; review of systems; relevant physical examination; admitting/provisional diagnosis; medical or surgical treatment; operative report; pathological findings; progress notes; multidisciplinary notes and flow sheets; medication administration records; special reports such as consultations, clinical laboratory reports, radiology/imaging reports, and a discharge summary including outcome of hospitalization, discharge-/final diagnoses, disposition of the case, and provisions for follow-up care. CMS

also requires evidence in the medical record of appropriate findings by clinical and other staff involved in the care of the patient; documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia; properly executed informed consent forms; all Practitioners' orders; nursing notes; reports of treatment; medication records; vital signs, and other information necessary to monitor the patient's condition.

b) Legibility: Appointees of the Medical Staff and others with Clinical Privileges have a responsibility to make legible entries into the medical record. The Medical Staff has a legibility policy to assure all individuals having access to patient medical records can read information contained within the medical record. Non-compliance may result in progressive corrective action including notification, education (including possible remedial handwriting programs), and suspension(s) for incomplete medical records.

c) Non-Medical Comments: Criticism, impertinent and inappropriate comments, drawings or language, or personal attacks against Practitioners/AHPs, Hospital personnel, or the Hospital and its policies shall not appear in the medical record. Any alleged violation of this rule shall be referred to the Chief of Staff and/or the Vice President of Medical Affairs for interpretation, judgment, and action. If warranted, they may refer the incident to the Medical Executive Committee for review and recommendation.

d) History and Physical: A current complete history and physical examination (H & P) consists of the following required elements: chief complaint, history of present illness, relevant past history, social history, family history, review of systems, relevant physical examination, impression, and plan of care. For those patients for which a surgery/procedure is to be performed, the H & P must include indications for the surgery/procedure as documented by the operating surgeon/Practitioner performing the procedure. A complete H & P, and any updates thereto, shall be placed on the patient's chart within twenty-four (24) hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

An osteopathic musculoskeletal examination is required as an integral part of the history and physical performed by osteopathic physician on their admitted patients unless contraindicated. The reason for omitting the musculoskeletal examination is documented in those cases where this examination is contraindicated.

The H & P records are the responsibility of the attending Physician. H & Ps shall be properly documented, and authenticated, dated, and timed. Medical student H & P's will not be part of the medical record unless they are written and signed by a supervising resident or the attending Physician. Medical student dictation will not be transcribed by the Hospital.

The H & P must be completed and documented by one of the following:

- Doctor of medicine or osteopathy
- Doctor of podiatric medicine (in accordance with Ohio State law and as indicated in the Credentials Policy Manual)
- Doctor of dental surgery or of dental medicine (in accordance with Ohio State law and as indicated in the Credentials Policy Manual)
- Physician Assistant [if privileged to do so by the Hospital and in accordance with Ohio State law (e.g., within scope of practice, etc.)]
- Certified Nurse Practitioner/Advanced Practice Nurse [if privileged to do so by the Hospital and in accordance with Ohio State law (e.g., within scope of practice, etc.)]

NOTE: H & P's completed and documented by a physician assistant or advanced practice nurse/nurse practitioner must be authenticated by the attending Physician.

Should the H&P be provided by a non-credentialed Practitioner, such as a Practitioner without appointment/Privileges at the Hospital (i.e. patient's primary care Practitioner), then an update meeting the required contents of the H&P as defined in this section must be completed and documented by a Practitioner who is appropriately credentialed and privileged in accordance with the Medical Staff Bylaws and other related Manuals.

The update, if any, shall indicate the following: the H & P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H & P was completed. Any changes in the patient's condition must be documented in the update note and placed in the patient's medical record within twenty-four (24) hours of admission or registration, but prior to surgery or a procedure requiring anesthesia.

If the Practitioner finds that the H & P done before admission is incomplete, inaccurate, or otherwise unacceptable, the Practitioner reviewing the H & P, examining the patient, and

completing the update may disregard the existing H & P and conduct and document in the medical record a new H & P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

e) Ambulatory/Outpatient H & P
Ambulatory patients who are undergoing procedures requiring moderate sedation or anesthesia require a complete H & P on the chart. Only a pertinent note concerning the nature of the disease process leading to the procedure and the intended procedure is necessary in other cases. Other pertinent positive findings, such as drug allergies and serious pre-existing disease entities should also be noted.

f) Anesthesia/Procedural Sedation: Outpatients undergoing surgery or procedures under any anesthesia or procedural sedation, except local anesthesia without any pre-operative medication, require an H & P.

g) Pre-Operative/Pre-procedure Record: Emergencies excepted, patients shall not be taken to the operating/procedure room unless the medical record contains a signed and witnessed informed consent form, a plan of care for the surgery/-procedure and anesthesia/-procedural sedation, and an acceptable current H & P. In emergency conditions, an acceptable H & P may be limited to major significant conditions requiring the immediate surgery/procedure. Surgery/procedure time may be forfeited on the authority of the Perioperative Governance Committee as outlined in the Operating/Procedure Room Policy, as such policy may be amended from time to time, when the start of the operation/procedure is delayed for more than fifteen (15) minutes.

h) Pre-Operative Attestation Informed Consent: To assist the patient in providing informed consent, the Practitioner performing the surgery or procedures shall provide a plan of care for the patient including informing the patient and/or appropriate surrogate(s) regarding the need for, benefits, alternative options, risks, and potential complications associated with the surgery/procedure.

To assist the patient in providing informed consent, the Practitioner responsible for managing the patient's care, treatment, and services (or his/her designee) shall ensure that the patient and/or appropriate surrogate(s) is informed of the potential benefits, risks, and side effects of the patient's proposed care, treatment and services, the likelihood of the

patient achieving treatment goals, and any potential problems that might occur during recuperation. This informed consent process includes a discussion about reasonable alternatives to the patient's proposed care, treatment and services. The discussion encompasses risks, benefits and side effects related to the alternatives and the risks related to not receiving the proposed care, treatment and services. Risks and benefits associated with blood transfusion when blood or blood components may be needed with an operative procedure are also discussed. Documentation of risks, benefits and alternatives must be present in the patient record. The Informed Consent Policy, as such policy may be amended from time to time, outlines the details of the informed consent process.

To assist the patient in providing informed consent, the Practitioner or CRNA providing anesthesia or procedural sedation shall provide an anesthesia or procedural sedation plan of care including documenting patient American Society of Anesthesiology (ASA) classification and informing the patient and/or appropriate surrogate(s) of the need for, benefits, alternative options, risks, and potential complications associated with anesthesia or procedural sedation prior to administration of pre-operative medication.

i) Anesthesia Documentation: a pre-anesthesia evaluation shall be completed and documented by an individual qualified to administer anesthesia within forty-eight (48) hours prior to surgery or a procedure requiring anesthesia services.

An intra-operative anesthesia record shall be maintained.

A post-anesthesia evaluation shall be completed and documented by an individual qualified to administer anesthesia no later than forty-eight (48) hours after surgery or a procedure requiring anesthesia services. The post-anesthesia evaluation for anesthesia recovery is completed in accordance with State law and regulation and Hospital policies and procedures that have been approved by the Medical Staff and that reflect current standards of anesthesia care

j) Surgical Record: All operations or procedures performed in the Hospital shall be described in full through immediate dictation or by a hand-written report. The operative report must be in sufficient detail to provide necessary clinical and billing information, must be entered immediately (no greater than twenty-four (24) hours) into the patient's medical record upon completion of the operative or high-risk procedure and before

the patient is transferred to the next level of care (unless an immediate progress note is entered—see below) and must include the following elements:

- Patient name and hospital identification number
- Date / time of surgery
- Name(s) of licensed independent practitioner(s) performing the procedure and assistant(s) (even when performing those tasks under supervision)
- Name of the procedure
- Findings of the procedure including complications, if any
- Description of the procedure(s)/technique(s) including the type of anesthesia administered
- Estimated blood loss
- Specimens/tissues removed or altered
- Pre-operative diagnosis
- Post-operative diagnosis
- Description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner. Significant surgical procedures include prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

The report/note must be dated, timed, and signed by the surgeon/Practitioner who performed the surgery/high risk procedure.

When the original or a hard copy of the full operative report is not placed in the medical record immediately after surgery or procedure, a progress note of the operation or procedure is entered immediately. This immediate postoperative/procedure note, completed before the patient is transferred to the next level of care, includes the same elements outlined above.

All tissues and foreign material surgically removed, will be processed in accordance with Hospital policy.

3.6.2 Discharge Summary

To facilitate continuity of care, a discharge summary containing at a minimum the reasons for and outcome of hospitalization, significant findings, procedures performed and care, treatment, and services rendered, the final diagnoses, the patient's condition and disposition at discharge, instructions to the patient and/or appropriate surrogate(s), and provisions for follow- up care will be

included in a completed medical record. The discharge summary must be completed within seven (7) days of discharge.

For normal newborns, uncomplicated deliveries, or patients whose admitted Hospital stay is less than forty-eight (48) hours with uncomplicated care, a discharge progress note, which includes the outcome of hospitalization, the patient's condition at discharge/disposition of the case, discharge instructions, and provisions for follow up care, may be substituted for a discharge summary. A discharge progress note may also be used to satisfy the discharge summary requirements for the initial hospitalization when a patient is transferred to another network facility.

Any multi-service patient (one whose medical care is provided by more than one specialist or attending Practitioner) shall have a single discharge summary, which includes all areas of care. The attending Physician will be responsible for the discharge summary.

3.6.3 Completion of Records - Requirements:

a) A history and physical (H&P), discharge summary, consultation and operative/procedure note shall be authenticated with a handwritten or electronic signature as well as timed and dated. Rubber stamp signatures are not acceptable for authentication. Electronic, verbal or telephone orders must be authenticated within forty-eight (48) hours.

b) Charts must be accurately and legibly completed within seven (7) days from allocation date / quality documentation clarification requests. Charts are complete only after dictated reports and required entries are signed, dated and timed within required timeframes; merely dictating before the deadline is not sufficient. Charts may be identified as incomplete prior to discharge if required elements are not performed as mandated by the stricter rules set forth in the Medical Staff Manuals, Hospital policy or accrediting and/or regulatory standards/requirements. Examples of such incomplete records would be lack of an immediate post-operative note and failure to authenticate electronic, verbal or telephone orders within forty-eight (48) hours.

c) After 21 days, notification of suspension of Hospital privileges for incomplete or delinquent medical records will be given to the Practitioner either verbally, by Special Notice, or by receipted facsimile. A prior waiver with time extension may be requested from the officers for records that are not able to be completed within fourteen (14) day period due to extenuating circumstances (e.g. illness, vacation).

d) Automatic suspension of Privileges for incomplete or delinquent medical records results in the affected Practitioner not being able to

admit or write orders for new patients; but does not in any way remove the Practitioner's responsibilities for call coverage, for patients already under his/her care in the Hospital, or for the provision of services which have been scheduled prior to the suspension and which cannot be appropriately rescheduled.

e) Suspension of Practitioners who supervise AHPs may result in the AHP's Privileges being suspended as well if the AHP has no other collaborating or supervising Practitioners.

f) Any Practitioner whose Hospital Privileges have been suspended because of incomplete or delinquent records, or portions thereof, may in the event of unusual or extenuating circumstances obtain authority to care for or admit a specific patient from the Chief of Staff or designee, Chief-Elect, Vice Chief, Medical Staff Credentials Program, Vice Chief at-Large, or the Vice President of Medical Affairs. The approving officer and Practitioner shall both notify the admissions office of the nature of the special circumstances prior to the admission of the patient. For removal of the suspension prior to curing medical records deficiencies, Practitioners may submit a plan of compliance and petition for restoration to one of the above officers. Upon approval of the plan, the officer will contact the Health Information Management Department to restore such Practitioner's admitting and ordering Privileges.

g) A Practitioner who has received three suspensions during any consecutive 12-month period, and who subsequently has incomplete or delinquent medical records or a Practitioner who has been under suspension for two (2) consecutive weeks without an excused waiver will be terminated from the Medical Staff. Notice of any termination will be sent by Special Notice, and reasonable attempts will be made to contact the Practitioner personally. Signature of receipt of the notice or documentation of the date of the personal contact will constitute completion of the notification process. The Practitioner who is so terminated will not be eligible for the hearing and appeal process and will need to reapply to the Medical Staff for appointment and Clinical Privileges. For patient safety reasons, and in order to not jeopardize the continuity of patient care, in the event of such imminent automatic termination, the Chief of Staff or his/her designee may intervene to permit the Practitioner to have a limited extension of appointment with Privileges restricted to caring for currently hospitalized patients and for patients previously scheduled for procedures or admission. Following the discharge of the last patient, the automatic termination will take effect. Reinstatement of Clinical Privileges cannot occur until the Practitioner completes all delinquent and incomplete records and reapplies for privileges. If Privileges are reinstated, any single subsequent suspension for medical record completion during the consecutive 12-month period will result in a termination of privileges.

The Practitioner will be required to present an acceptable corrective action plan for consideration of reappointment.

h) Practitioners who resign while under suspension will be designated as "Resigned: NOT in Good Standing" status and will be so reported by the Medical Staff Services Department in any future queries to the Medical Staff regarding status.

i) A suspension for failure to complete medical records lasting thirty one (31) days or more may be reportable to the National Practitioner Data Bank and the State licensing board if such failure is determined through a professional review action with final finding to relate to professional competence or conduct and adversely affects or could adversely affect a patient's health or welfare.

3.6.3.1 Chart Review: Clinical Service Chairs, or designees, who are assigned utilization or quality issues for review will have charts available. These charts shall be reviewed in a timely fashion and will be subject to addition to the Practitioner's incomplete medical record profile.

3.6.3.2 Denial Appeals Process: The attending Practitioner or consultant will appeal third party payor denial of payment for services rendered at Hospital when, in the Practitioner's opinion, such services were medically necessary. Appeals preferably occur while the patient is in-house or immediately following discharge. These appeals may be performed through direct verbal/written communication with the payer's medical director or through appropriate documentation in the medical record. Requests for appeals of denials post discharge will be placed in the medical record and will be a component of a Practitioner's incomplete medical records profile.

3.6.3.3 Ownership: All records, including medical images, are the property of the Hospital. Copies of the medical record may be removed from the Hospital's jurisdiction and safekeeping only in accordance with patient authorization, a court order/subpoena signed by a judge, or statute. In case of readmission of a patient, all available records shall be provided, if requested, for the use of the attending Practitioner, whether the patient is being attended by the same Practitioner or another.

3.6.3.4 Access to Records: Access to medical records shall be afforded to Medical Staff Appointees in Good Standing for bona fide study and research (with appropriate Institutional Review Board ("IRB") authority) consistent with preserving confidentiality of personal information concerning individual patients. Subject to the discretion of the Hospital President, former Appointees of the

Medical Staff shall be permitted free access to information from the medical records of their patients covering all periods in which they attended such patients in the Hospital. Review of medical records is limited to Medical Staff and Hospital professionals who are responsible for providing care to the patient. Practitioners performing peer review and utilization functions may review any chart assigned for review. Practitioners on the Medical Staff who have the permission of the attending Practitioner and the patient or patient*'s* legal representative may review the medical record of a currently hospitalized patient. Practitioners not on the Medical Staff, with the permission of the attending Practitioner or his/her designee, and with permission of the patient or patient's legal representative, may review the medical record of a currently hospitalized patient.

SECTION 3.7 CONSULTATION

The responsibility for patient care rests with the attending Practitioner but consultation is recommended when there is a reasonable doubt as to the diagnosis and/or treatment. Consultation is required when the patient needs care which is beyond the attending Practitioner's scope of Privileges. If the attending physician and the consultant disagree on management of a patient, a second opinion must be ordered.

Medical Staff Appointees are expected to respond to requests for consultations in a timely fashion that meets patient care demands and the need for appropriate utilization of services. The Medical Staff Appointee requesting consultation will be responsible to provide appropriate clinical information and time-to-response expectations on the order sheet. Guidelines for time-to-response expectations are as follows:

a) Emergent consultations: 30-60 minutes (*e.g.,* immediate threat to life, limb or body organ)

b) Urgent consultations: 4 hours (*e.g.*, impending threat to life, limb or body organ)

c) Routine consultations: 24 hours

Practitioner to Practitioner contact is the preferred way of initiating all consultations, and is required for emergent and urgent consultations.

Consultation with other active and courtesy Appointees shall be sought as appropriate in order to provide the best possible care for the Hospital's patients.

Care of patients in the intensive care unit requires management or consultation with by a physician board certified or board eligible in critical care.

If circumstances are such as to render consultation undesirable or unnecessary, consultation shall not be performed and the reasons thereof shall be communicated with the Practitioner requesting the consult.

Hospital patients with substance abuse issues are encouraged to be referred or consultation to an Appointee with substance abuse expertise or referred to an external community-based substance abuse service. .The consultant must be an Appointee of the Medical Staff, well qualified to give an opinion in the field in which his/her opinion is sought. Medical Staff Privileges in the field concerned are the usual accepted evidence of qualifications.

A satisfactory consultation includes examination of the patient, review of the chart, and a written report of the findings and recommendations signed, dated, and timed by the consultant which is made a part of the record. Pre-surgical consultation reports, at least in brief form, shall be recorded prior to the operation.

In circumstances of grave urgency or when consultation is required by rules of the Hospital, the Hospital President and/or designee shall at all times have the right to call in a consultant after conference with the Chief of Staff or an available member of the Medical Executive Committee.

SECTION 3.8 DISCHARGE

Patients shall be discharged only by order of the attending Physician or his/her covering Physician or appropriately credentialed AHP.

SECTION 3.9 BASIC RULES FOR THE USE OF HOSPITAL FACILITIES

The exercise of Privileges is contingent upon the Practitioner's abiding by the Medical Staff Bylaws, and other related Manuals, all applicable policies, and compliance with accreditation and regulatory requirements. Failure to do so may subject the Practitioner to corrective action in accordance with the process set forth in the Medical Staff Bylaws and other related Manuals.

SECTION 3.10 EMERGENCY DEPARTMENT ON-CALL PHYSICIANS

Appointees of the Medical Staff have an obligation to work with the Hospital administration to provide coverage of emergency medical conditions arising within or presenting to the Hospital as required by law. The Emergency On-Call list is developed by Medical Staff Services in conjunction with Hospital administration. Providers may be On-call at multiple network hospitals as long as there are plans to provide alternate coverage should more than one facility require emergent services at one time.

The Emergency On-Call list is intended to provide urgent and emergent consultation to patients either seeking care in the ED or within the Hospital and its affiliated units. Time constraints for urgent and emergent responses are further defined in Section 3.7. The call lists will be available on the Hospital Intranet.

If there are discrepancies, administrative or reimbursement concerns, the currently listed on-call Practitioner is responsible for the emergent needs of the patient first and deal with the non-clinical issues secondarily. If an on-call Practitioner is unavailable for duty on the day that they are specified for call, that individual is responsible to report to the Medical Staff Office and/or the Emergency Department a suitable on-call replacement Practitioner.

On-Call Practitioners must respond to emergency requests for evaluation in a timely fashion and provide stabilization and/or emergent definitive treatment as requested by the consulting Physician without regard to insurance status or payment capability. Emergency patients referred to the provider in the outpatient setting will also receive initial stabilizing care without regard to immediate payment capability.

If stabilization and/or definitive treatment of the patient's medical condition are not available within the current capabilities of the Hospital, the patient may be transferred to an appropriate facility upon certification by the physician that the medical benefits of the transfer outweigh the risks and that the transfer is in the best interest of the patient. An on-call Practitioner may not request that a patient be transferred to a second hospital for the Practitioner’s convenience. In the circumstance where needed services do exist at this facility, a patient or appropriate surrogate may still request a transfer to another Hospital. Transfer may occur only when that facility has verified availability of services and an accepting physician has been established. This process must be clearly documented in the medical record and on the appropriate COBRA Transfer form.

SECTION 3.11 SOURCES OF PATIENT CARE PROVIDED OUTSIDE HOSPITAL

The Medical Executive Committee will approve contractual sources of patient care provided by entities outside the Hospital. A written agreement defining the nature and scope of patient care will include providing care in a timely fashion and consistent performance of patient care processes according to appropriate

accreditation standards. Expectations for the performance of contracted services will be met by verification that all Practitioners who will be providing patient care, treatment and services have appropriate privileges by providing a copy of the list of privileges to the Hospital when requested. Written agreements will specify that the contracted organization will ensure that all contracted services provided by the Practitioners will be within the scope of their privileges. The written agreement will also include the expectation that consistent performance of patient care processes must be provided according to appropriate accreditation and regulatory standards.

SECTION 3.12 PROFESSIONAL LIABILITY ACTION

Each individual with Clinical Privileges at the Hospital will notify Medical Staff Services Department within thirty (30) days of a final settlement or judgment of a professional liability action.

SECTION 3.13 CONDUCT

Unprofessional and unethical conduct and the violation of this Organizational Manual or Hospital policy may be grounds for corrective action.

All Practitioners are required to abide by the Code of Conduct Policy and the terms of the Notice of Privacy Practices prepared and distributed to patients as required by the federal Health Insurance Portability and Accountability Act of 1996 regulations.

Violations in conduct will be evaluated and acted upon as delineated in the Bylaws.

SECTION 3.14 DISRUPTIVE MEDICAL STAFF MEMBER

The desired culture of the Medical Staff is to ensure professional behavior at all times that promotes patient safety and the delivery of competent quality care, fosters a congenial working environment, and does not disrupt the operations of the hospital. Any and all reports of disruptive behavior are taken seriously.

Disruptive behavior within the Hospital will be addressed in accordance with policies which are similar in goals for both Hospital employees and Practitioners. The intention of the Hospital administration and this Medical Staff is policies are enforced in a firm, fair and equitable manner. Any form of retaliation against the person(s) bringing complaint will not be tolerated.

Disruptive behavior by Medical Staff Practitioners will be dealt with by the Chief Medical Officer, Clinical Department Chair(s), and/or Chief of Staff. The report of the behavior will be documented, the incident investigated and appropriate actions will be taken. Collegial intervention is outlined in the Code of Conduct Policy and the corrective action procedure is set forth in the Bylaws. Behavior that creates a risk for immediate harm may result in summary

suspension of Medical Staff appointment and Clinical Privileges pending further investigation. As appropriate, the CMO may choose to involve the Hospital executive team when disruptive behavior poses risk to the Hospital. Consultation with the Wellness Committee and outside resources may also be utilized.

SECTION 3.15 COPYING OF MEDICAL STAFF FILES

All Medical Staff records (including those of Allied Health Professionals) are confidential, including but not limited to the credentialing files and anything used in the credentialing process, committees, services, and Medical Staff meeting minutes, reports and discussions and deliberations concerning this information. Such information shall be disclosed only to those persons and only for the purposes listed in the policy concerning Confidentiality of Medical Staff/AHP Records. Confidentiality must be maintained for subsequent use of the information, and is the responsibility of the person requesting the information and anyone receiving the information.

SECTION 3.16 RAPE EXAMINATIONS

Rape examination is a formal legal collection of evidence when the allegation of sexual assault has occurred. Emergency Department Physicians and nurses are specifically trained in this procedure. Patients presenting to the Emergency Department from the outpatient environment or the inpatient setting with a request for rape examination will be evaluated, evidence collected and medical treatment offered as dictated in the ED Policy Manual, as such manual may be amended from time to time. If a Sexual Assault Nurse Examiner ("SANE") professional is available, the evidence collection and exam may be deferred to that person. Medical treatment of injury or infection is addressed by the ED Physician or may be assumed by the patient's private Physician in attendance at the time of the evaluation.

SECTION 3.17 RESTRAINTS OR SECLUSION

The Medical Staff will minimize the use of physical and chemical restraints with proactive situation management. Should a need for short term restraint arise, the processes delineating their use are clearly outlined in Hospital policy.

SECTION 3.18 PRONOUNCEMENT OF DEATH

The pronouncement of death is a medical decision, which can be made only by a qualified Licensed Independent Practitioner (LIP). The LIP will make the final diagnosis of death based upon his/her assessment or the reporting of relevant signs by the nurse. If a physician is not available relevant signs verified by 2 Registered Nurses to be reported to the LIP are: absence of respirations, absence of blood pressure, absence of pulse, and absence of specific reflexes (i.e. Gag, blink, etc.). Documentation of physician's name, the reporting of the

above signs, and the time of pronouncement of death by the physician must be documented in the medical record (EPIC time of death smart phrase should be utilized to complete this documentation). If the LIP pronouncing the patient is not the patient's attending physician, the attending physician will be notified.

SECTION 3.19 USE OF INVESTIGATIONAL/EXPERIMENTAL DRUGS/DEVICES

A Practitioner must obtain Kettering Health Network ("KHN") Institutional Review Board ("IRB") approval prior to using any investigational/experimental drugs or devices for research studies or emergency use. Industry-sponsored research studies may be submitted to a KHN-approved central IRB for review. All IRB submissions begin initially with the KHN Innovation Center who will assist with preparation and submission to the IRB. Investigational/experimental drugs or devices are defined as any non-FDA approved drug/device or a drug/device used in a research study. IRB approval is for protection of patients' rights and does not imply credentials beyond those approved by the Medical Staff and Board. Requests for Privileges to perform investigational procedures shall be processed through the Hospital's usual credentialing and privileging process. The granting of Medical Staff Privileges for new procedures that are necessary to use investigational/experimental devices will follow the Medical Staff process for privileging described in the Credentials Policy Manual.

Research Studies: To obtain IRB approval of a research study of an investigational/experimental drug or device, contact KHN Innovation Center for assistance in preparing and submitting a protocol, informed consent form, and other required documents to the IRB Office for approval

Emergency Use: Emergency use is defined as the use of an investigational/experimental drug or device on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for its use. A written request, usually in letter form, that includes the risks, benefits, and consent, signed by the requesting Practitioner, stating the life-threatening situation or one-time need and, the absence of standard acceptable treatment, is submitted to the IRB Office with the assistance of the KHN Innovation Center. The IRB Chair or designee will review the request and approve or disapprove its use. In accordance with FDA Regulation 21 CFR 50.23 and CFR 56.104, the protocol and consent form are reviewed and approved by the IRB Committee within five (5) working days of initial approval. The standard guidelines for obtaining informed consent apply.

Patients currently on research protocols from the Hospital or other institutions who are admitted, must follow Pharmacy Department Policy, as such policy may be amended from time to time, covering investigational drug procedures.

When the IRB receives a request from a Practitioner for an emergency use of an investigational/experimental drug or device, the IRB must examine each case to assure itself and the Hospital that the emergency use was justified and compliant with FDA regulations 21 CFR 50.23 and CFR 56.104

SECTION 3.20 CANCER STAGING

All newly diagnosed cancers will be staged by the managing Physician (defined as the treating Physician, usually the surgeon, medical oncologist, or radiation oncologist) using the American Joint Commission on Cancer-TMN staging format or a format approved by the KHN Network Cancer Committee. The staging will be entered on a form adopted by the Cancer Committee and the completion of the staging will be required to complete the medical record on the patient. Cases that cannot be staged will include rationale on the staging form.

SECTION 3.21 FOCUSED PROFESSIONAL PRACTICE REVIEW

3.21.1 New Clinical Privileges

The performance and outcomes of each recipient of new clinical privileges (or reinstated clinical privileges, as determined appropriate by the medical executive committee) shall be monitored per hospital policy during a period of observation to determine current competence relative to the clinical privileges granted. The practitioner shall remain subject to such observation until the medical executive committee receives documentation of the results of the evaluation of the practitioner's performance and outcomes indicating that the practitioner meets all of the competency requirements relative to the clinical privileges under observation

3.21.2 Unexpected or Unacceptable Performance and/or Outcomes

Should concern arise as to the performance and/or outcomes of any practitioner holding clinical privileges, the medical executive committee shall assure that appropriate and adequate evaluation occurs per hospital policy to assure that the practitioner possesses and displays current competency relative to the clinical privileges in question.

SECTION 3.22 ONGOING PROFESSIONAL PRACTICE REVIEW

The performance outcomes of each practitioner holding clinical privileges shall be monitored per hospital policy on a routine basis to determine current competence relative to the clinical privileges held. Results of such evaluation shall be reported to the medical executive committee on a routine basis with appropriate intervention occurring as needed.

ARTICLE 4.
ADOPTION, AMENDMENT OR REPEAL

This Medical Staff Organization and Functions Manual may be adopted, amended, or repealed, in whole or in part, in accordance with the applicable provision set forth in the Medical Staff Bylaws.

CERTIFICATION OF ADOPTION AND APPROVAL

Adopted by the Medical Executive Committee on
January 11, 2019
Revision March 13, 2020

_____
Linda Reilman, MD
Chief of Staff

Approved by the Board of Directors on March 17, 2020
after receipt of a recommendation by the
Medical Executive Committee

_____
Ronald Connovich
President

SIGNED DOCUMENT KEPT IN MEDICAL STAFF OFFICE