Medical Staff Rules

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# Medical Staff Rules

## Rule 1 Appointment and Reappointment

### 1.1 Overview of Process

The following charts summarize the appointment, temporary privileges and reappointment processes. Details of each step are described in Rule 2.2 through Rule 2.9.

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<thead>
<tr>
<th>Person or Body</th>
<th>Function</th>
<th>Report to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Staff Coordinator</td>
<td>Verify application information</td>
<td>Credentials Committee (See Rule 2.7-1)</td>
</tr>
<tr>
<td>Credentials Committee</td>
<td>Review department's recommendation; review applicant's qualifications vis-à-vis Medical Staff bylaws general standards; recommend appointment and privileges</td>
<td>Department (See Rule 2.5)</td>
</tr>
<tr>
<td>Department</td>
<td>Review applicant’s qualifications vis-à-vis standards developed by department; recommend appointment and privileges</td>
<td>Medical Executive Committee (See Rule 2.7-2)</td>
</tr>
<tr>
<td>Medical Executive Committee</td>
<td>Review recommendations of department and Credentials Committee; recommend appointment and privileges</td>
<td>Governing Body (See Rule 2.7-3)</td>
</tr>
<tr>
<td>Governing Body</td>
<td>Review recommendations of the Medical Executive Committee; make decision</td>
<td>Final Action (See Rule 2.7-4)</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Person or Body</th>
<th>Function</th>
<th>Report to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Staff Coordinator</td>
<td>Verify key information</td>
<td>Department (See Rule 2.5 and Bylaws Section 5.5-2)</td>
</tr>
</tbody>
</table>
REAPPOINTMENT

<table>
<thead>
<tr>
<th>Person or Body</th>
<th>Function</th>
<th>Report to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Staff Coordinator</td>
<td>Verify reappointment information</td>
<td>[Department (See Rule 2.9-3)]</td>
</tr>
<tr>
<td>Department</td>
<td>Review applicant’s performance vis-à-vis standards developed by department; recommend appointment and privileges</td>
<td>Medical Executive Committee (See Rule 2.9-4)</td>
</tr>
<tr>
<td>Medical Executive Committee</td>
<td>Review recommendations of department Committee; recommend appointment and privileges</td>
<td>Governing Body (See Rule 2.9-5) or (See Optional Rule 2.9-5)</td>
</tr>
<tr>
<td>Governing Body</td>
<td>Review recommendations of the Medical Executive Committee; make decision</td>
<td>Final Action (See Rule 2.9-6)</td>
</tr>
</tbody>
</table>

1.2 Application

1.2-1 Each practitioner who expresses formal interest in a recognized and appropriate category of membership and privileges shall be provided an application form for Medical Staff membership. Upon completion by the practitioner, the form shall be returned to the Medical Staff office together with the nonrefundable application fee required by the rules.

1.2-2 The application form shall be approved by the Medical Executive Committee and the Governing Body and, once approved, shall be considered part of these rules. The application shall include an agreement to abide by the Medical Staff and hospital bylaws, rules and applicable policies. The application shall request information pertinent to the applicant’s qualifications, such as (but not limited to) information regarding the applicant’s education (including participation in continuing medical education), specialty training,
experience, abilities and current competencies, professional affiliations, proffered references (including the names and addresses of professional peers when possible from the same professional discipline as the applicant who will be able to attest in writing to the applicant’s relevant qualifications, experience, abilities and current competencies), relevant health status (as further described at Rule 2.3), as well as information regarding possible involvement in professional liability actions (including, but not limited to, all final judgments or settlements involving the applicant); previously completed or currently pending challenges involving professional licensure, certification or registration (state or district, Drug Enforcement Administration) or the voluntary relinquishment of such licensure, certification or registration; voluntary or involuntary termination, limitation, reduction or loss of Medical Staff or medical group membership and/or clinical privileges at any other hospital or health facility or entity; any formal investigation or disciplinary action at another hospital or health facility that was taken or is pending; and information detailing any prior or pending government agency or third party payor investigation, proceeding or litigation challenging or sanctioning the practitioner's patient admission, treatment, discharge, charging, charging, collection or utilization practices, including, but not limited to, Medicare or Medi-Cal fraud and abuse proceedings or convictions. The application shall also release all persons and entities from any liability that might arise from their investigating and/or acting on the application. Additionally, the practitioner shall provide the names and addresses of professional peers who are able to attest to the practitioner’s relevant qualifications.

1.3 Physical and Mental Capabilities

1.3-1 Obtaining Information

a. The application shall require the applicant to submit a statement attesting that no health problems exist that could affect his or her ability to perform the responsibilities of Medical Staff membership or exercise of requested clinical privileges. If the applicant does have a health condition and/or requires special accommodations with respect to a health condition, he/she shall provide information pertaining to his/her physical and mental health.

b. When the Medical Staff office verifies information and obtains references, it shall ask for any information concerning physical or mental status to be reported on a confidential form, which can be processed separately from the other information obtained regarding the applicant.

c. The Credentials Committee and MEC shall be responsible for assessing any practitioner who has or may have a physical or mental disability or condition that might affect the practitioner’s ability to exercise his or her requested privileges in a manner that meets the hospital and Medical Staff’s quality of care standards. This may include one or all of the following:

1. **Medical Examination:** To ascertain whether the practitioner has a physical or mental disability that might interfere with his or her ability to provide care which meets the hospital and Medical Staff’s quality of care standards.

2. **Interview:** To ascertain the condition of the practitioner and to assess if and how reasonable accommodations can be made.

d. Any practitioner who feels limited or challenged in any way by a qualified mental or physical disability in exercising his or her clinical privileges and in meeting quality of care standards should make such limitation immediately known to the Chief of Staff or CMO. Any such disclosure will be treated with the high degree of confidentiality that attaches to the Medical Staff’s peer review activities.

1.3-2 Review and Reasonable Accommodations
a. Any practitioner who discloses or manifests a qualified physical or mental disability or condition requiring accommodation will have his or her application processed in the usual manner without reference to the condition.

b. The Credentials Committee shall not disclose any information regarding any practitioner’s qualified physical or mental disability or condition until the Medical Executive Committee (or, in the case of temporary privileges, the Medical Staff representatives who review temporary privilege requests) has determined that the practitioner is otherwise qualified for membership and/or to exercise the privileges requested. Once the determination is made that the practitioner is otherwise qualified, the Credentials Committee may disclose information it has regarding any physical or mental disabilities or conditions and the effect of those on the practitioner’s application for membership and privileges. Any such disclosure shall be limited as necessary to protect the practitioner’s right to confidentiality of health information, while at the same time communicating sufficient information to permit the Medical Executive Committee to evaluate what, if any, accommodations may be necessary and feasible. The Well-Being Committee and any other appropriate committees may meet with the practitioner to discuss if and how reasonable accommodations can be made.

c. As required by law, the Medical Staff and hospital will attempt to provide reasonable accommodations to a practitioner with known physical or mental disabilities or conditions, if the practitioner is otherwise qualified and can perform the essential functions of the staff appointment and privileges in a manner which meets the hospital and Medical Staff quality of care standards. If reasonable accommodations are not possible under the standards set forth herein, it may be necessary to withdraw or modify a practitioner’s privileges and the practitioner shall have the hearing and appellate review rights described in Bylaws, Article 14, Hearings and Appellate Reviews.

1.4 Effect of Application
By applying for or by accepting appointment or reappointment to the Medical Staff, the applicant:

1.4-1 Signifies his or her willingness to appear for interviews in regard to his or her application for appointment.

1.4-2 Authorizes Medical Staff and hospital representatives to consult with other hospitals, persons or entities who have been associated with him or her and/or who may have information bearing on his or her competence and qualifications or that is otherwise relevant to the pending review and authorizes such persons to provide all information that is requested orally and in writing.

1.4-3 Consents to the inspection and copying, by hospital representatives, of all records and documents that may be relevant or lead to the discovery of information that is relevant to the pending review, regardless of who possesses these records, and directs individuals who have custody of such records and documents to permit inspection and/or copying.

1.4-4 Certifies that he or she will report any subsequent changes in the information submitted on the application form to the Chief of Staff, Chief Medical Officer and the Chief Executive Officer.

1.4-5 Releases from any and all liability the Medical Staff and the hospital and its representatives for their acts performed in connection with evaluating the applicant.

1.4-6 Releases from any and all liability all individuals and organizations who provide information concerning the applicant, including otherwise privileged or confidential information, to hospital representatives.

1.4-7 Authorizes and consents to hospital representatives providing other hospitals, professional societies, licensing boards and other organizations concerned with provider performance and the quality of patient
care with relevant information the hospital may have concerning him or her, and releases the hospital and hospital representatives from liability for so doing.

1.4-8 Consents to undergo and to release the results of a physical or mental health examination by a practitioner acceptable to the Medical Executive Committee, at the applicant’s expense, if deemed necessary by the Medical Executive Committee.

1.4-9 Signifies his or her willingness to abide by all the conditions of membership, as stated on the appointment application form, on the reappointment application form, and in the Bylaws and these Rules.

1.4-10 For purposes of this Rule 2.4, the term “hospital representative” includes the Governing Body, its individual Directors and committee members; the Chief Executive Officer, the Medical Staff, all Medical Staff department officers and/or committee members having responsibility for collecting information regarding or evaluating the applicant’s credentials; and any authorized representative or agent of any of the foregoing.

1.5 Verification of Information

The applicant shall fill out and deliver an application form to the Medical Staff office, which shall seek to verify the information submitted. Verification shall encompass, but is not limited to, written verification of peer references, licensure status, training and education, current proficiency with respect to the hospital’s general competencies (as applicable to the privileges requested), health status, other evidence submitted in support of the application, and confirmation that the practitioner is the same individual identified in the credentialing documents (by viewing a current, valid picture hospital ID card or a valid state or federal agency picture ID card). The application will be deemed complete when all necessary verifications have been obtained, including, but not limited to, current license, licensing board disciplinary records, specialty board certification status, National Practitioner Data Bank information, Drug Enforcement Administration certificate, if appropriate, verification of all practice from professional school through the present, current malpractice liability insurance and reference letters, verification of current proficiency in the Hospital’s general competencies (Bylaws, Section 5.2, Criteria for Privileges/General Competencies), and other evidence that the applicant submitted in support of his/her application. Additionally, the Medical Staff office may seek information from other relevant sources, such as the American Medical Association’s Physician Master file (for verification of a physician’s medical school graduation and residency completion), the American Board of Medical Specialties (for verification of a physician’s board certification), the Educational Commission for Foreign Medical Graduates (for verification of a physician’s graduation from a foreign medical school), the American Osteopathic Association Physician Database (for pre- and post-doctoral education), and the Federation of State Medical Boards Physician Disciplinary Data Bank (for all actions against a physician’s medical license). The Medical Staff office shall then transmit the application and all supporting materials to the Credentials Committee and to the Chief of each department in which the applicant seeks privileges.

1.6 Incomplete Application

1.6-1 If the Medical Staff office is unable to verify the information, or if all necessary references have not been received, or if the application is otherwise significantly incomplete, the Medical Staff office may delay further processing of the application, or may begin processing the application based only on the available information with a decision that further information may be considered upon receipt.

1.6-2 If the processing of the application is delayed for more than 60 days and if the missing information is reasonably deemed significant to a fair determination of the applicant’s qualifications, the affected practitioner shall be so informed. He or she shall then be given the opportunity to withdraw his or her application, or to request the continued processing of his or her application. If the applicant does not
respond within 30 days, he or she shall be deemed to have voluntarily withdrawn his or her application. If the applicant requests further processing, but then fails to provide or arrange for the provision within 45 days or any other date mutually agreed to when the extension was granted (whichever is later) of the necessary information that the practitioner could obtain using reasonable diligence, the practitioner shall be deemed to have voluntarily withdrawn his or her application.

1.6-3 Any application deemed incomplete and withdrawn under this rule may, thereafter, be reconsidered only if all requested information is submitted, and all other information has been updated.

1.7 Action on the Application

1.7-1 Credentials Committee Action
Upon receipt, the Credentials Committee shall review the application and supporting documentation, may personally interview the applicant, and, based upon the criteria for appointment (as applicable) described in the Bylaws, shall transmit to the Department Committee on the prescribed form a written recommendation as to staff appointment and clinical privileges.

1.7-2 Department Committee Action
The Department Committee shall review the application, the supporting documentation, the Credentials Committee's report and recommendations, and other such information available to it that may be relevant. The Department Committee or a subcommittee thereof may personally interview the applicant. The department shall then assess the applicant's health status, and determine whether the applicant is able to perform, with or without reasonable accommodation, the necessary functions of a member of the Medical Staff. The Department Committee shall then transmit to the Medical Executive Committee a recommendation as to staff appointment, and department affiliations and clinical privileges.

1.7-3 Medical Executive Committee Action
a. Preliminary Recommendation: At its next regular meeting after receipt of the department recommendation, the Medical Executive Committee shall consider all relevant information available to it. The Medical Executive Committee shall then formulate a preliminary recommendation as to whether the applicant meets the relevant criteria specified in Bylaws, Article 4, Procedures for Appointment and Reappointment (with respect to membership), and Article 5, Privileges (with respect to privileges).

b. Final Recommendation: Thereafter, a final recommendation shall be formulated, and the Medical Executive Committee shall forward to the Governing Body a written report and recommendations, as follows:

1. Favorable Recommendation: Favorable recommendations shall be promptly forwarded to the Governing Body together with the recommendation of the department as to staff appointment, and department affiliations and any special conditions to be attached to the appointment.

2. Adverse Recommendation: When the recommendation is adverse in whole or in part, the Chief of Staff shall immediately inform the practitioner by special notice, and he or she shall be entitled to such procedural rights as may be provided in Bylaws, Article 14, Hearings and Appellate Reviews. The Governing Body shall be generally informed of, but shall not receive detailed information and shall not take action on, the pending adverse recommendation until the applicant has exhausted or waived his or her procedural rights. (For the purposes of this section, an adverse recommendation by the Medical Executive Committee is as defined in Bylaws, Section 14.2, Grounds for Hearing.)

3. Deferral: The Credentials Committee, or Medical Executive Committee may defer its recommendation in order to obtain or clarify information, or in other special circumstances. A deferral must be followed up
within 60 days of receipt of information with a subsequent recommendation for appointment and privileges, or for rejection of staff membership.

1.7-4 Governing Body Action

a. On Favorable Medical Executive Committee Recommendation: The Governing Body shall adopt, reject or modify a favorable recommendation of the Medical Executive Committee, or shall refer the recommendation back to the Medical Executive Committee for further consideration, stating the reasons for the referral and setting a time limit within which the Medical Executive Committee shall respond. If the Governing Body's action is a ground for a hearing under the Bylaws, Section 14.2, Grounds for Hearing, the Chief Executive Officer shall promptly inform the applicant by special notice, and he or she shall be entitled to the procedural rights as provided in the Bylaws, Article 14, Hearings and Appellate Reviews.

b. Without Benefit of Medical Executive Committee Recommendation: If the Governing Body does not receive a Medical Executive Committee recommendation within the time specified in Rule 2.7-6, it may, after giving the Medical Executive Committee written notice and a reasonable time to act, take action on its own initiative. If such recommendation is favorable, it shall become effective as the final decision of the Governing Body. If the recommendation is a ground for a hearing under the Bylaws, Section 14.2, Grounds for Hearing, the Chief Executive Officer shall give the applicant special notice of the tentative adverse recommendation and of the applicant's right to request a hearing. The applicant shall be entitled to the Bylaws, Article 14, Hearings and Appellate Reviews, procedural rights before any final adverse action is taken.

c. After Procedural Rights: In the case of an adverse Medical Executive Committee recommendation pursuant to Rule 2.7-3 or an adverse Governing Body decision pursuant to Rule 2.7-4(a) or (b), the Governing Body shall take final action in the matter only after the applicant has exhausted or has waived his or her Bylaws, Article 14, Hearings and Appellate Reviews, procedural rights. Action thus taken shall be the conclusive decision of the Governing Body, except that the Governing Body may defer final determination by referring the matter back for reconsideration. Any such referral shall state the reasons therefore, shall set a reasonable time limit within which reply to the Governing Body shall be made, and may include a directive that additional hearings be conducted to clarify issues which are in doubt. After receiving the new recommendation and any new evidence, the Governing Body shall make a final decision.

d. Expedited Review: The Governing Body may use an expedited process for appointment, reappointment or when granting privileges when criteria for that process are met. The Governing Body may delegate this authority to any other committee of at least two voting members of the Governing Body; the decision regarding reappointment or privileging will then be reviewed by the Governing Body at its next regularly scheduled meeting. Expedited processing is generally not available if:

1. The practitioner or member submits an incomplete application;
2. The Medical Executive Committee's final recommendation is adverse in any respect or has any limitations;
3. There is a current challenge or a previously successful challenge to the practitioner's licensure or registration;
4. The practitioner has received an involuntary termination of Medical Staff membership or some or all privileges at another organization;
5. The practitioner has received involuntary limitation, reduction, denial, or loss of medical privileges;
6. There has been a final judgment adverse to the practitioner in a professional liability action.

1.7-5 Notice of Final Decision
A decision and notice to appoint shall include:

a. The staff category to which the applicant is appointed;
b. The department to which the practitioner is assigned;
c. The clinical privileges the practitioner may exercise; and
d. Any special conditions attached to the appointment.

If the decision is adverse, the notice to the applicant shall be by special notice, as further described in Bylaws, Section 14.3-1, Notice of Action or Proposed Action.

1.7-6 Guidelines for Time of Processing

All individuals and groups shall act on applications in a timely and good faith manner. Except when additional information must be secured, or for other good cause, each application should be processed within the following time guidelines:

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Time Frames for Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Staff Office</td>
<td>45 days after all necessary documentation is received</td>
</tr>
<tr>
<td>Credentials Committee</td>
<td>45 days after receiving application from Medical Staff Office</td>
</tr>
<tr>
<td>Department Committee</td>
<td>45 days after receiving application from Department Chief</td>
</tr>
<tr>
<td>Medical Executive Committee</td>
<td>45 days after receiving application from the department</td>
</tr>
<tr>
<td>Governing Body</td>
<td>45 days after receiving application from the Medical Executive Committee, except when the hearing and appeal rights of Bylaws, Article 14, Hearings and Appellate Reviews, apply</td>
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</table>

These time periods are guidelines and are not directives which create any rights for a practitioner to have an application processed within these precise periods. If action at a particular step in the process is delayed without good cause, the next higher authority may immediately proceed to consider the application upon its own initiative or at the direction of the Chief of Staff or the Chief Executive Officer.

1.8 Duration of Appointment

1.8-1 All new staff members shall be appointed to the provisional staff and subjected to a period of formal observation and review. Provisional appointments are not more than twelve months.

1.8-2 Reappointments to any staff category, other than provisional, shall be for a maximum period of two years, and shall be staggered throughout the year so as to enable thorough review of each member. Changes in staff category may be requested at any time during the reappointment period after requirements of provisional status are met.

1.9 Reappointment Process

1.9-1 Schedule for Reappointment

At least 120 days prior to the expiration date of each staff member’s term of appointment, the Medical Staff office shall provide the member with a reappointment form. Completed reappointment forms shall be
returned to the Medical Staff office at least 90 days prior to the expiration date. Failure, without good cause, to return the form shall result in automatic suspension or resignation as described in Rule 2.9-9.

1.9-2 Content of Reappointment Form

a. The reappointment form shall be approved by the Medical Executive Committee and the Governing Body and, once approved, shall be considered part of these rules. The form shall seek information concerning the changes in the member’s qualifications since his or her last review. Specifically, the form shall request an update of all of the information and certifications requested in the appointment application form, as described in Rule 2.2-2, with the exception of that information which cannot change over time, such as information regarding the member’s premedical and medical education, date of birth, and so forth. The form shall also require information as to whether the member requests any change in his or her staff status and/or in his or her clinical privileges, including any reduction, deletion or additional privileges. Requests for additional privileges must be supported by the type and nature of evidence which would be necessary for such privileges to be granted in an initial application.

b. If the staff member’s level of clinical activity at this hospital is not sufficient to permit the staff and board to evaluate his or her competence to exercise the clinical privileges requested, the staff member shall have the burden of providing evidence of clinical performance at his or her principal institution in whatever form as the staff may require.

c. In addition to completing the information requested on the reappointment form, the staff member shall submit his or her biennial dues.

1.9-3 Verification and Collection of Information

The Medical Staff shall, in timely fashion, seek to verify the additional information made available on each reappointment application and collect any other materials or information deemed pertinent by the Medical Executive Committee, the Credentials Committee, or Department Chief. The information shall address, without limitation:

a. Reasonable evidence of current ability to perform privileges that may be requested including, but not limited to, consideration of the member’s professional performance, judgment, clinical or technical skills and patterns of care and utilization as demonstrated in the findings of quality improvement, risk management and utilization management activities.

b. Participation in relevant continuing education activities.

c. Level/amount of clinical activity (patient care contacts) at the hospital.

d. Sanctions imposed or pending including, but not limited to, previously successful or currently pending challenges to any licensure or registration (state or district, Drug Enforcement Administration) or the voluntary relinquishment of such licensure or registration.

e. Health status including completion of a physical examination or psychiatric evaluation by a physician who is mutually accepted by the affected practitioner and staff, when requested by the Credentials Committee, Department Chief or Medical Executive Committee and subject to the standards set forth in Rule 2.3 pertaining to physical and mental capabilities.

f. Attendance at required Medical Staff department and committee meetings.

g. Participation as a staff officer and committee member/Chair.

h. Timely and accurate completion and preparation of medical records.

i. Cooperativeness and general demeanor in relationships with other practitioners, hospital personnel and patients.
j. Professional liability claim experience, including being named as a party in any professional liability claims and the disposition of any pending claims.

k. Compliance with all applicable Medical Staff and hospital bylaws, rules, and policies.

l. Professional references from at least one practitioner who is familiar with the member’s current qualifications by virtue of having recently worked with the member or having recently reviewed the member’s cases.

m. Any other pertinent information including the staff member’s activities at other hospitals and his or her medical practice outside the hospital.

n. Information concerning the member from the state licensing board and the federal National Practitioner Data Bank.

o. Information from other relevant sources, such as but not limited to the Federation of State Medical Boards Physician Disciplinary Data Bank.

The Medical Staff office shall transmit the completed reappointment application form and supporting materials to the Chief of the department to which the staff member belongs and to the Chief of any other department in which the staff member has or requests privileges.

1.9-4 Department Action
The Department Chief shall review the application and all other relevant available information. The Chief may confer with the Department Committee or the whole department, if there is no Department Committee. He or she shall transmit to the Medical Executive Committee his or her written recommendations, which are prepared in accordance with Rule 2.7-1.

1.9-5 Medical Executive Committee Action
a. The Medical Executive Committee shall review the Department Chief’s recommendations and all other relevant information available to it and shall forward to the Governing Body its favorable recommendations, which are prepared in accordance with Rule 2.7-3.

b. When the Medical Executive Committee recommends adverse action, as defined in the Bylaws, Section 14.2, Grounds for Hearing, either with respect to reappointment or clinical privileges, the Chief of Staff shall give the member special notice of the adverse recommendation and of the member’s right to request a hearing in the manner specified in the Bylaws, Section 14.3, Requests for Hearing. The member shall be entitled to the Bylaws, Article 14, Hearings and Appellate Reviews, procedural rights. The Governing Body shall be informed of, but not take action on, the pending recommendation until the member has exhausted or waived his or her procedural rights.

c. Thereafter, the procedures specified for members in Rule 2.7-4 (Governing Body action), Rule 2.7-5 (Notice of Final Decision) and in the Bylaws, Section 4.7, Waiting Period After Adverse Action, shall be followed. The committee may also defer action; however, any deferral must be followed up within 70 days with a recommendation.

1.9-6 Reappointment Recommendations
Reappointment recommendations shall be written and shall specify whether the member’s appointment should be renewed; renewed with modified membership category, department affiliation and/or clinical privileges; or terminated. The reason for any adverse recommendation shall be described. The Medical Staff may require additional proctoring of any clinical privileges that are used so infrequently as to make it difficult or unreliable to assess current competency without additional proctoring, and such proctoring requirements imposed for lack of activity shall not result in any hearing rights.
1.9-7 No Extension of Appointment
Except as provided in Bylaws, Limitations on Extension of Appointment, if the reappointment application has not been fully processed before the member's appointment expires, the staff member shall refrain from exercising his or her current membership status and clinical privileges until the reappointment review is complete.

1.9-8 Failure to File Reappointment Application
Failure to file a complete application for reappointment 90 days prior to the expiration of the appointment shall result in the automatic suspension of a practitioner’s privileges and prerogatives effective on the date the member's current appointment expires. Prior to suspension, the practitioner will be sent at least one letter by special notice warning of the impending suspension. If an application for reappointment is not submitted or completed as required before the appointment expires, the member shall be deemed to have resigned his or her membership in the Medical Staff, effective the date his or her appointment expires. Members who automatically resign under this rule will be processed as new applicants should they wish to reapply.

1.9-9 Relinquishment of Privileges
A staff member who wishes to relinquish or limit particular privileges shall send written notice to the Chief of Staff and the appropriate Department Chief identifying the particular privileges to be relinquished or limited. A copy of this notice shall be forwarded to the Medical Staff office for inclusion in the member's credentials file.
Rule 2 Standards of Conduct

2.1 Purpose
The purpose of this Rule is to clarify the provisions of Section 2.7 of the Medical Staff Bylaws, regarding expectations of all practitioners during any and all interactions with persons at the hospital, whether such persons are colleagues, other health care professionals, hospital employees, patients and/or other individuals. This Rule is intended to address conduct which does not meet the professional standards expected of Medical Staff members. In dealing with incidents of inappropriate conduct, the protection of patients, employees, practitioners and other persons at the hospital is the primary concern. In addition, the well-being of a practitioner whose conduct is in question is also of concern, as is the orderly operation of the hospital.

2.2 Examples of Inappropriate Conduct
Examples of common inappropriate conduct include, but are not limited to, the following:

2.2-1 Verbal abuse: Verbal abuse is usually in the form of vulgar, profane or demeaning language, screaming, sarcasm or criticism directed at an individual, having the intent or effect of lowering the recipient's reputation or self-esteem. It is often intimidating to the recipient, and often causes the recipient or others around him or her to become ineffective in performing their responsibilities (e.g., the individuals become afraid or unwilling to question or to communicate concerns, or to notify or involve either the involved practitioner or others when problems occur). This kind of conduct becomes disruptive at the point where it reaches beyond the bounds of fair professional comment or where it seriously impinges on staff morale.

2.2-2 Noncommunication: Refusal to communicate with responsible persons can be extremely disruptive in the patient care setting. This kind of behavior often results from individual fighting or feuding, or lack of trust. It becomes disruptive at the point where important information should be communicated, but is not. Closely related are incomplete or ambiguous communications. This becomes disruptive when it diverts patient care resources into having to devote substantial and unnecessary time obtaining follow-up clarification.

2.2-3 Refusal to return calls: Refusing to return telephone calls from the facility staff can be another form of the problem. Often this type of behavior is a result of what a practitioner feels are repeated, inappropriate phone calls from the facility's staff. However, unless a phone call is returned, the practitioner cannot know the urgency of the matter. The problem becomes disruptive at the point where patient care is placed in unnecessary jeopardy, or when matters that were not initially urgent, and needn't have become urgent, become so as a result of a refusal to return calls.

2.2-4 Inappropriate communication: It is inappropriate to criticize the facility, its staff, or professional peers outside of official problem-solving and peer review channels. This includes written or verbal derogatory statements to an inappropriate audience, such as patients and families, or statements placed in the medical records of patients. These kinds of communications indiscriminately undermine morale and reputation of the facility and its staff, and contribute to inaccurate perceptions of facility quality.

2.2-5 Failure to comply: Failure to comply with the bylaws, policies and procedures of the Medical Staff and the facility can be inadvertent, or it can be willful. Willful failure to comply — i.e., refusal to comply — with rules
becomes disruptive at the point that it places the Medical Staff or the facility in jeopardy with respect to licensing or accreditation requirements, complying with other applicable laws, or meeting other specific obligations to patients, potential patients and facility staff. Specific examples include:

a. Refusing to provide information or otherwise cooperate in the peer review process (e.g., refusing to meet with responsible committee members, refusing to answer reasonable questions relevant to the evaluation of patient care rendered in the facility, especially when coupled with an attitude that the responsible committee has no right to be questioning or examining the matter at hand).

b. Refusing to provide information necessary to process the facility's or a patient's paperwork. The facility, its patients and their families have a right to expect timely and thorough compliance with all requirements of the facility, third party payors, regulators, etc., as necessary to assure smooth functioning of the facility and that patients receive the benefits to which they are entitled.

c. Violating confidentiality rules — e.g., disclosing confidential peer review information outside the confines of the formal peer review process. This has the effect of undermining the peer review process, and jeopardizing important protections that often serve as inducements to assuring ongoing willingness to participate in peer review activities.

d. Refusing to comply with established protocols and standards, including, but not limited to, utilization review standards. Here, it is recognized that from time to time established protocols and standards may not adequately address a particular circumstance, and deviation is necessary in the best interests of patient care. However, in such circumstances, the member will be expected to account for the deviation, and in appropriate circumstances, to work cooperatively and constructively toward any necessary refinements of protocol or standards so as to avoid unnecessary problems in the future.

e. Refusing to participate in or meet Medical Staff obligations can be disruptive when it reaches the point that the individual's refusal obstructs or significantly impairs the ability of the Medical Staff to perform its delegated responsibilities — all of which, in the final analysis, are aimed at facilitating quality patient care.

f. Repeatedly abusing or ignoring scheduling policies, or reporting late for scheduled appointments, surgeries, and treatments, resulting in unnecessary delays in or hurrying of patient care services being rendered to any patient of the facility.

g. Sexual harassment — unwelcome comments or contacts of a sexual nature or characterized by sexual overtones, whether overt or covert, are both illegal and disruptive.

2.2-6 Physical abuse: Offensive or nonconsensual physical contact would generally be deemed disruptive, as would intentional damage to facility premises or equipment.

2.2-7 Threatening behavior: Threats to another's employment or position, or otherwise designed to intimidate a person from performing his or her designated responsibilities or interfering with his or her well-being are generally disruptive. Examples include threats of litigation against peer review participants or against persons who report concerns in accordance with established reporting channels, and threats to another's physical or emotional safety or property.

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2 This is not to suggest that individual staff members should not speak up if they feel there are shortcomings in other's performance or in the quality of care being rendered in the facility that are not being effectively responded to by the individual(s) in charge. In such instances, the proper reporting would be to the next higher step in the process (e.g., if a supervisor is not effectively dealing with a matter, the Medical Director or facility administrator should be notified; if the Medical Director is not effectively dealing with a matter, the Governing Body's designated representative (usually the CEO) should be contacted; if the CEO is not effectively dealing with a matter, the Chair of the Governing Body should be contacted. All contacts should be factual and professional.
2.2-8 **Combative behavior:** Combative behavior refers to that which is constantly challenging, verbally or physically, legitimate and generally recognized authority or generally recognized lines of professional interaction and communication. It becomes disruptive at the point that it results in an inability to acknowledge or to deliver constructive comments and criticism.

2.3 Procedures

2.3-1 **Reporting:** Any person may report potentially disruptive conduct in accordance with the hospital’s usual reporting procedures. The Medical Staff office or other appropriate recipient of a disruptive conduct complaint shall submit each report to the Chief of Staff or Chief Medical Officer for assessment. The Chief of Staff and Chief Medical Officer may agree to delegate the assessment and any action to an appropriate committee.

2.3-2 **Assessment**

a. The Chief of Staff and Chief Medical Officer, or designated committee, shall ensure that appropriate documentation of each incident of disruptive conduct is acquired in order to facilitate the assessment process. Such documentation should include:

1. Date, time and location of the reported disruptive behavior.
2. A statement by the reporting individual of whether the behavior involved a patient in any way, and, if so, information identifying the patient involved.
3. The reporter’s account of the circumstances that precipitated the situation.
4. A factual and objective description of the reported disruptive behavior.
5. To the extent known to the reporter, the consequences, if any, of the disruptive behavior as it relates to patient care or hospital operations.
6. The names of other witnesses to the incident.
7. A record of any action taken to address the situation, prior to the Medical Staff’s assessment as required by the Code of Conduct, including the date, time, place, action and name(s) of those taking such an action.
8. Name and signature of the individual reporting the complaint.

b. The Chief of Staff and Chief Medical Officer, or designated committee, shall conduct an appropriate assessment for each matter reported.

c. If the report of inappropriate conduct is anonymous, then, the Chief of Staff and Chief Medical Officer, or designated committee, shall exercise discretion as to whether or not to assess the matter.

d. The assessment shall take place within 21 calendar days from receipt of a report of inappropriate conduct.

e. The practitioner shall be advised that any retaliation against the reporting person, whether the identity is disclosed or not, will be grounds for immediate disciplinary action pursuant to these Bylaws.

2.3-3 **Action**

a. **Unfounded Report:** Based on the assessment, the Chief of Staff and Chief Medical Officer, or designee shall dismiss any unfounded report by providing a written explanation of the evidence supporting this conclusion. The report shall be maintained in the Medical Staff member’s file with the original complaint. The individual who initiated the report of the decision shall be notified of the decision.
b. **Confirmed Report:** A confirmed report will be addressed as follows: The Chief of Staff and Chief Medical Officer, or designee, shall consider a number of variables to determine how best to address each incident of disruptive behavior. These variables shall include, but not be limited to:

1. Degree of disruptiveness
2. Number of incidents (i.e., pattern of disruptive behavior over time)
3. Length of time between incidents of disruptive behavior, if multiple incidents have occurred.
4. A single, confirmed incident warrants a discussion with the offending practitioner, the Chief of Staff, Chief Medical Officer or designee shall initiate such discussion and emphasize that such conduct is inappropriate and must cease. The initial meeting should be an attempt to be educational and helpful to the practitioner.

c. **Plan for Addressing Disruptive Behavior:** Relying on the variables described above as well as the overall intent of Bylaws, Section 2.7, Standards of Conduct, the Chief of Staff and Chief Medical Officer, or the designated committee, shall document a plan for addressing the disruptive behavior. The copy of the plan shall be included in the individual's file. The plan shall include item (1) below and may include any portion or all of items (2) and (3) below:

1. The Chief of Staff and Chief Medical Officer, or designee, shall send a letter to the offending individual that describes the inappropriate conduct, explains that the behavior is in violation of Bylaws, Section 2.7, Standards of Conduct, notes any patient care or hospital operations implications, explains why the behavior in question is inappropriate, encourages the individual to be more thoughtful or careful in the future, invites the individual to respond, and makes clear that attempts to confront, intimidate, or otherwise retaliate against the individuals who reported the behavior in question is a violation of this Rule and grounds for further disciplinary action. A copy of Bylaws, Section 2.7, Standards of Conduct, and this Rule should be included with the letter. Documentation of both the letter and the individual’s response should be included in the individual’s file.

2. The Chief of Staff and Chief Medical Officer or the designated committee, and any other number of appropriate participants from the Medical Staff and Governing Body, shall initiate a discussion with the offending individual to discuss the inappropriateness of his or her behavior and require that such behavior cease. A copy of Bylaws, Section 2.7, Standards of Conduct, and this Rule may be hand delivered to the offending individual and he or she should be advised that the Medical Staff requires compliance with the Bylaws. Each individual or a designated member of a group, (if the group meets with the offending individual), shall send a follow-up letter documenting the content of the discussion and any specific actions the offending individual has agreed to perform. The offending individual should be invited to respond. This letter and any response will be included in the individual’s file.

3. The plan may incorporate additional components, including, but not limited to:
   
   i. Warning the offending individual that failure to abide by the terms of the Standards of Conduct shall be grounds for disciplinary action including, but not limited to, suspension and/or actual termination of Medical Staff membership.

   ii. Notifying one or all of the following individuals of the member’s disruptive behavior and any relevant history relating to the member: Chief of Staff, Medical Executive Committee and Chief Executive Officer.

   iii. Requiring the offending individual to agree to specific corrective actions aimed at eliminating that individual's disruptive behavior. Suggested actions are counseling, leave of absence, written apologies, courses or programs specific to the behavior trait (i.e., anger management), or requiring the offending
individual to sign a behavior modification contract. The Chief of Staff, Chief Medical Officer or designated committee shall document any corrective action and require the offending individual to sign his or her acceptance of this plan. The plan may clearly delineate the consequences for the offending individual not successfully completing the agreed upon corrective action.

iv. In appropriate circumstances, the plan may provide for immediate suspension and/or action to terminate Medical Staff membership without need of further warning or counseling.

2.3-4 **Final Warning:** If the Chief of Staff, Chief Medical Officer, or designated committee determines that the plan has been unsuccessful, the Medical Executive Committee shall be informed in writing of the offending individual’s disruptive behavior, including any relevant history regarding this behavior, and advise the Medical Executive Committee to proceed with a final warning. If the Medical Executive Committee determines that the offending individual deserves a final warning, the Chief of Staff/designee or CMO/designee shall meet with and advise the offending individual that the disruptive behavior in question is intolerable and must stop. The Chief of Staff/designee or CMO/designee will inform the individual that a single recurrence of disruptive behavior shall be sufficient cause to result in his/her suspension and/or termination of Medical Staff membership. This meeting shall not be a discussion, but rather will constitute the offending individual’s final warning. The offender will also receive a follow-up letter that reiterates the final warning and the consequence of suspension and possible termination of Medical Staff membership and privileges.

2.3-5 **Suspension:** If after the final warning the offending individual engages in disruptive behavior that is deemed to require intervention, the individual’s Medical Staff membership and privileges shall be subject to suspension consistent with the terms of the Medical Staff Bylaws and policies and procedures. Additional action may also be taken at this time. Action may be taken to revoke the individual’s membership and privileges. The individual may also be found ineligible to reapply to the Medical Staff for a period of at least two years.

2.3-6 **Consequences of a Member’s Failure to Comply with the Standards of Conduct:** Members who do not act in accordance with the Standards of Conduct shall be subject to corrective action and/or disciplinary action, up to and including termination of membership and privileges, pursuant to the Bylaws. Any recommendation to restrict, or restriction of Member’s membership or privileges shall entitle the member to the medical disciplinary or administrative hearing procedures set forth in the Bylaws.
Rule 3 Committees

3.1 Committees
The Medical Staff hereby establishes the following committees. The rules applicable to each committee are set forth in the corresponding appendix.

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Appendix 3A Ethics Committee

1. Composition
The Ethics Committee shall be composed of at least the following voting members: three practitioners, one of whom should be a psychiatrist or psychologist, one registered nurse, one medical social worker (or a comparable discipline), one member of hospital administration, one non-hospital local community member at large. Additional members may be appointed by the Chief of Staff.

2. Duties
The Ethics Committee shall strive to contribute to the quality of health care provided by the hospital by:

   a. Providing assistance and resources for decisions which have bioethical implications. The Bioethics Committee shall not, however, be a decision-maker in any case.

   b. Educating members within the hospital community concerning bioethical issues and dilemmas.

   c. Facilitating communication about ethical issues and dilemmas among members of the hospital community, in general, and among participants involved in bioethical dilemmas and decisions, in particular.

   d. Retrospectively reviewing cases to evaluate bioethical implications, and providing policy and education guidance relating to such matters.

3. Meetings
The Ethics Committee shall meet as often as necessary, but at least annually.
Appendix 3B Blood Usage Committee

1. Composition

The Blood Usage Committee shall consist of those medical staff members and ancillary support personnel as appointed by the Chief of Staff.

2. Duties

The duties of the Blood Usage Committee shall include:

a. Conducting a review of the use of each category of blood and blood components to identify single cases or patterns of cases that require more intensive evaluation; and/or through evaluation of a single case or of a group of cases. Screening criteria are utilized. An adequate number of cases is used in the process. Consideration shall be given to high volume, substantial risk to patients, and/or are thought or known to be problem prone usage;

b. the evaluation of confirmed transfusion reactions;

c. the development or approval of policies and procedures relating to the distribution, handling, use, and administration of blood and blood components;

d. the review of ordering practices for blood and blood components; and

e. the review of the adequacy of the Blood Bank to meet the needs of patients.

3. Meetings

The committee shall meet at least quarterly.
Appendix 3C Bylaws Committee

1. Composition
The Bylaws Committee shall include Chief of Staff, the Chief of Staff Elect, Immediate Past-Chief, and the CMO. Additional members may be appointed by the Medical Executive committee.

2. Duties
The duties of the Bylaws Committee shall include:

a. Conducting a review of the Medical Staff Bylaws, as well as the Rules at least every two years;
b. Receiving and evaluating suggestions for modification of the Medical Staff Bylaws, as well as the Rules;
c. Submitting recommendations to the Medical Executive Committee for changes in these documents as necessary to reflect current Medical Staff practices; and
d. Assuring that the Bylaws and Rules comply with applicable laws, regulations, and accreditation standards, and that they adequately and accurately describe the current structure of the Medical Staff, including, but not limited to:
   1) Establishing and enforcing criteria and standards for Medical Staff membership and clinical privileges, as well as the mechanisms for doing so;
   2) Establishing and enforcing clinical criteria and standards to oversee and manage quality improvement and assessment, utilization review, and other Medical Staff activities, including procedures for meetings of the Medical Staff and its committees and departments and review and analysis of patient medical records; as well as procedures for evaluating and revising such activities;
   3) The mechanism for terminating Medical Staff membership;
   4) The fair hearing and appeal procedures;
   5) Provisions for assessing Medical Staff dues and utilizing the Medical Staff dues as appropriate for the purposes of the Medical Staff;
   6) Provisions respecting the Medical Staff’s ability to retain and be represented by independent legal counsel at the expense of the Medical Staff; and
   7) Provisions requiring a physical examination and medical history to be completed within the time frames established by state hospital licensing regulations and federal Medicare law.

3. Meetings
The committee will meet as requested by the Bylaws Committee Chair or Chief of Staff.
Appendix 3D Cancer Committee

1. Composition
The Cancer Committee shall be multi-disciplinary, including members from the specialties of surgery, internal medicine, gynecology, pediatrics, diagnostic and therapeutic radiology, pathology, and family practice. The committee must also include representatives of hospital administration, nursing, social services, rehabilitation and the cancer registry.

2. Duties
The duties of the Cancer Committee are to:
   a. Make certain that educational programs address major cancer issues.
   b. Evaluate the quality of care given patients with cancer and report as necessary to assure that the results of such evaluations are incorporated into the hospital-wide quality assessment and improvement systems.
   c. Supervise the cancer data system.
   d. Appoint Cancer Committee members to act as registry physician advisors.
   e. Educate hospital and Medical Staff members and patients about cancer prevention, detection and treatment.

3. Meetings and Reporting
The committee shall meet as often as necessary, but no less than quarterly.
Appendix 3E Credentials Committee

1. Composition
The Credentials Committee shall be composed of at least seven (7) members of the active staff so selected as to ensure representation of the major specialties, and the CMO or his or her designee. The Secretary and Treasurer of the Medical Staff shall serve on the Credentials Committee. The other members of the Credentials Committee will serve on the Committee for two years, with two members appointed each year.

2. Duties
The Credentials Committee shall evaluate or coordinate the evaluation of the qualifications of all applicants for Medical Staff appointment. The committee shall develop recommendations based on its and the responsible departments’ evaluations of each applicant. The Credentials Committee may request a personal interview with the candidate.

3. Meetings
The Credentials Committee shall meet as often as necessary, but at least quarterly.
Appendix 3F

Department Committees

1. Composition
Each department shall have a committee consisting of the departmental chief, the chief-elect and others as established in the Rules and Regulations of each department.

2. Duties
The Department Committees shall assist the Department Chief to carry out the responsibilities assigned to the Department Chief, including the duties to recommend professional criteria for clinical privileges within the department, review applicants for appointment, reappointment, and clinical privileges, and to fulfill the responsibility for peer review. The Department Committees shall also fulfill the medical assessment and treatment, use of medications, use of blood and blood components, operative and other procedures, efficiency of clinical practice patterns, monitoring of departures from established clinical patterns, patients’ and families’ education, coordination of care, and medical records and functions.

3. Meetings
Each Department Committee shall meet as often as necessary, but at least quarterly.
Appendix 3G

Infection Control Committee

1. Composition
a. The Infection Control Committee shall be composed of at least five (5) members of the Medical Staff (to assure representation of Medicine, OB/GYN, Pediatrics and Surgery Departments and infectious disease, the Pathologist, Infection Control Nurse, a representative from Administration, and a representative from Nursing Service.

Representatives from the following areas shall be available on a consultative basis and invited to participate as needed or others as deemed necessary by the Chairman: Central Supply, Operating Room, Dietary, Maintenance, Housekeeping and Pharmacy. The chairman of the Infection Control Committee shall be a physician qualified by training or experience to carry out his/her responsibilities.

2. Duties
The Infection Control Committee shall develop and monitor the hospital’s infection control program and the staff’s treatment of infectious disease, including review of the clinical use of antimicrobials. The committee shall approve action to prevent or control infections and the infection potential among patients and hospital personnel. The committee shall ensure that the hospital’s infection control plan links with external support systems and with communitywide agencies as they relate to reduction of risk from the environment. The committee shall ensure that appropriate resources are available for infection control activities. The committee shall also assure that the results of infection control studies and reviews are incorporated into the hospital’s educational programs and into the hospital’s quality assessment and improvement activities. At least every two years, the committee shall review and approve all policies relating to the infection control program. The Chair or his or her designee shall be available for on-the-spot interpretation of applicable rules.

3. Meetings
The Infection Control Committee shall meet not less than quarterly.
Appendix 3H Institutional Review Board

1. Composition

a. Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the entity. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

b. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution’s consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

c. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

d. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

e. No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

f. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

2. Duties

a. The IRB must adopt and follow written procedures for carrying out the duties imposed by the HHS and FDA regulations, including procedures for:

   1) Conducting its initial and continuing review of approving research and for reporting its findings and actions to the investigator and to the institution.

   2) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

   3) Assuring prompt reporting to the IRB of proposed changes in a research activity, and for assuring that changes in approved research, during the period for which IRB approval was already given, may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.
4) Assuring prompt reporting to the IRB and institutional officials of unanticipated problems involving risks to subjects or others.

5) For research subject to HHS or FDA regulations, assuring prompt reporting of unanticipated problems involving risks to subjects or others by filing reports with the appropriate federal agency.

6) Assuring timely reporting to the appropriate institutional officials of: (i) any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB and (ii) any suspension or termination of IRB approval. For research subject to the HHS and FDA regulations, these reports must also be made to HHS, or to the FDA, as appropriate.

7) Except when an expedited review procedure is used, the IRB shall review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concern is in nonscientific areas. This review must be conducted in accordance with the provisions set forth in Paragraph 2.b. below. In order for the research to be approved, it must meet the criteria set forth in federal regulations and it must receive the approval of a majority of those members present at the meeting. Research which is approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution, but such review is not required. However, those officials may not approve any research subject to the federal regulations if it has not been approved by an IRB.

b. The Institutional Review Board shall:

1) Review and have authority to approve, require modifications in (to secure approval) or disapprove all research activities covered by HHS, FDA or state law and regulations.

2) Require that information given to subjects as part of the informed consent process complies with the provisions of the applicable law or regulations. The IRB may require that information, in addition to that specifically mentioned in the law or regulations, be given to the subjects when, in the IRB’s judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

3) Require documentation of informed consent or waive documentation in accordance with the provisions of applicable law or regulations.

4) Notify the investigator and the institution in writing of its decision to approve or disapprove a proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

5) Conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and have authority to observe or have a third party observe the consent process and the research.

6) Have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of all the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate institutional officials and appropriate regulatory authorities.

3. Meetings

The IRB shall meet as often as needed, but at least annually.
Appendix 3I Interdisciplinary Practice Committee

1. Composition
The Interdisciplinary Practice Committee (IPC) shall have an equal number of Medical Staff members and nursing staff members. It shall include a representative from the nursing administration. In addition, representatives of the categories of Allied Health Professionals (AHPs) granted privileges in the hospital should serve as consultants on an as-needed basis and shall participate, when available, in the committee proceedings when a member of the same specialty is applying for privileges.

2. Duties
   a. Standardized Procedures
      1) The IPC shall develop and review standardized procedures that apply to nurses or AHPs; identify functions that are appropriate for standardized procedures and initiate such procedures; and review and approve standardized procedures.
      2) Standardized procedures can be approved only after consultation with the Medical Staff department involved and by affirmative vote of the administrative representatives, a majority of physician members, and a majority of nurse members.
   b. Credentialing Allied Health Professionals
      1) The IPC shall recommend policies and procedures for expanded role privileges for assessing, planning and directing the patients’ diagnostic and therapeutic care.
      2) The IPC shall review AHPs’ applications and requests for privileges and forward its recommendations and the applications on to the appropriate clinical department.
      3) The IPC shall participate in AHP peer review and quality improvement. It may initiate corrective action when indicated against AHPs in accordance with the Medical Staff Bylaws, these Rules or guidelines governing AHPs.
      4) The IPC shall serve as liaison between AHPs and the Medical Staff.
   c. Education
      The IPC shall assure that appropriate ongoing educational programs are developed and implemented addressing issues of interest to the AHP staff.

3. Meetings
The IPC shall meet as often as needed, but at least quarterly.
Appendix 3J Library Committee

1. Composition
The Library Committee shall consist of three (3) members of the Medical Staff.

2. Duties
The Library Committee shall be responsible for recommending books and periodicals for, and the orderly maintenance of, the Medical Library.

3. Meetings
The committee shall meet at least annually and submit a report to the Executive Committee.
Appendix 3K Medical Records Committee

1. Composition
The Medical Records Committee shall consist of at least three (3) members of the Medical Staff, one of whom shall be the Director of the Residency Program or designee, and representatives from medical records, nursing staff, administration, and others as deemed necessary.

2. Duties
The duties of the Medical Records Committee are to:

a. Review the quality of medical records for clinical pertinence or quality of documentation and timely completion.

b. Assess that medical records reflect the diagnosis, results of diagnostic tests, therapy rendered, condition of in-hospital progress of the patient, and condition of the patient at discharge; and

c. Review the summary information regarding the timely completion of all medical records.

3. Meetings
The committee shall meet at least quarterly.
Appendix 3L Oversight Committee

1. Composition
The Oversight Committee shall be comprised of two members of the Board of Supervisors of Ventura County, the Administrator of the hospital, ambulatory care and behavioral health the HCA Director, the Chief of Staff, and the Medical Directors of the hospital, ambulatory care and behavioral health. It is a joint committee of the Board of Supervisors and the Medical Staff of Ventura County Medical Center.

2. Duties
The duties of the Oversight Committee are to:

a. Carry out the duties and responsibilities of the Governing Board (Board of Supervisors) and serving as liaison between the Medical Staff of Ventura County Medical Center, the Administration of Ventura County Medical Center and the Governing Board;

b. Serve further as a focal point for furthering understanding of the roles, relationships and responsibilities of the Governing Board, Hospital Administration and the Medical Staff;

c. Serve as a forum for discussing any hospital matters regarding the provision of patient care that required or would be aided by effective communication among the Governing Board, Hospital Administration and the Medical Staff.

3. Meetings
The committee shall meet at least quarterly, or as often as necessary to fulfill its responsibility.

Any member of the Committee shall have the authority to place matters on the agenda for consideration by the full Committee.
Appendix 3M Pharmacy & Therapeutics Committee

1. Composition

The Pharmacy and Therapeutics Committee function shall consist of at least five (5) members of the Medical Staff as well as the chief pharmacist, or his designee, a representative of the hospital administration as an ex-officio member, and a member of the Nursing Department as a consultant.

2. Duties

   a. the development or approval of policies and procedures relating to the selection, distribution, handling, use and administration of drugs and diagnostic testing materials, including nursing floors, the emergency department, radiology, anesthesiology, operating room, etc.;

   b. the development and maintenance of drug formulary or drug list;

   c. the definition and review of drug reactions; and

   d. drug usage review, which shall include the routine collection and assessment of information in order to identify opportunities to improve the use of drugs and to resolve problems in their use. Review may include the use of objective criteria to identify, for more intensive evaluation, problems in or opportunities to improve the use of a specific drug or category of drugs.

   e. Specific drugs for review shall include:

      1. high volume
      2. post a substantial risk to patients
      3. are thought or known to be problem prone; and/or
      4. are a critical component of the care provided for a specific diagnosis, condition or procedure.

3. Meetings

The Pharmacy and Therapeutics Committee shall meet at least quarterly and submit a report to the Executive Committee.
Appendix 3N

Performance Improvement Coordination Council (P.I.C.C.)

1. Composition

The PICC is composed of representatives from Administration, Nursing, and the Medical Staff, of which at least twenty-five percent (25%) shall be Medical Staff members. Medical Staff members are department Chiefs-Elect as well as others involved in the delivery of general medical care, ambulatory care and behavioral health care. The administrative and nursing leaders from these areas also serve on the Council.

2. Duties

a. The Performance Improvement Coordinating Council (PICC) is an organization-wide committee.

b. The Medical Staff is committed to participate in the Performance Improvement (P.I.) process, and the department chiefs and chiefs-elect have the overall responsibility to help implement the plan. This is accomplished by combining the oversight function of the elected departments with the ongoing and daily responsibilities of the service directors.

c. Physician directors of the ancillary departments are responsible for the PI process in their respective services. When appropriate, the functional responsibility to carry out the implementation may be delegated to the clinical managers of the ancillary departments or services.

d. The P.I.C.C. will evaluate the organization-wide activities and prioritize interdisciplinary, interdepartmental programs requiring further assessment.

e. The P.I. activities of the ancillary departments are documented and reported.

f. Regular reports of the Council (at least annually) are made to the Governing Board. Summary reports of such activities are presented to the Executive Committee and the Oversight Committee.

3. Meetings

The Council meets at least quarterly and reviews and assigns items of quality improvement.
Appendix 30

Utilization Review Committee

1. Composition
The committee shall consist of at least two members of the active staff, and representatives from utilization review, medical records, nursing, and a resident.

2. Duties
The Utilization Review Committee shall perform the following functions:

   a. General Duties
      Oversees the review of the medical necessity for admissions, extended stays and services rendered. The committee addresses over-utilization, under-utilization, and inefficient scheduling and use of resources. Patterns of care will be followed, and focused review may be undertaken as deemed necessary. They shall also work toward maintaining continuity of care upon discharge. The committee shall communicate pertinent data and results of review to the Medical Executive Committee and shall make recommendations for the utilization of resources and facilities commensurate with quality patient care and safety.

   b. Utilization Review Plan
      The committees shall establish and follow a Utilization Review Plan which shall be approved by the Medical Executive Committee and Governing Body, and shall comply with applicable federal and state regulations.

   c. Continuity of Care
      The committee shall promote continuity of care upon discharge and supervise the accumulation of data on the availability of health care resources outside the hospital.

   d. Education
      The committee shall assure that the overall results of quality improvement activities are used to guide educational programs throughout the hospital.

3. Meetings
The committees shall meet regularly, at least quarterly. The committee shall report matters pertaining to quality improvement to the Quality Improvement Committee as well as the Medical Executive Committee.
Appendix 3P Well-Being Committee

1. Composition
   a. The Well-Being Committee shall be composed of no fewer than three active Medical Staff members, a majority of whom, shall be physicians and one of whom should be a psychiatrist or psychologist whenever possible.
   b. Except for initial appointments, each member shall serve a term of three years. Insofar as possible, members of this committee shall not actively participate on other peer review or Quality Improvement Committees while serving on this committee. There is no limit to the number of terms that one may serve.

2. Duties
   a. The Well-Being Committee is charged to develop a process that provides education about physician health, addresses prevention of physical, psychiatric or emotional illness, and facilitates confidential diagnosis, treatment and rehabilitation of practitioners who suffer from a potentially impairing condition. These processes should include mechanisms for the following:
      1) Self-referral by a practitioner, and referral by other Medical Staff and hospital staff.
      2) Upon its own initiative, upon request of the involved practitioner, or upon request of a Medical Staff or department committee or officer, providing such advice, counseling or referrals to appropriate professional internal or external resources for diagnosis and treatment of the condition or concern.
      3) Assisting the Chief of Staff or Chief Medical Office in evaluating the credibility of a complaint, allegation or concern, including such assessment as reasonably deemed necessary.
      4) Monitoring the affected practitioner and the safety of patients until the rehabilitation or any corrective action process is complete; and in the event the member fails to complete a required rehabilitation program, informing the Medical Executive Committee so that need for other appropriate actions may be assessed.
      5) Confidentiality with respect to the affected member; however, if the committee receives information that demonstrates that the health or impairment of a Medical Staff member may pose a risk of harm to hospital patients (or prospective patients), that information shall be referred to the Chief of Staff, who will determine whether corrective action is necessary to protect patients.

3. Meetings, Reporting and Minutes
   The committee shall meet annually and as often as necessary. It shall maintain only such records of its proceedings as it deems advisable, and shall routinely report on its activities to the Chief of Staff.
Rule 4 Departments

4.1 Department Functions
Each department, through its officers and established committees, is responsible for the quality of care within the department, and for the effective performance of the following as it relates to the members and AHPs practicing within the department:

4.1-1 Performance evaluations and monitoring of all members and AHPs exercising privileges in the department and continuous assessment and improvement of the quality of care, treatment and services (including periodic demonstrations of ability), consistent with Bylaws, Article 7, Performance Evaluation and Monitoring, and with guidelines developed by the committees responsible for quality improvement, utilization review, education and medical records, and by the Medical Executive Committee.

4.1-2 Credentials review, consistent with guidelines developed by the Credentials Committee and the Medical Executive Committee.

4.1-3 Recommendation to the Medical Executive Committee criteria for the granting of Clinical Privileges, including, but not limited to, any privileges that may be appropriately performed by AHPs or via telemedicine, and the performance of specified services within the department.

4.1-4 Initiating and assisting in the conduct of performance improvement and corrective action, when indicated, in accordance with Bylaws, Article 13, Performance Improvement and Corrective Action.

4.1-5 Orientations and continuing education consistent with guidelines developed by the committee responsible for continuing medical education and the Medical Executive Committee.

4.1-6 Planning and budget review consistent with guidelines developed by the Medical Executive Committee. This includes making recommendations regarding space and other resources needed by the department.

4.2 Department Officer Qualifications
Each Chief and Chief Elect shall:

4.2-1 Be board certified or board admissible in his or her appropriate specialty, or affirmatively establish, through the privilege delineation process, that he/she possesses comparable competence.

4.2-2 Have demonstrated clinical competence in his or her field of practice sufficient to maintain the respect of the members of his or her department.

4.2-3 Have an understanding of the purposes and functions of the staff organization and a demonstrated willingness to promote patient safety over all other concerns.

4.2-4 Have an understanding of and willingness to work with the hospital toward attaining its lawful and reasonable goals.

4.2-5 Have an ability to work with and motivate others to achieve the objectives of the Medical Staff organization in the context of the hospital’s lawful and reasonable objectives.

4.2-6 Be (and remain during tenure in office) an active staff member in good standing.
4.2-7 Not have any significant conflict of interest.

4.3 Procedures for Selecting Department Officers

4.3-1 Each department through its Department Committee shall nominate at least one person meeting the qualifications in Rule 5.2 for each of the offices of Chief and Chief Elect.

4.3-2 In addition, the department members may select candidates for office by a petition signed by at least ten active staff members from the department. Such nominations must be received by the department Chief at least 30 days prior to the scheduled elections.

4.3-3 All nominees for election or appointment to department offices (including those nominated by petition of the department members, pursuant to Rule 5.3-2, above) shall, at least 20 days prior to the date of election or appointment, disclose in writing to the department Chief those personal, professional or financial affiliations or relationships of which they are reasonably aware that could foreseeably result in a conflict of interest with their activities or responsibilities on behalf of the department. The department Chief shall evaluate the significance of such disclosures and discuss any significant conflicts with the nominee. If a nominee with a significant conflict remains on the ballot, the nature of his or her conflict shall be disclosed, in writing, and circulated with the ballot.

4.4 Procedures for Removing Department Officers

Removal of a Department Chief or Chief Elect may be initiated by one-third of the Medical Executive Committee members or by a petition signed by at least one-third of the department’s voting members. Removal will take effect upon the approval of two-thirds of the hospital's Medical Executive Committee members or of two-thirds of the department’s voting members. All voting shall be conducted by written secret mail ballot, which shall be sent to those eligible to vote within 45 days after the initiation of removal pursuant to this Rule. The ballots must be received no later than 21 days after they are mailed and shall be counted by the Chief of Staff, CMO and manager of Medical Staff services. No removal shall be effective unless and until it is ratified by the Medical Executive Committee.

4.5 Responsibilities of Department Officers

4.5-1 Each Department Chief shall be responsible for:
   a. All department clinical activities.
   b. All administrative activities of the department (unless otherwise provided for by the hospital).
   c. Integrating the department into the primary functions of the organization.
   d. Coordinating and integrating interdepartmental and intradepartmental services.
   e. Developing and implementing policies and procedures that guide and support the provision of services in the department.
   f. Recommending qualified and competent persons to provide care/service in the department.
   g. Continuing surveillance of the professional performance of all individuals who have delineated clinical privileges in the department.
   h. Recommending the criteria for clinical privileges in the department.
   i. Evaluating the qualifications and competence of practitioners and Allied Health Professionals (AHPs) who provide patient care services within the purview of the department.
j. Recommending clinical privileges for each practitioner and AHP desiring to exercise privileges in the department.
k. Maintaining quality control programs, as appropriate and in coordination with the Medical Staff Quality Improvement Committee.
l. Continuously assessing and improving the quality of care and services provided in the department.
m. Overseeing the orientation and continuing education of all persons in the department, in coordination with the Medical Staff committee(s) responsible for continuing medical education.
n. Making recommendations regarding space and other resources needed by the department.
o. Making recommendations to the relevant hospital authority with respect to off-site sources needed for patient care services not provided by the department or the hospital system.
p. Chairing all department meetings.
q. Serving as an ex officio member of all committees of his or her department and attending such committee meetings as deemed necessary for adequate information flow.
r. Assuring that records of performance are maintained and updated for all members of his or her department.
s. Reporting on activities of the Medical Staff to the Governing Body when called upon to do so by the Chief of Staff or the Chief Executive Officer.
t. Serving as a member of the Medical Executive Committee.
u. Performing such additional responsibilities as may be delegated to him or her by the Medical Executive Committee or the Chief of Staff.

4.5-2 Each Chief Elect shall:
   a. Assist the Department Chief to perform his or her duties; and, in the absence or disability of the Department Chief, be responsible for performing the duties of the Department Chief (including, but not limited to, assuming the Chief’s voting rights on all Medical Staff or Department Committees).
b. Be a member of the Performance Improvement Coordination Council.
Rule 5 Allied Health Professionals

5.1 Overview

5.1-1 The credentialing process for Allied Health Professionals (AHPs) is similar to that for credentialing Medical Staff members. However, the Interdisciplinary Practices Committee (IPC), rather than the Credentials Committee, is responsible for overseeing the credentialing of AHPs. The credentialing process for AHPs is summarized in Rule 6.3, page 94.

5.1-2 Rule 6.4 reflects the basic requirements that all AHPs must meet, and Appendices 6A through 6R set forth requirements that specific types of AHPs must meet in addition to the basic requirements.

5.1-3 Also, the clinical department in which the AHP will exercise privileges has a role in establishing criteria for the exercise of specific privileges in that department, and in evaluating whether the particular applicant meets the established criteria. The departments also have the responsibility for generally supervising AHPs in their department, through their proctoring and peer review mechanisms.

5.1-4 Until the AHP has been granted privileges and assigned to a department, an AHP should not be practicing within the hospital.

5.1-5 This Rule 6 applies to AHPs who practice independently, as well as AHPs who are employees or independent contractors of a Medical Staff member.

5.2 Categories of AHPs Eligible to Apply for Practice Privileges

5.2-1 The types of AHPs allowed to practice in the hospital will be ultimately determined by the Governing Body, based upon the comments of the Medical Executive Committee and such other information as may be available to the Governing Body.

5.2-2 The types of AHPs currently eligible to apply for practice privileges are:
   - Nurse Practitioners
   - Optometrist
   - Physician Assistants
   b. The following categories may practice in the hospital only pursuant to an employment or independent contractor agreement with the hospital:
   - Perfusionists
   - Speech Pathologists
   - Orthotist/Prosthetist

5.2-3 When an AHP in a category that has not been approved as eligible to apply for clinical privileges under Bylaws, Article 6, Allied Health Professionals, requests privileges, the IPC may begin to process an application at the same time the request for recognition of the profession is processed; however, no right to practice in the hospital is thereby created or implied.
5.3 Processing the Application

5.3-1 Applications shall be submitted and processed in a manner parallel to that specified for Medical Staff applicants in Rule 2, Appointment and Reappointment, except that the applications shall be submitted to the IPC rather than the Credentials Committee.

5.3-2 Once the application is determined to be complete, it will be forwarded to the IPC for consideration. The IPC may meet with the applicant and the sponsoring or supervising practitioner (if applicable). The IPC shall evaluate the AHP based upon the standards set forth in Rule 2, Appointment and Reappointment and Rule 6.4. The IPC will also ascertain that appropriate monitoring mechanisms are in place. Whenever possible, the IPC shall include practitioners in the same AHP category when conducting its evaluation. The IPC shall forward its recommendations to the department to which the AHP would be assigned.

5.3-3 Upon receipt of an AHP application from the IPC, the Department Chief or Department Committee shall evaluate the AHP based upon the standards set forth in Rule 2, Appointment and Reappointment and Rule 6.4. The Department Chief or his or her designee or Department Committee may meet with the AHP as well as the sponsoring or supervising practitioner (if applicable) to further assess the AHP’s request for privileges. The Department Chief, Department Committee will make a recommendation to the Medical Executive Committee regarding the applicant’s qualifications to exercise the requested privileges.

5.3-4 Thereafter, the application shall be processed by the Medical Executive Committee and Governing Body in accordance with the procedures set forth in Rule 2.7-3 through Rule 2.7-6.

5.4 Credentialing Criteria

5.4-1 Basic Requirements
   a. The applicant must belong to an AHP category approved for practice in the hospital by the Governing Body.
   b. If required by law, the applicant must hold a current, unrestricted state license or certificate.
   c. In addition, hospital independent contractors shall meet all conditions of their contract with the hospital.
   d. The applicant must document his or her experience, education, background, training, demonstrated ability, judgment and physical and mental health status with sufficient adequacy to demonstrate that any patient he or she treats will receive care of the generally recognized professional level of quality and efficiency in the community and as established by the hospital, and that he or she is qualified to exercise clinical privileges within the hospital.
   e. The applicant must maintain in force professional liability insurance or its equivalent for the privileges exercised in the amounts of at least $1,000,000/occurrence and $3,000,000/aggregate.
   f. The applicant must submit a minimum of two references from either licensed physicians or adequately trained professionals in the appropriate field and who are familiar with his or her professional work and have demonstrated competency.
   g. The applicant must be determined, on the basis of documented references, to adhere strictly to the lawful ethics of his or her profession, to work cooperatively with others in the hospital setting so as not to adversely affect patient care, to be willing to participate in and properly discharge responsibilities as determined by the Medical Staff.

5.4-2 Specific Requirements
   In addition to meeting the general requirements outlined above, applicants must meet any specific requirements established for his or her category of AHP, as set forth in the applicable appendix:
5.4-3 **Supervising Practitioner Responsibilities**

a. Any supervising practitioner or group which employs or contracts with the AHP agrees that the AHP is solely his, her or its employee or agent and not the hospital’s employee or agent. The supervising practitioner or group has full and sole responsibility for paying the AHP, and for complying with all relevant laws, including federal and state income tax withholding laws, overtime laws and workers’ compensation insurance coverage laws.

b. A supervising practitioner or group which employs or contracts with the AHP agrees to indemnify the hospital against any expense, loss or adverse judgment it may incur as a result of allowing an AHP to practice at the hospital or as a result of denying or terminating the AHP’s privileges.

5.5 **Provisional Status**

All AHPs initially shall be appointed to a provisional status for at least 12 months. Advancement from the provisional status will be based upon whether the professional’s performance is satisfactory, as determined by the department in which the AHP is assigned, IPC (when its review is necessary for the privileges), the Medical Executive Committee and the Governing Body.

5.6 **Duration of Appointment and Reappointment**

5.6-1 AHPs shall be granted practice privileges for no more than 24 months. Reappointments to the AHP staff shall be processed every other year, in a parallel manner to that specified in the Rule 2, Appointment and Reappointment for Medical Staff members.

5.6-2 Applications for renewal of the AHP’s privilege and the supervising practitioner’s approval must be completed by the AHP and supervising practitioner and submitted for processing in a parallel manner to the reappointment procedures set forth in the Medical Staff Rules.

5.7 **Observation**

5.7-1 All new AHPs shall be subject to a performance evaluation and monitoring, consistent with the provisions of Bylaws, Article 7, Performance Evaluation and Monitoring as adapted to the scope of practice and privileges of the AHP.

5.7-2 Each department shall be responsible for establishing performance evaluation and monitoring programs appropriate to each category of AHP granted privileges within that department. The department shall determine the appropriate frequency and methods of initial Focused Professional Practice Evaluation, which may include proctoring, concurrent or retrospective chart review or consultations. AHPs exercising surgery or anesthesia practice privileges shall be observed during surgery.

5.7-3 The proctor or evaluator should be a member in good standing of the Medical Staff who exercises appropriate clinical privileges; however, in appropriate circumstances, the department chief may assign an appropriately credentialed AHP to serve as the proctor/evaluator. Whenever possible, the proctor/evaluator should not be the sponsoring or supervising practitioner of the AHP being observed.

5.7-4 The Governing Body may approve alternative observation procedures for employee or Contract AHPs.

5.8 **General**
5.8-1 Duties
Upon appointment, each AHP shall be expected to:

a. Consistent with the privileges granted to him or her, exercise independent judgment within his or her areas of competence and, if applicable, within the limits of an approved standardized procedure, provided that a Medical Staff member who has appropriate privileges shall retain the ultimate responsibility for each patient's care.

b. Participate directly in the management of patients to the extent authorized by his or her license, certificate, other legal credentials, any applicable standardized procedures, and by the privileges granted by the Governing Body.

c. Write orders to the extent established by any applicable Medical Staff or department policies, rules or standardized procedures and consistent with privileges granted to him or her.

d. Record reports and progress notes on patient charts to the extent determined by the appropriate department, and in accordance with any applicable standardized procedures.

e. Assure that records are countersigned as follows: (i) the supervising practitioner, if any, shall countersign all entries except routine progress notes; (ii) unless otherwise specified in the rules or specific supervision protocols, all chart entries that require countersignatures must be countersigned within fourteen days after the entry is made.

f. Consistent with the privileges granted to him or her, perform consultations as requested by a Medical Staff member.

g. Comply with all Medical Staff and hospital bylaws, rules and policies.

5.8-2 Prerogatives and Status
AHPs are not members of the Medical Staff, and hence shall not be entitled to vote on Medical Staff or department matters. AHPs shall not be required to pay dues. They are expected to attend and actively participate in the clinical meetings of their respective departments, to the extent consistent with applicable department rules.

5.9 Standardized Procedures

5.9-1 Definition
Standardized procedures means the written policies and protocols for the performance of standardized procedure functions, and which have been developed in accordance with the requirements of state law.

5.9-2 Functions Requiring Standardized Procedures
Standardized procedures are required whenever any registered nurse (including, but not by way of limitation, Nurse Anesthetists, Nurse Practitioners and Nurse Midwives) practices beyond the scope of practice taught in the basic curriculum for registered nurses as contemplated by the California Nurse Practice Act (i.e., whenever special training and/or experience are necessary in order for the nurse to perform the procedure or practice in question).

5.9-3 Development of Standardized Procedures
a. Standardized procedures may be initiated by the appropriate department, the affected AHPs, or sponsoring or supervising practitioners.

b. The IPC is responsible for assuring that standardized procedures are a collaborative effort among administrators and health professionals, including physicians and nurses. Representatives of the category of
AHPs that will be practicing pursuant to the standardized procedures shall be involved in developing the standardized procedures.

c. Each standardized procedure shall:
   1. Be in writing and show the date or dates of approval by the IPC.
   2. Specify which standardized procedure functions registered nurses may perform and under what circumstances.
   3. State any specific requirements which are to be followed by registered nurses in performing particular standardized procedure functions.
   4. Specify any experience, training and/or education requirements for performance of standardized procedure functions.
   5. Establish a method for initial and continuing evaluation of the competence of those registered nurses authorized to perform standardized procedure functions.
   6. Provide for a method of maintaining a written record of those persons authorized to perform standardized procedure functions.
   7. Specify the nature and scope of review and/or supervision required for performance of standardized procedure functions; for example, whether the functions must be performed under the immediate supervision of a physician.
   8. Set forth any specialized circumstances under which the registered nurse is to immediately communicate with a patient’s physician concerning the patient’s condition.
   9. State the limitations on settings or departments, if any, in which standardized procedure functions may be performed.
  10. Specify patient recordkeeping requirements.

d. Standardized procedures shall be reviewed by the department, and then must be approved by the IPC, the Medical Executive Committee and the Governing Body.
Appendix 5A Nurse Practitioners

1. Licensure and Certification
Nurse Practitioners shall be currently licensed as a registered nurse in California and currently certified as a Nurse Practitioner by the California Board of Registered Nursing.

2. Scope of Practice
Nurse Practitioners may receive privileges to perform the following professional services at the hospital:

a. Perform tasks or functions which fall within the customary scope of nursing practice; and

b. Furnish or order drugs or devices (other than controlled substances) to patients under the following conditions:
   1) The drug or device is furnished or ordered pursuant to a standardized procedure or protocol which is promulgated by the hospital in accordance with legal requirements;
   2) The drug or device furnished or ordered is consistent with the Nurse Practitioner’s educational preparation or established (and maintained) clinical competency.
   3) The drug or device is furnished or ordered under the supervision of the attending physician, who:
      i. Collaborated in the development of the standardized procedure;
      ii. Approved the standardized procedure;
      iii. Is available by telephone at the time of patient examination by the Nurse Practitioner; and
      iv. Supervises no more than four Nurse Practitioners at one time.
   4) The drug or device is furnished or ordered pursuant to certification from the Board of Registered Nursing that the Nurse Practitioner has completed:
      i. At least six months of physician-supervised experience in the furnishing of drugs or devices; and
      ii. A course in pharmacology covering the drugs and devices to be furnished.
   5) The drug or device is furnished or ordered under a number issued by the Board of Registered Nursing to the Nurse Practitioner, to be included on all transmittals of orders for drugs or devices.
   6) The Nurse Practitioner is registered with the United States Drug Enforcement Administration.

c. Furnish or order Schedule IV or Schedule V controlled substances if, in addition to the conditions above at (b) being met, the drugs or devices are further limited to those drugs agreed upon by the Nurse Practitioner and the supervising physician and specified in the standardized procedure.

d. Furnish or order Schedule III controlled substances if, in addition to the conditions above at (b) and (c) being met, the drugs or devices are furnished in accordance with a patient-specific protocol approved by the treating or supervising physician.

e. Furnish or order Schedule II controlled substances if, in addition to the conditions above at (b), (c), and (d) being met, the following conditions are met:
1) The provision in the protocol for furnishing Schedule II controlled substances addresses the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished; and

2) The Nurse Practitioner completes, as part of his or her continuing education requirements, a course including Schedule II controlled substances that meets the standards of the Board of Registered Nursing.

3) The term “furnish” shall include
   
i. Ordering a drug or device in accordance with the standardized procedure; and
   
   ii. Transmitting an order of a supervising physician.

f. Perform tasks or functions within the expanded scope of nursing practice as developed in collaboration with physicians and defined in standardized procedures, promulgated by the hospital in accordance with Rule 6.9.
Appendix 5B Physician Assistants

1. Requirements
Physician Assistants shall be currently licensed by the Physician Assistant Committee of the Medical Board of California.

Physician Assistants shall perform all services at the hospital under the direction of a qualified supervising physician.

2. Scope of Practice
a. Physician Assistants may receive privileges to perform the following professional services at the hospital pursuant to a delegation and protocols where present:

1) Take a history, perform a physical examination, assess the patient, make a diagnosis, and record the pertinent data in a manner meaningful to the supervising physician;

2) Order, transmit an order for and perform or assist in performing laboratory screening and therapeutic procedures, provided that the procedures are consistent with the supervising physician’s practice and with the patient’s condition;

3) Order or transmit an order for x-ray, other studies, therapeutic diets, physical therapy, occupational therapy, respiratory therapy and nursing services;

4) Recognize and evaluate situations which call for the immediate attention of a physician and institute, when necessary, treatment procedures essential for the life of the patient;

5) Administer or provide medication to patient or transmit orally or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication to the patient, subject to the following conditions:

i. Any prescription transmitted by the Physician Assistant shall be based either on a patient-specific order by the supervising physician or on a written practice-specific formulary and protocol approved by the supervising physician which specifies all criteria for the use of a specific drug or device and any contraindications for the selection. Protocols for Schedule II controlled substances shall address the diagnosis of illness, injury, or condition for which the Schedule II controlled substance is being administered, provided, or issued.

ii. The supervising physician must countersign and date within seven days the medical record of any patient cared for by the Physician Assistant for whom the Physician Assistant’s Schedule II drug order has been issued, transmitted or carried out;

iii. Physician Assistants may not administer, provide or issue a prescription for controlled substances listed in Schedules II through V inclusive without a patient-specific order by the supervising physician unless the Physician Assistant has completed an education course that covers controlled substances and meets all legal requirements set forth in California Business & Professions Code section 3502.1.

iv. Any drug order issued by a Physician Assistant shall be subject to a reasonable quantitative limitation consistent with customary medical practice in the supervising physician's practice.
v. All Physician Assistants who are authorized by their supervising physicians to issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration.

6) Instruct and counsel patients regarding matters pertaining to their physical and mental health, such as medications, diets, social habits, family planning, normal growth and development, aging and understanding and managing their diseases;

7) Assist the supervising physician by arranging admissions, making appropriate entries in the patient’s medical record, reviewing and revising treatment and therapy plans, ordering, transmitting orders for, performing, or assisting the performance of radiology services, therapeutic diets, physical therapy treatment, ordering occupational therapy treatment, ordering respiratory care services, and providing continuing care to patients following discharge;

8) Facilitate the supervising physician’s referral of patients to the appropriate health facilities, agencies and resources of the community;

9) Perform, outside the personal presence of the supervising physician, surgical procedures which are customarily performed under local anesthesia, which the supervising physician has determined the Physician Assistant has training to perform, and for which the Physician Assistant has privileges to perform; and

10) Act as a first or second assistant in surgery under the supervision of the supervising physician.

b. Physician Assistants shall not:

1) Perform any task or function that requires the particular skill, training, or experience of a physician, dentist or dental hygienist;

2) Determine eye refractions or fit glasses or contact lenses; or

3) Prescribe or use any optical device for eye exercises, visual training or orthoptics (this does not, however, preclude administering routine visual screening tests).

3. Supervision

a. Physician Assistants shall perform all services at the hospital under the direction of a supervising physician who:

1) Is currently licensed by the State of California; 2) Is not subject to a disciplinary condition imposed by the Medical Board of California prohibiting supervision or employment of a Physician Assistant;

3) Is a current member in good standing of the Medical Staff and practices actively at the hospital; and

4) Meets the requirements set forth in this Appendix 6L.

b. Before the Physician Assistant is permitted to perform services at the hospital, the supervising physician shall submit a signed, written request which describes the tasks and functions that the Physician Assistant would be performing. Those tasks and functions shall be consistent with the supervising physician’s specialty, with the supervising physician’s usual and customary practice, and with the patient’s health and condition.

c. The supervising physician shall establish the following in writing, together with any necessary documentation:

1) That the supervising physician accepts full legal and ethical responsibility for the performance of all professional activities of the Physician Assistant;
2) Those specific duties and acts, including histories and physical examinations, that the Physician Assistant would be permitted to perform outside of the supervising physician’s immediate supervision and control;

3) That the supervising physician is covered by professional liability insurance with limits as determined by the governing board, for acts or omissions arising from supervision of the Physician Assistant (the supervising physician shall verify such coverage in a form acceptable to the Medical Staff Executive Committee); and

4) That the supervising physician is not subject to a disciplinary condition imposed by the Medical Board of California prohibiting that supervision or the employment of a Physician Assistant.

d. The supervising physician shall agree in writing in a form acceptable to the hospital that:

1) He or she shall notify the hospital and its Medical Staff immediately in the event that he or she becomes subject to any disciplinary condition, or an action to impose a disciplinary condition, by the Medical Board of California; and

2) He or she shall comply with all Medical Board of California regulations regarding supervision of the Physician Assistant.

e. No supervising physician shall have a supervisory relationship with more than four Physician Assistants at any one time. (Notwithstanding the foregoing, an emergency physician may have a supervisory relationship with more than four emergency care Physician Assistants at any one time, provided that the emergency physician does not oversee the work of more than four such Physician Assistants while on duty at any one time.)

f. The supervision of the Physician Assistant by the supervising physician shall include all of the following:

1) Availability of the supervising physician in person or by electronic communication when the Physician Assistant is caring for patients;

2) Observation or review of the Physician Assistant’s performance of all tasks and procedures that the supervising physician will delegate to the Physician Assistant until the supervising physician is assured of competency;

3) Establishment of written transport and back-up procedures for the immediate care of patients who are in need of emergency care beyond the Physician Assistant’s scope of practice for such times when the supervising physician is not on the premises;

4) Establishment of written guidelines for the adequate supervision of the Physician Assistant.

i. This requirement may be satisfied by the supervising physician adopting protocols for some or all of the tasks performed by the Physician Assistant. These protocols shall comply with all of the following:

- The minimum content for any such protocol governing diagnosis and management shall include the presence or absence of symptoms, signs and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient and education to be given the patient.

- For protocols governing procedures, the protocol shall state the information to be given the patient, the nature of the consent to be obtained from the patient, the preparation and technique of the procedure, and the follow-up care.

- Protocols shall be developed by the supervising physician, adopted from, or referred to, texts or other sources.
• Protocols shall be signed and dated by the supervising physician and the Physician Assistant.

ii. Alternatively, the requirement of adequate supervision of the Physician Assistant may be satisfied by alternative mechanisms established by the Medical Board of California.

5) The supervising physician shall review, countersign, and date a minimum sample of five percent of medical records of patients treated by the Physician Assistant functioning under these protocols within 24 hours. The supervising physician shall select for review those cases which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient.

6) On-site supervision by the supervising physician of any surgery requiring anesthesia other than local anesthesia; and

7) Responsibility on the part of the supervising physician to follow the progress of the patient and to make certain that the Physician Assistant does not function autonomously.
Rule 6 Admissions

6.1-1 Provisional Diagnosis - Except in emergency, no patient shall be admitted to the hospital until after a provisional diagnosis has been stated. In cases of emergency, the provisional diagnosis shall be stated as soon after admission as possible.

6.1-2 Responsible Physician - A physician with appropriate privileges shall be responsible for the medical aspects of admission, hospital care, and discharge of each patient.

6.1-3 Private Patients - Private patients may be admitted by physician in private practices who are members of the medical staff.

6.1-4 Sufficient Information - The admitting physician shall be held responsible for giving such information as may be necessary to the protection of the patient from self harm and to assure the protection of others whenever his patient might be a source of danger from any cause whatever.

6.1-5 Transfer of Patient Responsibilities - Whenever the Attending Physician transfers the patient responsibilities to another staff member, a note covering the transfer of responsibilities shall be entered on the order sheet of the medical record and the physician will be responsible for notifying the physician to whom he/she is referring the patient.
Rule 7 Consultations

7.1-1 Psychiatric Consultations - All suicide attempt and overdose patients should be offered psychiatric consultations.

7.1-2 Consultation Recommended - Consultation is recommended for selected critically ill patients and in difficult diagnostic or therapeutic situations where additional expertise might be helpful in resolving the problem:
   a. Where the patient’s condition is deteriorating for unknown reasons;
   b. Where diagnosis is obscure;
   c. For continued and/or multiple therapeutic choices of unusual complexity;
   d. For situations of unusual risk;
   e. For disease processes or procedures with which practitioner is not fully current or familiar;
   f. Where consultation is requested by the patient or family;
   g. When declaration of brain death is required;
   8. When withdrawal of life support is being considered in non-brain dead patients.

7.1-3 Required Consultations - The Department Chief, Chief of Staff, the Medical Director or the Service Director may recommend or require consultation where it appears advisable in the interest of patient care.
Rule 8 Discharges

8.1-1 Discharges - Patients shall be discharged on order of a physician. At the time of discharge, the responsible physician will see that the record is complete, including final diagnoses, procedure reports, discharge summary and record signatures. All records must be completed within fourteen (14) days following the patient’s discharge from the hospital.

8.1-2 Discharge Summary - Conclusions at the termination of hospitalization shall be recorded in the discharge summary. The summary shall concisely recapitulate the reason for the hospitalization, the significant findings, the procedures performed and treatment rendered, the condition of the patient on discharge, and any specific instructions given to the patient and/or the family. Instructions shall relate to the physical activity, medication, diet, and follow-up care.
Rule 9 Medical Records

9.1-1 Responsible Physician - The responsible physician shall complete the medical record for each patient.

9.1-2 Attending Staff Documentation - Every medical record shall contain written evidence of patient care and critical review of the patient by a member of the attending staff.

9.1-3 Entries – All medical record entries will be legible, dated, timed and signed.

9.1-4 Medical Record Content – The Medical Record shall contain the following information:
   a. Identification data
   b. Medical History and Physical
   c. Diagnostic & Therapeutic orders
   d. Informed consent, where applicable
   e. Reports of procedures, tests and results
   f. Operative notes
   g. Progress notes
   h. Consultation reports
   i. Discharge summary

9.1-5 Components of History & Physical – The History & Physical shall include:
   a. Chief complaint;
   b. Details of present illness, including when appropriate, assessment of patient’s emotional, behavioral, and social status;
   c. Relevant past, social and family history appropriate to the age of the patient;
   d. Review of body systems;
   e. Physical examination;
   f. Statement of conclusions or impression drawn;
   g. Statement of course of action planned.

9.1-6 Pediatric History and Physical Components – In regards to children and adolescents, the Medical History and Physical shall also include:
   a. An evaluation of patient’s developmental age;
   b. Consideration of educational needs and daily activities, as appropriate;
   c. The patient’s report or other documentation of patient’s immunization status;
   d. The family’s and/or guardian’s expectations for, and involvement in, assessment, treatment and continuous care of the patient.

9.1-7 Orders: Diagnostic & Therapeutic – All orders for treatment shall be in writing, dated, timed & signed with printed last name or physician ID number.

9.1-8 Telephone/Verbal Orders - A telephone order shall be considered to be in writing from a licensed independent practitioner when received by telephone, by nurses and by technicians of specific departments who have been authorized to receive.
   a. Verbal orders will be allowed in emergency situations only.
b. All orders given over the telephone shall be signed by a physician responsible for the patient's care or the ordering physician, noting date and time and practitioner's name. The covering or attending physician shall authenticate such orders within 48 hours.

c. All staff receiving a telephone order shall write the order in the Medical Record and read back the complete order for verification from the ordering physician.

d. Telephone orders are to be used infrequently and not primarily for the convenience of the ordering practitioner.

e. Do Not Resuscitate orders may not be documented as telephone/verbal orders.

9.1-9 Telephone orders for administration of medications - Telephone orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patients’ medical record, noting the name of the person giving the verbal order and the signature of the person receiving the order. Telephone orders may be given to the R.N., L.V.N., Licensed Psychiatric Technician; Pharmacist, Physician and Physician’s Assistant (P.A. from Supervising Physician only), Physical Therapists (for certain topical drugs only), and Respiratory Therapists when the orders relate specifically to respiratory therapy.

9.1-10 Telephone orders for other than drugs - Licensed, registered or nationally certified health professional provided that the orders received relate to the area of competence of the individual receiving the orders: Audiologists, Cardiopulmonary/Pulmonary Technologists/Technicians, Dietitians (except parenteral nutrition), Laboratory Technologists, Occupational Therapists, Physical Therapists, Radiological Technologists, Respiratory Therapists, and Speech Pathologist.

9.1-11 Progress Notes – Progress Notes, including nursing and others. Notes reflect the course of hospitalization and significant changes in patient status. Abnormal test results are discussed. Progress notes must be timed, dated and signed with printed last name or physician ID number.

9.1-12 Non-Removal of Records – Medical records may not be removed from the hospital except under court order, subpoena or state statute. There are no exceptions to this rule.

9.1-13 File Complete – No medical record shall be filed until it is complete, except on order of the Medical Records Committee.
Rule 10 Surgery

10.1-1 Surgical Consent - Written, signed surgical consent shall be obtained prior to the operative procedure except in those situations wherein the patient’s life is in jeopardy and suitable signatures cannot be obtained. In emergencies involving a minor or unconscious patient, in which consent for surgery cannot be obtained from parents, guardian or next of kin, these circumstances should be fully explained on the patient medical record.

10.1-2 Labs and Pre-Op Tests - The ordering of labs and other pre-operative tests will be left to the discretion of the Surgeon and Anesthesiologist based on the individual needs of the patient.

10.1-3 Commence Operation - Surgeons must be in the Operating Room and ready to commence operation at the time scheduled. In no case will the operating room be held longer than fifteen (15) minutes after scheduled time of operation.

10.1-4 Operative Report - The Operative Report shall include the pre-operative diagnosis, description of findings, technique used, and tissue removed or altered.
   a. An immediate operative report shall be entered in the medical record immediately after the completion of any invasive procedure. This note must include: Name of primary surgeon and assistants, Findings, Technical Procedure used; Specimens removed, Post-Operative Diagnosis, Estimated Blood Loss.
   b. A dictated, detailed, operative/procedure report shall be completed, authenticated, and filed in the medical record as soon as reasonably possible after any invasive procedure requiring more than simple local anesthesia.

10.1-5 Specimen Removed During Surgery - All tissue removed at operation; with the following exceptions, shall be sent to the Hospital Pathologist, who shall make such examinations as may be considered necessary to arrive at a diagnosis and who shall sign such report.

10.1-6 List of Specimens - The following list of specimens removed during surgery may, at the discretion of the surgeon, be exempt from the requirement for pathology examination:
   a. Specimens by nature or condition do not permit fruitful examination, such as a cataract, orthopedic appliance, foreign body or removed only to enhance operative exposure;
   b. Therapeutic radioactive sources, the removal of which shall be guided by radiation safety monitoring requirements;
   c. Traumatically injured members that have been amputated and for which examination for either medical or legal reasons is not deemed necessary;
   d. Foreign bodies (e.g. bullets) that for legal reasons are given directly in the chain of custody to law enforcement representatives;
   e. Specimens known to rarely, if ever, show pathological change and removal of which is highly visible post-op, such as the foreskin from the circumcision of a newborn infant;
   f. Placentas that are grossly normal and have been removed in the course of operative and non-operative obstetrics;
   g. Teeth, provided the number, including fragments, is recorded in the medical record;
   h. Tissues debrided from areas of trauma;
   i. Cartilage or bone removed in the course of septoplasty/rhinoplasty;
j. Ventilation tubes removed from the tympanic membrane or external auditory canal.
k. Arch bars;
l. Dentures and intra-oral prosthetic splints;
m. Toenails and fingernails;
n. Burn debridement specimens;
o. K-wires and Steinmann pins;
p. Breast implants;
q. Normal bone, muscle tissue, adipose tissue, skin or cartilage removed incidental to the primary procedure;
r. Scribner shunt parts, Hickman catheter parts;
s. Unused donor site skin removed for application as a skin graft;
t. Orthopedic hardware, i.e., screws, nails, etc.
u. Meniscus fragments removed at arthroscopy;
v. Phalanges removed for hammer toe;
w. Sutures removed at surgery.

10.1-7 **Oral/Dental/Podiatric Surgery** - Patients admitted for oral or dental surgery or podiatric surgery shall be under the joint responsibility of a doctor of dental surgery or podiatrist and a physician. The doctor of dental surgery or podiatrist shall be responsible for documenting treatment including the surgical reports. A physician shall be responsible for the general care of the patient, including the general medical history and physical.

10.1-8 **Cancel Surgery** - When the history and physical examination is not recorded before the time slated for surgery, the surgery shall be canceled unless the attending surgeon states in writing that such a delay would be detrimental to the patient.
Rule 11 Autopsies

11.1-1 Securing Autopsies - Every member of the Medical Staff is expected to be actively interested in securing autopsies. No autopsy shall be performed without written consent of a relative or legally authorized agent.

11.1-2 Performed by Pathologist – All autopsies shall be performed by the hospital pathologist, or a physician to whom he/she may delegate the duty.

11.1-3 Information/Education – Autopsies shall be used as a source of clinical information in performance improvement and continuing Medical Education programs of the medical staff.

11.1-4 Autopsy as Part of Record - When an autopsy is performed, provisional anatomic diagnosis shall be recorded in the medical record within three (3) days, and the complete protocol shall be made part of the record within sixty (60) days. An exception for special studies may be established by the Medical Records Committee.

11.1-5 Autopsy Criteria – The following criteria shall be used to identify deaths in which an autopsy should be performed:

a. Unanticipated death;

b. Death occurring while the patient is being treated under an experimental regimen;

c. Intra-operative or intra-procedural death;

d. Death occurring within 48 hours after surgery or an invasive diagnostic procedure;

e. Death incident to pregnancy within seven (7) days following delivery;

f. All deaths on the psychiatric inpatient service;

g. Death where the cause is sufficiently obscure to delay completion of the death certificate;

h. Death in infants/children with unexplained congenital malformations;

i. Deaths reportable to the Coroner referenced in the hospital administrative policy.