CREDENTIALS MANUAL

OBTAINING AND RETAINING
MEDICAL STAFF PRIVILEGES:
A GUIDE TO CREDENTIALING PROCEDURES

June 26, 1981

Recent Board Approved Changes June 28, 2017
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ARTICLE I
GENERAL PROVISIONS

1.1 Preamble
Shady Grove Medical Center seeks to serve its community by providing accessible medical care of consistently high quality. The Hospital thus strives to allow its facilities and equipment to be utilized in a fair and efficient manner by competent health care professionals committed to assisting the Hospital in meeting this objective. The Hospital encourages the application of such professionals to its Medical Staff or Allied Health Professional Staff. Individuals may only provide health care services to Hospital patients if they are members of the Medical Staff and Allied Health Professional Staff or otherwise employed by or under contract to the Hospital.

The Medical Staff of the Hospital, with the approval of the Hospital's Governing Board, has adopted Bylaws, which include certain rules and regulations, in order to provide for governance of the Medical Staff. Subject to the provisions of such Bylaws, and certain State and accreditation requirements, the Hospital has prepared this Manual in order to facilitate the application for and maintenance of privileges on the Hospital's Medical Staff.

This Manual, which has been prepared under the supervision of the Director of Medical Staff Services, is intended to facilitate both the initial application and the biennial reapplication to the Medical Staff of the Hospital.

All members of the Medical Staff, and Allied Health Professional Staff of Shady Grove Medical Center are credentialed to provide care to patients at both the hospital and the Germantown Emergency Center.

1.2 Definitions
Active Candidate Status means that the Member's specialty board has ruled that the applicant or Member has fulfilled the requirements of the board and is approved for admission to the certification examination.

Active Staff, Courtesy Staff, Emeritus Staff, Community Staff, and Consulting Staff shall refer to Members of either the Physician Staff or Dentists and Podiatrists as appropriate, unless otherwise specified.

Allied Health Professional shall refer to those who provide services as a Physician Assistants, Nurse Practitioners, Nurse Anesthetists, Nurse Midwives, and Psychologists.

Governing Board means the Governing Board of the Hospital.

Bylaws means the bylaws, rules and regulations of the Medical Staff, including the rules and regulations of the applicable department and section (unless the context requires otherwise), as validly adopted and as amended from time to time. The Bylaws include this Manual, unless the context or text of this Manual provides otherwise.

Hospital’s President means the individual appointed by the Governing Board to act in its behalf in the overall management of the Hospital.

Credentials Committee shall mean the Credentials Committee of the Medical Staff, as convened in accordance with the Bylaws.

Director of Medical Staff Services means the individual employed by the Hospital to serve as secretary to the Medical Staff in support of its day-to-day organizational functions.

Executive Committee means the Executive Committee of the Medical Staff unless specific reference is made to the Executive Committee of the Governing Board.

Hospital means Shady Grove Medical Center in Rockville, Maryland.

Hospital’s President means the individual appointed by the Governing Board to act in its behalf in the overall management of the Hospital.

Medical Staff means all Physician, Dentist and Podiatrist Members who are privileged to attend patients at the Hospital.

Medical Staff Services Coordinator means the individual employed by the Hospital to perform credentialing activities for the Medical Staff.

Medical Staff Term shall mean the period for which the Member is appointed to the Medical Staff prior to the next period of reappointment.

Medical Staff Year means the first day of January through the thirty-first day of December of each year, inclusive.

Member means any health care professional admitted to the Medical Staff, unless the context of this Manual requires otherwise.
1.2 Definitions (con't)

Physician refers to an appropriately licensed medical physician, osteopathic physician or qualified oral and maxillofacial surgeon.

Physician Staff means those Physicians admitted to the Medical Staff.

Professional Affairs Sub-Committee means the committee designated by the Governing Board to act on its behalf to approve medical staff, credentialing and quality actions.

State means the State of Maryland.

1.3 Conformity With Bylaws

This Manual is not intended to replace the Bylaws. It generally describes the rights, privileges and obligations applicable to membership on the Medical Staff of the Hospital, and is a convenient reference document for such provisions. In the event of conflict between this Manual and the Bylaws, the provisions of the Bylaws shall govern.

1.4 Adoption and Amendments

This Manual, and any amendments thereto, shall become effective after they have been recommended by the Credentials Committee and the Executive Committee and have been approved by the Governing Board.

1.5 Access to Medical Staff Files

a.) To preserve and protect the confidentiality of credentialing, peer review and disciplinary proceedings, as required by the Bylaws and State law, no applicant, Member, or past Member shall have access to any information in any files maintained by the Medical Staff Coordinator; provided, however, that the applicant or Member shall have access to such information in the event of credentialing, peer review or disciplinary proceedings at the Hospital involving such applicant or Member. If the applicant or Member requests access to his or her Medical Staff files, the applicant or Member shall be permitted to review such file in the presence of the Medical Staff Coordinator and the Chair of the applicant or Member's department or section; however, in such event, all confidential information (e.g., reference letters, peer review information) shall be removed from the file prior to such review.

b.) The Maryland Board of Physicians or other Regulatory bodies has the legal authority to subpoena copies of a current or past Member's credentialing, peer review and disciplinary proceedings files. The Member will be notified in writing of said subpoena.

c.) The Maryland Department of Health and Mental Hygiene (including but not limited to the Maryland Board of Physicians), Joint Commission, or other Regulatory bodies has the legal authority to review a current or past Member's credentialing files during a survey process or investigation process. Peer review and disciplinary materials will not be shared unless required by subpoena or law, authorized in writing by the Member, or allowed pursuant to a joint credentialing process with an entity that is afforded the same or similar peer review protections.

1.6 Confidentiality

All hard copies and electronic credentialing files/information, including computer passwords, are held in the strictest confidence. Access to the file/information of a specific applicant or medical staff member is only on a need-to-know basis.

The accuracy of the credentialing information displayed in the practitioner directory is consistent with the credentialing data stored in the medical staff credentialing database.
ARTICLE II
CONDITIONS AND DURATION OF APPOINTMENT

2.1 **Acceptance of Membership:** Acceptance of membership on the Physician Staff shall constitute the Physician's agreement that he or she will strictly abide by the Principles of Medical Ethics of the American Medical Association, American Dental Association, and American Podiatry Association and the Bylaws and as such principles may from time to time be amended or expanded. The Member shall recognize the Executive Committee as the proper authority to interpret any doubtful points of ethics. Each member during initial appointment and reappointment shall sign the Clinical Practice Expectation and agree to abide by them.

2.2 **Ethical Fees and Services:** Applicants for membership on the Medical Staff shall pledge themselves neither to receive from nor pay to another health care professional, either directly or indirectly, any part of a fee received for professional services except as ethically acceptable.

2.3 **Action by Governing Board:** Initial appointments and reappointments to the Medical Staff shall be made by the Governing Board. The Governing Board shall take final action on appointments, reappointments, or revocation of appointment only after there has been a recommendation from the Medical Staff as provided in this Manual or in the Bylaws; provided that in the event of unwarranted delay on the part of the Medical Staff, the Governing Board may act without such recommendation on the basis of documented evidence of the applicant's or Member's professional and ethical qualifications obtained from reliable sources and a review of the application.

2.4 **Term of Appointment:** Initial appointments to the Medical Staff shall be for a period not to exceed two years or until the end of the current Medical Staff Term and shall be active for two years unless the physician only provides consulting services. All new physicians requesting membership only to the hospital will be approved with Community Staff status for two years. Reappointments shall be for a period of two years or less.

2.5 **Clinical Privileges for Physician Staff:** Appointment to the Physician Staff shall confer on the appointee only such clinical privileges as have been granted by the Governing Board, in accordance with the Bylaws.

2.6 **Application for Appointment:** Every application for staff appointment shall be signed by the applicant and shall contain the applicant's specific acknowledgment of every Member's obligations to provide continuous care and supervision of his or her patients, to abide by the Bylaws, to accept committee assignments, to accept consultation and Medical Staff assignments, to participate in staffing the emergency service area and other special care units, to be loyal to the Hospital, to work harmoniously and respectfully with the Medical Staff, Hospital employees and staff, and Hospital administration, and to cooperate with the Hospital's administration in carrying out its functions. The Medical Staff Office will inform the applicant via e-mail and/or phone when credentialing information obtained from other sources varies substantially from that provided by the practitioner.

2.7 **Leave of Absence:** Members of the Active Physician Staff may request a leave of absence for a period not to exceed one year. All such requests shall be in writing and include the reason and length of the requested leave. In exceptional circumstances, at the member's written request, the Credentials Committee may recommend that the Governing Board grant up to a one-year extension to the original leave of absence. In the event of military activation, members of the medical staff may request a leave of absence regardless of staff status. Under extraordinary circumstances, such as call to active military duty, such leave may be further extended, but this will again require the member's written request, recommendation of the Credentials Committee and Medical Executive Committee, and Board approval. Upon Member's return, before resuming hospital practice, the member must first request reinstatement of clinical privileges in writing. This reinstatement request must be accompanied by a full written explanation and documentation of member's activities during said leave of absence. If a Member seeks appointment twelve or more months after expiration of said leave of absence, this will be treated as an initial application, pursuant to the Bylaws and Credentials Manuals.

2.8 **Physician and Allied Health Professionals Health:** (See Appendix D –Health Policy) We abide by, cooperate with, and support the Maryland Physician Health Program as run by the Maryland Board of Physicians in order to provide education about health, address prevention of physical, psychiatric, behavioral or emotional illness, and facilitate confidential diagnosis, treatment, and rehabilitation of physicians who suffer from a potentially impairing condition.

2.9 **Death of Member:** Staff membership shall be automatically voluntarily resigned upon death of a Member.
2.10 **Failure to Maintain Office in Community:** All Members must maintain their bonafide medical office in Montgomery County or Frederick County, Maryland, limited to 15 miles North of Montgomery County/Frederick County borderline; failure to do so shall result in automatic resignation of Medical Staff membership without the fair hearing rights set forth in the Bylaws. With the exception of Consulting Staff Members, Emeritus without privileges, telemedicine physicians, and Community Staff. Members who have their medical practice in the County as of the effective date of this manual must continue to do so. Members who utilize their home as an office must submit a certificate from Montgomery or Frederick County indicating approval to use their home as their office. After the Member has or obtains such an office in Montgomery or Frederick County, failure to continuously maintain his or her practice within Montgomery or Frederick County shall result in automatic resignation of Medical Staff membership without the fair hearing rights set forth in the Bylaws.

2.11 **Voluntary Resignation:** Members who voluntarily resign from the Medical Staff shall submit in writing to the Medical Staff Services Coordinator the reason(s) for such resignation. No Member shall be permitted to resign voluntarily while a corrective action is pending against the Member, or where the Member has been recommended to be denied reappointment “for cause” by the Executive Committee. A Member may not voluntarily resign without complying with all pending peer review and quality assurance inquiries and completion of all patient medical records for which he or she is responsible. A resignation by a Member in lieu of corrective action or during a pending investigation will require a report to the National Practitioner Data Bank and the Maryland Board of Physicians. In case of a Member employed by a Contracted Service, the appropriate Medical Director or Department Chair of the Contracted Service will notify the Medical Staff Office of the resignation of their contracted member. A member who does not submit their reappointment application prior to the end of their medical staff term will have their membership and privileges recommended as a voluntary resignation.

2.12 **Liability and Release:** All acts, communications, reports, recommendations and disclosures performed by or made in good faith to an authorized representative of the Hospital or any other health care facility shall be privileged to the fullest extent permitted under the Bylaws and any State and federal law. All applicants and Members agree to hold harmless any person who acts in good faith and without malice in any activity whose purpose is the achievement and maintenance of quality patient care in the Hospital or any other health care facility or program.

2.13 **Withdrawal of Application:** An applicant for initial appointment or reappointment may withdraw his or her application without prejudice at any time prior to its consideration by the Executive Committee. Further, an applicant for initial appointment or reappointment recommended for denial without prejudice on the basis of his or her failure to meet minimum objective eligibility criteria (e.g., malpractice insurance, board eligibility or certification) may withdraw his or her application at any time prior to action by the Governing Board. Otherwise, an applicant for initial appointment or reappointment may withdraw his or her application only with the consent of the Executive Committee, which may deem such withdrawal to be with prejudice. “With prejudice” shall invoke the bars to reapplication set forth in the Medical Staff Bylaws.

2.14 **Ongoing Responsibilities:** The ongoing responsibilities of each Member of the Medical Staff include:

A. Providing patients with the quality of care which meets the professional standards of the Medical Staff;
B. Abiding by the Bylaws;
C. Completing such reasonable responsibilities and assignments imposed upon the Member by virtue of Medical Staff membership, including committee assignments;
D. Promptly preparing and completing medical records for all the patients to whom the Member provides care in the Hospital;
E. Agrees to provide continuous care of his or her patients and making appropriate arrangements for coverage for his or her patients with another Member of the Shady Grove Medical Center Medical Staff; with the exception of referring physicians and consulting physicians; Additionally, contracted groups are also exempt from this responsibility as the group is required to provide continuous care for his or her patients at all times;
F. Refusing to engage in improper inducements for patient referral;
G. Participating in continuing education programs, as determined by the Medical Staff;
H. Participating in such emergency service coverage or consultation panels as may be determined by the Medical Staff or Hospital;
I. Maintaining professional liability insurance in at least the minimum amount required by the Hospital;
J. Interacting with the Medical Staff, Hospital employees and staff, and Hospital administration in a harmonious and respectful manner;
K. Discharging such other Medical Staff obligations as may be lawfully established from time to time by the Executive Committee or Hospital;
L. Pay initial and reappointment processing fees as well as annual Medical Staff dues and department dues, as required;
M. Participate in performance improvement activities;
N. Agrees to abide by Maryland State Law regarding Continuing Medical Education (CME) requirements;
O. Agrees to cooperatively participate in the Hospital’s Case Management (CM) Program;
P. Agrees to notify the President of the Medical Staff immediately of any change of status to include: licensure, professional liability insurance coverage, DEA or Maryland CDS Certificate, physician coverage, and health status.
**2.14 Ongoing Responsibilities (con't)**

Q. Agrees to notify the President of the Medical Staff of any arrests or criminal charges carrying a possible penalty of incarceration in any jurisdiction, including but not limited to DUI and DWI, within 10 days after such arrests are made or charges are filed, and to keep the President of the Medical Staff promptly apprised of any significant developments in such matters, including but not limited to pleas, convictions, and sentencing;

R. Agrees to notify the President of the Medical Staff within 10 business days of any charges filed by any State or federal licensing or regulatory board, including but not limited to the Maryland Board of Physicians, CDS, DEA, or Medicare, Medicaid and Campus;

S. Agrees to notify the President of the Medical Staff within 10 business days of any proposed or actual reduction in privileges at any other hospital or institution, whether voluntary or involuntarily imposed;

T. Agrees to notify the President of the Medical Staff immediately of the provider’s exclusion or notification of investigation for exclusion of participation in the Medicare or Medicaid programs. Exclusion from Medicare or Medicaid program participation will result in immediate termination of privileges without rights of hearing and appeal. (See Medical Staff Bylaws, Corrective Action, Section 4. Automatic Termination.);

U. Agrees to remain free of illegal drug use;

V. Agrees to fully cooperate with any inquiry or investigation undertaken by the Medical Staff or Hospital in connection with the matters set forth in Sections 2.14 (Q) - (U) above;

W. Agrees to provide and maintain a working e-mail address to allow for ongoing Hospital and Medical Staff communication and all other correspondence. E-mail is the primary source of communication from the Medical Staff Office and the Hospital;

X. Agrees to complete all required training, orientation, re-certification, etc., including, but not limited to electronic medical record, HIPAA compliance, initial or continued privileges for fluoroscopy, moderate sedation, or any other privileges that the Hospital or Medical Staff deem necessary. The Applicant/Member is responsible for any fees associated with any training/re-certification required by a regulatory body;

Y. Agrees to abide by the Conflict of Interest policy of Adventist HealthCare and sign a form during initial appointment and reappointment indicating if you have any potential conflicts;

Z. Agrees to abide by the Organizational Integrity Policy of Adventist HealthCare and attest to this agreement during initial appointment and reappointment.

**2.15 Board Certification Status:** Effective May 21, 2000, new MD, DO, DPM, and DMD/DDS (Oral Surgeons only) applicants to the medical staff must be board certified or board admissible.

For those boards that have Maintenance of Certification requirements, they must meet all requirements as per your specialty Board. For those boards that have Maintenance of Certification with Annual re-verification dates, you must be in compliance when re-verification dates are verified. All Members must notify the Medical Staff Office within 10 business of loss if their Board Certification in their primary specialty.

Effective June 27, 2005, all MD, DO, DPM, and DMD/DDS (Oral Surgeons Only) applicants who completed their residency program after January 1, 1990 must be board certified or board admissible by the appropriate Board recognized by the American Board of Medical Specialties or the American Osteopathic Association Boards or by the American Board of Oral and Maxillofacial Surgery or the American Board of Pediatric Dentistry by the American Board of Podiatric Surgery pertinent to their field of expertise and request for privileges.

Effective August 30, 2006, the American Osteopathic Association Boards (AOA) are considered equivalent to the American Board of Medical Specialties (ABMS) Boards for the purposes of credentialing and are accepted for membership and privileges. All new applicants must be board certified in their primary specialty with in 5 years of completion of their residency.

If fellowship trained, the applicant must be board certified in their sub-specialty within 5 years of fellowship completion in order to practice that sub-specialty in this institution.

Effective April 28, 2010, all Dentists coming on staff must be board certified by the American Board of Pediatric Dentistry in their sub-specialty within 5 years of fellowship completion in order to practice that sub-specialty in this institution. If a board certification is not available for their sub-specialty (i.e. General Dentistry), this rule does not apply.

Failure to achieve certification within the 5-year grace period will result in automatic termination of medical staff membership and clinical privileges at reappointment anniversary. This termination is not reportable to the National Practitioner Data Bank.
2.16 **Board Recertification:** Effective January 1, 2006, all new applicants who have completed residency in the year 2005 or after must comply with the re-certification requirements of their Board in their primary area of practice.

2.17 **Malpractice Insurance Purchase Requirements Upon Loss of Privileges or Change to Non-Clinical Status:** In the following instances, the Hospital may require, at its discretion, that any present or former Member purchase additional adequate malpractice insurance to cover malpractice claims arising out of treatment rendered to patients at the Hospital but not asserted until after the cessation of privileges of the Member at the Hospital (including "tail" and "prior acts" coverage):

A. Voluntary resignation or leave of absence from the Medical Staff;
B. Revocation of Medical Staff membership and/or clinical privileges;
C. Other termination of Medical Staff membership and/or clinical privileges.

2.18 **Reinstatements:** Reinstatement to the Medical or AHP Staff may be requested in writing with an explanation of what the provider has been doing since they left the Medical or AHP staff. A reinstatement may be requested within one year of leaving the Medical and AHP staff and will require a full reappointment application process for the following reasons:

a) Due to personal/family illness or injury. A $100 fee may be assessed.
b) Reappointment non-compliance. Fee of $300 will be assessed.
c) Administrative Delay of reappointment. No fee will be assessed.
d) Leave of Absence. No fee will be assessed.
e) Moved out of Area with Reappointment within last twelve months. Fee of $100 will be assessed.
f) When Medicaid or Medicare program exclusion or investigation is cleared, participant may request reinstatement within twelve months and no fee will be assessed.

2.19 **Credentialing Physicians and AHPs in the Event of a Disaster:** During a disaster, when the Hospital Emergency Operations Plan (Code Yellow-Disaster Plan) has been activated and Shady Grove Medical Center (SGAH) is unable to handle the immediate patient needs, the Hospital President, the President of the Medical Staff or their designee (s) at the time the disaster is implemented has the option to grant disaster privileges to physicians and allied health professionals who volunteer their services but are not members of the hospital’s medical staff. On a case by case basis at his/her discretion following review of the volunteer’s application for disaster privileges. The Hospital’s Chief Medical Officer will determine the type (s) of medical and technical staff needed to assist with the disaster. The procedures to follow can be found in the Disaster Policy Appendix H of the Bylaws.

2.20 **Annual Orientation**
Annual orientation is provided to practitioners for the following areas. Practitioners must review the orientation and sign an attestation stating that they have read and understand the content or the materials. This attestation is kept in the practitioners credentialing file.

- Assessment and Management of Pain
- Conflict of Interest
- Illness and Impairment recognition issues specific to licenses independent practitioners
- How to report Environment of Care Risks
- Actions to take in the event of an Environment of Care incident (including Fire Plan, Infection Control Plan, etc.)
- Hospital’s Mission, Vision and Values
- Hospital’s Patient Safety, Quality Goals and Evidence-Based Practice and Use of Core Measures
- Potentially Preventable Complications (PPCs)
- Situational Briefing Model (SBAR)
- Electronic Incident Reporting (RL Solutions)
- Use of Restraints
- Life Safety
- Code Alerts
- Responsibility in the Event of a Disaster
- I.T. Downtime Procedures
- Internal and External Reporting of Safety and Quality Concerns
Infection Prevention and Control re: TB Exposure Control Plan, Contact Precautions
Influenza
Hand Hygiene
Pharmacy Information and Anticoagulants
Multi-Drug Resistant Organisms
Hospital and Community Acquired Infections
Hybrid Medical Record Information
Hospital Department information, ie. Case Management, Security, Health Information Management (formerly Medical Records), Patient Relations, Medical Staff Services, Bed Control and Information Technology
Patient Safety
Universal Protocols
Any other regulatory required education

ARTICLE III
DETERMINATION AND CHANGE IN STATUS OR CLINICAL PRIVILEGES

3.1 Determination of Clinical Privileges

3.1-1 **Basis for Determination:** The determination of the clinical privileges to be granted to applicants approved for membership shall be based on the applicant's current licensure, training, experience, references, demonstrated current competence, and where applicable, upon an examination of the records of previous cases treated, and other such information as may be relevant. The Credentials Committee may recommend that current requirements for training be waived for specific physicians who trained prior to such training being readily available, and who demonstrate current clinical competence for the privileges requested. The extent of the clinical privileges granted and the need for proctoring, if any, of an applicant or Member who requests new clinical privileges shall be determined by the appropriate department and the Credentials Committee, subject to the concurrence of the Executive Committee and the Governing Board. Each Member shall be assigned membership in at least one department, and to a section, if any, within such department, but may also be granted membership and/or clinical privileges in other departments or sections consistent with the clinical privileges granted. The exercise of clinical privileges within any department (and section, if any) is subject to the rules and regulations of that department (and section, if any) and is subject to the authority of the Chair of the department (and section, if any).

3.1-2 **Biennial Determination:** The biennial determination of whether a Member's clinical privileges shall be recommended by the appropriate department and section (if any) and shall be based upon direct observation, review of the records, or any portion thereof, of patients treated in this Hospital or other hospitals, review of numbers and types of cases treated and procedures performed, and review of the records of Medical Staff committees, including peer review, Medical Records, continuing medical education credits, and such other statistics/data as may be relevant. If applying for Community Status, the Member must continue to maintain or obtain a current Maryland license, be in good standing with Medicare and Medicaid (if applicable). The department shall make its recommendations to the Credentials Committee, as provided in Article V of the Bylaws, and they shall be subject to the concurrence of the Executive Committee and the Governing Board.

3.2 Change in Staff Category, Clinical Privileges, and Clinical Department or Section

3.2-1 **Request for Staff Category Change:** Any Member may apply in writing to have his or her Medical Staff category changed to be effective once per year. An application for change in Medical Staff category shall be processed in the same manner as an initial application. Such application may include a request for at least one reference from a practitioner who may, but need not, be a Member of the Medical Staff who is familiar with the Member's work or who has responsibility for assessing the Member's work at this Hospital or another facility. It shall be the responsibility of the Member to ensure that the application and reference form, if any, are completed and promptly returned to the Medical Staff Services Coordinator.

3.2-2 **Request for Change in or Additional Clinical Privileges:** A change in clinical privileges may be requested in writing by the Member or recommended by the appropriate departments at any time. In order to obtain additional privileges, any Member shall make written request indicating any privileges requested and indicating the justification therefore including any supporting documentation for the requested privileges. Such application or recommendation shall be processed as if it were an initial application. A National Practitioner Data Bank report will be obtained for any Member requesting additional privilege.

3.2-3 **Request for Change in Clinical Department or Section:** A change in clinical department or section may be
requested by the Member or recommended by the appropriate department or section at any time. In order to obtain change in clinical department or section, any Member shall make written request stating the privileges and department or section requested and indicating the justification thereof including any supporting documentation required, i.e. board certification. Such application or recommendation shall be processed as if it were an initial application.

3.2-4 Biennial Review

A. Usual review for recommendations as to change in staff category or clinical privileges shall be made biennially in connection with the Member's application for reappointment.

B. The biennial review for reappointment and determination of clinical privileges shall be conducted for every Member, regardless of whether a change in staff category or clinical privileges has been granted during the preceding term of appointment.

C. Members without clinical privileges will complete a demographic update at their biennial review in lieu of a reappointment application.

ARTICLE IV

MEDICO-ADMINISTRATIVE OFFICERS AND LIMITATION OF ADMITTING PRIVILEGES

4.1 Medico-Administrative Officers

4.1-1 Responsibilities: A medico-administrative officer is a Member employed by the Hospital on either a full- or part-time basis in an administratively responsible capacity. The officer's activities shall include clinical responsibilities such as direct patient care or supervision of the patient care activities of other Members under his or her direction. A medico-administrative officer must achieve and maintain Medical Staff membership and clinical privileges appropriate to his or her clinical responsibilities and discharge staff obligations appropriate to his or her staff category in the same manner applicable to all other Members.

4.1-2 Removal from Office: The effect of the removal from his or her medico-administrative office on the officer's Medical Staff membership status and clinical privileges is governed solely by the terms of the contract between the officer and the Hospital. In the absence of a contract or where the contract is silent on the matter, removal from office alone will have no effect on membership status or clinical privileges, except that the removed officer may not thereafter exercise clinical privileges for which exclusive contractual arrangements have been made. Unless the contract provides otherwise, a health care professional who believes that his or her removal from a medico-administrative office has or will have an adverse effect on his or her exercise of clinical privileges in any aspects specified in the Bylaws is entitled to the procedural rights contained in Article VIII of the Bylaws.

4.1-3 Adverse Change in Clinical Privileges/Membership Status: The effect of an adverse change in an officer's Medical Staff membership status or clinical privileges on continuance in his or her medico-administrative office is determined by the Governing Board after soliciting and considering the recommendations of the Medical Staff. An adverse change in membership status or clinical privileges as defined in the Bylaws that is not triggered by removal from a medico-administrative office entitles the officer to the procedural rights contained in Article VIII of the Bylaws. Any change in the officer's contract shall in no way affect his or her Medical Staff privileges and responsibility, unless the contract provides otherwise.

4.2 Limitation on Inpatient Admitting Privileges for Hospital-Based Physicians

4.2-1 Anesthesia Department: Members who are affiliated with the Department of Anesthesia shall not have admitting privileges to the Hospital except for the purposes of managing acute and/or chronic pain and the complications directly arising from such management. Such privileges shall not extend to patients admitted for medical or surgical management of other diseases, unless a written consultation is made for pain management and is accepted by the anesthesiologist, nor shall such privileges extend to patients with anesthesia-related complications of surgical procedures. Applications for such privileges shall conform with the provisions of the Medical Staff Bylaws and shall include a written description of the nature and extent of privileges desired.

4.2-2 Emergency Medicine Department: Members who are affiliated with the Department of Emergency Medicine and who have contracts of employment with the hospital shall not have admitting privileges to the Hospital with the exception of the short stay/observation unit.

4.2-3 Pathology Department: Members who are affiliated with the Department of Pathology and who have contracts of employment with the Hospital shall not have admitting privileges to the Hospital.

4.2-4 Radiology Department: Members who are affiliated with the Department of Radiology and who have contracts of
employment with the Hospital shall not have admitting privileges to the Hospital except for Interventional Radiologists and Nuclear Medicine Physicians. Consults with the primary care physician or appropriate specialty physician must be obtained as needed.

ARTICLE V
PROCTORING AND MENTORING

5.1 Proctoring: In the event that proctoring of a practitioner is deemed to be appropriate, whether it is for evaluation of granting of new clinical privileges or as part of the Medical Staff's quality assurance functions with respect to any practitioner, the following principles shall apply:

A. The proctor's purpose is to evaluate the technical and cognitive skills of the practitioner who is the subject of the proctoring requirement. Accordingly, the proctor differs from a consultant or supervising instructor, in that the proctor is not responsible for training the proctored practitioner. Except as provided in Section "E" below, the proctor does not participate directly in patient care, does not receive a fee from the patient, and is not part of the physician/patient relationship between the proctored practitioner and his/her patient. The proctor represents the Medical Staff and the Hospital in evaluating the proctored practitioner's abilities, and the proctor is responsible only to the Medical Staff and Hospital in completing all proctoring functions. The proctor is not responsible for providing patient care. The proctor's presence need not be noted in the patient's medical record unless the proctor provides services to the patient.

B. Only those individuals already admitted to the Medical Staff are appropriately the subject of proctoring. Proctoring may only be done by well-qualified practitioners who are in the same specialty as the proctored Member and who hold clinical privileges in the proctored procedure or area. It is preferable that the proctor be a Medical Staff Member, although if an appropriately qualified Medical Staff Member is not available, an appropriately qualified non-Member with appropriate privileges at another hospital may serve. Insofar as practicable, the proctor should be free of actual or perceived conflicts of interest with or bias (whether in favor of or against) the proctored practitioner. The member to be proctored for new clinical privileges must submit a written request along with a current CV for the proctor. The proctor's Maryland State license will be verified and a current NPDB report will be run prior to proctoring.

C. The review procedure (concurrent, prospective, and/or retrospective) and duration shall be determined by the body that institutes the proctoring requirement. If concurrent proctoring is required, the proctor must engage in direct observation of the proctored practitioner's performance. All observation shall be for a specified time or number of procedures. It is the responsibility of the proctored practitioner to make any necessary scheduling arrangements and to pay any fees or expenses that may be associated with the proctoring.

D. All proctoring shall be done at the direction of the Credentials Committee, with the concurrence of the Executive Committee, although if the proctoring is due to the practitioner's request for new clinical privileges, the protocol set forth in Section 3.2-1 shall govern. The proctor shall prepare a written report on the prescribed form within five business days of the proctored practitioner's performance which describes the number and types of cases observed and the practitioner's performance in such cases; the proctor shall promptly forward such report to the Credentials Committee. The proctor's report shall be made a part of the practitioner's Medical Staff file and shall be utilized during the credentialing process.

E. A proctoring Physician is empowered to intervene as necessary to ensure patient safety. If the proctor intervenes and/or otherwise becomes directly involved in the patient's care, his/her name and actions with regard to the patient shall be noted in the medical record, as it would be for any other treating practitioner.

F. All records relating to the proctoring process shall be kept confidential.
5.2 Mentoring

A. An appropriately licensed practitioner with special expertise in a particular procedure/treatment modality who is not an applicant for Membership may be granted Clinical Privileges in that particular procedure/treatment modality. Such Privileges shall be granted on a patient-specific basis, or for a specific period of time, for purposes of training Hospital staff regarding the procedure/treatment modality. The practitioner will not be permitted to admit, write orders, or otherwise act as a treating practitioner and shall act at all times under the oversight of a Medical Staff Member.

B. To be granted mentor privileges, the practitioner must complete an application on a form that has been prescribed by the Governing Board after consultation with the Executive Committee. Verification of education, training, board certification, current State licensure, and primary hospital affiliation(s) will occur in the same manner as set forth in the Medical Staff Bylaws. If the practitioner is not licensed to practice in the State of Maryland, either the Maryland Board of Physician Quality Assurance (or other applicable agency) must grant approval for an exception from licensing if the practitioner is to provide any patient care services, or the Hospital administration, in its sole determination, shall have determined the practitioner to be exempt from Maryland licensing requirements.

C. The practitioner's application must be approved by the section and department chairs, the Credentials Committee, the Executive Committee, and the Hospital's Governing Board, provided that the provisions of the Medical Staff Bylaws regarding interim privileges will apply to the granting of mentor privileges. The practitioner shall not be entitled to any procedural rights under the Bylaws for any failure to approve his/her application or termination of his/her Privileges as a mentor.
## SHADY GROVE MEDICAL CENTER
### MEDICAL STAFF POLICY MANUAL

## NEW PROCEDURES, CREDENTIALING FOR:

| Effective Date: | 9/28/94 |
| Cross Referenced: | n/a |
| Revised: | 7/25/07; 10/30/08; 11/30/11 |
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| Origin: | Credentials Comm. |
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### POLICY:
It is the policy of Shady Grove Medical Center to ensure patient safety through proper training of physicians and support staff (nurses, techs, etc.) on new and improved procedures as they become available.

### DEFINITIONS/GUIDELINES:
1. Enhancement to current procedures should be encouraged. The hospital staff, working with individual departments and physicians, should continue to add and upgrade equipment without impediment. Physicians should not be inhibited from offering enhancements to current procedures/technologies as soon as they become available.
2. New procedures are defined as those requiring a unique technical approach, an innovative treatment of a disease (not previously seen in the community and/or hospital), or an application of new technology, such as laparoscopic surgery. Physicians and their specialty peers are best able to define which procedures require privileging. This process should occur through the organized Medical Staff structure before a new procedure is scheduled and is facilitated through the Medical Staff Services Department.
3. Privileging requirements can take a variety of forms. These include but are not limited to specialty courses or technical training, proctoring by physicians who are already credentialed, instruction by visiting physicians, and manufacturer required training. Again, physicians and their specialty peers are best able to define which procedures require privileging. In turn, they should also define the criteria for the new procedure.
4. The hospital departments will continually monitor their schedules for new procedures. When questions arise with regard to privileging for new procedures, the Medical Staff Services Department will be notified and appropriate investigation undertaken.

### PROCEDURE:
The development of separate privileging criteria should be considered if any of the following conditions exist:

1. If additional training is required; OR
2. If nationally published privileging criteria exists; OR
3. If the equipment manufacturer requires privileging and/or training; OR
4. If the procedure is considered to be experimental.

### CRITERIA:
The proposed criteria may include: 1) basic education requirements; 2) number of years of formal training required and the field of formal training; 3) if the procedure is learned outside of residency or fellowship, a specific number of hours of postgraduate CME training and in what venue; 4) the amount of recent, direct, or indirect experience needed. All experience must be within the past 12 months and must occur within an institution with formal quality improvement programs; and 5) number and type of required references, and from where they must come.

### APPROVAL PROCESS:
Once the proposed privileging criteria is developed by the applicant requesting the new procedure with input from his or her peers and approved at the service line level, it is then forwarded to the appropriate medical staff department and/or section for review. Once approved by the department and/or section, the criteria are then forwarded to Credentials Committee. (If there is more than one specialty/department or service line affected by the privileges, each specialty/department or service line must have provided input into the criteria and have signed off on recommendation of the final proposed criteria.) The proposed criteria is then forwarded on to the Medical Executive Committee for review and recommendation before being routed to the Hospital’s Governing Board for final action. Only after final action by the Governing Board may the implementation or a new procedure (i.e., budgeting, acquisition, training of staff, etc.) begin.

### RATIONALE:
The pace of development of new procedures continues to expand exponentially. Physicians often schedule or wish to schedule new procedures without formal privileging criteria being established or approved. New procedures are sometimes scheduled without adequate OR and other hospital staff preparation, such as training, without adequate budgeting and without input from peers on the medical staff. The hospital faces serious liability issues when physicians proceed on the premises with procedures for which no privileging criteria exist. On the other hand, enhancements to existing procedures for which no new privileging is necessary also occur. Industry and surgical innovators are continuously enhancing existing equipment for improved safety and efficiency. Common procedures are frequently enhanced with added nuances to allow improvements in cost and efficacy. These enhancements to existing procedures should not require additional privileging.

The medical products industry can form alliances to perform new procedures. Physicians may wish to be viewed as innovators in their fields and wish to be the first at Shady Grove Medical Center to perform new procedures. While most of these new procedures will benefit patients, the potential exists for ethical compromise on the part of the physician. Procedures are marketed to the public through media, creating increased pressure on physicians to perform a procedure.
ALLIED HEALTH PROFESSIONALS

POLICY:
This policy addresses those Allied Health Professionals who are permitted to practice or provide services in Shady Grove Medical Center and its facilities. Allied Health Professionals practice under supervisory agreement with a licensed physician on the Hospital Staff or by direct consultation of a staff physician.

PROCEDURE:
Only those classes of Allied Health Professionals that have been approved by the Governing Board shall be permitted to practice at Shady Grove Medical Center. When the Governing Board determines there is a need for the services a particular type of Allied Health Professional it shall establish the minimum qualifications that must be demonstrated by such individuals. The Board shall also determine the scope of practice and supervision requirements for these practitioners in the hospital. This listing may be modified or supplemental by action of the Governing Board.

This Policy contains the credentialing processes for Allied Health Professionals at Shady Grove Medical Center.

Allied Health Professionals shall include:

- Psychologists
- Certified Registered Nurse Practitioners
- Certified Registered Physician Assistants
- Certified Nurse Midwives
- Certified Registered First Nurse Assistants
- Certified Registered Nurse Anesthetists

APPLICATION:
An application to provide specific services may be submitted via MSONet (our online credentialing module) and on such forms as approved by the Medical Executive Committee and the Governing Board to the Medical Staff Office at Shady Grove Medical Center. Information required in the application will be the following, but not limited to:
NO ENTITLEMENT TO MEDICAL STAFF APPOINTMENT:

Individuals applying for permission to provide clinical services as Allied Health Professionals are not eligible for appointment to the Medical Staff of Shady Grove Medical Center, or entitled to the rights, privileges and/or prerogatives attendant to Medical Staff appointment.

(A) The application forms for AHP shall require information about the applicant’s professional qualifications, including:

1. the names and addresses of a minimum of two (2), but preferably three (3) individuals who have had recent experience in observing and working with the applicant and who can provide adequate information pertaining to the applicant’s professional competence and character;
2. current curriculum vitae;
3. the names and addresses of the department chairs or any and all other hospitals at which the applicant has worked or trained;
4. current State licensure, Drug Enforcement Administrative Certificate (DEA), Controlled Drug Substance Certificate (CDS), and job-specific certification (if applicable);
5. information as to whether the applicant’s appointment, clinical privileges, and/or affiliation have ever been voluntarily or involuntarily relinquished, denied, revoked, suspended, reduced, or not renewed at any hospital or health care facility;
6. information as to whether the applicant has ever withdrawn an application for appointment or clinical privileges or resigned such affiliation or privileges before a final decision by the hospital’s or health care facility’s governing board was rendered;
7. information as to whether the applicant’s membership in any local, state, or national professional society, license to practice any profession in any state, or Drug Enforcement Administration certification (if applicable) is, or has ever been, suspended, modified, terminated, restricted, or is currently being challenged;
8. Applicants to the Allied Health Professional Staff shall present written evidence of adequate and continuous professional liability insurance in the required minimum amount of $1,000,000/$3,000,000;
9. information concerning the applicant’s malpractice litigation experience and/or any professional misconduct or disciplinary proceedings involving the applicant in this state or any other state, whether such proceedings are closed or still pending, including the substance of the allegations of such proceedings or actions, the substance of the findings of such proceedings or actions, the ultimate disposition of any such proceedings or actions that have been closed, and any additional information concerning such proceedings or actions as the applicant may deem appropriate;
10. information concerning the suspension or termination for any period of time of the right or privilege to participate in Medicare, Medicaid, or any other government sponsored program or any private or public medical insurance program;
11. current information regarding the applicant’s physical and mental health status;
12. information as to whether the applicant has ever been a defendant in a criminal action or convicted of a felony which details about any such instance;
13. information on the citizenship and/or visa status of the applicant;
14. complete on-line orientation within required timeframe;
15. New physician assistants coming on staff, must submit a copy of the e-mail received from the Maryland Board of Physicians (Board) verifying that their delegation agreement has been received by the Board. After 90 days of submitting delegation agreement to the Board, the new physician assistant must sign an Attestation that they have not received a disapproval from the Board regarding their delegation agreement;
16. Current physician assistants on staff, must submit their current written delegation agreement as approved by the Maryland Board of Physicians;
17. a letter from the primary supervising physician(s) listing alternate supervising physicians;
18. documentation of annual PPD testing as well as flu vaccine documentation (during seasonal requirement).
NO ENTITLEMENT TO MEDICAL STAFF APPOINTMENT (con't):

(21) All nurse practitioners must submit a copy of the attestation filed with the State of Maryland Nursing Board declaring and affirming that they have a named collaborator and will adhere to the Nurse Practice Act and all rules governing the scope of practice for their certification;

(22) Agreement to follow AHC’s Conflict of Interest Policy;

(23) Agreement to follow AHC’s Electronic Health Record Policy;

(24) Agreement to follow Medical Staff Bylaws, Credentials Manual and respective Department Rules and Regulations;

(25) Agreement to follow AHC’s organizational integrity program;

(26) Must obtain Hospital I.D. badge;

(27) The applicant’s signature; and

(28) Such other information as the hospital may require.

BURDEN OF PROVIDING INFORMATION:

(a) The applicant shall have the burden of producing information deemed adequate by the hospital for a proper evaluation of competence, character, ethics and other qualifications and of resolving any doubts about such qualifications.

(b) The applicant shall have the burden of proving that all the statements made and information given on the application are true and correct.

RELEASE AND IMMUNITY:

(a) The applicant specifically authorizes the hospital and its authorized representatives to consult with any third party who may have information bearing on the applicant’s professional qualifications, credentials, clinical competence, character, mental or emotional stability, physical condition, ethics, behavior, or any other matter reasonably having a bearing on the applicant’s qualifications for clinical privileges as an Allied Health Professional. This authorization includes the right to inspect or obtain any and all communications; reports, records, and documents from said third parties. The applicant also specifically authorizes said third parties to release said information to the hospital and its authorized representatives upon request.

(b) To the fullest extent permitted by law, the applicant releases from any and all liability, extends absolute immunity to, and agrees not to sue the hospital, its authorized representatives, and any third parties with respect to any acts, communications or documents, recommendations, or disclosures involving the applicant.

SUBMISSION OF APPLICATION:

Completed applications to practice as Allied Health Professionals shall be submitted to the Medical Staff Office via MSONet (our online credentialing module) and must be accompanied by the designated processing fee. After reviewing the application to determine that all questions have been answered, reviewing all references and other information or materials deemed pertinent, and verifying the information provided in the application with the primary sources, the Medical Staff Office shall transmit the completed application along with all supporting materials to the Credentials Committee, via the Fast Track Criteria or Regular Track Criteria.
FAST TRACKING CREDENTIAL FILES

**POLICY:** In order to increase efficiency of the Allied Health Professional credentialing process, all applications will be categorized into a fast track category or a regular track category. Those applicants classified into the fast track will be processed in an expeditious manner once the file is deemed to be complete by the Medical Staff Office. Applications classified into the regular track will be processed separately.

A fast track application will be associated with a recently trained practitioner in practice for whom there was absolutely no difficulty in verifying information on the application and the application meets all of the criteria for fast track.

A regular track application will be processed for a practitioner in accordance with the criteria described below.

**Fast Track Criteria**

1. Recently trained applicant within five years of appropriate training program, i.e., nursing school, PA, ARNP training, etc.
2. Three or fewer prior hospital appointments.
3. No references suggesting potential problems.
4. No prior malpractice actions including notice of intent over the past five years.
5. No reports of disciplinary action, licensure restrictions or investigations.
6. Requests standard services consistent with specialty and training.

**FAST TRACKING CREDENTIAL FILES (con't)**

7. Meets criteria for all requested specific privileges.
8. No unexplained chronological gaps.

**Regular Track Criteria**

1. Letters of reference suggest applicant may have problems in behavior, ethics or patient care.
2. Report of malpractice event, either open case(s) or closed case(s) with awards during the past five years.
3. Report of challenge, limitation or revocation of license, DEA Certificate, membership or privileges voluntarily or involuntarily relinquished.
4. Requests privileges varying from that expected of specialty.
5. Unexplained chronological gaps.

**CREDENTIALING PROCEDURE:**

(a) If the application has not been fast tracked, the Credentials Committee shall examine the application and all supporting information and documentation, evaluate the applicant's education, training and experience, and make a recommendations to the Executive Committee regarding the applicant's qualifications for affiliation and clinical privileges as an Allied Health Professional. The Credentials Committee may use the expertise of any individual on the Medical Staff, or an outside consultant, if additional information is required regarding the applicant's qualifications. In evaluating the application, the Credentials Committee may also meet with the applicant.

(b) At its next regular meeting after receipt of the written findings and recommendation of the Credentials Committee, the Medical Executive Committee shall:

1. adopt the findings and recommendation of the Credentials Committee;
2. refer the matter back to the Credentials Committee for further consideration and preparation of responses to specific questions raised by the Medical Executive Committee prior to its recommendation to the Governing Board; or
3. set forth in its report and recommendation specific reasons, along with supporting information, for its disagreement with the Credentials Committee's recommendation. Thereafter, the Medical Executive Committee's recommendation shall be forwarded together with the Credentials Committee's findings and recommendation, through the Hospital President to the Governing Board.
PROCEDURAL RIGHTS FOR ALLIED HEALTH PROFESSIONALS:

Allied Health Professionals are entitled to a fair hearing process. Each practitioner may be subject to discipline and remedial action, and his or her privilege to provide selected clinical services may be denied, restricted, reduced, suspended or revoked. In the event an action is taken that is adverse to the practitioner as defined below, the practitioner may request an appeal consistent with this policy.

APPEAL OF ADVERSE ACTION

A. The following recommendations or actions shall, if deemed adverse as noted below, entitle the practitioner to an appeal under timely and proper request:

- Denial or restriction of requested clinical privileges
- Reduction of clinical privileges
- Suspension of clinical privileges
- Revocation of clinical privileges

B. A recommendation or action listed above in section ‘A’ is adverse only when it has been:

- recommended by the Medical Executive Committee to the Governing Board approved by the Governing Board

C. The Vice President of Quality and Medical Staff Services shall promptly give the practitioner special notice of an adverse recommendation or action taken pursuant to section ‘B’ above. The notice shall do the following:

- Advise the practitioner of the recommendation or action and of his or her right to request an appeal pursuant to the provisions of this policy
- Specify that the practitioner has thirty (30) days after receiving the notice within which to submit a request for an appeal
- Indicate that the right to appeal may be forfeited if the practitioner fails, without good cause, to appear at the scheduled appeal
- State that as part of the appeal the practitioner involved has the right to receive an explanation of the decision made and to submit any additional information the practitioner deems relevant to the review and appeal of this decision
- State that upon completion of the appeal, the practitioner involved has the right to receive a written decision of the hospital, including a statement of the basis of the decision

D. The practitioner has thirty (30) days after receiving notice under section ‘C’ to file a request for an appeal. The request must be delivered to the Director of Medical Staff Services and Hospital President either in person or by certified or registered mail.

E. A practitioner who fails to request an appeal within the time, and in the manner specified in section ‘D’, waives his or her right to an appeal to which he or she might otherwise have been entitled.

F. When a practitioner requests an appeal, the appeal shall consist of a single meeting attended by the practitioner, the Hospital President or designee and the President of the Medical Staff or designee. During this meeting, the basis of the decision adverse to the practitioner which gave rise to the appeal will be reviewed with the practitioner, and the practitioner will have the opportunity to present any additional information the practitioner deems relevant to the review and appeal of the decision. Following this meeting, the Hospital President or designee and the President of the Medical Staff or designee will make a recommendation to the Board, which will then determine whether the adverse decision will stand, be modified, or be reversed. The practitioner will receive a written decision of the hospital stating the result of the appeal and the basis of the decision.

G. The appeal process will be the sole remedy available to a practitioner who qualifies for this appeal who experiences an adverse decision in section ‘B’ above.

H. Nothing in this policy shall be deemed to deny a practitioner the right to engage or be advised by legal counsel. However, participation by legal counsel at the appeal meeting shall be at the sole discretion of the hospital.
AUTOMATIC TERMINATION OF PRIVILEGES
A physician who has privileges of Shady Grove Medical Center may apply on behalf of allied health professionals (AHP) for AHP privileges. Such AHP privileges shall be contingent upon the supervising/sponsoring physician's privileges. When a physician loses privileges or resigns, the AHPs whom he or she has supervised/sponsored automatically lose their privileges. They are not entitled to fair hearing procedures enumerated in the medical staff bylaws, collective bargaining agreements, or elsewhere. Additionally, employed AHPs who have their employment terminated will automatically have their privileges terminated. This termination will be reported to the National Practitioner Data Bank and the respective Maryland Board.

NO ENTITLEMENT TO MEDICAL STAFF APPOINTMENT:
Individuals applying to serve as Allied Health Professionals are not eligible for appointment to the Medical Staff of Shady Grove Medical Center, nor entitled to the rights, privileges, and/or prerogatives relevant to Medical Staff appointment.

APPLICATION FOR RENEWED SCOPE OF PRACTICE:
(a) Permission to practice at Shady Grove Medical Center as an Allied Health Practitioner shall be granted for a period not to exceed two years. In seeking renewed permission and scope of practice, AHPs shall be required to complete an appropriate re-application form.
(b) These re-applications shall be evaluated in the same manner and follow the same procedures as initial applications.

HOSPITAL EMPLOYEES:
Individuals who are employees of Shady Grove Medical Center shall not function in the hospital as Allied Health Professionals, but shall be governed by such hospital policies, manuals, and descriptions as may be established from time to time by the Hospital President or other appropriate designees. Where applicable, the Hospital President (or designee) shall consult with appropriate Medical Staff appointees and/or committees regarding the qualifications of those hospital employees whose responsibilities require the delineation of clinical privileges or scope of practice.

AMENDMENTS:
This Policy may be amended by a majority vote of the members of the Medical Executive Committee present and voting at any meeting of that committee where a quorum exists, provided the written recommendations of the Credentials Committee concerning the proposed amendments shall have first been received and reviewed by the MEC and upon approval by the Governing Board.
PURPOSE
To optimize patient safety by establishing consistent hospital-wide processes for the management of patients receiving procedural sedation by non-anesthesiologists. In general, non-anesthesiologists will administer sedative medications in doses intended to produce moderate levels of sedation.*

Related Policies
Ketamine Sedation Policy #101-01-228, Discharge Criteria from PACU #101-08-002, Fast-Track Policy for PACU #101-08-003, Propofol Sedation Policy #019, Surgical/Invasive Procedure Site Verification Process #101-10-131

POLICY
Moderate sedation is intended to reduce patients’ pain and awareness during diagnostic or therapeutic procedures. The sedative medication dosages are not intended to result in loss of protective airway reflexes, significantly depress ventilation, or cause cardiovascular compromise. However, because sedation is a continuum and because there is wide variation in patient response to sedative agents, it is not always possible to predict how an individual patient will respond. Occasionally a patient who receives sedation medication in doses that typically produce moderate sedation will slip into a deeper level of sedation. The deeper level of sedation may be associated with potentially catastrophic airway obstruction, hypoventilation, or cardiovascular instability. At Shady Grove Medical Center medical staff and nurses who participate in moderate sedation will have the skills and equipment necessary to recognize the different levels of sedation and then “rescue” patients who slip into deeper-than-intended levels of sedation. Pre-sedation evaluation will be designed to identify appropriate candidates for sedation by non-anesthesiologists and then optimize these patients prior to sedation. Intra-procedure monitoring and post-sedation care will insure that adverse physiologic changes are rapidly recognized and corrected. The processes included in this policy are based upon standards and guidelines developed by the American Society of Anesthesiologists, the American Academy of Pediatrics, and the Joint Commission on Accreditation of Healthcare Organizations.

*Only specially-credentialed emergency medicine physicians may administer sedation in doses intended to produce deep sedation. Please see Shady Grove Hospital policies on the use of propofol and ketamine by non-anesthesiologists for specific requirements.

Exceptions. The moderate sedation policy applies only when sedation is given under the direction of a non-anesthesiologist for patients undergoing diagnostic or therapeutic procedures. The policy specifically excludes the following:

1. Sedation/Analgesia for the control of pain, anxiety, seizures or insomnia.
2. Sedation of patients on ventilators.
3. Sedation/Analgesia used in obstetrical labor.
4. Patients requiring urgent intubation.
5. Sedation/Analgesia given by an anesthesiologist’s order in the pre-operative or PACU areas.
6. Sedation/Analgesia administered in the NICU under the direction of a neonatologist.
Locations. This policy applies to moderate sedation in all locations within Shady Grove Medical Center and the Germantown Emergency Center. This includes the Cardiovascular/Interventional Radiology Labs, Emergency Department, Critical Care areas, Surgical Services, GI endoscopy, and any other area at the discretion of the supervising physician where appropriate staff and equipment are available.

Staff. A physician and registered nurse must be involved in the care of each patient undergoing moderate sedation during the entire procedure:

1. A qualified physician who performs the diagnostic or therapeutic procedure supervises the administration of sedation. The physician must remain immediately available from the time of the first dose of sedation until the patient is accepted by a recovery room nurse.
2. A Registered Nurse with special training is responsible for administering sedation and monitoring the patient at the direction of the physician. The nurse should remain at the head of the bed whenever possible to facilitate direct observation of the airway.
3. If assistance is required with the procedure, then additional personnel (>2) must be utilized. The nurse monitoring the patient may not assist with the procedure.

Essential Equipment. The following equipment and supplies must be available wherever sedation is to be used:

1. Minimal monitoring equipment includes non-invasive blood pressure, continuous EKG, pulse oximeter, and end-tidal CO2 monitor. Whenever possible the monitor alarms will be set to indicate oxygen saturation less than 90% and apnea ≥ 30 seconds. In addition, when available, the pulse oximeter will be set to have a variable-pitch tone that is audible to the supervising physician. When audible alarms are not available the sedation nurse will remain at the head of bed in continuous visual contact with both the patient and display of vital signs.
2. Resuscitation equipment for management of the airway (including ambu-bag and intubation tray) along with a fully assembled and functioning suction apparatus must be immediately available. Airway equipment must be of appropriate size for the patient.
3. A defibrillator and cardiac resuscitation drugs in accordance with ACLS standards must be readily available.
4. Reversal agents must be immediately available.
5. Wall oxygen source must be present and at least one full oxygen E-cylinder with regulator as back-up must be readily available.
6. Appropriate equipment to administer intravenous fluids and drugs must be immediately available.

DEFINITIONS

Definitions of four levels of sedation and anesthesia include the following:

1. Minimal sedation (anxiolysis)
   A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

2. Moderate sedation/analgesia (formerly conscious sedation)
   A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Note: reflex withdrawal from a painful stimulus is not considered a purposeful response). No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

3. Deep Sedation
   A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation.
may be inadequate. Cardiovascular function is usually maintained. Deep sedation is restricted for use by anesthesiologists and specially-credentialed emergency medicine physicians.

4. **Anesthesia**
   Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. Anesthesia is restricted for use by anesthesia providers.

5. **Aldrete Score**
   Physiologic assessment scoring system used to evaluate patients' recovery from sedation or anesthesia (Appendix 1).

6. **ASA Score**
   American Society of Anesthesiologists physical status classification system (Appendix 2).

7. **Mallampati Classification**
   Airway evaluation technique that predicts difficult intubation using direct laryngoscopy (Appendix 3).

8. **Motor Activity Assessment Scale**
   Scale used to assess level of sedation (Appendix 4)

9. **Fasting Protocol**
   Nationally recognized guidelines that establish the safe length of time from intake of food or liquid until administration of sedation. It represents the time necessary to ensure gastric emptying and is intended to reduce the risk of catastrophic aspiration of gastric contents (Appendix 5)

10. **Recommended Doses of Sedative Medications**
    Institution specific guidelines for drug dosages intended to produce a moderate level of sedation (Appendix 6)

11. **Immediately available**
    Located at the bedside and obtainable within seconds.

12. **Readily available**
    Located within the same suite and obtainable within one to two minutes.

**CREDENTIALING REQUIREMENTS**

Only physicians are qualified by specialized training will be permitted to supervise the administration of moderate sedation. Physicians must demonstrate competency in: (1) the safe administration of sedative and analgesic drugs used to establish a moderate level of sedation, (2) rescue of patients who exhibit adverse physiologic consequences of a deeper-than-intended level of sedation, and (3) awareness of the patient care processes outlined in this policy. The Chairman of the Department of Anesthesia is responsible for reviewing each application for privileges in moderate sedation and making a recommendation to the Credentials Committee regarding competency.
Physician Adult Sedation Privileges. Physicians with adult sedation privileges may provide sedation care to patients fifteen years of age and older. Adult moderate sedation privileges are part of core privileges for the Department of Emergency Medicine. Physicians who are not members of the Department of Emergency Medicine must fulfill the following requirements:

1. **Initial Competency Requirements.**
   b. Completion of a residency/fellowship training program within the last two (2) years that includes a formalized education component on the safe administration of sedative drugs. (letter from the residency director required).

   **OR**

   Review of the Shady Grove self-education module on moderate sedation including:
   a) ASA Guidelines on Preoperative Fasting
   b) ASA Guidelines for Administration of Moderate Sedation
   c) ASA Video on Sedation and Analgesia by Non-Anesthesiologists

   c. Review of the Shady Grove Medical Center Policy on Moderate Sedation.
   d. Score of ≥ 80% on the Shady Grove Medical Center Moderate Sedation Competency Test.

2. **Ongoing Competency Requirements.** Recredentialing of sedation privileges will be evaluated on the same two year cycle as staff appointments.
   b. Review of the most recent revision of the Shady Grove Medical Center Hospital Policy on Moderate Sedation.
   c. Evidence of at least eight (8) sedations during the previous two years submitted by the requesting physician.

   **OR**

   Completion of the above Initial Competency Requirements in Moderate Sedation.

**Pediatric Sedation Privileges.** Only physicians with pediatric moderate sedation privileges may administer moderate sedation to patients less than fifteen (15) years of age. Pediatric moderate sedation privileges are part of core privileges for the Department of Emergency Medicine. Privileges to administer moderate and deep sedation to patients admitted to the NICU are part of core privileges for the Neonatology Subsection.

**Competency Requirements for Nurses.**

1. Only Registered Nurses who have completed the Shady Grove sedation competency module may assist in the administration of sedation.
2. Current ACLS certification or PALS certification (for those nurses who assist in the administration of sedation to patients less than fifteen years of age).
Special Considerations for Pediatric Sedation

Sedation of pediatric patients has serious associated risks such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment. Because pediatric patients have less physiologic reserve than adult patients, a more rapid deterioration in vital signs usually follows an adverse respiratory event. Therefore the presence of appropriate resuscitation equipment as well as a physician with advanced pediatric airway skills are essential. Younger children (less than six years of age) and those with developmental delays frequently require deep levels of sedation in order to cooperate with even relatively minor procedures (see the ketamine and propofol sedation Policies for details).

Equipment. Locations where pediatric sedation is administered must be equipped with resuscitation equipment of appropriate age-specific sizes. This includes laryngoscope blades, endotracheal tubes, oral/nasal airways, suction catheters, yankauer tips, defibrillator and pads, monitoring equipment and resuscitation drugs. Typically airway supplies (airways, endotracheal tubes) of the patient's size and one size smaller should be immediately available.

Pre-procedure Evaluation. The pre-procedure evaluation must include the patient's weight, history of reactive airway disease, symptoms of upper respiratory infection (if present), and family history of anesthetic complications.

Consent. A responsible adult must understand and sign a consent form for patients less than eighteen (18) years of age unless the patient is an emancipated minor.

Monitoring. It is recognized that some children will not tolerate placement of routine sedation monitors without becoming agitated. In this circumstance, it is acceptable to administer sedation under careful observation until the child shows clinical signs such as drowsiness or spontaneous eye closure. At this point, monitors should be placed and the child should be monitored according to the standards detailed in this policy.

Patient Care Process

Pre-procedure Care.

RN Responsibilities. Nursing is responsible for collecting pertinent data and preparing the patient for the physician pre-sedation assessment. The nurse performs this task by completing The standard Pre-procedure Checklist which includes:

a. Confirmation that a valid history and physical exam is part of the medical record (the H&P must be performed within 30 days with updated heart and lung assessment within 7 days). The history and physical must be signed or co-signed by a credentialed member of the Shady Grove medical staff.

b. Most recent laboratory values.

c. Pregnancy tests should be considered for females greater than 12 years of age.

d. Point of care blood glucose measurement is performed for diabetic patients.

e. Consent signed by the performing physician and patient. The consent must include The name of the procedure, the side (for procedures that involve laterality), and designate that moderate sedation will be used.

f. Completed nursing assessment.

g. DNR status documented, if applicable

h. Up-to-date medication administration record.

i. Pre-procedure vital signs.

j. NPO status. The physician should be notified whenever a patient does not Meet the criteria set forth in the fasting protocol.

k. Confirmation that the anatomical site is marked by the physician.

2. Physician Responsibilities

a. Informed Consent. The physician performing the procedure and supervising the sedation must inform the patient/guardian about the risks, possible complications benefits and alternatives to sedation as a component of the planned procedure. Patients or their authorized representatives should agree to the administration of moderate sedation before the procedure begins.

b. The physician orders and reviews the results of pertinent laboratory testing. Pre-sedation testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation.
c. The physician conducts and documents a pre-sedation assessment within 24 hours of the start of the procedure. The assessment may be documented on the standard “Pre-sedation Assessment Form” (appendix 6) and must include the following:

i. Physical Status Classification.
ii. Focused history documenting any interim changes in health or previous adverse reaction to sedation/anesthesia.
iii. Airway Examination.
iv. NPO status*.
v. Review of pertinent lab values (patients with end-stage renal disease must have a basic metabolic panel within 24 hours of sedation).
vi. Plan for sedation.
vii. Re-evaluation of the patient (including vital signs and mental status) just prior to sedation.

d. The physician conducts a “Time-Out” according to the Shady Grove Policy# 101-10131 just prior to starting the procedure.

e. For outpatients, the physician will confirm that appropriate arrangements have been made for a responsible adult to drive the patient home.

f. The physician will consider consultation with an anesthesiologist for high-risk patients. The criteria listed in Appendix 7 may be used as guide to help determine when consultation is indicated.

*The NPO protocol should be observed whenever a delay will not jeopardize the well being of the patient. Emergent and urgent clinical situations are expected to arise that preclude strict adherence to these guidelines. In these cases the amount of sedation should be minimized and carefully titrated in order to prevent the loss of protective airway reflexes. The risk of aspiration pneumonitis may be further reduced by the use of a non-particulate antacid (bicitra), H2-blockers and/or metoclopramide prior to sedation.

Intra-Procedure Care.

1. RN responsibilities. The nurse is responsible for administering sedation at the order of the physician while continuously assessing the patient’s physiologic status.

a. Documentation of the physiologic status of the patient.

i. Vital signs including blood pressure, heart rate, respiratory rate, oxygen saturation, and level of consciousness will be assessed and recorded prior to initiation of the procedure and on arrival to the recovery area.

ii. Blood pressure and heart rate will be assessed and documented every five minutes during the procedure. Cardiac rhythm, respiratory rate, level of consciousness, presence of EtCO2 and oxygen saturation will be continuously monitored and recorded at least every fifteen minutes.

iii. Medication administration, including dose, route, and times.

iv. IV fluid replacement.

b. The nurse will be positioned at the head of the bed and assess the patient continuously for changes in condition or appearance. The nurse will report any of these changes to the responsible physician immediately and initiate the appropriate intervention.

c. Administer oxygen as needed. Typically oxygen via nasal cannula will be administered in order to maintain oxygen saturation above 92% with the following considerations:

i. The application of oxygen reduces the incidence and severity of hypoxemia during moderate sedation. However, it must be remembered that the use of supplemental oxygen will delay the detection of apnea by the pulse oximeter. This emphasizes the importance of monitoring respiratory function by observation of chest excursion and EtCO2 detection.
ii. Fire Safety: If electrocautery is to be used near the airway, then oxygen flow should be minimized to the lowest amount necessary to maintain acceptable hemoglobin saturation. Sedation providers must minimize the build-up of oxygen beneath drapes and in oropharynx and position drapes so that gases will not collect. If possible, supplemental oxygen should be stopped at least one minute before and during the activation of the electrosurgical unit.

2. **Physician Responsibilities.** The physician orders sedative medication, determines dosage, and responds to adverse physiologic effects.
   
a. The responsible physician selects and orders all sedative medication.

b. The physician is responsible for airway interventions, if necessary.

c. The physician orders the administration of reversal agents when indicated.

   **Note:** Because reversal agents may have serious side-effects their use should be minimized and their dose titrated to effect (see recommended drug doses). Naloxone is relatively contraindicated in patients with a history of narcotic tolerance. Flumazenil is relatively contraindicated in patients with a history of alcohol abuse or long-standing benzodiazepine use.

### Post-Procedure Care

1. **RN Responsibilities.** Nursing is responsible for collecting pertinent data and preparing the patient for the physician pre-sedation assessment. The nurse performs this task by completing the standard Pre-procedure Checklist which includes:
   
a. Confirmation that a valid history and physical exam is part of the medical record (the H&P must be performed within 30 days with updated heart and lung assessment within 7 days). The history and physical must be signed or co-signed by a credentialed member of the Shady Grove medical staff.

b. Most recent laboratory values.

c. Pregnancy tests should be considered for females greater than 10 years of age.

d. Point of care blood glucose measurement is performed for diabetic patients.

e. Consent signed by the performing physician and patient. The consent must include the name of the procedure, the side (for procedures that involve laterality), and designate that moderate sedation will be used.

f. Completed nursing assessment.

  **g.** DNR status documented, if applicable

  **h.** Up-to-date medication administration record.

  **i.** Pre-procedure vital signs.

  **j.** NPO status. The physician should be notified whenever a patient does not meet the criteria set forth in the fasting protocol.

  **k.** Confirmation that the anatomical site is marked by the physician.

2. **Physician Responsibilities**

   a. Informed Consent. The physician performing the procedure and supervising the sedation must inform the patient/guardian about the risks, possible complications, benefits and alternatives to sedation as a component of the planned procedure. Patients or their authorized representatives should agree to the administration of moderate sedation before the procedure begins.

   b. The physician orders and reviews the results of pertinent laboratory testing. Pre-sedation testing should be guided by the patient’s underlying medical condition and the likelihood that the results will affect the management of sedation.

   c. The physician conducts and documents a pre-sedation assessment within 24 hours of the start of the procedure. The assessment may be documented in the EMR or on the standard “Pre-sedation Assessment Form” (appendix 6) and must include the following:

      i. Physical Status Classification.

      ii. Focused history documenting any interim changes in health or previous adverse reaction to sedation/anesthesia.

      iii. Airway Examination.

      iv. NPO status*. 


v. Review of pertinent lab values (patients with end-stage renal disease must have a basic metabolic panel within 24 hours of sedation).
vi. Plan for sedation.
vii. Re-evaluation of the patient (including vital signs and mental status) just prior to sedation.

d. The physician conducts a “Time-Out” according to the Shady Grove Policy# 101-10-131 just prior to starting the procedure.
e. For outpatients, the physician will confirm that appropriate arrangements have been made for a responsible adult to drive the patient home.
f. The physician will consider consultation with an anesthesiologist for high-risk patients. The criteria listed in Appendix 7 may be used as guide to help determine when consultation is indicated.

*The NPO protocol should be observed whenever a delay will not jeopardize the well being of the patient. Emergent and urgent clinical situations are expected to arise that preclude strict adherence to these guidelines. In these cases the amount of sedation should be minimized and carefully titrated in order to prevent the loss of protective airway reflexes. The risk of aspiration pneumonitis may be further reduced by the use of a non-particulate antacid (bicitra), H2-blockers and/or metoclopramide prior to sedation.

Intra-Procedure Care

1. RN responsibilities. The nurse is responsible for administering sedation at the order of the physician while continuously assessing the patient’s physiologic status.
   a. Documentation of the physiologic status of the patient may be in the EMR or on the Shady Grove Sedation and Analgesia Flowsheet (Appendix 9).
      i. Vital signs including blood pressure, heart rate, respiratory rate, oxygen saturation, and level of consciousness will be assessed and recorded prior to initiation of the procedure and on arrival to the recovery area.
      ii. Blood pressure and heart rate will be assessed and documented every five minutes during the procedure. Cardiac rhythm, respiratory rate, level of consciousness, presence of EtCO2 and oxygen saturation will be continuously monitored and recorded at least every fifteen minutes.
      iii. Medication administration, including dose, route, and times.
      iv. IV fluid replacement.
   b. Whenever possible the nurse will be positioned at the head of the bed and assess the patient continuously for changes in condition or appearance. The nurse will report any of these changes to the responsible physician immediately and initiate the appropriate intervention.
   c. Administer oxygen. Typically oxygen via nasal cannula will be administered in order to maintain oxygen saturation above 92% with the following considerations:
      i. The application of oxygen reduces the incidence and severity of hypoxemia during moderate sedation. However, it must be remembered that the use of supplemental oxygen will delay the detection of apnea by the pulse oximeter. This emphasizes the importance of monitoring respiratory function by observation of chest excursion and EtCO2 detection.
      ii. Fire Safety: If electrocautery is to be used near the airway, then oxygen flow should be minimized to the lowest amount necessary to maintain acceptable hemoglobin saturation. Sedation providers must minimize the build-up of oxygen beneath drapes and in oropharynx and position drapes so that gases will not collect. If possible, supplemental oxygen should be stopped at least one minute before and during the activation of the electrosurgical unit.

2. Physician Responsibilities. The physician orders sedative medication, determines dosage, and responds to adverse physiologic effects.
   a. The responsible physician selects and orders all sedative medication.
   b. The physician is responsible for airway interventions, if necessary.
   c. The physician orders the administration of reversal agents when indicated.

   Note: Because reversal agents may have serious side-effects their use should be minimized and their dose titrated to effect (see recommended drug doses). Naloxone is relatively contraindicated in patients with a history of narcotic tolerance. Flumazenil is relatively contraindicated in patients with a history of alcohol abuse or long-standing benzodiazepine use.
Post-Procedure Care

1. **RN Responsibilities.** Nursing is responsible for monitoring the patient until their physiologic status has returned to a level at or close to their baseline. The following standards for monitoring and discharge criteria will be used:
   a. Oxygen saturation and EKG will be continuously monitored. Vital signs including blood pressure, heart rate, oxygen saturation, level of consciousness and respiratory rate will be documented on arrival to the recovery area and every fifteen (15) minutes thereafter.
   b. Significant changes in the patient’s condition are reported to the physician immediately. These include:
      i. Symptomatic changes in blood pressure.
      ii. Oxygen saturation less than 90% with supplemental oxygen.
      iii. Heart rate <45 or >110.
      iv. Dyspnea, apnea, diaphoresis.
      v. Inability to arouse.
      vi. Need for mechanical airway support.
      vii. Any other unexpected patient response
   c. Pain level will be assessed every fifteen (15) minutes using a visual analog scale. Pain score greater than five (5) not easily controlled with ordered post-procedure analgesics will be reported to the responsible physician.
   d. The nurse will assess the Aldrete score every fifteen minutes and discharge the patient according to the below criteria as approved by the Medical Staff.
   e. Those patients who meet the criteria for the SGMC Fast-Track Protocol at the conclusion of the procedure may be admitted directly to Phase II PACU and be advanced immediately to the Phase II care guidelines

2. **Physician Responsibilities.**
   a. The procedural physician is responsible for all orders in the recovery phase including but not limited to: analgesics, oxygen therapy, hemodynamic medications and reversal agents.
   b. The procedural physician signs the discharge order.
   c. The procedural physician documents a post-procedure/sedation progress note immediately following the procedure.

3. **Discharge Criteria.**
   a. Inpatients will be discharged from the recovery area to other inpatient areas when they have met the following criteria and after SBAR report is given to the receiving nurse. Inpatients will be transported via stretcher or wheelchair accompanied by a staff member. Patients will be instructed regarding post-procedure status and activities.
      i. Aldrete score of ten (10). Patients with an Aldrete score less than ten may be discharged only by physician order.
      ii. If reversal agents are used then the patient must be observed for two hours after the last dose of an antagonist to insure that respiratory depression does not recur.
      iii. Stable vital signs over a period of at least fifteen minutes.
      iv. Adequate ventilation and oxygenation as evidenced by a stable respiratory rate and oxygen saturation appropriate for the patient. (Patients with room air oxygen saturation of less than 90 percent will be transported with supplemental oxygen).
      v. Ability to maintain/protect airway with level of alertness and orientation appropriate to pre-procedure status.
b. Outpatients will be discharged to home from the recovery area when they have met the following criteria:
   i. All discharge criteria listed above for inpatients have been met.
   ii. Patients who have received sedation are discharged in the company of a responsible adult. The patient will have arrangements for transportation home. Patients who have received sedation will not be allowed to drive themselves home.
   iii. The patient has received written discharge instructions that have been reviewed with the patient and/or escort.

Performance Improvement

Data Collection.

1. Peer Review. Each Department will review adverse sedation related events as part of their peer review process. Cases that receive a standard of care score of III or IV will be forwarded to the multidisciplinary Professional Peer Evaluation Committee for action.

2. Performance Improvement Indicators. The following adverse sedation-related events will be reported through the hospital's incident reporting system.

Reportable adverse events:
   i. Sustained SpO2 < 88% (>3 minutes) with supplemental oxygen.
   ii. Prolonged unresponsiveness (>30 minutes).
   iii. Sedation related death.
   iv. Sedation related cardiac/respiratory arrest.
   v. Aspiration pneumonia.
   vi. Sedation related rapid response or "Anesthesia stat" call

References

American Society of Anesthesiologists Standards and Guidelines:

1. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation, October 2014
2. Statement on Granting Privileges for Administration of Moderate Sedation to Non-Anesthesiologists, October 2011
4. Standards for Basic Anesthesia Monitoring, October 2015
5. Standards for Postanesthesia Care, October 2014
6. Practice Guidelines for Post-Anesthesia Care, October 2012
7. Basic Standards for Preanesthesia Care, October 2015
8. Practice Guidelines for Preop Fasting, October 2010
Appendix 1.

Aldrete Scoring System

<table>
<thead>
<tr>
<th>Activity</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to move four extremities voluntarily or on command</td>
<td>2</td>
</tr>
<tr>
<td>Able to move two extremities voluntarily or on command</td>
<td>1</td>
</tr>
<tr>
<td>Unable to move extremities voluntarily or on command</td>
<td>0</td>
</tr>
</tbody>
</table>

Respiration

<table>
<thead>
<tr>
<th>Ability</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to breathe freely and cough deeply</td>
<td>2</td>
</tr>
<tr>
<td>Dyspnea or limited breathing</td>
<td>1</td>
</tr>
<tr>
<td>Apneic</td>
<td>0</td>
</tr>
</tbody>
</table>

Circulation

| BP within 20% of pre-sedation level  | 2     |
| BP within 21 to 49% of pre-sedation level | 1     |
| BP more than 50% different from pre-sedation level | 0     |

Consciousness

<table>
<thead>
<tr>
<th>Awareness</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully awake</td>
<td>2</td>
</tr>
<tr>
<td>Arousable on calling</td>
<td>1</td>
</tr>
<tr>
<td>No response</td>
<td>0</td>
</tr>
</tbody>
</table>

Oxygen saturation

<table>
<thead>
<tr>
<th>O2 saturation</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to maintain O2 saturation greater than 92% on room air</td>
<td>2</td>
</tr>
<tr>
<td>Needs O2 inhalation to maintain O2 saturation greater than 90%</td>
<td>1</td>
</tr>
<tr>
<td>O2 saturation 90% or less even with O2 supplementation</td>
<td>0</td>
</tr>
</tbody>
</table>
Appendix 2.

ASA Physical Status Classification

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Normal healthy patient</td>
</tr>
<tr>
<td>II</td>
<td>Mild systemic disease</td>
</tr>
<tr>
<td>III</td>
<td>Severe systemic disease with definite functional impairment</td>
</tr>
<tr>
<td>IV</td>
<td>Severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>V</td>
<td>Moribund patient, not expected to survive</td>
</tr>
</tbody>
</table>
Appendix 3.
Mallampati Classification

![Mallampati Classification Diagram](image)

The Mallampati classification is a tool used to predict the ease or difficulty of intubation. It is determined by looking at the anatomy of the oral cavity. A high classification score (class 3 or 4) is predictive of difficult intubation and sleep apnea.

**Technique:**

The patient sits upright with head tipped back, mouth opened and tongue protruded. Classifications are described below.

- **Class I:** Can visualize soft palate, all of uvula, tonsillar pillars
- **Class II:** Can visualize soft palate, tip of uvula is obscured
- **Class III:** Can visualize soft palate
- **Class IV:** Can visualize hard palate only
Appendix 4.

Motor Activity Assessment Scale

The MAAS is a standardized method for describing level of sedation. Target MAAS scores for patients under moderate sedation are 2 to 3.

<table>
<thead>
<tr>
<th>Clinical Score</th>
<th>MAAS – Level of Sedation Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Unresponsive - Does not move with noxious stimuli</td>
</tr>
<tr>
<td>1</td>
<td>Responsive only to noxious stimuli - Opens eyes, OR raises eyebrows, OR turns head toward stimulus, OR moves limbs with noxious stimuli</td>
</tr>
<tr>
<td>2</td>
<td>Responsive only to touch - Opens eyes, OR raises eyebrows, OR turns head toward stimulus, OR moves limbs when touched, OR when name loudly spoken</td>
</tr>
<tr>
<td>3</td>
<td>Calm &amp; cooperative - No external stimulus required to elicit movement AND patient adjusts sheets or clothes purposefully and follows Commands</td>
</tr>
<tr>
<td>4</td>
<td>Restless &amp; cooperative - No external stimulus required to elicit Movement AND patient picks at sheets or tubes uncovering self AND follows command</td>
</tr>
<tr>
<td>5</td>
<td>Agitated - No external stimulus required to elicit movement AND patient attempts to sit up or move limbs out of bed AND does not consistently follow commands</td>
</tr>
<tr>
<td>6</td>
<td>Dangerously agitated - No external stimulus required to elicit movement AND patient pulls at tubes or catheters, OR thrashes side to side, OR strikes at staff, OR tries to climb out of bed and does not calm down when asked</td>
</tr>
</tbody>
</table>
Appendix 5.
Fasting Protocol

The following is a summary of American Society of Anesthesiologists Pre-procedure Fasting Guidelines:

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids</td>
<td>2 hours</td>
</tr>
<tr>
<td>Breast milk</td>
<td>4 hours</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6 hours</td>
</tr>
<tr>
<td>Non-human milk</td>
<td>6 hours</td>
</tr>
<tr>
<td>Light meal</td>
<td>6 hours</td>
</tr>
<tr>
<td>Full meal</td>
<td>8 hours</td>
</tr>
</tbody>
</table>

Please note:

1. These recommendations apply to healthy patients who are undergoing elective procedures. Following these guidelines does not guarantee that complete gastric emptying has occurred.

2. In emergency situations, when following the guidelines might result in patient harm, the physician providing sedation may proceed with the procedure while using precautions to minimize the risk of pulmonary aspiration.

3. Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

4. A light meal typically consists of toast and clear liquids.

5. Full meals include fried, fatty foods, or meats.
### SHADY GROVE MEDICAL CENTER MODERATE SEDATION
### ADULT DOSING SCHEDULE

<table>
<thead>
<tr>
<th>Generic Name (Trade Name)</th>
<th>Use</th>
<th>Dosing Guidelines</th>
<th>Onset, Peak, Duration of Action</th>
<th>Adverse Effects</th>
<th>Reversal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BENZODIAZEPINES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midazolam (Versed)</td>
<td>Sedation</td>
<td>Adults &lt;60 years old: IV: 0.5mg to 2.5mg over 2 to 3 minutes. Wait 2 minutes to evaluate sedative effect before giving additional doses. IM: 0.07 to 0.08mg/kg as one time dose Total Dose: 7.5 mg IV</td>
<td>Onset: IV: 1-5 min IM: 15 min Peak: IV: 20-60 min IM: 30-60 min Duration: IV: 1-2 hours IM: 6 hours</td>
<td>Respiratory depression Paradoxical agitation Hypotension (especially with opioid) Arrhythmias Nausea/ emesis/ Headache Hallucinations Hiccoughs</td>
<td>Flumazenil (Watch for rebound sedation)</td>
</tr>
<tr>
<td></td>
<td>Amnesia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anxiolysis</td>
<td>Adults ≥60 years old: IV: 0.5 to 1.5mg IV over 2 to 3 minutes. Titrate as above. IM: 0.02 to 0.05mg/kg Total Dose: 5mg IV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>Sedation</td>
<td>IV: 2-3 mg over 2-5 min IM: 0.025 to 0.05mg/kg PO: 2 to 4mg Total Dose: 4mg</td>
<td>Onset: IV: 1-5 min IM: 15 min IM: 30-60 minutes Peak: IV: 15-20 min IM: 2-3 hours PO: 2 hours Duration: 4-8 hours</td>
<td>See Midazolam</td>
<td>Flumazenil</td>
</tr>
<tr>
<td></td>
<td>Amnesia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diazepam (Valium)</td>
<td>Sedation</td>
<td>IV: 2-5 mg Administer at a rate less than 1.5mg/min to avoid phlebitis IM: 5-10 mg Total Dose: 10mg</td>
<td>Onset: IV: 1-5 min IM: 30 min Peak: IV: 10-30 min IM: 2-3 hours Duration: 2-6 hours</td>
<td>Venous thrombosis and phlebitis at injection site See Midazolam</td>
<td>Flumazenil</td>
</tr>
<tr>
<td></td>
<td>Amnesia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### SHADY GROVE MEDICAL CENTER MODERATE SEDATION
### ADULT DOSING SCHEDULE (CONT)

#### OPIOIDS

<table>
<thead>
<tr>
<th>Generic Name (Trade Name)</th>
<th>Use</th>
<th>Dosing Guidelines</th>
<th>Onset, Peak, Duration of Action</th>
<th>Adverse Effects</th>
<th>Reversal</th>
</tr>
</thead>
</table>
| Fentanyl (Sublimaze)      | Sedation       | 0.5-1.0 mcg/kg/dose IV/IM  
**Administer slowly over** 1-2 minutes  
Total Dose 3mcg/kg | Onset:  
IV: 1 minutes  
IM: 7-8 minutes  
Peak:  
IV: 3-5 minutes  
IM: No data  
Duration:  
IV: 30-60 minutes  
IM: 1-2 hours | Respiratory depression  
Hypotension  
Bradycardia  
Chest wall rigidity with rapid dosing | Naloxone |
| Morphine Sulfate          | Sedation       | **Adults<60 years old:**  
2-5 mg/dose IV  
Total dose- 15 mg  
**Adults>= 60 years old:**  
2-3 mg/dose IV  
Total dose- 10 mg | Onset:  
IV: 5-10 minutes  
Peak:  
IV: 20 minutes  
Duration:  
IV: 4-5 hours | Respiratory depression  
Hypotension  
Bradycardia  
Nausea  
Pruritis  
Urinary retention | Naloxone |
| Meperidine (Demerol)      | Sedation       | **Adults<60 years old:**  
25-50 mg IV  
Total dose- 150 mg  
**Adults>=65 years old:**  
25-50 mg IV  
Total dose- 100 mg | Onset:  
IV: 5-10 minutes  
Peak:  
IV: 10-15 minutes  
Duration:  
IV: 2-4 hours | Respiratory depression  
Hypotension  
Bradycardia  
Tachycardia  
Nausea  
Pruritis  
Urinary retention  
Epileptogenic | Naloxone |
<table>
<thead>
<tr>
<th>Generic Name (Trade Name)</th>
<th>Use</th>
<th>Dosing Guidelines</th>
<th>Onset, Peak Duration of Action</th>
<th>Adverse Effects</th>
<th>Reversal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naloxone (Narcan)</td>
<td>Reverses opioid induced analgesia &amp; sedation</td>
<td>For Respiratory Depression: 0.1 mg IV every 2-3 minutes with 0.1 mg increments&lt;br&gt;Total dose - 1 mg in 5 min For Apnea/Arrest: 0.4 to 2mg IV/IM every 2-3 minutes&lt;br&gt;Total dose - 10 mg</td>
<td>Onset: IV: 1-2 minutes IM: 2-4 minutes Peak: No data Duration: IV: &lt;45 minutes IM: 60 minutes The duration of opioid may be longer than the duration of the antagonist</td>
<td>Nausea/Vomiting Diaphoresis Seizures Severe pain Excitement Hypertension Tachycardia Ventricular arrhythmia Pulmonary edema Myocardial ischemia Watch for return of respiratory depression</td>
<td>N/A</td>
</tr>
<tr>
<td>Flumazeil (Romazicon)</td>
<td>Complete or partial reversal of benzodiazepine sedation</td>
<td>0.2 mg IV followed in one minute by 0.3 mg then 0.5 mg IV q 1 min&lt;br&gt;Total dose - 3 mg IV</td>
<td>Onset: IV: 1-2 minutes Peak: IV: 6-10 minutes Duration IV: 60 minutes</td>
<td>May precipitate seizures</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### SHADY GROVE MEDICAL CENTER MODERATE SEDATION
**PEDIATRIC DOSING SCHEDULE**

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Use</th>
<th>Dosing Guidelines</th>
<th>Onset and Duration of Action</th>
<th>Adverse Effects</th>
<th>Reversals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral Hydrate</td>
<td>Pediatric Sedative/ Hypnotic</td>
<td>25-100 mg/kg PO or PR Total Dose: 1 gram or 2 grams/24 hours</td>
<td>Onset: 45-60 min Duration: 4-9 hours</td>
<td>CNS Depression Resp Depression Arrhythmias Paradoxical Agitation Urticaria</td>
<td>None</td>
<td>Wide safety margin Not a good choice if attempt to titrate dose to effect</td>
</tr>
</tbody>
</table>

### BENZODIAZEPINES

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Use</th>
<th>Dosing Guidelines</th>
<th>Onset and Duration of Action</th>
<th>Adverse Effects</th>
<th>Reversals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midazolam (Versed)</td>
<td>Sedation Amnesia Anxiolytic</td>
<td>IV: 0.05-0.1 mg/kg/dose IV Total IV Dose: 0.2 mg/kg PO 0.5-0.75 mg/kg Total dose: 15 mg PO IM 0.1-0.2 mg/kg/dose IN: 0.3-0.4 mg/kg</td>
<td>Onset: IV: 1-5 min IN: 10-15 min PO: 15 min Duration: 20-60 min PO: up to 2 hours</td>
<td>Resp Depression Paradoxical agitation Hypotension (esp w opioid) Arrhythmias Nausea/ vomiting Headache Hallucinations Hiccoughs</td>
<td>Flumazenil: Reduce dose by 25-50% when giving with narcotic (e.g Fentanyl) and wait 10 min for desired effect</td>
<td></td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>Sedation Amnesia</td>
<td>IV: 0.05-0.1 mg/kg PO: 0.05-0.2 mg/kg Max: 4 mg total</td>
<td>Onset: IV: 1-5 min Duration: 4-6 hours</td>
<td>See Midazolam</td>
<td>Flumazenil Midazolam a better choice unless desire a long duration of action</td>
<td></td>
</tr>
</tbody>
</table>
### SHADY GROVE MEDICAL CENTER MODERATE SEDATION
### PEDIATRIC DOSING SCHEDULE (con’t)

#### OPIOIDS

- Avoid repeat IM dosing
- If titrating to response, IV route is recommended

<table>
<thead>
<tr>
<th>Generic Name (Trade Name)</th>
<th>Use</th>
<th>Dosing Guidelines</th>
<th>Onset and Duration of Action</th>
<th>Adverse Effects</th>
<th>Reversals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl (Sublimaze)</td>
<td>Sedation Analgesia</td>
<td>0.7-1.0 mcg/kg/dose May repeat in 2-3 min Total dose:5 mcg/kg</td>
<td>Onset: 1 min IV Duration 30-60 min IV</td>
<td>Respiratory depression Hypotension Bradycardia Chest wall rigidity w/ rapid admin. Facial pruritis</td>
<td>Naloxone</td>
<td>Do NOT exceed rate of admin of 1 mcg/kg/min IV</td>
</tr>
<tr>
<td>Morphine sulfate</td>
<td>Sedation Analgesia</td>
<td>0.05-0.15 mg/kg/dose IV 0.1 mg/kg IM or SC Total dose: 0.2 mg/kg</td>
<td>Onset: 5 min IV 15-30 min IM or SC Duration: 1-5 hr</td>
<td>Resp depression Hypotension Bradycardia Nausea Pruritis Urinary retention Epileptogenic</td>
<td>Naloxone</td>
<td>Reduce dose by 50% if given with Benzodiazepine</td>
</tr>
<tr>
<td>Meperidine (Demerol)</td>
<td>Sedation Analgesia</td>
<td>0.5-1 mg/kg/dose IV 1-2 mg/kg IM Max total: 3 mg/kg or 150 mg</td>
<td>Onset 5 min IV 15-30 min IM Duration: 2-4 hours</td>
<td>Resp depression Hypotension Bradycardia Tachycardia Nausea Pruritis Urinary retention Epileptogenic</td>
<td>Naloxone</td>
<td>Avoid rapid IV push Better choices exist (Fentanyl/ MSO4)</td>
</tr>
</tbody>
</table>
# SHADY GROVE MEDICAL CENTER MODERATE SEDATION
## PEDIATRIC DOSING SCHEDULE (con’t)

## BARBITURATES

<table>
<thead>
<tr>
<th>Generic name (Trade name)</th>
<th>Use</th>
<th>Dosing guidelines</th>
<th>Onset and Duration of Action</th>
<th>Adverse Effects</th>
<th>Reversals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital (Nembutal)</td>
<td>Sedation Amnesia</td>
<td>IV: 1-2 mg/kg IM: 2-6 mg/kg PO: 2-6 mg/kg PR: 2-6 mg/kg Total: 6 mg/kg= 100mg</td>
<td>Onset: IV: 1-5 min IM: 10-15 min PO/PR: 30-60 min Duration: IV: 15 min PO/PR: 1-4 hours</td>
<td>Resp depression Hypertension Painful injection Hyperactive after awakening</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Methohexital (Brevital)</td>
<td>Sedation</td>
<td>PR: 20-30 mg/kg Use 100mg/ml solution</td>
<td>Onset: 5-10 min Duration: PR: 1-1.5 hours</td>
<td>See Pentobarbital Also: Hiccups, laryngospasm Seizures Muscle twitching, tremors</td>
<td>None</td>
<td>Rectal only</td>
</tr>
</tbody>
</table>

## REVERSAL AGENTS

<table>
<thead>
<tr>
<th>Generic name (Trade name)</th>
<th>Use</th>
<th>Dosing Guidelines</th>
<th>Onset and Duration of Action</th>
<th>Adverse Effects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naloxone (Narcan)</td>
<td>Reverses opioid induced analgesia &amp; sedation May reverse chest wall rigidity</td>
<td>Apnea or arrest: 0.01-0.1 mg/kg; redose at 2 min intervals to effect Resp depression: 0.001 mg/kg/dose OR Narcan drip: 1-30 ug/kg/hour</td>
<td>IV: 1-2 min IM/ETT: 2-5 min Duration: &lt; 45 min The duration of the opioid may be longer than the duration of the antagonist</td>
<td>Severe pain Excitement Hypertension Tachycardia Ventricular arrhythmia Pulmonary edema Myocardial Ischemia</td>
<td>Watch for return of respiratory depression</td>
</tr>
<tr>
<td>Flumazenil (Romazicon)</td>
<td>Complete or partial reversal of benzodiazepine Sedation</td>
<td>0.01 mg/kg IV q 1 min Total dose: 0.2 mg</td>
<td>Onset 1-3 min IV Duration: 45-60 min</td>
<td>May precipitate seizures</td>
<td>Use with extreme caution Watch for return of sedation/respiratory depression</td>
</tr>
</tbody>
</table>
Guidelines for Determining Need for Anesthesia Consultation

This document is intended to serve as a guide for physicians when deciding on the need for consultation with an anesthesiologist prior to sedation. These recommendations have been developed by consensus opinion of the Department of Anesthesia and are based on the best available medical evidence. The incidence of adverse outcomes related to sedation is increased in the presence of multiple risk factors and is especially high when risk factors from multiple categories (medical, behavioral, procedure-related) are present. In general, consultation is usually only necessary for the highest risk patients.

Patient related medical risk factors:

- ASA status ≥ 3 (especially due to end-stage renal/liver disease, severe pulmonary disease, obstructive sleep apnea, morbid obesity, ejection fraction < 25%)
- History of drug reaction to sedative agent
- History of drug or alcohol abuse/dependence
- Orthopnea
- Pregnancy
- Difficult airway by history or exam (Mallampati score ≥3, rigid c-spine, mouth opening <3cm, prominent incisors)

Patient behavioral risk factors:

- Dementia
- Highly anxious
- Uncooperative/hostile
- Altered mental status/delirium
- Significant mental illness (schizophrenia, bipolar)
- Autism

Procedure related risk factors:

- Procedures with the potential for causing significant pain
- Prolonged procedures (> 2 hours)
- Procedures requiring unusual positioning (prone)

Anesthesia consultation should be considered whenever one of the above risk factors is present. Consultation is recommended whenever risk factors from more than one category are present. For emergency procedures the physician should weigh the risk of proceeding immediately against the risk of delay associated with obtaining consultation.
This supplemental form must be completed by the procedural physician in addition to the History and Physical examination prior to implementation of sedation.

Pre-sedation Assessment:
- Morbid obesity*
- History adverse reaction to sedation*
- History of alcohol or narcotic dependence*
- End stage renal/liver disease*
- Other: ________________________________________________________________
- Other: ________________________________________________________________

Airway Assessment:
1. Circle patient’s Mallampati classification:
   - Class 1
   - Class 2
   - Class 3
   - Class 4

ASA Classification:
- Status I: Normal healthy patient
- Status II: Mild systemic disease
- Status III*: Severe organic disease with functional impairment
- Status IV*: Severe systemic disease that is a constant threat to life
- Status V*: Moribund patient, not expected to survive

NPO Status: Last solid food intake: __________ Last clear liquid intake: __________

*Associated with increased risk of an adverse sedation related event. Anesthesia consult should be considered when one or more of the above risk factors are present. Consult is recommended when risk factors exist and patient is uncooperative or undergoing high risk procedure.

☐ In light of the above evaluation, I believe this patient is an acceptable candidate for sedation/analgesia and have discussed the sedation/analgesia alternatives, indications for, and risks of sedation with the patient/parent/guardian, who understands and consents. ☐ Yes ☐ No

Comments: ________________________________________________________________

Signature of MD ___________________________________________ ID # __________ Date _____ Time __________

*IMMEDIATE PREOPERATIVE ASSESSMENT*

I have re-evaluated the patient immediately prior to the administration of sedation/analgesia medication and: (check appropriate box)

☐ The status is unchanged and I consider the patient an acceptable candidate for the procedure/sedation.
☐ Status has changed but still consider the patient to be an appropriate candidate for the procedure/sedation.
   Comment: ________________________________________________________________

☐ Due to a change in status the procedure will be canceled at the current time.
   Comment: ________________________________________________________________

Signature of MD ___________________________________________ ID # __________ Date _____ Time __________

Shady Grove Adventist Hospital

PRE-SEDATION/ ANALGESIA ASSESSMENT FORM

MEDICAL STAFF POLICY
SEDATION/ANALGESIA

Appendix 9.
### APPENDIX D

SHADY GROVE MEDICAL CENTER

- 45 -
**HEALTH POLICY**

**Effective Date:** January 14, 2002  
**Policy No:** #006  
**Cross Reference:** n/a  
**Origin:** Credentials Comm.  
**Reviewed:** 11/30/11  
**Revised:** June 28, 2006; 10/30/08; 08/26/09; 09/23/09  
**Authority:** Med. Exec. Comm.  
**Approved:** 09/23/09; 11/30/11  
**Page:** 1 of 7

### Policy Statement

1. The hospital and its medical staff are committed to providing patients with quality care. The delivery of quality care can be compromised if a member of the medical staff is suffering from impairment. Impairment may result from a physical, psychiatric or emotional condition.

2. Impairment is defined as one whose ability to practice medicine with reasonable skill and safety, is impaired because of a physical or mental illness, including deterioration through the aging process or loss of motor skill, or excessive use or abuse of drugs including alcohol.

3. The Health Committee shall consist of the President of the Medical Staff, Credentials Committee, Vice President/President/Chief Medical Officer and Hospital President.

4. Medical Staff Members who are suffering from an impairment that affects their ability to practice are encouraged to voluntarily bring the issue to the Health Committee so that appropriate steps can be taken to protect patients and to help the individual to practice safely and competently.

5. To the extent possible, and consistent with quality of care concerns, the Health Committee will handle impairment matters in a confidential fashion. The Health Committee shall keep the Hospital President, apprised of matters under review.

6. Presentation at Grand Rounds or other meetings by the Maryland Board of Physicians Professional Rehabilitation Program will provide education to Medical and Administration staff.

### Mechanism for Reporting and Reviewing Potential Impairment

1. If any individual has a concern that a member of the medical staff may be impaired in any way that may affect his or her practice at the hospital, a written report shall be given to the Hospital President, the President of the Medical Staff, the Chairperson of the Credentials Committee, or any member of the Health Committee or via RL Solutions (incident reporting software) and forward to the respective staff noted here. The report shall include a factual description of the incident(s) that led to the concern.

   - **Signs and Symptoms (examples):**
     - Slurred speech, tremors, impaired coordination
     - Unusual smells on breath, body or clothing
     - Deterioration of physical appearance and personal grooming habits
     - Bloodshot eyes or pupils that are larger or smaller than usual
     - Constant Irritability or Anxiety
     - Aggression
     - Reduced performance or cognitive skills
     - Reduced judgment, perception or reasoning skills
     - Memory deficiency

2. If, after discussing the incident(s) with the individual who filed the report, the Hospital President, the President of the Medical Staff, the Chairperson of the Credentials Committee, and/or any member of the Health Committee believes there is enough information to warrant a review, the matter shall be referred to the Health Committee.

3. The Health Committee shall act expeditiously in reviewing concerns of potential impairment that are brought to its attention.
4. As part of its review, the Health Committee may meet with the individual(s) who prepared the report.

1. If the Health Committee has reason to believe that the staff member is or might be impaired, it shall meet with the individual. At this meeting, the staff member should be told that there is a concern that he or she might be suffering from an impairment that affects his or her practice. The staff member should not be told who filed the initial report, but should be advised of the nature of the concern.

2. As part of its review, the Health Committee may request that the staff member be evaluated by an outside organization or person and have the results of the evaluation provided to it. A consent for the release of information to the Health Committee is attached as Appendix A. The Health Committee also has the ability to request that the staff member obtain drug, alcohol, physical and/or psychiatric/psychological testing by an institution or individual. The staff member’s failure to cooperate with such evaluation and testing may be considered by the Health Committee as it evaluates the situation.

3. Depending upon the severity of the problem, the information available to the Health Committee, and the nature of the impairment, the Health Committee has the following options available to it:
   a. recommend that the staff member voluntarily take a leave of absence, during which time he or she would participate in a rehabilitation or treatment program to address and resolve the impairment;
   b. recommend that appropriate conditions or limitations be placed on the staff member’s practice;
   c. recommend that the staff member voluntarily agree to refrain from exercising some or all privileges in the hospital until rehabilitation or treatment has been completed or an accommodation has been made to ensure that the individual is able to practice safely and competently;
   d. recommend that some or all of the staff member’s privileges be suspended if he/she does not voluntarily agree to refrain from practicing in the hospital;
   e. recommend that the staff member consent to and complete an immediate and/or ongoing alcohol and/or drug testing; and
   f. recommend that the staff member consent to and complete ongoing psychological and/or psychiatric therapy and/or rehabilitation.

4. If the Health Committee recommends that the staff member participate in a rehabilitation or treatment program, it will assist the individual in locating a suitable program. Shady Grove Medical Center participates with the Maryland Board of Physicians Professional Physician Rehabilitation Program.

5. If the staff member agrees to abide by the recommendation of the Health Committee, then a confidential report will be made to the Hospital President, the President of the Medical Staff, and the Chairperson of the staff member’s department.

6. If any individual has a reasonable concern that a member of the medical staff may be impaired while on hospital premises and the individual believes that an immediate response is necessary in order to protect the health and safety of patients or the orderly operation of the hospital, the individual shall immediately notify the relevant department chair and/or Hospital President or their designee. The department chair (or designee) shall assess the staff member and determine whether it appears that an impairment exists that may immediately affect the ability to safely practice medicine in the Hospital. The department chair (or designee) may relieve the staff member of responsibility for the patient or patients and assign to another individual with appropriate clinical privileges responsibility for care of the affected staff member’s hospitalized patients. The wishes of the patient shall be considered, to the extent practicable, in the selection of a covering medical staff member. Patients may be assigned to the physician on call. The affected patients shall be informed that the staff member is unable to proceed with their care due to illness.

7. Following the immediate response, the individual and the department chair shall file formal reports as described in this Policy in order for the question of impairment to be more fully assessed and addressed.
Reinstatement

1. Upon sufficient proof that a staff member who has an impairment has successfully completed a rehabilitation or treatment program, the Health Committee may recommend that the individual’s clinical privileges be reinstated. In making a recommendation that an impaired staff member be reinstated, the Health Committee must consider patient care interests as paramount.

2. Prior to recommending reinstatement, the Health Committee must obtain a letter from the physician overseeing the rehabilitation or treatment program. (A copy of a release from the Medical Staff Member authorizing this letter is attached as Appendix B.) The letter should address the following:
   
   a. the nature of the staff member’s condition;
   
   b. whether the staff member is participating in a rehabilitation or treatment program and a description of the program;
   
   c. whether the staff member is in compliance with all of the terms of the program;
   
   d. to what extent the staff member’s behavior and conduct need to be monitored;
   
   e. whether the staff member is rehabilitated;
   
   f. whether an after-care program has been recommended to the staff member and, if so, a description of the after-care program; and
   
   g. whether the staff member is capable of resuming medical practice and providing continuous, competent care to patients.

3. Before recommending reinstatement, the Health Committee may request a second opinion on the above issues from a physician of its choice.

4. Assuming that all of the information received indicates that the physician is capable of resuming care of patients, the following additional precautions shall be taken before the staff member’s clinical privileges are reinstated:
   
   a. the staff member must identify at least one practitioner who is willing to assume responsibility for the care of his or her patients in the event of the staff member’s inability or unavailability; and
   
   b. the staff member shall be required to provide periodic reports to the Health Committee from his or her attending physician, for a period of time specified by the Committee, stating that the staff member is continuing rehabilitation or treatment, as appropriate, and that his or her ability to treat and care for patients in the hospital is not impaired. Additional conditions may also be recommended for the staff member’s reinstatement.

5. The final decision to reinstate a staff member’s clinical privileges must be approved by the Hospital President in consultation with the President of the Medical Staff and/or the Chairperson of the Credentials Committee.

6. The staff member’s exercise of clinical privileges in the hospital shall be monitored by the department chief or by a physician appointed by the department chief. The nature of that monitoring shall be recommended by the Health Committee in consultation with the President of the Medical Staff.

7. In the event of any apparent or actual conflict between this policy and the bylaws, rules and regulations, or other policies of the hospital or its medical staff, including the investigation, hearing and appeal sections of those bylaws and policies, the provisions of this policy shall control.
Documentation And Confidentiality

1. The original report and a description of any recommendations made by the Health Committee shall be included in the staff member’s credentials file. If, however, the review reveals that there was no merit to the report, the report should be destroyed. If the review reveals that there may be some merit to the report, but not enough to warrant immediate action, the report shall be included in the staff member’s credentials file and the staff member’s activities and practice may be monitored until it can be established whether there is an impairment that might affect the staff member’s practice. The staff member shall have an opportunity to provide a written response to the concern about the potential impairment and this shall also be included in his or her credentials file.

2. The Hospital President or the President of the Medical Staff shall inform the individual who filed the report that follow-up action was taken.

3. Throughout this process, all parties should avoid speculation, conclusions, gossip, and any discussions of this matter with anyone other than those described in this policy.

4. If at any time it becomes apparent that the matter cannot be handled internally, or jeopardizes the safety of the staff member or others, the Hospital President may contact law enforcement authorities or other governmental agencies.

5. All requests for information concerning the impaired staff member shall be forwarded to the Health Committee.

6. Nothing in this policy precludes immediate referral to the Executive Committee (or to the Board) or the elimination of any particular step in the policy in dealing with conduct that may compromise patient care.
APPENDIX A
CONSENT FOR RELEASE OF INFORMATION PERTAINING TO EVALUATION

I hereby request that ____________________ [the facility/practitioner] provide Shady Grove Medical Center ("the Hospital") and its Health Committee with all information relevant to your evaluation of my ability to care for patients safely, to competently fulfill the responsibilities of medical staff appointment and to relate cooperatively to others in the Hospital.

I also request that the Hospital and Health Committee provide ____________________ [the facility/practitioner] with a copy of any information which it believes supports the need for the evaluation and any other information that ____________________ [the facility/practitioner] might request.

I release from liability and grant absolute immunity to, and agree not to sue, ____________________ [the facility/practitioner] and the Hospital and its Health Committee (and any physician on the Hospital’s medical staff who is involved in reviewing my practice) for providing the information set forth above.

☐ I wish ☐ do not wish to have information about HIV/AIDS status released under this authorization.

☐ I wish ☐ do not wish to have information about mental health treatment released under this authorization.

☐ I wish ☐ do not wish to have information about drug/alcohol abuse treatment released under this authorization.

This authorization will expire one year from the date of its signature.

I understand that:

- This authorization is voluntary.
- My treatment, payment for it and/or eligibility for enrollment or benefits cannot be conditioned on my signing this authorization form.
- I may receive a copy of this form.
- I may inspect my protected health information without signing this form.
- This authorization to disclose information may be revoked by me at any time, except to the Extent that action has been taken prior to receipt of revocation. To revoke the authorization, I understand that I must notify the facility/practitioner in writing.
- I understand that once information covered by this authorization has been disclosed, redisclosure of the information by the recipient is possible and the information may no longer be protected by the federal regulations referenced above but may be protected by Maryland law.

_________________________  ____________________________
Date                               Signature of Member
APPENDIX B
CONSENT FOR RELEASE OF INFORMATION

I hereby request that Dr. _________________ [physician overseeing treatment] provide Shady Grove Adventist Hospital ("the Hospital") and its Health Committee with information pertaining to my rehabilitation or treatment program. Specifically, this information should include:

(a) the nature of my condition;
(b) whether I am participating in a rehabilitation or treatment program;
(c) whether I am in compliance with all of the terms of the program;
(d) to what extent my behavior and/or conduct needs to be monitored;
(e) whether I am rehabilitated;
(f) whether an after-care program has been recommended for me and, if so, a description of the after-care program; and
(g) whether I am capable of resuming medical practice and providing continuous, competent care to patients.

I also request that Dr. _________________ provide the Hospital and its Health Committee with periodic reports relating to my ongoing rehabilitation or treatment and my ability to treat and care for patients in the Hospital.

I release from liability, grant absolute immunity to and agree not to sue Dr. _________________ for providing the information set forth above.

☐ I wish ☐ do not wish to have information about HIV/AIDS status released under this authorization.

☐ I wish ☐ do not wish to have information about mental health treatment released under this authorization.

☐ I wish ☐ do not wish to have information about drug/alcohol abuse treatment released under this authorization.

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• I may receive a copy of this form.
• I may inspect my protected health information without signing this form.
• This authorization to disclose information may be revoked by me at any time, except to the Extent that action has been taken prior to receipt of revocation. To revoke the authorization, I understand that I must notify the facility/practitioner in writing.
• I understand that once information covered by this authorization has been disclosed, redisclosure of the information by the recipient is possible and the information may no longer be protected by the federal regulations referenced above but may be protected by Maryland law.

_________________________  ____________________________
Date                     Signature of Member
### HEALTH STATUS ASSESSMENT

Please respond to the following questions based upon your assessment of Dr. ________________’s current health status (if additional space is required, please attach separate sheet):

1. **Does Dr. ________________ have any physical, psychiatric, or emotional condition that could affect his/her ability safely to exercise the clinical privileges set forth on the attached list and/or perform the duties of appointment, including response to emergency call?**
   - [ ] Yes   [ ] No
   
   If yes, please provide the diagnosis/diagnoses and prognosis: __________________________

2. **Is Dr. ________________ currently taking any medication that may affect either clinical judgment or motor skills?**
   - [ ] Yes   [ ] No
   
   If yes, please specify medications and any side effects: __________________________

3. **Is Dr. ________________ currently under any limitations concerning activities or work load?**
   - [ ] Yes   [ ] No
   
   If yes, please specify: ___________________________________________________________

4. **Is Dr. __________ currently under the care of a physician?**
   - [ ] Yes   [ ] No
   
   If yes, please identify: __________________________________________________________

5. **In your opinion, is any accommodation necessary to permit Dr. ________________ to exercise privileges safely and/or to fulfill medical staff responsibilities appropriately?**
   - [ ] Yes   [ ] No
   
   If yes, please explain any such accommodation: ________________________________
   ________________________________  ________________________________  ________________________________

   Date  __________________________  Signature of Physician Evaluator
## INSTITUTIONAL REVIEW BOARD & PHYSICIAN PRIVILEGES POLICY

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>February 11, 2002</th>
<th>Policy No:</th>
<th>#007</th>
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<td>Cross Reference:</td>
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<td>Origin:</td>
<td>Credentials Comm.</td>
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<td>1 of 1</td>
</tr>
<tr>
<td>Approved:</td>
<td>10/30/08; 11/30/11</td>
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</tbody>
</table>

### PURPOSE:

To provide a mechanism to assure that physicians participating in research protocols approved by Institutional Review Board (IRB) also obtain appropriate privileges through the Medical Staff credentialing process.

### POLICY:

1. When a research trial involving invasive procedures is submitted to the Institutional Review Board, an IRB Staff Member is responsible to access the Medical Staff Information On-Line system for Shady Grove Medical Center and document that the physicians involved with each study possess the appropriate privileges to perform the invasive procedure. Appropriate documentation is kept in the IRB protocol file.
2. If it is found that a physician does not possess the appropriate privileges, the IRB Administrator or IRB Staff member will be responsible for notifying Medical Staff Services.
3. Privileges to perform any procedure must be specifically granted by the Credentials Committee, either through core privileges or specialty privileges.
4. Physicians are not authorized to begin performance of any invasive procedure involved in a research trial until the privileging process has been successfully completed.
5. Final IRB approval will not be granted until all physicians associated with a research trial have obtained the necessary privileges.
PURPOSE:

The Centers for Disease Control and Prevention (CDC) has determined that Shady Grove Medical Center and Washington Adventist Hospital are in the high risk category for nosocomial tuberculosis infection. As such, all Health Care Providers are required to undergo an Annual evaluation for newly acquired tuberculosis infection. This change in risk category requires some changes in how Medical Staff Members are assessed for new tuberculosis infection.

POLICY:

1) Medical Staff Services will send your reappointment application via MSONet (our on-line credentialing module), the form to complete PPD testing/or TB questionnaire, whichever applies as well as annually via e-mail request to those with clinical privileges.

2) Documentation accepted:

Providers must provide the following based on the recommendation of the Centers of Disease Control (CDC) for positive and negative TB:

a) Newly credentialed providers with a history of Negative Tuberculosis Skin Test (TST) will receive a TST at the Adventist HealthCare entity accordingly (or) provide proof of a TST (or) provide proof of T-Spot test within 1 year of the application date.

b) Current Providers with a known Negative Tuberculosis Skin Test will receive a TST or T-Spot test every other year and will complete a Tuberculosis Symptom Screening Survey every other year (opposite the TST).

c) Newly credentialed providers with a history of Positive Tuberculosis Skin Test will receive baseline Interferon Gamma Release Assay and will receive baseline chest x-ray or provide a chest x-ray within 90 days of the application date. Only a one-time baseline chest x-ray is required.

d) Current providers with a history of Positive Tuberculosis Skin Test will receive baseline Interferon Gamma Release Assay if not already on file and will complete a Tuberculosis Symptom Screening Survey annually.

e) Testing is provided by the hospital’s Occupational Health Department.

f) Occupational Health does not obtain copies of test results. Please keep copies for your file and future reference.
# PRIMARY SOURCE VERIFICATIONS

<table>
<thead>
<tr>
<th>Physician – Initial Appointment &amp; Reappointment (MD, DO, DMD)</th>
<th>Physician Assistant – Initial Appointment &amp; Reappointment (PA)</th>
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</thead>
<tbody>
<tr>
<td><strong>MDs</strong></td>
<td>- AMA (Training, State Licensures, Federal DEA)</td>
</tr>
<tr>
<td>- AMA (for MDs - Residency, Fellowship, Board Certification, State Licensures, Federal DEA)</td>
<td>- National Commission of Certification of Physician Assistants (Certification)</td>
</tr>
<tr>
<td><strong>DOs</strong></td>
<td>- DHMH (CDS)</td>
</tr>
<tr>
<td>- AOA (for DOs - Residency, Fellowship, Board Certification, State Licensures, Federal DEA)</td>
<td>- NPDB (Malpractice Claims Info/Settlements/Amount of Monies Paid Out)</td>
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<tr>
<td><strong>DMDs</strong></td>
<td>- Sanction Check (Medicaid/Medicare Sanctions and Disciplinary Action)</td>
</tr>
<tr>
<td>- American Board of Maxillofacial Surgery (Board Certification)</td>
<td>- 5-Year Malpractice Claims History</td>
</tr>
<tr>
<td>- State Board of Dental Examiners (State Licensures)</td>
<td>- Affiliation/Privileges with Other Facilities</td>
</tr>
<tr>
<td>- NTIS (DEA)</td>
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</tr>
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<td><strong>ALL</strong></td>
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<td>- DHMH (CDS)</td>
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<td>- NPDB (Malpractice Claims Info/Settlements/Amount of Monies Paid Out)</td>
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</tr>
<tr>
<td>- ECFMG (if applicable – Education of Foreign Graduate)</td>
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<td>- Sanction Check (Medicaid/Medicare Sanctions and Disciplinary Action)</td>
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</tr>
<tr>
<td>- 5-Year Malpractice Claims History</td>
<td></td>
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<td>- Affiliation/Privileges with Other Facilities</td>
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<table>
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<tr>
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<th>Nurse Practitioner – Initial Appointment &amp; Reappointment (NP)</th>
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<tr>
<td>- American Board of Podiatric Surgery (Board Certification)</td>
<td>- Maryland State Board of Nursing (State Licensures)</td>
</tr>
<tr>
<td>- State Board of Podiatric Medical Examiners (State Licensures)</td>
<td>- American Academy of Nurse Practitioners or American Nurses Credentialing Center (Certification)</td>
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<td>- NTIS (DEA)</td>
<td>- NTIS (DEA)</td>
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<tr>
<td>- DHMH (CDS)</td>
<td>- DHMH (CDS)</td>
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<tr>
<td>- NPDB (Malpractice Claims Info/Settlements/Amount of Monies Paid Out)</td>
<td>- NPDB (Malpractice Claims Info/Settlements/Amount of Monies Paid Out)</td>
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<tr>
<td>- Sanction Check (Medicaid/Medicare Sanctions and Disciplinary Action)</td>
<td>- Sanction Check (Medicaid/Medicare Sanctions and Disciplinary Action)</td>
</tr>
<tr>
<td>- 5-Year Malpractice Claims History (available online)</td>
<td>- 5-Year Malpractice Claims History (available online)</td>
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<tr>
<td>- *Affiliation/Privileges with Other Facilities</td>
<td>- *Affiliation/Privileges with Other Facilities</td>
</tr>
<tr>
<td>- Education and Training via Schools (via mail)</td>
<td>- Education and Training via Schools (via mail)</td>
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**Pediatric Nurse Practitioner**
- Pediatric Nursing Certification Board (Certification)
**PRIMARY SOURCE VERIFICATIONS (CON’T)**

<table>
<thead>
<tr>
<th>PRIMARY SOURCE VERIFICATIONS (CON’T)</th>
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<tr>
<td><strong>Dentist – Initial Appointment &amp; Reappointment (DDS)</strong></td>
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<td>State Board of Dental Examiners (licensures)</td>
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<td>DHMH (CDS)</td>
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<tr>
<td>5-Year Malpractice Claims History</td>
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<tr>
<td>Affiliation/Privileges with Other Facilities</td>
</tr>
<tr>
<td>Education and Training via Schools (via mail)</td>
</tr>
<tr>
<td><strong>Note:</strong> There is no current Accredited Board Certification.</td>
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<tr>
<td>American Board of Pediatric Dentistry (Board Certification - via mail)</td>
</tr>
<tr>
<td>Maryland Board of Nursing (RN &amp; CRNFA Licensures)</td>
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<tr>
<td>CCI Competency &amp; Training Institute (Certification)</td>
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<td>*Affiliation/Privileges with Other Facilities</td>
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<td>Education and Training via Schools (via mail)</td>
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<td><strong>Psychologist - Initial Appointment &amp; Reappointment</strong></td>
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<tr>
<td>Maryland Board of Psychologist</td>
</tr>
<tr>
<td>American Board of Professional Psychology (Certification)</td>
</tr>
<tr>
<td>NPDB (Malpractice Claims Info/Settlements/Amount of Monies Paid Out)</td>
</tr>
<tr>
<td>Sanction Check (Medicaid/Medicare Sanctions and Disciplinary Action)</td>
</tr>
</tbody>
</table>
| 5-Year Malpractice Claims History | **Note:** If a provider has more than 10 current hospital affiliations, a minimum of 5 must be received for each provider. If one hospital affiliation is negative, the medical staff will require receiving one more. 

**SAMS – To be performed for every provider (according to NCQA guidelines) on an annual bases by the corporate compliance office.**

Board Approved: 10/30/08; 06/22/11; 04/25/12; 06/25/14; 10/19/16

- 56 -
# PROFESSIONAL PRACTICE EVALUATION (FPPE AND OPPE)

<table>
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<th>Effective Date:</th>
<th>12/01/08</th>
<th>Policy No:</th>
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<td>06/01/10; 06/21/10; 08/31/10; 4/25/12; 10/19/16</td>
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<td>11/19/08; 11/30/11; 04/25/12; 10/19/16</td>
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## PURPOSE

To assure that the hospital, through the activities of its medical staff, assesses on an ongoing basis the professional practice and competence of its medical staff, conducts professional practice evaluations, and uses the results of such assessments and evaluations to improve professional competency, practice, and care.

Throughout this policy, the phrase “Professional Practice Evaluation” (PPE) replaces the traditional phrase “Peer Review”. The Medical Staff has the responsibility of evaluation and improvement of the quality of care rendered in the Hospital. The records and proceedings of Medical Staff activities that relate to this policy in any way are protected from discovery pursuant to Maryland law. Relevant information resulting from the evaluation process is integrated into performance improvement activities, consistent with the organization’s policies and procedures that are intended to preserve confidentiality and privilege of information.

The goals of this policy include to:

1. Determine that individual practitioners are performing well or within expectation and that no further action is warranted.
2. Identify opportunities for practice and performance improvement of individual practitioners.
3. Monitor for significant trends in individual performance by analyzing aggregate data and case findings.
4. Ensure that the process for professional practice evaluation is clearly defined, objective, equitable, defensible, timely, and useful.
5. Provide suggested areas for system-wide improvement.
6. Evaluate the performance of the practitioner when issues are affecting the provisions of safe, high quality patient care.

## PEOPLE AFFECTED

All members of the Medical Staff and Allied Health Professionals credentialed and privileged through the Medical Staff Services.

## SUPPORTIVE DATA

Joint Commission Standards MS.08.01.01-03

## DEFINITIONS AND RESPONSIBILITIES

### I. Focused Professional Practice Evaluation (FPPE):

This is a process whereby the Medical Staff evaluates the privilege-specific competence of a practitioner who does not have documented evidence of competently performing the requested privilege. FPPE may also be used when a question arises regarding a currently privileged practitioner’s ability to provide safe, high quality patient care. FPPE is a time-limited period during which the organization evaluates and determines the practitioners’ professional performance. FPPE process will be implemented consistently.

#### A. The organized medical staff does the following:

- Evaluates practitioners without current performance documentation at the organization
- Evaluates practitioners in response to concerns regarding the provision of safe, high quality patient care
- Develops criteria for extending the evaluation period
- Communicates to the appropriate parties the evaluation results and recommendations based on results
- Implements changes to improve performance

#### B. Scope of FPPE:

- All Newly credentialed and privileged practitioners
- All existing practitioners who have been granted new privileges
- Existing practitioners who are identified as requiring more intensive review as determined by OPPE or by some other triggering event or circumstance

#### C. Methodology/FPPE Plan may include:

1. Direct Observation of the required number of procedures/cases as determined by the Department Chair with final review by the Medical Executive Committee.

And/Or
DEFINITIONS AND RESPONSIBILITIES (con’t)

2. Chart Review of no fewer than 3 Medical Record Reviews. Medical Record Review Indicators with Satisfactory performance = 100% compliance for (if applicable):
   - Quality Content and Completion of History and Physical within 24 hours
   - Quality Content and Completion of Operative Reports within 24 hours
   - No Copying and Pasting within Medical Record
   - Quality Content and Discharge Summary Report within 30 days of Patient’s Discharge
   - Specialty-Specific Indicators defined by the Department Chair

D. Timeframe for FPPE: will be for the first six months and/or until all required methodology has been evaluated. The time period of the evaluation can be extended up to 3 months maximum with total review period not to exceed 9 months.

E. Circumstances under which external review is required: Need for specialty review, when there are a limited number or no medical staff members within the required specialty (or with the appropriate technical expertise) on the medical staff.

F. Focused Professional Practice Evaluations (FPPE) consist of individual practitioner reviews that are based upon significant clinical events identified by:
   - Occurrence reports
   - Patient/family complaints
   - Sentinel events and events required by regulatory agencies to be reported
   - Referral from other practitioners
   - Referral from Professional Practice Evaluation Committee
   - Cases identified by patterns or trends noted in rule or rate based indicators

G. End of review period:
   1. Confirmation that the practitioner has been reviewed and that there are no potential problems with the performance or trends that would impact quality of care and patient safety
   2. FPPE successfully completed; continue existing privileges; enter OPPE phase of credentialing.
   3. FPPE unsuccessfully completed; privileges to be limited or revoked.

II. Ongoing Professional Practice Evaluation (OPPE): Ongoing professional practice evaluation is a process that allows the Medical Staff to identify professional practice trends that impact on quality of care and patient safety on an ongoing basis. The process includes:
   - The evaluation of an individual practitioner’s professional performance and identification of opportunities to improve care based on recognized standards. It differs from other quality improvement processes in that it evaluates the strengths and opportunities of an individual practitioner’s performance and competence related to their privileges rather than appraising the quality of care rendered by a group of professionals or by a system.
   - The use of multiple sources of information, including but not limited to direct observation, review of individual cases, aggregate data, compliance with Hospital policies, protocols, and the Bylaws and the Rules and Regulations of the Medical Staff, clinical standards, and the use of rates compared against established benchmarks or norms.
   - Individual evaluation is based on generally recognized standards of care. This process provides practitioners with feedback for personal improvement or confirmation of personal achievement related to the effectiveness of their professional, technical, and interpersonal skills in providing medical care.
   - Relevant information obtained from the ongoing professional practice evaluation is integrated into performance improvement activities. Findings from ongoing professional practice evaluation are factored into the decision to maintain existing privileges, to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal.

A. The organized medical staff does the following:
   - Develops criteria for extending the evaluation period
   - Communicates to the appropriate parties the evaluation results and recommendations based on results
   - Implements changes to improve performance

B. Scope of OPPE:
   - All existing practitioners not currently undergoing FPPE

C. Methodology/OPPE includes:
   - The indicators are based off of the six core competencies for the practitioner under review.
     - Patient-Based Learning
     - Medical/Clinical Knowledge
     - Interpersonal and Communication Skills
     - Patient Care
     - Professionalism
     - System Based Practice
2. The type of data to be collected is determined by the individual departments.
   - Core Measures
   - Hours of CME per two year period
   - Number of cases undergoing peer review
   - Number of behavioral occurrence reports
   - Medical Records Completion Compliance including: H&Ps, Discharge Summaries, Operative Reports and Copy and Paste and Auto-Test, if used, are edited for relevance and accuracy
   - Department/Section Meeting Attendance
   - List of Committee Membership
   - Annual OIG Screening Results
   - Number of episodes and days of suspension for delinquent medical records
   - Specialty-Specific Indicators defined by the Department Chair

D. Timeframe for OPPE: will be conducted at least every eight months.

E. Circumstances under which external review is required: Need for specialty review, when there are a limited number or no medical staff members within the required specialty (or with the appropriate technical expertise) on the medical staff.

F. End of review period:
   1. Confirmation that the practitioner has been reviewed and that there are no potential problems with the performance or trends that would impact quality of care and patient safety
   2. If any problems do raise, FPPE might be implemented (See FPPE Procedures)

**Professional Practice Evaluation Time Frames:** Professional practice evaluation will be conducted by the Medical Staff in a timely manner. The goal is for routine cases to be completed within 90 days from the data the case is identified for review. Complex cases (such as those where multiple services are involved or those that may require external review) may require additional review time beyond 90 days.

**External Professional Practice Evaluation**

A. In certain situations, The Department/Section or the PPEC may determine that a case should be sent to an external source for review. This may occur when:
   1. There is ambiguity and/or the PPEC receives vague or conflicting recommendations from reviewers or Department/Section.
   2. There is lack of internal expertise in the specialty under review or when the only practitioners on the Medical Staff with that expertise are determined to have a conflict of interest regarding the practitioner under review.

**Professional Practice Evaluation Committee (PPEC)**

A. The Medical Executive Committee has designated the Professional Practice Evaluation Committee (PPEC) as having direct oversight of the ongoing professional practice evaluation process.

B. Department Chairs or a designee of each department may serve as a representative on PPEC.

C. Ongoing data review and findings are evaluated by the Professional Practice Evaluation Committee. The information resulting from the evaluation is used by the committee to make recommendations to Credentials Committee and to MEC to determine whether to continue, limit, or revoke any existing privilege(s) at the time the information is analyzed.

D. The PPEC will meet at least quarterly and more often as needed to review the findings of the professional practice evaluation and recommendations from the Departments/Sections.

E. The PPEC will report the findings of the ongoing professional practice evaluation to the Medical Executive Committee at least quarterly.

**Department Chair:** Has initial responsibility for the continuing surveillance of the professional performance of all Licensed Independent Practitioners in his/her respective department and:

1. Oversees the performance improvement program and provides summary reports to the PPEC at least quarterly, of ongoing quality assessment and improvement activities in his/her department and sub-sections.

2. Presents PPEC findings, cases with educational value, and rate-based data at Department Meetings. The Department Meeting minutes will reflect findings, conclusions, recommendations, and actions taken.

3. Approval of Focused Professional Practice Evaluation plan for each initial physician/AHP coming on staff.

**Medical Staff President:** Responsible for ensuring the findings, conclusions, recommendations, and actions to improve individual and organizational performance are communicated to appropriate medical staff members and committees.

**Quality Improvement Coordinators:**

1. Screen charts against pre-established criteria and forward to appropriate person/committee.

2. Aggregate rate based measures data.

3. Provide correspondence and/or copies to Medical Staff Services for placement in physicians' Medical Staff credentials files.

4. Enter data into Physicians’ MSO database.
Medical Staff Services: Maintains individual OPPE/FPPE information in the Medical Staff credentials file.

Credentials Committee: Considers all professional practice evaluation data at the time of reappointment and privileging. Is notified that practitioner is off of FPPE or recommendation on an extension.

Conflict of Interest: A member of the Medical Staff asked to perform professional practice evaluation may have a conflict of interest if he or she might not be able to render an unbiased opinion due to either involvement in the patient’s care or a relationship with the practitioner involved as a direct competitor or partner. Individuals determined to have a conflict may be present during discussions of professional practice evaluation, but they will be required to recuse themselves from the actual evaluation process.

CONTENT

I. Principles
   A. Professional practice evaluation information is privileged and confidential in accordance with Medical Staff and Hospital Bylaws, state and federal laws, and regulations pertaining to confidentiality and non-disclosurability.
   B. Individuals involved in professional practice evaluation will sign a statement of confidentiality.
   C. Professional practice evaluation is conducted in a manner that is objective, equitable, timely and consistent.

II. Measures and Indicators for Focused Professional Practice Evaluation
   A. Cases identified for FPPE will be reviewed by the Department/Section Chair or his/her designee. If additional information is needed to complete the review, the practitioner is notified and given the opportunity to provide additional information.
      1. After the review is completed and the case is scored, the case and results are forwarded to the Department/Section Chair or recommendation for follow up actions if indicated.

III. Measures and Indicators for Ongoing Professional Practice Evaluation
   B. Performance measures used for OPPE are selected and approved by the Medical Staff, and include the following:
      1. Rule-based indicators, which identify individual instances of non-compliance with administrative or clinical processes, policies, or other established rules. These occurrences are reviewed by the Department/Section Chair.
      2. Rate-based indicators, which identify potential performance differences among physicians using aggregated data on outcomes or processes of care, taking into account differences in activity. These indicators are evaluated for evidence of a clinical practice trend and are reviewed at Department/Section meetings.
      3. After the Department/Section has finalized any recommendations for follow up actions, the case is reported to the Professional Practice Evaluation Committee (PPEC) for approval.
      4. The practitioner is informed of the outcome of the review and advised of any additional requirements. For OPPE the practitioner is notified of continued, limited or revoked privileges.
      5. Written notification of case review determinations:
         • Action and follow-up, as determined by the PPEC, is in a written response or a documented meeting of the Department Chair with the individual practitioner.
         • All correspondence is confidential. Certified / Return Receipt U.S. mail is the mechanism for notification
         • Copies of letters and notifications of peer review determinations are filed in the Medical Staff Office in the individual practitioner’s confidential Performance Improvement file.
      6. Causal analysis is determined for all reviews assigned an Outcome Score of ‘B’ ‘E’ or ‘F’ and documented on the OPPE Report.

IV. Scoring for FPPE/OPPE cases are as followed:
   Standard of Care Scores:
   I = Standard of care met, no problem with process or documentation.
   II = Standard of care met but documentation inadequate to support standard of care.
   III = Controversy among physician reviewers whether standard of care was met.
   IV = Standard of care not met.

   Outcome Scores:
   A = No effect on outcome
   B = Minor effect on outcome: problem allowed disease or symptoms to progress, temporary or reversible.
   C = Major adverse outcome: death attributable to natural disease progression
   D = Major adverse outcome: known, documented complication of procedure/disease process
   E = Major adverse outcome: problem resulted in reduction of longevity, functional quality of life, or adverse reaction by medical action or inaction.
   F = Major adverse outcome: death attributable to acts of omission or commission.
PURPOSE
To establish standards for the preparation, intra-procedure care, and recovery of patients receiving propofol for procedural sedation in the Emergency Department by non-anesthesiologists. This document is an adjunct to the Shady Grove Adventist Hospital policy on Moderate Sedation.

POLICY
Propofol is a short-acting potent hypnotic medication that was originally developed as an intravenous induction agent for general anesthesia. Because of its short duration, rapid onset of action, and excellent side-effect profile, it has gained popularity as a sedative agent for minor procedures. When used in the usual clinical doses it produces a state of deep sedation characterized by responsiveness to only repeated or painful stimuli. In this state patients may lose the ability to maintain a patent airway and independent ventilatory function. In addition, it may cause sudden and severe hypotension. Due to the possible need for advanced airway maneuvers and hemodynamic intervention, propofol’s use will be restricted to emergency medicine physicians who have completed a separate competency-based credentialing program. All processes stipulated in the moderate sedation policy will apply to patients who receive propofol sedation. Additional requirements, limitations and exclusions are outlined below.

Pharmacology
Following IV administration, propofol is rapidly distributed in the plasma and then well-perfused brain tissue. The effects of propofol are usually seen within 40 seconds, which corresponds to one blood/brain circulation time. It is then rapidly redistributed to other tissues in the body. Plasma levels decrease with this redistribution as well as through rapid metabolism. An adequate period of time (1 to 3 minutes) should be allowed after an initial dose in order to assess the clinical effects of propofol prior to subsequent doses. Although it is primarily eliminated by hepatic conjugation and renal excretion, the dosage of propofol does not need to be adjusted for renal or hepatic insufficiency.

Administration
Propofol is available in 20 cc bottles at a concentration of 10mg/cc. For the purpose of procedural sedation in the emergency room, it will be administered in boluses. The initial dose is 0.3 to 1.0 mg/kg followed in 1 to 3 minutes by boluses of 0.3 to 0.5mg/kg, if necessary. The dosage is based on ideal body weight and may need to be decreased in elderly patients or when administered in combination with other sedatives. The maximum total cumulative dose is 2.0 mg/kg. Lidocaine 0.5 to 1 mg/kg may be administered as a bolus just prior to, or mixed with the initial bolus of propofol to decrease pain on injection (unless otherwise contraindicated).

Handling
Propofol injectable emulsion can support the growth of microorganisms as it is not an antimicrobially preserved product under usp standards. Accordingly, strict aseptic technique must be adhered to. Propofol should be prepared for use just prior to initiation of each individual sedation. The rubber vial stopper should be disinfected using 70% isopropyl alcohol. Propofol should be drawn into sterile syringes immediately after vials are opened and the syringe should be labeled with date, time, concentration, and initials of preparer. Administration should commence promptly and be completed within 6 hours after the vials have been opened. Propofol should be prepared for single –patient use only. Any unused portion of propofol drawn into a syringe must be discarded at the end of 6 hours.

Special Precautions
1. **Procedures.** This policy applies to short, (<10 minutes) moderately painful procedures that may be performed with one or two boluses of propofol. Appropriate indications include minor orthopedic procedures (e.g. closed reductions of fractures and dislocations), or emergent cardioversions. Specifically excluded from this policy are GI endoscopy procedures, D&C’s and other procedures that are usually scheduled in the operating room.

2. **Locations.** This policy applies only to procedures performed within the Emergency Department, the Pediatric Emergency Department and the Germantown Emergency Center.

3. **NPO Status.** Propofol sedation frequently and unpredictably results in loss of normal protective airway reflexes. Therefore the Department of Anesthesia strongly recommends that the fasting protocol (see moderate sedation policy) be observed whenever propofol is administered. Anesthesia consultation should be considered whenever the emergent nature of a procedure precludes adherence to the normal fasting requirements.
4. **Supplemental Oxygen.** Suplemental oxygen will always be administered during propofol sedation.

5. **Staffing.** Propofol sedation will be administered by an appropriately credentialed emergency medicine physician who is solely responsible for sedation, airway management, and monitoring and not in any way involved in the procedure. The sedating physician will remain with the patient until return of consciousness (defined as the ability to follow a simple command).

6. **Equipment.** An ambu-bag, working suction with yankauer tip, intubation tray, and intubation drug pack will be kept at the bedside during the procedure.

7. **Patient Selection.** ASA I and II patients are appropriate candidates for propofol sedation by a non-anesthesiologist.

**Credentialing**

Only physicians with specialized training in advanced airway techniques and deep sedation will be permitted to administer Propofol. Physicians must demonstrate competency in the pharmacology and physiologic effects of the medication. Recredentialing of propofol sedation privileges will occur on the same two year cycle as staff reappointments. Physicians who do not meet the minimum case requirement may apply for a mentorship opportunity with the Department of Anesthesia. Specific requirements are as follows:

**Initial Competency Requirements:**

1. Active Medical staff privileges in Emergency Medicine.
2. Medical Staff privileges in Moderate Sedation.
3. Completion of an Emergency Medicine residency program within the last (2) years that includes a formalized education component on the safe administration of propofol sedation (letter from the residency director required). OR Evidence of at least five (5) sedations using propofol within the last two years along with evidence of satisfactory outcomes (letter from department chair will suffice).
5. Score of ≥80% on the Shady Grove Adventist Hospital Propofol Sedation Test.

**Ongoing Competency Requirements**

1. Active Medical Staff privileges in Emergency Medicine.
2. Active privileges in Moderate Sedation.
3. Evidence of at least five (5) sedations during the previous two years with satisfactory outcomes as documented in the physician’s OPPE.
4. Attestation of review of the most recent version of the Shady Grove Policy on Propofol Sedation.

**Quality Assurance**

The following adverse sedation related events will be reported through the hospital’s incident reporting system and will be forwarded to the Emergency Medicine Review Committee.

**QA events:**

- Death
- Cardiac Arrest
- Intubation
- Aspiration