

BEAUMONT HEALTH SYSTEM

MEDICAL STAFF PHYSICIAN HANDBOOK

RULES / REGULATIONS / POLICIES

Approved by Board of Directors
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SECTION I: CARE OF PATIENTS

1.1 CONDUCT OF PATIENT CARE

1.1.1. ADMISSION PROCEDURE (HOSPITAL INPATIENT AND OUTPATIENT)

Each hospital patient must be under the care of an attending physician. The attending physician should be the physician most responsible for the patient's care, whose delineated clinical privileges are consistent with the required clinical treatment

Patients who are being admitted as an inpatient primarily for surgery should be under the care of the surgeon / group who will perform the procedure unless the surgeon / proceduralist makes prior arrangements with the patient's primary physician for the primary physician or his / her designee to be the attending physician. Medicare beneficiaries who are undergoing a surgical procedure that is listed on the Medicare yearly inpatient only list must be admitted to the hospital as an inpatient.

Emergency Center (E.C.) patients may be admitted as hospital inpatient or hospital outpatient observation patients by an E.C. Physician who has evaluated the patient and determined the need for a hospital inpatient or outpatient course of care. The E.C. physician transfers the patient's care to an attending physician.

Medical Patients Who Undergo Surgery

If, during the course of hospitalization, a patient admitted to the medical service requires surgery, the attending physician designation should be changed to the operating surgeon or group unless (1) requested otherwise by the first physician of record (usually for minor surgical procedures such as biopsy) or (2) the patient is returned to a medical unit and the operating surgeon does not specifically request designation as the attending.

In all cases where a patient admitted on the medical service has a procedure performed in the operating room and after surgery is transferred to a surgical unit, the attending physician designation is changed to the operating surgeon by operating room personnel with a notation on the operating room record unless the surgeon / proceduralist makes prior arrangements with the attending physician to continue as the attending physician. This requires physician-to-physician communication and is the surgeon's / proceduralist's responsibility to call the attending physician to obtain this approval.

If the post-operative care is complete and the patient still requires inpatient medical care, the designation should be changed to the first physician of record upon written order of the attending surgeon.

Provisional Diagnosis on Admission or Referral to the Hospital

Physicians and / or dentists admitting or referring patients to the Hospital for diagnostic and / or therapeutic procedures shall disclose such health care information as is necessary to protect health care workers and other patients. For example, physicians referring patients carrying a potentially communicable disease must make this information available to the consulting physician and Hospital to ensure that appropriate precautionary measures are instituted.

Admission Priorities

Patients will be admitted according to Hospital procedures in order of priority in the event of a critical bed shortage. The specific categories shall be defined by the Medical Executive Board.

Admitting Restrictions, Sole Diagnosis Psychiatric – RO Facility Only

Patients admitted to the inpatient Psychiatric Unit must be at least 18 years of age. Adult patients with guardians may be admitted only if the patient is agreeable to the admission, and the guardian provides consent. Only voluntary admissions will be accepted to the Psychiatric Unit at Royal Oak. Patients with a sole diagnosis of a psychiatric problem will not be admitted to a non-psychiatric floor.

Admitting Restrictions, Patient has Both Medical and Psychiatric Diagnosis

Patients with both medical and psychiatric problems (for example, drug overdose, self-inflicted injury, intoxication, or impending delirium) may be admitted to the appropriate medical or surgical service. The Admitting Office will notify the appropriate nursing supervisor of the intended admission.

All combined psychiatric / medical patients admitted to the general medical / surgical floors shall have a psychiatric consultation within 24 hours.

Suicide precautions can only be discontinued by the physician psychiatric coordinator on call or the psychiatrist initially consulted on that admission or transfer, or by the Attending Physician. A progress note documenting that the precautions may be discontinued and an order discontinuing such precautions must be recorded.

Admission of Patients on Suicide Precautions (See Full Corporate Policy #730)

Patients admitted with suicide precautions are to have a psychiatric consultation ordered with the psychiatrist on call. If available in a timely manner, the patient's private psychiatrist, if on Beaumont's medical staff, may do the consultation instead of the psychiatrist on call.

Admission to Hospital Outpatient Observation

A designation "Outpatient Observation" has been established for patients who receive short-term hospital outpatient (OP) observation and treatment while a decision is being made whether to admit the patient as a hospital inpatient. This designation typically is to be less than a 24-hour time period so as not to be considered a hospital inpatient admission but rather a continuation of outpatient treatment. Cardiac monitoring is available to OP observation patients if needed. The timing begins at the time an order for OP observation is written by a physician and recorded by Patient Registration. Medicare rules for hospital OP observation and inpatient stays are based on the expectation of the physician regarding the length of stay. If a Medicare beneficiary is expected to require less than a two midnight stay in OP observation, the order should be written for OP observation. If, after the first midnight, the physician now expects that the patient will require hospital care (medical necessity) beyond the second midnight the physician should write an order to admit the patient to the hospital inpatient. The term medical necessity refers to care that cannot be provided at a lower level of care; eg., home.

Method of Admission:

- a. Emergency Center - The Emergency Center (E.C.) physician evaluates the patient and determines that a period of observation is needed beyond a typical E.C. stay while a Hospital inpatient stay is still undetermined. If the attending physician agrees, the patient will be admitted as a Medical Observation status.
- b. A Medical Staff member with admitting privileges may determine that a patient seen in his office or elsewhere requires a period of observation and may make such a request through the Access and Transfer Office as either a direct hospital outpatient observation admission or an E.C. admission.

Hospital outpatient observation may be appropriate following unanticipated complications of outpatient surgery based on an InterQual review and an attending physician order. Medicare beneficiaries who have had an elective outpatient surgery but require care crossing two midnights should be admitted as an inpatient by a written order.

The Observation patient's attending physician will be responsible for providing an admitting note, orders, discharge instructions and a discharge summary. The attending physician will be expected to enter an appropriate progress note and is responsible for the patient's care throughout the Observation stay. The attending physician may have the usual access to the house physician for problems that need immediate attention. The attending physician will see these patients before the 24-hour period elapses. In conjunction with a utilization review by Care Management and the attending physician, a decision can be made whether the patient can be discharged or the patient should be moved to a different level of care. In the event that the attending physician has a strong belief, based on the patient's history and risk factors, that the patient should be an inpatient, he / she must document thoroughly his / her rationale and concerns. In addition, Care Management will conduct a second level physician.

1.1.2. DAILY CARE

Daily Care / Requirement for

Physicians serving as a patient's attending physician or designated covering physicians with appropriate privileges as defined by Medical Staff Bylaws must see their hospitalized patients daily and document a pertinent progress note at the time of the visit. On the day of discharge, the attending or designated covering physician may delegate this responsibility to an appropriate resident, physician assistant or nurse practitioner or certified clinical nurse specialist.

A physician shall not maintain an excessive inpatient volume or coverage responsibility at the Hospital, which in the judgment of his or her Department Chief or Section Head has the potential to diminish patient safety, clinical quality, or the efficient running of Hospital operations. The appropriate Department Chief or Section Head will take action to assist any physician involved in such a situation to correct the matter and may take action to ensure compliance.

1.1.3. CONTINUOUS CARE AND CALL COVERAGE RESPONSIBILITIES

Coverage during Unavailability

Each member of the Medical Staff intending to be unavailable shall identify to the Hospital, a member of the Medical Staff with similar specialty, and if applicable subspecialty privileges, pursuant to Department policy who will be called to attend that Medical Staff member's patients in the Hospital. The physician must arrange such coverage by physician-to-physician communication. In cases of failure to name such member and arrange such coverage, the Department Chief and / or Section Head may take Corrective Action authorized under the Medical Staff Bylaws and shall have authority to call any members of the Medical Staff to provide coverage.

Telephone Contact in Emergencies

All Medical Staff members must maintain accurate and updated telephone numbers (primary and alternatives, such as pager, answering service and home) with the Communications Department (Operator) and at the Troy and Grosse Pointe hospitals shall maintain such numbers with the Medical Administration Office as well.

On-call Lists and Back-up Coverage Plans

Each Department and / or Section of the Medical Staff of the Hospital shall maintain an on-call list of physicians assigned to that Department and / or Section as established by that Department or Section and a back-up coverage plan for circumstances when the on-call physician cannot respond because of circumstance beyond the physician's control, e.g. the physician is in the operating room. The on-call list and back-up coverage plan of each Department and / or Section will be provided to the Communications Department (Operator) and at the Troy and Grosse Pointe Hospitals such plan will be also provided to Medical Administration and the Emergency Center in the format delineated by Medical Administration.

Emergency Center Call Responsibility

The Hospital and its Medical Staff have an obligation to ensure that timely care is available to all individuals who present to the Hospital for care regardless of the day, time or their ability to pay. A physician on-call is required to be available to respond within thirty (30) minutes of a call from the Emergency Center. All Emergency Center patients must be provided with an appropriate medical screening examination and stabilizing treatment within the capability of the Hospital's Medical Staff and capacity of the Emergency Center.

When a physician is on-call, the Emergency Medical Treatment and Active Labor Act ("EMTALA") requires the physician to personally attend the patient when requested by the Emergency Center Physician unless the on-call physician cannot respond because of circumstances beyond the physician's control. On-call physicians who refuse to come to the Emergency Center to see the patient, do so in less than a timely manner, or direct that the patient be transferred without coming to the Emergency Center to assess and / or stabilize the patient, put themselves and the Hospital at risk for EMTALA violations.

If the patient is transferred from the Hospital because the on-call physician delays or refuses to evaluate the patient, the Hospital must send the receiving hospital all patient records and the name and address of the on-call physician who has refused or failed to appear within a reasonable time to provide the necessary stabilizing treatment. When this occurs, the on-call physician may be subject to a fine of up to \$50,000 and exclusion from participation in Medicare under EMTALA.

Hospital Call Responsibility

When a physician is identified by his / her Department or Section as being on-call to the Emergency Center, that physician may also be responsible, under the system established by his / her Department or Section, for responding to all calls by the Department Chief or Section Head or his / her designee to care for patients of the Hospital in areas other than the Emergency Center within thirty (30) minutes of such call, and shall come on-site to the Hospital to attend to such patient if requested by the Department Chief or Section Head or his / her designee.

Staff Service

Staff members who attend to a patient under Emergency Center call and Hospital call responsibilities will be covered for medical professional liability claims arising out of that care, under the Hospital's Staff Service Indemnification Policy in effect at the time of the occurrence. This policy will also apply to patients who are in transit to another unit.

1.1.4. CONSULTATIONS

Consultation / When to Request

Although judgment as to the nature of an illness and questions concerning prognosis rest with the attending physician, good medical practice requires the proper and timely use of consultation with persons qualified to give opinions in the field in which the advice is sought. To ensure that each patient is treated by an appropriately qualified physician or other licensed independent practitioner, the Department Chief, Physician-in-Chief, or Medical Executive Board may establish criteria for required consultation or consultation and management, for selected procedures, treatments, or conditions. The Physician-in-Chief or Medical Executive Board may likewise establish criteria for when a physician or other licensed independent practitioner response to a consult is mandated and under what circumstances a response by a mid-level provider may suffice in the interest of patient care.

When requesting a consultation, note whether the request is for consultation only, consultation and management of a problem, or consultation and request for change transfer of service.

To emphasize the key role of the attending physician as the “quarterback” physician who is responsible for the makeup of the medical team caring for the patient, the attending physician and / or designee should initiate all consults except in urgent situations requiring immediate attention.

All requests for consults must be must be given to a person. A message cannot be left on an answering machine. If contact is sent via text page, then the sender must include a call back telephone number for the physician to respond so as to verify receipt of the message.

	ROUTINE CONSULT	URGENT CONSULT
CONSULTANT OBLIGATIONS FOR A NEW CONSULT	<ul style="list-style-type: none">• Must be answered within 24 hours	<ul style="list-style-type: none">• Physician-to-physician contact is required, by either the attending physician or the resident
CONSULTANT PREROGATIVES IN CHANGING / SUBSTITUTING CONSULTANTS WITHIN THE SAME SPECIALTY	<ul style="list-style-type: none">• If a prior relationship exists between the patient and a consultant, the consult may be redirected to him / her without the requirement for contact with the attending physician• Clarification with the attending or patient regarding the choice of consultant is encouraged• To maintain timeliness of consultation process, the consult must be answered within 24 hours of the original request	<ul style="list-style-type: none">• Physician-to-physician contact is required
CONSULTANT PREROGATIVES IN CHANGING / SUBSTITUTING CONSULTANTS NOT WITHIN THE SAME SPECIALTY	<ul style="list-style-type: none">• May not initiate, modify, or cancel a previously placed physician consultation without express permission of the attending physician• To maintain timeliness of consultation process, the consult must be answered within 24 hours of the original request	<ul style="list-style-type: none">• Physician-to-physician contact is required
CONSULTANT CONSULTING ANOTHER CONSULTANT	<ul style="list-style-type: none">• Recommendation for such a consult is permitted but the order may be placed only by the attending physician / designee or after verbal approval by the attending physician / designee	<ul style="list-style-type: none">• Physician-to-physician contact is required

Consultation / Notice of Reason

It is important to give a specific reason for requesting a consultation. "Patient known to you" is an unacceptable reason. The following order is appropriate when requesting a consultation:

Please consult Dr. _____ for (reason, e.g.diabetes).

Consultation / Documentation

Proper consultation includes examination of the patient, review of the record and a written opinion signed by the consultant and made a part of the record. When operative procedures are involved, the consultant note, except in emergency, shall be recorded prior to the operation.

1.1.5. PHYSICIAN ORDERS

Routine Vital Signs / Orders for

In the event that "routine vital signs" are ordered, the following guidelines are to be followed:

- a. For critical / intensive care units, routine vital signs consist of temperature, pulse, respiration, and blood pressure taken every hour.
- b. For telemetry units, the routine vital signs listed in (1) are taken every four hours.
- c. On the general medical, surgical and gynecology units, the routine vital signs listed in (1) are taken once per shift.
- d. For pediatric units, routine vital signs consist of temperature, pulse and respiration taken once per shift. Blood pressure is taken only on admission and as ordered by the physician or nurse.
- e. Vital signs may be taken less often than once per shift only on a physician's specific order.
- f. If no vital signs are ordered, routine vital signs, as defined above, will be implemented until physician clarification can be obtained.

Verbal / Telephone Orders Policy

Verbal / telephone communication of orders will be used only in the following situations:

- When writing / entering an order is not possible, such as during a CPR, during a procedure, or while the physician is scrubbed for a surgery / procedure
- If the physician is not in the immediate area / patient care unit

Verbal / Telephone Orders – Who Can Accept

All orders for treatment by physicians, physician assistants, nurse practitioners or nurse midwives shall be in writing. An order shall be considered to be in writing if dictated to hospital-employed registered nurses, specified respiratory personnel (RRT), registered dietitians, registered pharmacists, physical therapists, occupational therapists, speech pathologists, radiologic technicians, and / or members of other disciplines, acting within the scope of their license or registration.

To ensure that verbal / telephone orders are accurate, the person accepting the order must hear it, place it (write or enter electronically) in the medical record and read it back to the prescriber.

Verbal / Telephone Orders / Signature

Verbal / telephone orders must be documented and signed by the person to whom they were dictated, with the name of the ordering physician or dentist displayed. Verbal / telephone orders must be co-signed, either hand signature or electronically, by the physician who gave the order as soon as possible but not later than 24 hours after the verbal / telephone order was issued. The physician must include his / her four-digit identification number. In the absence of the ordering physician, a covering physician or a resident responsible for the care of the patient may co-sign the order.

Orders for Transfer of Care from One Physician to Another

To accomplish the transfer of care of an inpatient from one physician to another, the medical record must contain the following notations:

- a. Order to transfer care
- b. Written indication of the receiving physician's acceptance of transfer. This may take the form of a note by the receiving physician documenting the acceptance of the transfer or a note by a nurse documenting the nurse's direct conversation with the receiving physician in which the physician accepted transfer.

If transfer of care is attempted but not successfully concluded, the following will apply:

- a. The transferring physician will be notified, if not aware through personal involvement in the attempted transfer, of the unsuccessful attempt.
- b. If the transferring physician is not available in a timely manner to continue care of the patient, the issue will be referred to the transferring physician's Department Chief.

Orders for Diagnostic Procedures / Tests Must Include Reason for Exam

When a physician writes an order for diagnostic procedures / tests, including lab tests, nuclear medicine procedures, radiology procedures, ECGs, the reason for the procedure / test must be included in the written order. Clinical information should include patient symptoms and the working diagnosis. These requirements apply to inpatient and outpatient procedures / tests.

If an inpatient diagnostic order does not contain a reason for the exam, the unit secretary will call the ordering physician. STAT orders will be processed while the unit secretary is trying to obtain the clinical information.

Orders / Legibility and Abbreviations

- Written orders must be legible
- The physician's ID number must be written legibly next to his / her signature
- "Units" must be written out; never abbreviated (u)
- "Push" must be written out; never abbreviated (IVP)
- PRN orders must include the dosage and the criteria for administration
- All applicable order sets must be used, e.g. PCA, Insulin Sliding Scale
- Dosages must not be written with a leading decimal point and whole numbers must not contain a decimal:

<u>Correct</u>	<u>Incorrect</u>
0.25 mg	.25 mg
4 units	4.0 units

- Medication names must be written out (no abbreviations) with the exception of orders for IV fluids, electrolytes, vaccines and the following specified medications:

<u>Abbreviation</u>	<u>Medication</u>
ASA	aspirin
5-FU	5-fluorouracil
I131	radioactive iodine
MOM	milk of magnesia
MVI	multiple vitamins
NTG	nitroglycerin
PCN	penicillin
TMP-SMX	trimethoprim / sulfamethoxazole
TSH	thyroid stimulating hormone

If the interpretation of an order is questionable, either because of an abbreviation or illegibility, the physician who wrote the order will be contacted immediately.

“Do Not Use” Abbreviation Policy

A table of “Do Not Use” abbreviations established by the Medical Staff may be placed in inpatient medical records. Whenever a prohibited abbreviation is used in clinical documentation, written confirmation of the intended meaning will be obtained before the order is carried out. If, in the judgment of the staff caring for the patient, the order is clear and complete and the delay in obtaining confirmation from the prescriber would place the patient at risk, then the order should be carried out and the confirmation obtained as soon as possible thereafter.

1.1.6. PATIENT IDENTIFICATION REQUIREMENT

Verifying a patient's identification against a relevant clinical document is necessary to assure that the correct patient is receiving the intended care or procedure. This verification action is taken by the physician when he / she performs an admission history & physical examination, a consultation; a first bedside visit (for example, when covering a colleague); any diagnostic or invasive procedure, or surgery (this is incorporated into the time out before every surgery); and giving medication.

The verification process requires two elements of a patient's identification, such as name and birth date. Examples of relevant clinical documents include the physician's patient list, a consult form, a consent form or other document pertinent to the clinical situation. The physician may ask the patient to state their full name and birth date or use the information on the wristband as the reference for the match. Even when the patient is known to the physician, checking the wristband is appropriate at the initial inpatient contact. A patient's room number is not an acceptable element of a patient's identification.

1.2 GENERAL PATIENT CARE POLICIES

1.2.1. ADVERSE DRUG REACTION

Physicians should document in the medical record the nature of serious adverse drug reactions and all allergic drug reactions, and may write an order for an allergy update. The documentation should include a statement as to whether the patient (or where appropriate the patient's guardian or significant other) has been made aware of the reaction. In the case of allergic reactions the patient should be informed and the allergy should be noted in both the discharge instructions and on the discharge summary. In cases of suspected unusual or unanticipated drug reactions, the pharmacy should be notified, and will assist in completing the appropriate documentation for the FDA's post-marketing surveillance system.

1.2.2. INFECTION CONTROL POLICIES

Standard Precautions

Beaumont Hospitals practice "Standard Precautions", which emphasizes the need for health care workers to consider all patients as potentially infected with blood-borne pathogens and to adhere rigorously to infection control precautions for minimizing the risk of exposure to blood and body fluids of all patients. Hand hygiene before and after patient contact is mandatory

Transmission Precautions

Beaumont Hospitals use Transmission Precautions to limit the spread of epidemiologically significant organisms. Gloves and gown must be worn when entering an Enhanced Contact isolation room, and when direct contact with a patient in Contact isolation is anticipated. A surgical mask is worn for Droplet isolation, and an N-95 mask must be worn when entering an Airborne isolation room. Policies for isolation are located on Beaumont's internal website and should be consulted when appropriate. Department of Epidemiology staff are always available on call should questions arise regarding isolation procedures.

Exposure Follow-up

If a health care worker sustains a significant exposure to a patient's blood or body fluids, the patient should be informed of the incident and that testing will proceed in accordance with State law as disclosed on the General Consent to Treatment Form. See the Occupational Health Policy for further details.

Occupational Health Services (OHS)

Provides screening for immunity to infectious diseases and post-exposure follow-up to all Beaumont physicians. Influenza vaccine is provided to all Beaumont physicians. OHS also provides physicians with assessment, testing as indicated, prophylaxis / treatment, and counseling if they have an infectious disease that puts others at risk.

Emerging Infectious Diseases

Information will be posted on "Inside Beaumont" regarding mode of transmission, prevention, and treatment, if available.

1.2.3. DISCHARGE FROM PHASE II RECOVERY

At the Royal Oak Hospital only there is a standing order for discharge of a patient from Phase II recovery services when the patient meets Medical Staff approved discharge criteria. If a physician wishes that a patient remain in Phase II Recovery after the criteria have been met, a patient specific order must be written in the medical record.

1.2.4. OPERATIVE SPECIMENS

All tissue or matter and devices removed from a patient during the course of surgical intervention are considered a specimen. All specimens must be properly contained and transferred to the appropriate laboratory. The surgeon will determine if a specimen will be sent to the Surgical Pathology Department. Any exception to the requirement to send all specimens to the appropriate laboratory must be approved by written agreement between the Chief of the specific clinical department and the Chief of Pathology and Laboratory Medicine. Such agreements are subject to approval of the Physician-in-Chief of the respective Hospitals except those that that approved through the Medical Executive Board.

1.2.5 RADIOACTIVE MATERIALS

All clinical use of radioactive materials shall be by physicians and dentists with appropriate privileges under the supervision of the Radiation Safety Committee. NO use of radioactive material may be made without the written approval of the Radiation Safety Committee.

All users and uses of radioactive material must be approved by the Radiation Safety Committee prior to commencing work with radioactive material. Application forms for requesting approval may be obtained from the Research Institute office (248-551-0650) or the Radiation Safety Officer's office (248-551-0548).

The Radiation Safety Committee meets quarterly. Provisional approvals for use and users are possible after a review of the completed application form.

1.2.6 RESPIRATORY CARE PROTOCOLS

Respiratory Therapists provide care in keeping with the standards developed by professional organizations (ATS, ACCP, AARC, etc) and regulatory agencies. Services provided to the patient are driven by physician order and Hospital-approved protocols and care plans. Respiratory care protocols and disease-specific care plans are based on current national practice guidelines and are designed to move the patients along a continuum from intensive treatment to minimal / home regimen at discharge.

1.2.7. RESTRAINT USE AND / OR SECLUSION POLICY AND DEFINITIONS (See Full Corporate Policy #240)

1. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion (Note: Seclusion is only on the psychiatric unit at Royal Oak) may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time. Hospital and medical administration support this philosophy.
2. Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.
3. Efforts are made to limit restraint use because restraint itself can lead to adverse outcomes, including death, asphyxiation, delirium, tissue necrosis, peripheral edema,

diminished peripheral circulation, pressure ulcers, skin tears, accelerated osteoporosis, contracture, agitation, cardiovascular symptoms, withdrawal or depression, constipation, infections. Seclusion is not to be utilized in situations where there is risk the patient may harm him/herself in seclusion.

4. The use of restraint or seclusion will be ordered by a physician or physician extender (PA / NP) who is responsible for the care of the patient. If the restraint or seclusion is ordered by a provider other than the attending physician, he / she must be consulted as soon as possible by the ordering provider. The type of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm and removed at the earliest possible time.
5. A physician, PA / NP must perform a face-to-face assessment within 1 hour of the initial use of a medication used as a restraint or within 1 hour of the initiation of restraint or seclusion for violent / self-destructive behavior (even if restraint / seclusion has been terminated).
6. PRN orders for restraints are not permitted and new orders for restraints are to be given upon transfer to another level of care.
7. Restraint order duration for non-violent behavior and violent / self-destructive behavior is outlined in the full policy #240.

1.2.8. SEIZURE PRECAUTIONS

It is important that the attending physician inform the nursing staff or house physician / staff of a patient with a history of seizures or use of medication for seizure control so that the Seizure Precaution Policy (found in the Nursing Policy/Procedure Manual) may be instituted. Please refer to this Policy for specifics. Upon such notification, the nurse will institute Seizure Precautions as outlined in each respective Hospital's Nursing Policy.

1.2.9. SELF-TREATMENT OR TREATMENT OF FAMILY MEMBERS

The Beaumont Hospital Medical Staff subscribes to the AMA Code of Medical Ethics and Current Opinions with respect to this issue and is incorporated by reference in section 1.1 of the Bylaws of the Medical Staff.

- a. Medical Staff members shall not admit immediate family Members to the Hospital.
- b. Medical Staff members shall not write orders or dictate verbal orders for the care of themselves or immediate family members. Any suggestions for care should be communicated to the physician of record.
- c. With the exceptions for emergencies or routine care for short-term, minor problems, Medical Staff Members shall not perform treatments, procedures, surgery or obstetrical delivery on immediate family members.

Immediate family members are defined as:

- | | |
|---------------------------------------|--------------------------------|
| • Spouse | • Grandchild's spouse |
| • Child (biological and / or adopted) | • Parent |
| • Child's spouse | • Stepparent or adopted parent |
| • Stepchild | • Parent-in-law |
| • Stepchild's spouse | • Sibling |
| • Grandchild | • Domestic partner |

1.2.10. SMOKING POLICY

Beaumont Hospitals and State law prohibit smoking inside any Beaumont facility / structure, whether owned or leased, and immediately outside the entrances or exits. This smoke-free campus eliminates smoking from all entrances and Hospital grounds, allowing for a cleaner and more healing environment for patients, visitors, employees, physicians, and volunteers. A physician is not authorized to permit a patient to smoke, and may not write such an order.

1.3 HOSPITAL DEPARTMENTAL SERVICES

1.3.1. ADMISSION / REGISTRATION PROCESS

Prior to or at the time of admission, the Admitting / Registration Department assists the registration of all patients and the paper flow management of the initial patient medical and financial records.

1.3.2. BED ASSIGNMENT

Royal Oak:

- Handles bed assignments, direct admissions and transfers from other facilities. Call Direct Access Center: 248-898-0880.

Troy:

- Handles bed assignment for inpatients and observation patients. Call Bed Operations: 248-964-9105
- Handles direct admissions from physician offices and transfers from other facilities: Call Access Transfer Office: 248-964-7055

Grosse Pointe:

- Handles bed assignments, direct admissions and transfers from other facilities: Call Patient Registration: 313-343-1200

1.3.3. MEDICAL / PRE-AUTHORIZATION REQUIREMENTS

Information is gathered on all admissions and transfers to coordinate the services needed by the patient and to assure that all authorizations required by third party payers are obtained. Care coordinators / managers / registered nurses, in collaboration with the physician, may explore alternatives to hospital admission as patient needs warrant. Note that CMS may require inpatient admission for certain procedures

Royal Oak: Care managers / registered nurses handle this function whenever the review agency allows the Hospital, on behalf of the physician, to do so.

- Surgical / elective admissions: Admissions Transfer Office: 248-898-6102
- Direct admissions and transfers from other facilities: Direct Access Center: 248-898-0880

Troy: The physician's office is responsible for obtaining a preauthorization number from the insurance company prior to admission. Questions should be directed to the Care Management Department: 248-964-8900

Grosse Pointe: The physician's office is responsible for obtaining a preauthorization number from the insurance company prior to admission. Questions should be directed to the Care Management: 313-343-1781 or Patient Registration: 313-343-1200.

1.3.4. ADVANCE TESTING

The Advance Testing Department screens electively scheduled inpatient and outpatient surgical / invasive diagnostic procedure patients requiring services of the anesthesia Department. The screening is typically conducted via a telephone call. In addition to screening, the staff may provide patient education.

Royal Oak:

- Requests for Advance Testing are made at the time of scheduling and physician orders are to indicate 'Advance Testing'
- Cardiovascular Surgery, Cath Lab, Heart Rhythm Center patients requiring Anesthesia Services: Pre-procedure assessment and testing is handled by Heart and Vascular Pre-Testing: 248 -898-4240

Troy:

- The history and age of the patient, the invasiveness of the procedure, and type of proposed anesthetic may determine whether the patient needs to come into the department prior to their procedure.
- Cardiovascular Surgery Patients Requiring Anesthesia Services: Initial screening is done via a telephone call. Additionally, an appointment is set up with Advance Testing to complete pre-procedure assessment and testing. The Department's number is 248-964-4810.

1.3.5. CARE MANAGEMENT

Care Management staff facilitate patient care across the continuum from admission to discharge. Throughout each patient's stay, Continuing Care nurses assess the patient's status and plan of care to determine whether criteria are met for continued utilization of Hospital resources, and to provide comprehensive care coordination and discharge planning.

Utilization Review

The Utilization Management component of the Care Management Plan provides a process to determine effective utilization of hospital resources through a continuous and systematic review program. The goal is to maintain the highest quality patient care, and to assist physicians in meeting various insurance regulations that control payment for services.

Inpatients

Documented medical information is screened against established McKesson InterQual criteria or Medicare rules. These are utilization review guidelines only, and do not constitute standards of care. If the information in the medical record does not meet the criteria for inpatient admission or continued stay, the Care Management staff may contact the attending or a designated Physician Advisor to obtain more information and determine an appropriate setting for a level of care.

The chart documentation must reflect severity of illness and intensity of service:

- (IS) Intensity of Service Criteria. Diagnostic and therapeutic services that can generally only be provided in a hospital inpatient setting.

- (SI) Severity of Illness Criteria. Objective, clinical parameters that reflect the severity of illness.
- (D) Discharge Screening Criteria. Specific indicators of patient stability and discharge readiness.

Assistance with Insurance Authorization Issues

The expectation is that physicians (attending and E.C.) respond to all insurance company / review entity correspondence and telephone requests for medical information to justify a hospital outpatient observation admission and / or an inpatient admission. Commercial insurers have contracts with the Hospital that require timely compliance with review procedures. These third party payers may deny payment to the Hospital and physicians due to lack of medical information.

Discharge Planning

Care Management collaborates with all health care professionals, patients and families to provide a discharge management plan for post-acute hospital care.

1.3.6. PATIENT FINANCIAL SERVICES

The primary function of the Patient Financial Services representatives is to secure payment for the Hospital through any available funding, e.g. insurance, Medicaid, Childrens Special Healthcare Services and to assist the patient with necessary information to arrange payment.

Questions concerning payment for Beaumont services may be directed to 248-577-9292.

1.3.7. PHARMACY

General

The Department of Pharmaceutical Services is open 24 hours a day and provides a variety of distributive and clinical pharmacy services. Medications are dispensed by a unit dose drug distribution system to assure compliance with physician prescribing and minimize medication errors. IV solutions are prepared under aseptic conditions.

Hospital Formulary

The Hospital Formulary of Accepted Drugs is available on the "Inside Beaumont" web site. The Formulary is maintained by the Medication Management Committee of the Medical Staff and allows for therapeutic interchange of many medications. The Medication Administration Record describes any interchange that has occurred. Information regarding formulary changes is published and communicated to the Medical Staff by the Pharmacy.

Medication Policies

Medication policies include an Automatic Stop Order Policy (all medications are subject to an automatic stop order date) and an automatic cancellation of medication orders when patients are transferred into CCU and PCU or into the Telemetry Unit. A separate medication order form is used for prescribing parenteral nutrition. Pre-printed medication order forms have been developed for individual Clinical Practice Guidelines as well as standing protocols.

Clinical Services

Pharmacokinetic dosing of aminoglycoside antibiotics, anticoagulants (heparin and warfarin), theophylline, and vancomycin are available upon physician request.

IV antibiotic therapy is reviewed by the Antibiotic Service (pharmacist and infectious disease physician). Recommendations are made to prevent bacterial resistance and to improve antibiotic therapy. Dosages are automatically adjusted for renal dysfunction. Specific antibiotics are automatically converted from IV to oral based upon the patient's clinical improvement.

Pharmacists provide patient specific drug information to patients receiving MAO Inhibitors, theophylline and warfarin. Patient education is also provided to other patients receiving selected medications.

A "snapshot" interface of the patient's active drug profile is available on the electronic medical record system. This profile lists only current, active drug orders for inpatients.

1.3.8. SERVICE EXCELLENCE

If a patient is not satisfied with the Hospital's services, the patient should contact the manager of the involved Department. If the patient is still not satisfied, the patient should call the Service Excellence Department at 248-551-0500 for Royal Oak, 248-964-1800 for Troy and 313-417-6816 for Grosse Pointe.

1.3.9. SPIRITUAL / PASTORAL CARE

Chaplains from Spiritual / Pastoral Care are present in the Hospitals twenty-four (24) hours per day, seven days per week and can be reached through the Hospital operator. The Chaplains see each patient admitted to the Hospital and provide a ministry of Spiritual / Pastoral Care. Religious services are held in the Chapels on weekends. In addition, Chaplains are trained counselors and can assist patients and families with their various needs including decisions near the end of life, such as organ donations and issues related to death. Spiritual / Pastoral Care can be contacted directly from 8:00 a.m. – 4:30 p.m. The nursing supervisor can be contacted after hours to request Spiritual / Pastoral Care visits.

1.4. MEDICAL RECORD REQUIREMENTS

1.4.1. MEDICAL RECORD / PURPOSE

The primary purpose of a patient's medical record is to serve as a document of the care provided to assist in the rendering of quality medical care. This is accomplished by utilizing the record as a means of communicating pertinent and precise medical information concerning a patient to all health care providers involved in that patient's care. The medical record contains sufficient information to identify the patient, support the diagnosis, justify the treatment, document the course of treatment and results accurately, and facilitate continuity of care among health care workers.

1.4.2. COMPLETE MEDICAL RECORD / DEFINITION

The attending physician, dentist, or podiatrist shall be responsible for the preparation of a complete medical record for each patient under his / her care. This record shall include patient identification data, patient assessments, provisional diagnoses and impressions including all comorbidities, documentation of emergency care, relevant diagnoses established during the course of care, reason(s) for admission, goals and plans for treatment, evidence of informed consent and advance directives when appropriate, all

diagnostic, therapeutic, and medication orders, all diagnostic and therapeutic procedures / tests performed and their results, all operative and other invasive procedures performed, progress notes documenting necessary reassessments, clinical observations and the patient's response to care, consultation reports, medications administered, any complications, hospital-acquired infections, and unfavorable reactions to drugs or anesthesia, condition on discharge, any referrals and communications made to other care providers or community agencies, and autopsy report when applicable. All entries in the medical record must be timed, dated and legible.

At a minimum, documentation of the assessment / reassessment of each patient must include:

- a. Establish and document the initial status of the patient. This must include a pertinent History and Physical examination (minimum content outlined below) together with baseline laboratory values and diagnostic testing, if appropriate, and an identification of the reason for admission.
- b. Once a reliable baseline has been established, only deviations from baseline values, studies, observations, significant changes in a patient's mental or physical status, and indications for treatment and medical care rendered are to be recorded in the medical record. Additional documentation may be required in specific Hospital units by written policy.
- a. Documentation of medical necessity and severity of illness should be provided in sufficient depth / detail to support the admission and the continued stay. The patient's clinical status must reflect the need for the Hospital resources ordered and utilized.
- b. Radiology, laboratory and diagnostic tests require an order and a diagnosis / sign / symptom to justify the medical necessity of the test / examination.

1.4.3. DOCUMENTATION DEFICIENCIES AT THE POINT OF CARE

Documentation of informed consent, patient assessments, and appropriate timed, dated and legible orders must be present to assure safe patient care. All members of the healthcare team are authorized and empowered by the Medical Staff to "stop the line" if the clinical documentation necessary for the provision of safe patient care is not present in the medical record, provided that such delay would not place the patient at additional risk. The caregiver that intervenes to "stop the line" should first discuss the concerns with the attending physician. If any issues remain unresolved, the Chain of Command policy #312 should then be activated.

1.4.4. ELECTRONIC HEALTH RECORD

The medical record consists not only of the paper chart but also the electronic health record. It is essential that all physicians review the electronic health record database in addition to the paper portion of the chart, and that all edits to electronic health record data be made on the electronic health record database.

Physicians must review and edit each report they author, before they authenticate it. Batch signatures for authentication are not acceptable. Each physician must provide the Hospital with a signed acknowledgment that he/she alone will use his / her electronic health record system access password(s) to authenticate reports or entries in the electronic health record. Revisions to electronic data entered in the system by anyone other than the physician will require review and authentication by the originating physician.

1.4.5. CONFIDENTIALITY

It is the policy of Beaumont Hospitals to afford its patients the level of privacy and confidentiality required under law whenever it is entrusted with medical information (protected health information) concerning any of its patients. Protected health information is defined by the Privacy Regulations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as individually identifiable health information, including demographic information that identifies or can be reasonably believed to identify a patient, which is created or received by the Hospital and relates to the past, present, or future physical or mental health condition of a patient; the provision of health care to a patient; or, the past, present, or future payment for the provision of health care. All protected health information, oral, electronic, written, or maintained in any medium, must be held in the confidence as required by law and utilized only for purposes permitted by law.

Physicians who have connection to the Hospital electronic health record system in their private offices are fully responsible for the conduct of their office staff while accessing the system and are responsible, as well, for instructing their staff as to the necessity of maintaining the confidentiality of patient information accessed through the electronic system.

Medical Staff members who want to review the medical records of a family member should first discuss this with the physician of record. Medical information (verbal, written, printed or electronic) may be reviewed only with the written permission of the patient. A Medical Staff member who seeks to review medical records of his / her family members or that of his / her minor child should complete the Hospital's standard Authorization for Release of Patient Medical Information form, which may be obtained from the Medical Information Services Department. This authorization is valid for 30 days.

Medical Staff members may view their own medical records by completing the Authorization for Release as defined above.

1.4.6. HISTORY AND PHYSICAL EXAMINATION CONTENTS

The minimum data required for the history and physical examination is:

- History of present illness
- Past medical history
- Social history
- Family history
- Medications
- Allergies
- Assessment
- Plan of care

The physical examination is to consist of a clinical assessment and focused examination relative to the patient's chief complaint.

A history and physical examination is required for all inpatients. For outpatients undergoing surgery or a major diagnostic procedure requiring general, spinal or regional anesthesia, a history and physical examination must also be completed.

The data gathered through interview and / or observation for the history, including history of present illness, past medical and surgical history, family history, medications, allergies, and review of systems, may be completed by a physician, resident, certified registered nurse

anesthetist, physician assistant, nurse practitioner, certified nurse mid-wife, master's-prepared clinical nurse specialist, medical student, nurse clinician or registered nurse.

The examination and interpretation and analysis to determine the plan of care, including physical examination, initial labs / diagnostic tests, and impression and plan of care, may be completed by a physician, resident, certified registered nurse anesthetist, physician assistant, nurse practitioner, certified nurse mid-wife or master's-prepared clinical nurse specialist.

All entries into the medical record must be signed, dated and timed. If more than one individual completes the history and physical, the individual signing the plan of care assumes responsibility for the contents of the complete history and physical examination.

As defined in 1.5.4, if the history and physical examination is completed by a resident, the supervising attending physician will authenticate and countersign the history and physical examination.

While a resident, certified registered nurse anesthetist, physician assistant, nurse practitioner, certified nurse midwife or master's prepared clinical nurse specialist may sign the history and physical examination, it is the attending physician who is responsible for integrating the information in the history and physical examination, the formulation of the plan of care of the patient and its execution while the patient is hospitalized.

1.4.7. TIMING OF HISTORY AND PHYSICAL

For patients undergoing surgery or a major diagnostic procedure requiring general, spinal or regional anesthesia, the history and physical examination must be completed before the procedure is performed. A dictated history and physical examination that has not been transcribed and authenticated does not satisfy this requirement since it is not available for review in a timely manner. In an emergency, when there is no time to record a complete history and physical examination, a progress or admission note describing a brief history and appropriate physical findings and the pre-operative finding shall be entered in the medical record before surgery or the administration of anesthesia.

An appropriate history and physical examination of all inpatients shall be completed, recorded in the Hospital medical record within twenty-four (24) hours after admission. A dictated history and physical examination is also accessible via the dictation system on an immediate basis but because it is not readily available in emergent circumstances, the physician or qualified practitioner as stipulated in Section 1.4.6. must also complete a brief admission note as a bridge until the history and physical examination is transcribed. Dictated reports are available in the electronic medical record upon transcription as 'unverified'. All patient records must contain a signed history and physical examination within seven (7) days after admission.

If a history and physical examination has been performed by a qualified practitioner as stipulated in Section 1.4.6 within 30 days before admission, a legible copy of this report may be used in the patient's medical record, provided that it is updated in writing within twenty-four (24) hours of admission, and the authenticated update reflects pertinent clinical changes since the history and physical examination was performed. For both inpatients and outpatients undergoing surgery or a major diagnostic procedure requiring general, spinal or regional anesthesia, the history and physical examination update must be completed before the procedure is performed. The update must be completed by a qualified practitioner as stipulated in Section 1.4.6.

When a dentist or podiatrist is to perform a surgical procedure, the responsible dentist or podiatrist must record the dental or podiatric portion of the history and physical examination in the medical record.

1.4.8. NEWBORN ADMISSIONS

All infants born at Beaumont Hospitals must have an admission note written within twenty-four (24) hours of birth, a daily progress note, an order for discharge, and a final progress note that suffices for the discharge summary.

All newborns admitted to the Neonatal Intensive Care Nursery will require the same documentation as other admissions.

1.4.9. PRE-PROCEDURE EVALUATION, PRE-PROCEDURE SEDATION PLANS AND UNIVERSAL PROTOCOL

Section 1.4.6 defines the requirements for a history and physical examination. For all other patients scheduled for major diagnostic or operative / invasive procedures requiring sedation and performed by a physician or an advanced practice professional, a pre-procedure evaluation must be completed before any intervention is undertaken.

A procedure may have up to three levels of information based on the nature of the procedure. The three levels of information are: 1) Information applicable to all procedures, 2) Information applicable to a procedure where sedating IV or IM sedation is commonly used, and 3) Information applicable to a procedure requiring deep sedation or anesthesia involving general, spinal or major regional anesthesia.

The documentation requirements may be summarized as follows:

	ALL PROCEDURES With or without LOCAL Anesthesia or Oral Anxiolysis	PROCEDURES WITH SEDATION Where Moderate Sedation is the Goal, Usually Involving the Administration of IV or IM Sedatives	PROCEDURES WITH ANESTHESIA Deep sedation or General Anesthesia, Spinal, or Major Regional Block
Level I	<ul style="list-style-type: none">• Current medications• Patient, procedure, site identification• Pertinent clinical information• Time Out• Post-Procedure progress note	<ul style="list-style-type: none">• Current medications• Patient, procedure, site identification• Pertinent clinical information• Time Out• Post-Procedure progress note	<ul style="list-style-type: none">• Current medications• Patient, procedure, site identification• Pertinent clinical information• Time Out• Post-Procedure progress note
Level II		<ul style="list-style-type: none">• Pre-procedure evaluation based on clinical pertinence and plan for sedation• Immediate pre-sedation reassessment• Nursing assessment• Intra-procedural monitoring• Post-procedure monitoring• Discharge assessment	<ul style="list-style-type: none">• Plan for anesthesia• Immediate pre-induction reassessment• Nursing assessment• Intra-procedural monitoring• Post-procedure assessment• Discharge assessment

	ALL PROCEDURES	PROCEDURES WITH SEDATION	PROCEDURES WITH ANESTHESIA
Level III			<ul style="list-style-type: none"> • H & P (within 30 days) • Update to H&P (day of procedure) • Pre-anesthesia evaluation (within 72 hours) • Post-anesthesia evaluation (within 48 hours after the procedure)

The data gathering portion of a pre-procedure evaluation may be completed by a physician, resident, certified registered nurse anesthetist, physician assistant, nurse practitioner, certified nurse mid-wife, master's-prepared clinical nurse specialist, medical student, nurse clinician or registered nurse.

The documented need and plan for procedure may be completed by a physician, resident, certified registered nurse anesthetist, physician assistant, nurse practitioner, certified nurse mid-wife or master's-prepared clinical nurse specialist.

The content of the pre-procedure evaluation is to be appropriate to the risk of the procedure to be performed, the anesthesia to be used and the condition of the patient and should be adequate to determine the need for additional diagnostic data. Specific requirements, if any, for the content of the pre-procedure medical evaluation shall be determined by the appropriate Department Chief.

All entries into the medical record must be signed, dated and timed. If more than one individual completes the pre-procedure evaluation, the individual signing the plan of care assumes responsibility for the contents of the complete pre-procedure evaluation.

The data gathering portion of pre-procedure evaluations and documentation for the need and plan for the procedure may be completed by a non-physician as stipulated above. The physician performing the procedure or operation is ultimately responsible for the knowledge of the key information in the pre-procedure evaluation, history and physical, the plan of care and its appropriate execution.

The Universal Protocol must be completed prior to beginning an operative procedure or a major diagnostic procedure. The Universal Protocol requirements are:

- 1) Conduct a pre-procedure verification process:
 - a. Verify correct patient, correct procedure, and correct site with patient involvement if possible
 - b. Review items that must be available for the procedure such as:
 - i. Relevant documentation such as history and physical examination, pre-procedure evaluation, signed and executed informed consent, nursing assessment, and pre-anesthesia assessment
 - ii. Labeled diagnostic testing and radiology tests that are properly displayed
 - iii. Any required blood products, implants, devices, and / or special equipment for the procedure
 - c. Match the items that are to be available in the procedure area to the patient

2) Mark the site

- a. Site marking is required when there is more than one possible location for the procedure and when performing the procedure in a different location would negatively affect quality or safety
 - i. For spinal procedures, in addition to skin marking of the general spinal region, special intraoperative imaging techniques may be used for locating and marking the exact vertebral level
- b. Mark the procedure site before the procedure is performed and, if possible, with patient involvement
- c. The procedure site should be marked by the individual who is accountable for the procedure and will be present when the procedure is performed; a resident supervised by the physician performing the procedure and involved in the care of the patient may mark the site
- d. Site marking is unambiguous and is consistent with Hospital policy. The marking should be sufficiently permanent to be visible after skin preparation and draping.
- e. If the site cannot be marked or the patient refuses sit marking, then the site marking is documented on a diagram
- f. Site marking is not required when the individual doing the procedure is continuously with the patient from the time of the decision to do the procedure through to the performance of the procedure.

3) Perform a time out immediately before the procedure

- a. Time out must be performed immediately before the invasive procedure or making an incision
- b. Time out is initiated by one team member but involves all team members
- c. When two or more procedures are performed on the same patient and the individual performing the procedure changes, a second time out is required
- d. During the time out, the team members agree on the following: Correct patient identity, correct site, and correct procedure
- e. The completion of the time out must be documented

1.4.10. PRE-PROCEDURE SEDATION ASSESSMENT FOR PATIENTS RECEIVING MODERATE OR DEEP SEDATION

Documentation of the pre-procedure assessment and sedation plan is the responsibility of the physician performing the procedure and must be completed prior to initiation of the surgery or procedure except in emergency situations. The assessment and documentation must be completed as outlined in the "Guidelines for Sedation Policy."

1.4.11. OPERATIVE / INVASIVE PROCEDURE NOTES AND REPORTS

An operative progress note is hand-written or computer generated and entered into the medical record by the attending physician or designee before the patient is transferred to the next level of care.

The operative progress note will contain the following elements:

- Patient name, medical record number and birth date
- Procedure date and time

- Name(s) of the primary surgeon(s) and assistant(s)
- Anesthesia type or sedation administered
- Procedures performed
- Pre-operative diagnosis
- Post-operative diagnosis
- Procedure description
- Estimated blood loss
- Specimens removed or altered
- Condition of patient prior to leaving the operating room or procedure area
- Unanticipated findings / occurrences

A full operative report must be completed within 24 hours of the surgical procedure. The full operative report shall include elements identified for the operative progress note and the following additional elements:

- Indications for procedure
- Technical details of the procedure
- Devices, grafts, tissues or transplants implanted (may be viewed on the nursing operative record as well)

These requirements apply to all major procedures in all units or settings including the operating room, cardiac catheterization laboratory, radiology department, short stay unit, endoscopy unit, and patient bedside. Dictated reports are available in the electronic medical record upon transcription as 'unverified'. All patient records must contain a signed operative report within seven (7) days after any operative procedure. If a physician will not be available due to a vacation / conference, etc., then a seven (7) day extension in signing the operative report will be granted beginning at the time of his / her return.

As defined in 1.5.4, if the operative note is completed by a resident, the supervising attending physician will authenticate and countersign the operative note.

1.4.12. ANESTHESIA NOTES

A pre-anesthetic evaluation should be completed by an anesthesiologist within 48 hours prior to a procedure requiring anesthesia, which includes documentation of relevant history and the patient's condition and that the anesthesia options and risks have been communicated.

1.4.13. PROGRESS NOTES

All individuals providing direct and indirect care to the patient are permitted to make entries in the progress notes, or other appropriate areas in the medical record. Such individuals could include, for example, consultants providing case management or training for medical equipment.

Frequency of Progress Notes

Progress notes, by the attending physician or his / her designate, should be documented daily to reflect any significant clinical observations, the response to treatment, and changes in the patient's clinical condition to enhance continuity of care and support the need for continued stay.

1.4.14. DISCHARGE SUMMARY AND FINAL DIAGNOSIS

A discharge summary and final diagnosis if known at the time of discharge must be documented in the medical record or dictated for all patients designated as inpatient (excluding discharge from the well-baby nursery) regardless of the length of stay. The discharge summary should include the reason for hospitalization, the significant findings, the procedures performed and treatment rendered, the patient's condition on discharge, and any specific instructions given to the patient and / or family including prescribed medications, diet and activity restrictions, and suggested follow-up care. A final progress note, labeled "Discharge Note" may be substituted for a discharge summary for those patients who have had a stay of forty-eight (48) hours or less. The discharge summary should be dictated within 24 hours of discharge. Dictated reports are available in the electronic medical record upon transcription as 'unverified'. All patient records must contain a signed discharge summary within seven (7) days after discharge. If a physician will not be available due to a vacation / conference, etc., then a seven (7) day extension in signing the discharge summary will be granted beginning at the time of his / her return.

As defined in 1.5.4, if the discharge summary is completed by a resident, the supervising attending physician will authenticate and countersign the discharge summary.

The discharge summary should be available at the time of discharge for all patients being sent to an extended care facility, and may be dictated 24 hours in advance of the planned discharge, with an addendum when appropriate. If it is not possible to complete the discharge summary at the time of discharge to an extended care facility, then a brief note must be written and include the reason for the patient's discharge or transfer, the patient's physical and psychosocial status, a summary of care, treatment, and services provided, and the patient's progress toward goals. A dictated Expiration Summary is required on all expirations regardless of length of stay.

1.4.15. DISCHARGE INSTRUCTIONS

Each patient must receive discharge instructions that at a minimum include medications, follow up, diet and activity.

1.4.16. DISCHARGE FORMS AND ORDERS / PHYSICIAN RESPONSIBILITIES

The attending physician's signature is required on transfer forms for all patients discharged to another health care facility.

The attending physician must review and sign all orders and authorizations for home health care, skilled nursing facility care and durable medical equipment.

1.4.17. SIGNATURE STAMPS NOT ACCEPTABLE

It is not acceptable to use a signature stamp to authenticate any part of a medical record. A signature stamp may be used as a clarification to the hand-written signature.

1.4.18. PHYSICIAN AUTHENTICATION

The attending physician, or other physician as appropriate (e.g., emergency physician, surgeon, or consultant) is required to review and authenticate by signing and dating all operative notes, consultation reports and the discharge summary.

1.4.19. RECORD COMPLETION PROCEDURE

As defined in 1.5.4, the supervising attending physician will authenticate and countersign at a minimum the history and physical examination, discharge summary, operative note, and consultations.

Each physician is responsible for monitoring their chart deficiencies electronically on the *oneChart* system. Chart deficiencies that cannot be addressed electronically must be reviewed and addressed in the Medical Information Services Department at least once every seven (7) days. At that visit he / she should complete all medical record deficiencies presented.

All physicians who will be absent from practice for five (5) or more days should notify the Medical Information Services Department, (248) 551-6500 for Royal Oak, (248) 964-8606 for Troy or (313) 343-1625 for Grosse Pointe, giving dates of departure and return. Physicians should remedy all chart deficiencies assigned to them before being absent from practice. Chart deficiency tracking will 'hold' if the physician has notified the Medical Information Services Department, but will resume upon the physician's return; i.e., chart deficiencies will not continue to age while the physician is absent.

It is the physician's responsibility to notify the Medical Information Services Department if a medical record has been incorrectly assigned to him / her.

It is the expectation that all medical record documentation, including the final diagnosis, handwritten and electronic signatures, is complete within seven (7) days following a patient's discharge or procedure. Records incomplete beyond fourteen (14) days represent a significant deviation from the standard.

If a physician will not be available within the specified time frame due to a vacation / conference, etc., then a seven (7) day extension in completing the medical record will be granted beginning at the time of his / her return.

A physician who has any record that is incomplete for more than fourteen (14) days may receive notification from the Physician-in-Chief or Department Chief that his / her record keeping is substantially out of compliance with the Medical Staff Rules / Regulations / Policies and that his / her admitting and / or consulting privileges will be restricted or suspended until completion of the medical record(s).

Repeated instances of substantial noncompliance with record keeping will be considered during the staff reappointment process and may trigger a recommendation for non-reappointment to the Medical Staff.

Incomplete Records / Physician Unavailable to Complete

If the attending physician or dentist cannot complete the record, the Department Chief, or his designee, may order the record to be filed and available for statistical billing purposes and continuity of patient care.

1.4.20. DIAGNOSIS AND PROCEDURE RECORD

The Hospital is responsible for reporting accurate information regarding diagnoses and procedures for the purposes of research, planning and billing, based upon documentation provided by the physician and in compliance with all federal regulations and applicable coding guidelines. Physician concurrence with diagnosis coding via review and signature is encouraged but not required. Physicians are encouraged to provide any clarifications or correction that would provide a more accurate picture of the episode of care.

1.4.21. CORRECTNESS OF THE MEDICAL RECORD

Electronic Portion

- Documentation that is “accepted” by the author is permanently recorded.
- A modification made after acceptance replaces the original documentation only in the current version. The audit trail will identify the original and any / all changed versions. The document will have a status of “corrected” or “supplemented”

Paper Portion

- Documentation can be corrected by drawing a line through the incorrect information making it still clearly readable and indicating the date and time of this change.
- The correct information can be added with the correction date and author’s signature.

1.4.22. RECORD AVAILABILITY (FILING / REMOVAL)

No medical record shall be tendered for filing or filed by the Medical Information Services Department until it is complete, with the exception of those filed by order of the Department Chief.

Removal of Medical Records from Patient Care Units

The medical record should be maintained on the unit with the patient so that it is available for review by consultants and for patient care emergencies. The medical record should accompany the patient when the patient receives services outside the unit.

Medical records should not be sent to ancillary service departments for pre-procedure review. All consultants should review the record on the patient care unit or in their Department when the patient arrives.

Removal of Medical Records From the Hospital

All records are the property of the Hospital and shall not be removed from the Hospital premises without authorization by the Hospital President or his designee, or in accordance with the provisions of a court order, subpoena or statute.

Readmission of Patient / Medical Record Availability

In case of re-admission of a patient, all previous records or microfilm condensation thereof, online data or printed copies of online data, shall be available for the use of the attending physician, dentist, or podiatrist.

1.4.23. DISTRIBUTION OF LABORATORY REPORTS AND TRANSCRIBED RECORDS

Staff members receive reports from the Hospital according to a "single distribution method" via FAX or other means. To change the distribution method, obtain a form from Royal Oak Medical Administration at 551-0411, Troy Medical Administration at 964-1000, or contact Medical Transcription Services at 248-423-2520.

1.4.24. TEACHING PHYSICIANS' DOCUMENTATION, CODING AND BILLING OF PROFESSIONAL SERVICES

A. The General Rule

If a resident participates in a service furnished in a teaching setting, a physician fee schedule payment is made to the teaching physician (TP) only if 1) the teaching physician personally performs the service; or 2) is present while the resident performs the critical or key portion of any service or procedure for which payment is sought; or 3) certain E/M services are furnished by residents under the primary care exception.

Key portions of E/M services must be performed or observed and documented by the teaching physician.

Must document, at a minimum, "**P D R A**"

- 1) **P**ersonal **P**resence / **P**erformance
- 2) **D**iscussion / Participation
- 3) **R**eviewed and
- 4) **A**greed or **A**mend

"I have interviewed and examined the patient, and I agree with (or performed) the history and physical findings as recorded by Dr. (Resident) in his / her note of (date) and plan of care except for"

B. Documentation

The "key elements" of history, examination, and medical decision-making are defined as those elements that, in the judgment of the teaching physician, best summarize: a) the relevant history, physical examination, and prior diagnostic tests; b) assessment, clinical impression, or diagnosis; and c) the plan for care.

For any E/M service the level selected is based on either the 1995 or 1997 "Documentation Guidelines for Evaluation and Management Services" developed by the AMA and CMS, whichever set of guidelines is most favorable to the physician. The 1995 and 1997 guidelines may not be mixed for any given date of service.

NOTE:

- The resident cannot document the presence of the teaching physician during the E/M service.
- When assigning codes to services billed by teaching physician, reviewers will combine the documentation of both the resident and the teaching physician.

C. Time Component

- In the case where counseling and / or coordination (c/c) of care dominates greater than 50% of the patient care unit / floor time, time can be considered the key factor.
- The time must be documented in the medical record to include the estimated cc and total length of patient care unit / floor time.
- Based on *face-to-face* interaction.
- Time the resident spends with the patient alone should not be considered, only the time the resident and physician spend together or the physician spends time *alone*.

D. Surgery, Minor Procedures, Scope Exams

1) Surgical Services - performed by or with a resident under the supervision of the teaching physician.

- a. Surgery or Endoscopies – Documentation must support that the teaching physician was present for the “key portions” and be immediately available for the non-key or critical portions (e.g. cannot be performing another procedure)
- b. Minor procedures that take only a few minutes (five minutes or less) to complete and involve relatively little decision making once the need for the operation is determined. The teaching physician must be present for the entire procedure in order to bill for the service.
- a. Two Overlapping Surgeries – Documentation must support that the teaching physician was present during the ‘critical or key portion’ of both operations.

2) Radiology and Diagnostic Tests

Payment for radiology and diagnostic tests is made *only* if the teaching physician:

- a. Personally performs the service, or
- b. Reviews the film and the resident’s interpretation with the resident.

‘Interpretation’ of Diagnostic Radiology and Other Diagnostic Tests:

- Teaching physician signature is the only signature CMS assumes he/she personally performed the interpretation.
- Resident prepares, signs the interpretation, the teaching physician must indicate he/she personally reviewed the image, the resident’s interpretation and either agrees or edits the findings. Medicare does not pay for an interpretation if the teaching physician *only* countersigns the resident’s interpretation.

E. Psychiatry

The teaching physician can fulfill the physical presence requirements by concurrent observation via a two-way mirror or video camera for the entire session, followed by immediate consultation with the resident. Review after the service is over is not sufficient for the teaching physician to submit a bill. The teaching physician must be “present” during the entire therapy session in order to bill.

1.5. MID-LEVEL PROVIDERS, RESIDENTS, FELLOWS AND MEDICAL STUDENTS

1.5.1. MID-LEVEL PROVIDER APPLICATION AND EVALUATION

The Board of Directors annually defines categories of health care practitioners that shall be eligible to participate in patient care at Beaumont Hospitals as employees of Beaumont medical staff members. The Medical Executive Board shall define limitations of patient care for each category.

Individual Mid-level Providers prior to rendering services in the Hospital, must complete an appropriate application documenting his / her educational background, training, and current health status, and must be qualified and receive approval by the appropriate Credentials Committee, and Medical Executive Board / written approval, in advance, from the

Department Chief and / or the designee of the Physician-in-Chief. An individualized job description including authorized services that may be rendered in the Hospital and within the limitations defined by the Medical Executive Board must have been approved in writing by the Department Chief and / or the designee of the Physician-in-Chief / by the Credentials Committee and Medical Executive Board.

All such Mid-level Providers shall be subject to all rules, regulations and policies of Beaumont Hospitals and shall be subject to disciplinary action including suspension at the discretion of the Department Chief / Section Head and Physician-in-Chief and shall acknowledge such in writing. Each physician extender must also sign an acknowledgment agreeing to abide by all Beaumont Hospital rules, regulations and policies and to provide documentation of compliance upon request. For purposes of identification, privately employed Mid-level Providers will document in the medical record the following information: "PE (name) rounding privately for Dr. (name)".

Performance evaluations on Mid-level Providers must be completed by the supervising physician and submitted to the Department Chief, and / or the designee of the Physician-in-Chief and the Director of Human Resources as appropriate. A personnel file for each physician extender shall be maintained in Medical Administration containing documentation of current licensure, the description of duties and performance evaluations. Appointment to the physician extender staff shall not exceed two (2) years, whereupon the appointment may be renewed or terminated.

Each physician extender must complete an appropriate reapplication documenting his / her educational background, training and current health.

1.5.2. MID-LEVEL PROVIDER SUPERVISION

Mid-level Providers may provide medical care services within their area of competence providing they do so under the supervision of a member of the Medical Staff who shall at all times maintain responsibility for patient care. All Mid-level Providers shall:

- a. Be licensed by and in good standing with the State.
- b. Have their credentials and qualifications approved by the Board of Directors upon the recommendation of the appropriate Credentials and Qualifications Committee and Medical Executive Board.
- c. Be assigned to an appropriate Department or Section.
- d. Carry out their clinical activities subject to the policies and procedures of the entity referred to in (c), and subject to the administrative policies then in effect of Medical Administration.
- e. Provide patient care services under the direction and supervision of a Medical Staff member, within the scope and limitations of their job description / approved procedures.
- f. Be subject to focused and ongoing professional practice evaluation as described in the Medical Staff Peer Review Policy.
- g. Receive performance evaluations from their hospital supervisor or supervising physician, reviewed by the Department Chief.
- h. Not be considered members of the Medical Staff for any purpose.

1.5.3. RESIDENT AND FELLOW JOB DESCRIPTION

Residents / fellows are selected, appointed, evaluated and provided graduated responsibility under supervision in accordance with the William Beaumont Hospital Institutional Review Document as approved by the Accreditation Council on Graduate Medical Education (ACGME).

Residents / fellows must agree to and sign the terms of the Contract for Residency / Fellowship Training prior to beginning their employment. This contract spells out, in summary form, the duties and responsibilities of the Resident or Fellow.

Department Chief / Program Director shall assign residents / fellows to specific duties and arrange proper supervision of residents / fellows. Both the Graduate Medical Education Department and the individual Residency & Fellowship programs shall maintain written policies and guidelines of the roles, responsibilities, and patient care activities of residents / fellows, including required supervision. These written policies and guidelines shall define the mechanisms by which the Program Director and supervising physicians determine appropriate levels of progressive responsibilities in patient care for each resident / fellow.

Residents / fellows shall be supervised by members of the medical staff in accordance with the Rules / Regulations / Policies defined herein.

1.5.4. RESIDENT AND FELLOW SUPERVISION

- a. All patient care provided by residents / fellows must be supervised by members of the Medical Staff with appropriate clinical privileges.
- b. Residents / fellows shall promptly see all newly admitted patients assigned to them and complete the required medical evaluation. Residents / fellows will notify the attending physician that the patient has been admitted and discuss the initial management of the case with him / her.
- c. Residents / fellows should report to the attending physician all complications and should promptly report to the attending physician any significant change in a patient's condition.
- d. The order documenting a decision for withholding CPR may be in writing, or entered electronically, and may be a telephone order from an attending physician to another physician / mid-level provider or to a registered nurse (the latter must be witnessed by another registered nurse on the telephone and documented as such). All No CPR orders will be on form #4562 "Orders for CPR Status." The order may be reviewed by the patient / surrogate for accuracy with the physician / mid-level provider.

In this case, the order must be countersigned by the attending physician and a progress note describing the basis for the order must be written by the ordering physician / mid-level provider. The progress note should address any discussion with the patient and / or the patient's surrogate, which indicates knowledge of the patient's wishes including consideration of any written Advance Directives known to the physician / mid-level provider.

- e. When a patient dies, the resident / fellow shall immediately notify the attending physician and shall discuss with him / her the question of obtaining an autopsy, anatomic gift and notification of the family. Additionally, the resident / fellow should contact the bereavement representative to assist with issues surrounding the patient's death.
- f. The supervising attending physician will authenticate and countersign, at a minimum, the history and physical examination, discharge summary, operative note, and consultations.

1.5.5. MEDICAL STUDENT SUPERVISION

- a. Roles and responsibilities of medical students shall be defined by their medical school and the responsible Department Chief and Program Director.
- b. All patient care provided by medical students must be supervised by residents, fellows and / or members of the Medical Staff with appropriate clinical privileges. Medical student documentation may not be used for professional billing by the Teaching Physician.

SECTION II: PATIENT SAFETY AND QUALITY IMPROVEMENT

2.1. PEER REVIEW

The Medical Staff is responsible for monitoring, evaluation and improvement of the quality and appropriateness of patient care. It carries out these responsibilities under the authority of the Beaumont Hospital Corporate Performance Improvement and Patient Safety Plan. This Plan and relevant Patient Safety policies may be found in the Management Manual or on the Inside Beaumont website and include the following:

- Policy 218 Patient Safety and Quality Improvement (Variance) Reports
- Policy 219 Sentinel Events (found in the General Management Manual)
- Policy 269 Employees Involved in Clinical Errors (found in Human Resources – Corporate Manual)
- Policy 304: Informed Consent (found in the Patient Care – Corporate Manual)
- Policy 312: Chain of Command (found in the Patient Care – Corporate Manual)
- Policy 319: Disclosure of Unanticipated Outcomes (found in the Patient Care – Corporate Manual)

These policies should be consulted whenever related patient care issues arise. In addition, all members of the Medical Staff must fully comply with the intent of the National Patient Safety Goals (NPSGs) that are established annually by the Joint Commission. NPSGs are accessible via the Inside Beaumont website.

These policies and procedures shall apply to all practitioners credentialed by Beaumont Hospitals including, but not limited to MDs, DOs, Oral Surgeons, Dentists, DPMs, psychologists, physician assistants and advanced practice nurses (CNM, CRNA, NP).

Peer review information, including data relating to the physical or psychological condition of a person, the necessity, appropriateness, or quality of health care rendered to a person, the qualifications, competence or performance of a health care provider at the Hospital, or prevention of complications or deaths, shall be utilized by Medical Staff Officers, Medical Staff Administrators, Medical Staff committees, the Board of Directors and its committees and designated employees in discharging their responsibilities. Peer review activities shall strive for consistent, timely conclusions, adhering to relevant Medical Staff definitions, procedures and guidelines, as well as expert peer review literature. The process will integrate assessment of core competencies as well as human factors into the assessment and feedback following accepted practice guidelines. The peer review process shall assure balanced consideration of minority opinions and views.

Sources and Type of Peer Review Information and Measures

Peer review information may be acquired through appropriate data and information including, without limitation, periodic chart review, direct observation, monitoring of diagnostic and treatment patterns, simulation, proctoring, discussion with other individuals involved in the care of each patient and other means determined to be relevant by the individual or entity conducting such review. The information is gathered in processes approved by individual departments and the Medical Staff or provide for in the Medical Staff Bylaws. Such information is integrated into ongoing performance improvement activities to evaluate practitioners and to factor into decisions regarding the maintenance, revision or revocation of privileges as set forth in the Medical Staff Bylaws. At a minimum the elements of ongoing peer review will include:

- a. Systematic information collection regarding core competencies of all members of the Medical Staff and those granted privileges at the Hospitals:

- b. Outcome measures for selected procedures identified by Department Chiefs, Section Heads, peer review committees and Medical Administration;
- c. Core measures; and
- d. National patient safety goals.

2.1.1. ONGOING PROFESSIONAL PRACTICE EVALUATION (OPPE)

The Hospital Medical Staffs will conduct ongoing evaluation of each practitioner's professional performance. This process is directed to identify and resolve any potential or ongoing problems with a practitioner's performance or trends that might impact the quality of care or patient safety issues in our institutions in a timely fashion. The OPPE also fosters an efficient, evidence-based privilege renewal process. The information gathered from the ongoing professional practice evaluation will be used to determine whether any existing privilege(s) should be continued, limited or even revoked.

1. The respective Department Chief / Section Head will be responsible for coordinating the Ongoing Professional Practice Evaluation (OPPE) review for members of their Department / Section. The OPPE will be performed on all active staff practitioners at least every 11 months.
2. The type and extent of information to be gathered and the process for each department's OPPE must be approved by the Medical Executive Board. (see below).
3. At each interval review, every practitioner will be evaluated by the Department Chief / representative. This review will be factored into the decision to maintain existing staff appointment and privileges as well as to revise or revoke existing privileges prior to or at the time of reappointment. The fact that a practitioner may not be identified on screening criteria (zero data is still data) this may be evidence of good performance (i.e. no returns to the OR, no complaints, etc.) These can be further reviewed as to why there is no data at the time of reappointments.
4. Data reports and information that are included in the OPPE include, as applicable: Physician Dashboard UHC / Maxsys / Press Ganey Reports – These reports may include inpatient and outpatient data for both the individual physician and comparison with the aggregate data of the physicians in that specialty:
 - a. Admission Activity and Length of Stay Data (actual and expected)
 - b. Mortality Data (actual and expected)
 - c. Readmission within 30 days
 - d. Patient Safety Indicators
 - e. CME
 - f. Patient Satisfaction
 - g. Staff Meeting Attendance
 - h. Use of Consultants
 - i. Use of Resources
 - j. Medical Record Delinquencies
 - k. Professionalism
 - l. Procedures by ICD9
 - m. Other Department-specific data that the Department Chief deems appropriate

5. The Department Chief or Representative will document pertinent findings and recommendations on the review form to include:
 - a. Confirmation that the practitioner has been reviewed and there are no potential problems with performance or trends that would impact the quality of care and patient safety. The individual practitioner will then be reviewed again at their next scheduled OPPE.
 - b. Request for a focused professional practice evaluation (FPPE) for an individual practitioner based on an identified issue. Information gathered for review may include, but not be limited to:
 - Drill down reports
 - Additional performance of a specific procedure
 - Additional Monthly Review
 - Direct Observation
 - Concurrent Monitoring
 - Retrospective Chart Review
 - Discussion with other individuals involved in the care of the practitioner's patients including consulting physicians, assistants at surgery, nursing and administrative personnel
 - c. This review process will continue until the Department Chief or Representative is either:
 - Satisfied with the information received and reviewed, or
 - Recommendations are made to the Credentials Committee or Physician Well Being Committee, as applicable, for review and recommendation to the Medical Executive Board for action including, but not limited to the initiation of the Collegial Investigation per the Medical Staff Bylaws Credentials Policy Manual.
 - d. Request for immediate action according to the Medical Staff Bylaws can be taken at any time during the OPPE process, which may include, but not limited to, forwarding concerns to the following committees:
 - Credentials Committee for review
 - Medical Executive Board
6. The information gained by the review of the above information will be filed in the credentials file and incorporated into the two-year reappointment process. Single incidents or trending of quality and safety issues that impact the safety of patients will require immediate action by the Medical Staff.
7. "Trigger" -There may be circumstances where a single incident or evidence of a clinical practice trend may be identified through the OPPE process. If so, this will trigger a Focused Professional Practice Evaluation, which will be conducted according to Medical Staff Policy.
8. If behavior is identified as a possible issue, the Medical Staff Code of Conduct Policy will be followed as a component of the OPPE.
9. Relevant information obtained from the OPPE will be forwarded for inclusion into the performance improvement activities maintaining confidentiality.

The goal of the OPPE / FPPE initiative is to evaluate physicians' performance and effective and cohesive practice patterns. The economy, society's demand for change and health

care reform will continue to drive physicians and organizations to meet these heightened expectations.

2.1.2. FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE)

Focused professional practice evaluation is a process to evaluate the current competency of a practitioner's performance of his / her privileges at Beaumont Hospitals. A time-limited evaluation will be completed in the following circumstances:

1. All newly appointed practitioners
2. All new privileges for existing practitioners
3. All practitioners returning from a leave of absence of one year or longer.
4. When there are concerns regarding the provision of safe or high quality care by a current Medical Staff member (i.e., initiated by a sentinel or high-priority event or any patient care matter referred for review by a Department Chief, or Medical Leader).
5. When an OPPE result suggests a concern with a provider's competence.
6. Physicians with low or no current documented performance at Beaumont Hospitals.

FPPE for New Applicants / New Privileges (1-3)

- FPPE will begin with initiation of clinical activity or performance of the newly approved privilege(s) and must be completed within the first six months. If FPPE cannot be completed due to inadequate case volume, it may be extended until volume is sufficient, but may not exceed 12 months.
- Evaluation by the Department Chief / Section Head or Designee will be accomplished by one or more of the following sources / methods: Personal interaction with practitioner; direct observation of procedure being performed; discussion(s) with other individuals observing / interacting with practitioner; retrospective chart evaluation; performance monitoring findings; review of OPPE or other statistical reports; proctoring; simulation; other.
- Evaluation results and recommendations will be communicated to the appropriate parties.

FPPE When Potential Concerns are Identified (4-6)

- The need to conduct FPPE for potential concerns will be conveyed to the involved practitioner(s) by the appropriate Department Chief.
- Reviews will be conducted in house through the peer review mechanism unless it is determined that an external evaluation is required.
- At completion of the review, a determination will be made concerning continuation of privileges, additional ongoing review or request for corrective action. The recommendation will be made to the Medical Executive Board. If a serious threat to patient welfare is discovered, the corrective action process should be immediately initiated.

2.1.3. PEER REVIEW CONFIDENTIALITY

All peer review information is privileged and confidential in accordance with Medical Staff, Hospital Bylaws and State and Federal laws. Medical Administration will keep practitioner-specific peer review and other quality information concerning a practitioner in secured files. Practitioner-specific peer review information includes the following information:

- Quality and utilization review data;
- Peer reviewed content of Sentinel and High-Priority events requiring Root Cause Analysis
- Materials relating to applications for Medical Staff Membership and reappointment and privileges
- Materials regarding Focused and Ongoing Professional Practice Evaluation
- Correspondence regarding practice performance or corrective action

Peer review information is available only to authorized individuals who have a legitimate need to know this information. Access will be granted only when required to carry out assigned peer review responsibilities. The following individuals have a legitimate need to know this information:

- Corporate and Division Medical Staff Officers and Medical Administration:
- Medical Staff Department Chiefs, and Section Heads (for members of their Department / Sections only)
- Members of the Medical Executive Boards and Credentials and Qualifications Committee:
- Appointed or delegated Corporate and Divisional quality improvement or patient safety committee members and similarly engaged staff members and employees
- Participants in investigations, hearings and appeals under the Medical Staff Bylaws.
- Medical Staff Services professionals to the extent necessary to perform official functions (maintain file, monitor access, etc.);
- Individuals surveying for accrediting bodies with appropriate jurisdiction, e.g., Joint Commission and NCQA;
- Individuals with a legitimate purpose for access as determined by the Hospital legal counsel and / or Board of Directors.

No copies of peer review documents will be created and distributed unless authorized by legal counsel or policy.

Reviewee Rights

The individual under review must be provided the opportunity to respond in writing within a reasonable period of time, to a letter of inquiry from a peer review committee.

Departmental Peer Review

Departmental Peer Review Committees may be established to conduct ongoing peer review. If specific circumstances warrant the establishment of additional peer review panels, then the Department Chief in conjunction with Medical Administration may appoint an appropriate review committee.

2.1.4. EXTERNAL PEER REVIEW

External peer review may take place under the following circumstances if deemed appropriate by Medical Administration on recommendation from a Department Chief or Section Head. No practitioner can require the Hospital to obtain external peer review. Circumstances in which Medical Administration may ask for external review include, but are not limited to the following:

- Litigation – when dealing with a potential or actual lawsuit.
- Ambiguity – when dealing with ambiguous or conflicting recommendations from internal reviewers or Medical Staff committees and conclusions from this review will directly impact a practitioner's membership or privileges.
- Lack of internal expertise – When no one on the Medical Staff has adequate expertise in the specialty under review; or when the only practitioners on the Medical Staff with the expertise have a potential or actual conflict of interest that cannot be appropriately resolved by the Medical Executive Board or Governing Board.
- New technology – when a Medical Staff member requests permission to use new technology or perform a procedure new to the Hospital and the Medical Staff does not have the necessary subject matter expertise to evaluate adequately the quality of care implications.
- Miscellaneous issues – when the Medical Staff needs an expert witness for a fair hearing, for evaluation of a credential file, or for assistance in developing a benchmark for quality monitoring.
- In addition, the Medical Executive Board or Governing Board may require external peer review in any circumstances deemed appropriate by either of these bodies.

2.1.5. TIMELINESS OF REVIEWS

Peer review activities addressed in the Medical Staff Bylaws should be conducted and results reported as set forth therein.

Sentinel Events Reviews should be conducted in compliance with Joint Commission timeliness, including a review within forty-five (45) day of the time the panel or committee becomes aware of an issue.

Other reviews, such as High Priority, Focused Professional Practice Evaluation, and other reviews should be conducted under time guidelines set forth by the individual Hospital or Division and may be expedited if Medical Administration or a peer review committee determines that individual circumstances warrant.

2.2. SENTINEL EVENTS

2.2.1. SENTINEL EVENT DEFINITION

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

Certain types of sentinel events are subject to review by the Joint Commission. These include the following:

- Any patient death, paralysis, coma or other major permanent loss of function associated with a medication error.
- Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge.
- Any elopement that is an unauthorized departure of a patient from an around-the-clock care setting resulting in a temporally related death (suicide, accidental death, or homicide) or major permanent loss of function.

- Abduction of any patient receiving care, treatment, and services.
- Death of a full-term infant (unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams).
- Any intrapartum (related to the birth process) maternal death.
- Discharge of an infant to the wrong family.
- Surgery on the wrong patient or wrong body part.
- Assault, homicide, or other crime resulting in patient death or major permanent loss of function.
- Rape
- A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall.
- Unintended retention of a foreign object in a patient after surgery or other procedure.
- Severe neonatal hyperbilirubinemia (bilirubin greater than 30 milligrams / deciliter).
- Prolonged fluoroscopy with cumulative dose greater than 1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or greater than 25% above the planned radiotherapy dose.
- Any other events that may be deemed reviewable by the Joint Commission in the future.

2.2.2. ROOT CAUSE ANALYSIS

Root cause analysis is a process for identifying the basic or causal factors that underlies variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist.

2.2.3. REPORTING

If an attending physician becomes aware of a possible sentinel event, he / she should promptly notify the quality management staff and / or Department of Legal Affairs.

2.2.4. DISCLOSURE

In the event of an unanticipated outcome the patient and / or family should be informed as soon as possible. During this discussion, the attending physician and, when appropriate, other members of the healthcare team should provide: (1) a factual explanation of what occurred, (2) the follow-up plan of care for the patient, (3) an organizational apology if the unanticipated outcome is the result of a clinical error, and (4) assurance that the case will be appropriately reviewed to assure that measures will be taken to avoid future occurrences.

2.3. TRANSFUSION GUIDELINES

Transfusion of Blood Components / Practice Guidelines

As part of its quality improvement program, Beaumont reviews transfusions of blood components. The following practice guidelines are used for initial screening of the medical record:

Red Blood Cells

1. Chronic Anemia: Unless diagnosis is iron deficiency anemia, pernicious anemia, nutritional anemia, or normovolemic anemia following blood loss.
 - a. Adult: Hemoglobin less than 8g / dl or hematocrit less than 24
Exception: Hemoglobin less than 10g / dl or hematocrit less than 30 when general anesthesia is to be given.
 - b. Children: Same as adults.
 - c. Newborn: Hematocrit (HCT) less than 40% in infants with significant respiratory distress. HCT less than 24% in anemia of prematurity.
2. Blood Loss: Hypovolemia secondary to surgery, trauma or internal bleeding
 - a. Adult: Evidence of acute blood loss of over 15% blood volume or greater than 750ml.
 - b. Children: 13 or younger, loss of more than 10% blood volume
(lbs)(3.18) = 10% of blood volume OR (kg)(7) = 10% of blood volume
 - c. Newborn: Loss of more than 10% total blood volume
(kg)(9) = 10% of blood volume in full term infant
(kg)(11) = 10% of blood volume in premature infant
3. Outcome: A patient who receives a transfusion with RBCs must have a hemoglobin value or hematocrit in his chart within 24 hours of the end of the transfusion episode. For patients undergoing an elective surgical procedure, the postoperative value must not be greater than the preoperative value.
4. Autologous Blood: Transfusion of autologous blood will be monitored using the same criteria.

Fresh Frozen Plasma

1. History of clinical course suggestive of a coagulopathy due to deficiency(s) of coagulation factors, with bleeding and documented by one of the following:
 - a. Prothrombin Time greater than 18 seconds
OR
 - b. Activated Partial Thromboplastin Time greater than 55 seconds
OR
 - c. Coagulation Factor Assay less than 25%
 1. Hypofibrinogenemia less than 100 mg/%

2. Massive Blood Transfusion
 - a. Loss of over 1 blood volume (5000 ml. in adult) within several hours with evidence of coagulation factor deficiency (PT greater than 18) with bleeding.
 - b. Prophylactic use to prevent or stop bleeding without clotting factor tests, **MUST BE REVIEWED BY THE COMMITTEE.**
3. Reversal of Coumadin Effect (if immediate hemostasis is required to stop bleeding or for emergency surgery or procedure)
4. Documented Congenital Deficiencies of isolated clotting factors used prophylactically for a procedure or surgery and therapeutically for bleeding.
 - a. Von Willebrand's Disease
 - b. Isolated deficiencies of Factors II, V, VII, IX, X, or XI
5. Congenital Deficiency of AT-III
6. Immunodeficiency Syndromes documented by history and evidence of decreased serum immunoglobulin levels in the chart
 - a. Treatment of immunodeficiencies when purified IgG (IM or IV) cannot be used
OR
 - b. When IgA or IgM are needed
7. Use in plasma exchange for thrombotic thrombocytopenic purpura

Practice guidelines for use of other blood components may be obtained from the Chairman of the Blood Transfusion Committee.

SECTION III TREATMENT DECISIONS

The Board of Directors and the Medical Staff of Beaumont Hospitals are dedicated to preserving life and rendering treatment in accordance with the proper medical standard of care and recognized principles of medical ethics. The Hospital respects the legal and moral prerogatives of all patients in arriving at decisions involving medical care and treatment recommended by their physicians. The Hospital and its Medical Staff will consider written expressions of these decisions such as living wills and durable powers of attorney for health care, but such documents are not required for application of the following policies. The Hospital also respects the legal and moral prerogatives of individual physicians and health care workers to practice the art of medicine in a manner consistent with their personal religious, ethical, or moral beliefs.

To ensure that medical care is rendered consistent with the rights and philosophy of the Hospital, the physicians and the patients, the Hospital has developed guidelines.

- Advance Directives (See Full Corporate Policy #305)
- CPR Status Policy (Corporate Policy #457)
- Ethical Issues
- Informed Consent Policy (Corporate Policy #304)
- Medical Marihuana (See Full Corporate Policy #210)
- Medically Non Beneficial or Potentially Harmful Interventions (Corporate Policy 318)
- Organ Donation Following Cardiac Death (DCD) (Corporate Policy #310)
- Patient Rights and Responsibilities (Corporate Policy #313)
- Refusal of Care on the Grounds of Personal Belief (See Full Corporate Policy #306)
- Terminal Illness
- Withdrawing or Withholding Life Sustaining Treatment (Corporate Policy #307)

The physician is directed to consult with Medical Administration and the Department of Legal Affairs in circumstances where the physician questions whether the situation is expressly covered by these guidelines or perceives a potential conflict within or among these guidelines.

3.1. ADVANCE DIRECTIVES (SEE FULL CORPORATE POLICY #305)

A patient has the right to make decisions regarding medical and mental health treatment. This includes the right to accept or refuse care and the right to formulate Advance Directives. Beaumont Hospital will not discriminate against any patient based upon the patient's decision to execute or refrain from executing an Advance Directive.

Definition

An **Advance Directive** is a written document in which a competent adult patient specifies what medical care or mental health treatment the patient would want to have or forego should he/she lose the ability to make treatment decisions. There are two types of Advance Directives: Durable Power of Attorney for Health Care and Living Will.

Description

A Durable Power of Attorney for Health Care is a form of Advance directive by which a patient gives another person the power to make medical treatment, mental health treatment and personal care decisions. It may also authorize that person to make an anatomical gift of all or part of the patient's body. In addition to designating someone to make these

decisions, the patient may include a statement of his / her wishes regarding care, treatment and anatomical gifts. It must be part of the patient's medical record before it is implemented. The designated person is called the "Patient Advocate." The Patient Advocate:

- May make healthcare decisions for the patient only when the patient is unable to participate in treatment decisions. The determination that a patient is unable to participate in treatment decisions must be documented by two (2) physicians or one (1) physician and a licensed psychologist.
- May make mental health treatment decisions for the patient only when the patient is unable to give informed consent to mental health treatment. The determination that a patient is unable to give informed consent for mental health treatment must be documented by two (2) physicians one of whom is a licensed psychiatrist.
- Cannot make decisions to withhold or withdraw life-sustaining treatment unless the Durable Power of Attorney for Health Care contains a clear and convincing statement authorizing the Patient Advocate to make such decisions and acknowledging the patient's understanding that such a decision could or would result in the patient's death.
- Cannot consent to the forced administration of medication in connection with mental health treatment unless the Durable Power of Attorney for Health Care contains a clear and convincing statement authorizing the Patient Advocate to make such a decision.
- May consent to an anatomical gift of all or part of the deceased patient's body provided all of the following conditions are met:
 1. The patient's Durable Power of Attorney for Health Care authorizes the Patient Advocate to make an anatomical gift;
 2. The patient has been declared dead by a licensed physician or determined to be unable to participate in medical treatment decision by two (2) physicians or one (1) physician and a licensed psychologist;
 3. The patient advocate's consent to the anatomical gift is obtained upon or immediately before the patient's death.
- May not consent to an anatomical gift of all or part of the deceased patient's body if any of the following apply:
 1. The deceased patient had made an anatomical gift by will, donor card or other properly executed document of gift;
 2. The deceased patient had expressed an unwillingness to make an anatomical gift;
 3. The deceased patient had revoked his / her Durable Power of Attorney for Health Care;
 4. The anatomical gift of all or part of a body is contrary to the religious beliefs of the deceased patient.

A Living Will is a form of Advance Directive by which the patient informs the health care team and family members what types of medical care and treatment the patient wishes to receive or not receive should he/she become terminally ill or permanently unconscious and unable to make or communicate decisions. Living Wills are not authorized by statute in Michigan; however, they do provide doctors and hospitals with evidence of the patient's wishes. A Living Will should be respected.

Informing Patient of Decision-Making Rights and Options - Self-Determination Act

Federal law requires the Hospital to inform all adult inpatients at the time of admission about their rights under State law to have an Advance Directive and the Hospital's policy concerning the implementation of Advance Directives.

Patient Registration or other specified personnel are responsible for providing this information to the patient. As part of the initial admitting process, the following will be distributed:

- Written description of a patient's rights under State law to make decisions regarding medical care, including the right to accept and refuse treatment and the right to formulate an Advance Directive.
- Written information describing Beaumont Hospital's policies governing implementation of such rights.

This information is contained in the patient publications, entitled "My Instructions to Health Care Providers (Troy) or Advance Directives: A Patient's Right (Royal Oak).

At the time of the adult inpatient's admission, the Patient Registration personnel will ask if the patient has an Advance Directive; (i.e., Durable Power of Attorney for Health Care or Living Will). If the patient provides the Hospital with a copy of his / her Advance Directive, it will be placed in the patient's medical record and documented on the electronic record. If the patient has an Advance Directive but has not provided the Hospital with a copy, the patient or the patient's surrogate will be asked to do so. If a patient asks for additional information from a health care worker, a referral will be made Social Work (Royal Oak) or Pastoral Care or Patient Representative (when Pastoral Care is unavailable) (Troy). If the patient has no Advance Directive, does not wish to make one and specifically requests that no further information be provided, then the matter will not be pursued.

On subsequent admissions, any patient with an Advance Directive in his / her medical record will be asked whether they have updated or revoked the existing Advance Directive. If the Advance Directive has been revoked or updated, the new document will be placed in the patient's medical record and documented on the electronic record.

Executing Advance Directive After Admission

Beaumont Hospitals provides a general form for Durable Power of Attorney for Health Care. A sample form is provided with the patient publications.

Michigan Law requires that the Durable Power of Attorney for Health Care be:

- Dated and signed by the patient in the presence of two witnesses; and
- Signed by two (2) witnesses. (Witnesses must be at least 18 years of age and competent.)

Witnesses CANNOT be:

- Beaumont Hospital employee or volunteer;
- Physician;
- Patient Advocate;
- Spouse, parent, child, grandchild, brother, sister of the patient;
- Beneficiary of the patient's will or presumptive heir;
- Employee of a life or health insurance provider or other health care facility that is treating the patient.

Patient Advocate Acceptance Form

Before allowing the Patient Advocate to participate in the decision-making process for a patient, the Patient Advocate Acceptance Form must be signed by the Patient Advocate and placed into the medical record. The sample form in the patient handbook contains the Patient Advocate Acceptance Form.

Revocation

A patient may revoke his / her Advance Directive at any time by any manner that communicates the patient's intent to revoke, even if the patient is deemed incompetent.

A patient may waive the right to revoke a patient advocate's authority to make mental health treatment decisions by specifically including the waiver in his / her Durable Power of Attorney for Health Care.

If the patient's revocation is not in writing, the health care worker who witnesses the revocation shall notify the physician and administrative supervisor / manager designee. The patient's revocation shall be documented in the medical record. The administrative supervisor / manager / designee will notify the Patient Advocate of the revocation and Legal Affairs as necessary.

Implementation of Advance Directives

Implementation of a patient's treatment wish, as expressed in the patient's Advance Directive, must be by a specific physician's order.

If the physician's beliefs or values are such that he / she cannot implement the patient's Advance Directive, the physician must so inform the patient, Patient Advocate or appropriate surrogate. Consideration should be given to requesting a clinical ethics consultation. If the issue cannot be resolved, the physician should make arrangements to transfer care of the patient to another physician within the Hospital or to another health care facility willing to honor the patient's treatment decision.

The Department of Legal Affairs shall be contacted if any question or conflict arises regarding the interpretation or implementation or revocation of an Advance Directive.

3.2. CPR STATUS POLICY (CORPORATE POLICY #457)

The purpose of the policy is to assist in the implementation of decisions regarding resuscitation. Only two orders choices are permitted regarding cardiopulmonary resuscitation (CPR).

General Information:

1. Cardiopulmonary resuscitation (CPR) is a standard component of emergency medical care. Because its effectiveness depends upon prompt initiation, attempts at resuscitation are made for all patients in the event of cardiopulmonary arrest unless there exists a specific order to the contrary.
2. Physicians should clarify with the patient in advance whether attempts at resuscitation are desired. A copy of an Advance Directive (see policy #305 "Advance Directive" Patient Care Corporate Policies) is placed in a folder in the medical record. It is the physician's responsibility to review such a directive or discuss the patient's choice before entering orders for changing the CPR status.

3. Only two orders are permitted for patients found in cardiopulmonary arrest:
 - a. Full CPR: a full attempt at resuscitation in accordance with ACLS guidelines, or
 - b. No CPR: no intervention will be attempted.
4. Definitions:
 - a. Full CPR: The CPR team will be called for a patient found in cardiopulmonary arrest, or its equivalent, unless a No CPR order is written. The CPR team will conform to ACLS / PALS guidelines.
 - b. No CPR: In the event of a cardiopulmonary arrest (complete cessation of heartbeat, pulse, blood pressure and respirations), no chest compressions or any other interventions will be initiated and the CPR team will not be called.
 - A No CPR order is a specific directive and does not apply to other active treatment orders which may be appropriately ordered for the care of the patient, for circumstances other than cardiopulmonary arrest.
 - Restrictions in Non-Arrest situations for patients with a No CPR order: If the patient wishes to have other therapies or active treatments withheld during the course of hospitalization, orders must be appropriately entered. A patient that wishes restrictions on active treatments during hospitalization such as intubation, vasopressors, antiarrhythmic, cardioversion cannot be a full CPR status.
 - 1) No CPR orders must be entered into the electronic medical record accordingly with the following:
 - In a non-arrest state, permit intubation (yes / no)
 - In a non-arrest state, permit vaso-active medications (yes / no)
 - In a non-arrest state, permit antiarrhythmics (yes / no)
 - In a non-arrest state, permit cardioversion (yes / no)
5. No CPR Orders during Operative and / or Other Invasive Procedures

All orders for Withholding or Withdrawing Treatment including CPR are to be reviewed before a patient undergoes a surgical or invasive procedure. The patient, proceduralist (surgeon, angiographer, radiologist, endoscopist, etc.) and anesthesiologist must discuss and document goals of treatment and determine whether any orders to withhold treatment should be suspended or not during the surgical or invasive procedure. The CPR status during a procedure is documented on the "Peri-Procedure CPR Status Patient's consent and Physician's Order" (Form #232).

Post-operatively, upon return to the nursing unit, the previous No CPR order will resume, unless there is an order by the physician / mid-level provider to change the status to Full CPR.
6. Incompetent Patient: If the patient is incapable of rendering a decision, the patient's surrogate (that is a court appointed guardian, advocate appointed under a medical durable power of attorney, or next of kin in order of priority) and physician may consider a course of events based on any advanced directive prepared when the patient was competent including a living will, durable power of attorney for health care, or other reliable instructions written or verbal.
 - a. Legal consultation is advisable if the patient has never been competent (with or without a guardian).
 - b. Ethics consultations is advisable, if the incompetent patient does not have a valid advance directive, and the health care team, including the patient's surrogate does not agree on the plan (Full CPR / No CPR), Or, if there is a disagreement among family members. (See Patient Care Corporate policy "Clinical Ethics").

7. Order Processing

- a. The discussion with the patient / surrogate regarding a decision to withhold CPR may be with the attending physician, another physician or mid-level provider. If the attending physician was not present, the physician or mid-level provider must contact the attending physician and obtain concurrence with the decision regarding the CPR status prior to writing the CPR order status, this must be documented in the progress notes.
 - b. The order documenting a decision for withholding CPR are to be entered electronically and may be a telephone order from an attending physician to another physician / mid-level provider or to a registered nurse (the latter must be witnessed by another RN on the phone and documented as such). The order may be reviewed by the patient / surrogate for accuracy with the physician / mid-level provider.
 - c. An order that states one or more of the following: No Intubation, No Vasopressors, No anti-arrhythmics, No cardioversion, requires that the patient be a NO CPR.
 - d. The order must be countersigned by the attending physician and a Progress Note describing the basis for the order must be entered by the ordering physician / mid-level provider. The progress note should address any discussion with the patient and / or the patient's surrogate, which indicates knowledge of the patient's wishes including consideration of any written Advance Directives known to the physician / mid-level provider.
8. Following the order of "NO CPR", or change in status, the physician should verbally notify the nurse assigned to the patient of the new CPR status.
- a. RNs may clarify CPR orders by calling the attending or designee to verify the treatment measures. The RN may take telephone orders (without a witness) on intubation, vasoactive, anti-arrhythmics, and cardioversion as long as the initial "NO CPR" order has been ordered by the physician.
9. Duration of "NO CPR" order.
- a. The order is valid only for the current hospitalization. The order must be entered directly on subsequent admissions.
 - b. Upon patient transfer into or out of a Critical Care Unit, CPR orders must be addressed via the order reconciliation process.
10. Any patient intubated as the result of cardiopulmonary arrest, must be transferred to an Intensive Care Unit area prior to any attempt at extubation. The only exception to this would be if during the code it is determined by way of a valid (written and patient signed) advance directive that the patient did not want CPR or the patient's status is changed to 'No CPR' by an attending physician and the family requests extubation of the patient (see also, policy #307 – Withholding / Withdrawing life Sustaining Treatment)
11. If members of the health care team, including patient, family or other surrogate do not agree with the plan regarding CPR status, a Clinical Ethics Consult is advisable.

3.3. ETHICAL ISSUES

The Hospital encourages the patient's participation in the consideration of ethical issues that arise in the provision of his or her care. The patient is advised upon admission through the Patient Handbook, that should there be a need to discuss an ethical issue, the patient should notify the attending physician. In some instances an ethical issue may be addressed at a departmental or multi-disciplinary conference. The attending physician will document the resolution of the issue in the patient's medical record. The Corporate Office of Clinical Bioethics at Royal Oak (248-551-4747) or Medical Administration at Troy (248-

964-1000) and Grosse Pointe (313-343-1962) may also be contacted for assistance with an ethical issue.

The Physician-in-Chief will also be responsible for providing a program for the continuing education of the Medical Staff on ethical issues.

3.4. INFORMED CONSENT POLICY (CORPORATE POLICY #304)

Policy:

Only those patients who have voluntarily and knowingly consented to surgical and other intensive and/or invasive procedures shall receive those treatments at Beaumont Health System. Appropriate documentation of informed consent shall be required before commencing those treatments.

Informed consent is required, in general, when treatment is undertaken where a substantial risk of harm exists, where mandated by statute or by hospital policy or when treatment is of an experimental nature under the purview of Beaumont's Human Investigation Committee.

No documentation of informed consent is required for routine care or non-invasive treatment that involves an insubstantial risk of harm to the patient because the patient has consented to such care upon signing the General Consent to Treatment form.

In the event of an emergency situation, this policy would not apply.

Elements of Informed Consent:

1. Capacity: The patient must have the capacity to consent. Capacity is determined by a physician. Competency is determined by a Court.
2. Sufficient Information: The patient must have sufficient information upon which to base the consent. This must include information about the patient's medical condition; proposed and reasonable alternative treatments, including their risks, benefits, significant complications and side effects; the consequences of foregoing treatment; prospects for recovery; potential problems during recuperation and the likelihood of achieving the patient's goals.
3. Documentation: The patient's receipt of the information and consent to the treatment must be documented.

Process For Obtaining and Documenting Informed Consent

1. When the Process is Initiated in Physician's Office
 - a. The physician must document in the office records that the patient has been given sufficient information concerning the proposed treatment, alternatives, risks, benefits, complications, prognosis and goals. Except where a specific consent form is required by statute, regulation or Hospital policy, a copy of the Physician's documentation of informed consent need not be provided to the Hospital.
 - b. If a specific consent form required by statute, regulation or Hospital policy is signed in the physician's office prior to Hospitalization:
 - The patient must be admitted within the effective time frame if specified in the regulation, statute or Hospital policy, and
 - A copy of the specific consent form must be provided to the Hospital and in the Hospital medical record at the time of admission. (See Medicaid regulations for sterilization).
 - c. The patient must complete the Acknowledgment of Informed Consent ("Form #232") at the Hospital prior to the treatment. The patient's signature must be witnessed by

a treating physician, a nurse or a designated Hospital employee. The signed Form #232 is maintained in the Hospital medical record.

2. When the Process is Initiated at the Hospital

- a. If a specific consent form IS NOT required by statute, regulation or Hospital policy:
 - The attending physician or his/her designee must document in the Hospital medical record that he/she has discussed the proposed treatment, alternatives, risks, benefits, complications, prognosis and goals with the patient and that the patient consents to the treatment; and
 - The patient must sign the Form #232. The patient's signature must be witnessed by a physician, a nurse or designated Hospital employee. The signed Form #232 is maintained in the Hospital medical record.
- b. If a specific consent form, other than the Form #232, IS required by Hospital policy, statute or regulation, for example, for sterilization, transfusions, or human investigation research:
 - The specific consent form must include the sufficient information upon which the patient's consent is based and must document that the patient has consented. Specific consent forms must be approved in accordance with the Hospital policy on approval of new consent forms; and
 - The attending physician shall be available to discuss the content of the specific consent form with the patient; and
 - The patient must sign the specific consent form. The patient's signature must be witnessed by a physician, nurse or designated Hospital employee. The signed specific consent form shall be made a part of the Hospital medical record.
 - Consent for transfusion of blood or blood products may be obtained by the ordering physician or that physician's designee who may be a mid-level provider or nurse.

Responsibility for Providing Information to the Patient

1. Physician

- a. As a general rule, the physician performing the procedure or serving as the attending physician shall ensure that the patient has sufficient information about the procedure and that the appropriate documentation exists as to the informed consent procedure.
- b. In the event that a procedure involves administration of an anesthetic, the physician administering the anesthetic shall be responsible for ensuring that the patient has sufficient information regarding the anesthesia to be used during the procedure and for documenting that the information was given to the patient in accordance with the anesthesia consent.

2. Health Care Worker

- a. The health care worker may provide additional information to patients per Hospital policy.
- b. In general, if a patient requires additional information or displays confusion or hesitation about a scheduled treatment, it is the health care worker's responsibility to notify the attending physician.
- c. If the attending physician fails to resolve the problem to the satisfaction of the reporting health care worker, the health care worker shall report the incident to his/her supervisor.
- d. If the attending physician fails to resolve the problem to the satisfaction of the supervisor, the supervisor shall report the incident to the Chairman of the Department. If the Chairman of the Department is unavailable, the supervisor shall

report the incident to the Hospital Administrator and Medical Administrator on call. See Patient Care – Corporate Policy #312 – Patient Care Concerns / Chain of Command.

Documentation Requirements Related to Informed Consent

1. With respect to Form #232, the role of the health care worker is to witness the signature of the patient, not the obtaining of informed consent.
2. All dates, times, and signatures must be in ink. If the signature is other than the patient's, then the relationship of the signer to the patient should be noted below the signature.
3. In the event of a technical flaw in a specific consent form, the physician need not re-obtain the patient's consent, but may proceed with the treatment after appropriate documentation in the medical record.
4. In general, the specific consent form remains effective for the duration of the hospitalization and is valid if:
 - a. The nature or scope of the treatment, and the patient's diagnosis, prognosis and medical condition is unchanged, and
 - b. The patient or legal representative continues to demonstrate a willingness to undergo the treatment.
5. Where consent for a definite treatment is obtained pursuant to a court order, the consent is valid until the treatment has been accomplished.
6. Barriers to receipt of information and documentation of consent must be resolved.
 - a. If a patient's disability presents a barrier to communicating his/her understanding of the content and purpose of the Form #232, the law requires the use of special equipment and /or personnel to enable the disabled patient to give informed consent.
 - b. If the patient or legal representative has a hearing disability, auxiliary aids, including a video phone and/or a relay service, or a qualified oral or sign language interpreter must be provided. See, Corporate Policy #315, "Interpreters for Deaf and Hard of Hearing Patients."
 - c. If the patient or legal representative has a visual impairment, the Physician or nurse should read the form to the patient or legal representative, and document that the reading took place.
 - d. If the patient's ability to speak, read, or understand English is limited, an interpreter must be provided. See, Corporate Policy #316, "Interpreters for Patients with Limited English Proficiency."

Exceptions to Informed Consent Policy

1. Emergencies. In an emergency situation, the Physician must document the nature of the emergency and the reasons why he/she was unable to obtain written or verbal consent from the patient or the patient's legally authorized representative. Consent is implied unless the physician or other health care worker has reason to know that the patient would not consent to the treatment, such as where there is an Advance Directive declining the treatment.
 - a. Competent Adult
 - i. Consent is implied where a patient is unconscious and unable to give his/her consent and immediate treatment is necessary to preserve the patient's life or to prevent serious impairment of the patient's health.

- ii. Consent is implied not only in medical emergencies, but also for unanticipated events. A physician is justified in performing a procedure different from that which the patient agrees to when an unanticipated event or condition arises that is or may become life-threatening as a result of surgery or due to an unexpected complication discovered during surgery, and it is impractical or impossible to obtain the consent of the patient or one authorized to act in his/her behalf.
 - b. Incompetent Adult: Consent to treat an incompetent adult is implied in an emergency and attempts to obtain appointment of a legal guardian would delay treatment and cause permanent harm. If available, parents of an incompetent adult, who is incompetent from birth or becomes incompetent during minor years, may give consent.
 - c. Minors
 - i. Consent to treat a minor is presumed in an emergency just when attempts to reach the parents or legal guardian for consent would delay treatment and cause permanent harm.
 - ii. If the minor is not living at home, and does not have a legal guardian, consent should be implied in an emergency, where attempts to reach the Michigan Department of Human Services to obtain a legal guardian would delay treatment and cause harm to the patient.
 - iii. An abortion may be performed upon a minor in an emergency without a parent's written consent or Court order waiving parental consent. An emergency is a situation in which continuation of the pregnancy would create an immediate threat and grave risk to the life of the minor, as certified in writing by a physician.
2. Therapeutic Privilege. If a psychiatrist chooses to withhold information from a patient based upon therapeutic privilege, he/she must document in the medical record his/her reasons for invoking such a privilege. By law, "therapeutic privilege" applies only to psychiatry.
 3. Assumption of the Risk. The physician must document in the medical record any occurrence where the patient refuses to allow the physician to explain the risks, benefits, and reasonable alternatives of a proposed operation or medical intervention, but insists upon signing the written consent form. The physician should then have this discussion with a person authorized by the patient to hear this information and seek that person's concurrence. The physician must also document when the patient orally consents to treatment.
 4. Telephone Consent. Consent and authorization for treatment may be obtained by telephone if no reasonable opportunity to obtain written consent exists. The medical record should reflect who consented, the nature of the consent given, the date and time, and the names of two (2) witnesses to the obtaining of telephone consent.
 5. Police Department.
 - a. If a police officer requests that a test be performed on a patient to determine the amount of alcohol or presence of a controlled substance, or both, in the patient's blood, the police officer is responsible for obtaining written consent of the patient, or his/her representative (EC Form #2323). If the patient refuses to submit to the test, the Hospital shall honor the patient's wishes and not proceed with the test unless the police officer obtains and presents a court order/search warrant.
 - b. Assuming a court order/search warrant has been obtained, the Hospital shall abide by it. The Hospital department in receipt of a court order/search warrant must refer to the Department of Legal Affairs before complying.

- c. In the event that the patient becomes combative and refuses to remain at the Hospital, it is the police officer's responsibility, not the Hospital's, to restrain the patient.
- 6. First Responders. A First Responder who has either transported an emergency patient (the "Source Patient") to the Hospital or assisted a Source Patient who is later transported to the Hospital for purposes of medical treatment may request that the Source Patient be tested for HIV and/or HBV if it is believed that the First Responder has sustained a percutaneous, mucous membrane or open wound exposure to the Source Patient's blood or other body fluids. See EC Policy#312 – First Responder Exposure.

Who May Consent

1. Competent Adult. A competent adult is one who is eighteen (18) years of age or older and can understand his/her medical condition, proposed treatment, alternatives, risks, benefits, complications, prognosis and goals.
 - a. Before proceeding with treatment, the consent of a competent adult must be obtained. A competent adult has the right to refuse any treatment.
 - b. An adult psychiatric patient is not presumed to be incompetent to consent to medical treatment. The patient's psychiatrist and attending physician (if applicable) should make the determination as to whether the patient can understand his/her medical condition and proposed treatment. The determination should be documented in the medical record.
2. Incompetent Adult. An incompetent adult is one who, though eighteen (18) years of age or older, cannot understand his/her medical condition, proposed treatment, alternatives, risks, benefits, complications, prognosis and goals.
 - a. An adult is presumed to be competent. If the treating physician questions whether the patient is competent, he/she should request the appropriate consultation, e.g., psychiatric or geriatric as appropriate to the patient's condition/status. After consultation, the treating physician should assess whether the patient has sufficient capacity to make informed decisions regarding treatment and document that assessment in the medical record.
 - b. If the treating physician concludes that the patient is not competent to give or refuse consent, treatment decisions may be made by one of the following surrogate decision makers:
 - i. Legal Guardian: If a patient is declared incompetent by a Probate Court, consent of the court appointed guardian ("Legal Guardian") is necessary for non-emergent medical/surgical treatment and, if readily available, for emergency treatment. The Legal Guardian may or may not be a family member and will have a Letter of Guardianship evidencing the appointment. Once appointed, only the Legal Guardian has authority to consent to or refuse medical/surgical treatment. If there is a difference of opinion between the family and the Legal Guardian, the Legal Guardian prevails. If there are any questions related to the Letter of Guardianship, please contact the Department of Legal Affairs. A copy of the Letter of Guardianship must be made part of the patient's medical record.
 - ii. Patient Advocate Acting Under a Durable Power of Attorney for Health Care: A Durable Power of Attorney ("DPOA") is a written document by which a competent adult patient gives another adult the power to make medical treatment, psychiatric treatment and personal care decisions for the patient when the patient is unable to participate in treatment decisions. The adult designated by the patient is called the Patient Advocate.

1. If the patient has executed a DPOA and is subsequently found to be incompetent, the consent of the Patient Advocate is necessary for non-emergent medical/surgical treatment or psychiatric treatment and for emergency treatment if readily available.
 - a. For medical/surgical treatment, incapacity is determined and documented by two physicians or by one physician and a licensed psychologist.
 - b. For psychiatric treatment, incapacity is determined and documented by two physicians, one of whom is a licensed psychiatrist.
 2. Before the Patient Advocate may make treatment decisions for the patient, the Patient Advocate must sign an Acceptance Form. Both the DPOA and the Patient Advocate's Acceptance Form must be part of the patient's medical record.
- iii. Family
1. If it is determined that the patient is incompetent and the patient does not have a legal guardian or a Patient Advocate acting under a DPOA, then the next of kin may consent to medical/surgical treatment provided all of the following conditions are met:
 - a. The treating physician, relying on his/her medical judgment, believes the treatment, though not emergent, should not be delayed until the patient recovers sufficiently to give consent; and
 - b. The treating physician documents these reasons in the patient's medical record; and
 - c. Neither the physician nor the next of kin knows, or has reason to know, that the patient, if competent, would be opposed to the proposed medical/surgical treatment, given the specific set of circumstances.
 2. Consent should be obtained from the closest next of kin in the following order of priority:
 - a. Spouse
 - b. Adult son or daughter
 - c. Either parent
 - d. Adult sibling
 3. When the person with the highest priority is not available, the next in order should be contacted. It is strongly recommended that the consent of persons, other than those listed above, be used with caution. The more distant the relationship between the patient and the next of kin, the greater the probability that the procedure should be delayed until consent can be obtained from a person authorized to give consent, such as a Legal Guardian.
 4. The opinion of a patient's domestic partner, including those of the same sex as the patient, should be considered for purposes of consent. If conflict arises between a domestic partner and the next of kin, then an Ethics consultation should be obtained and Legal Affairs should be contacted.
 5. If the patient's lack of competency is long-term or unrelated to the present illness, appointment of a Legal Guardian should be discussed with the family.
- c. If the patient is not competent and there is no surrogate decision maker, the treating physician should contact the Department of Legal Affairs to request appointment of a Legal Guardian.
 - d. If a question arises regarding consent on behalf of an incompetent patient or there is disagreement among next of kin or between the treating physician and surrogate

decision maker, the treating physician should contact the Department of Legal Affairs.

3. Medicated Patients. A patient should never be informed of the proposed treatment, alternatives, risks, benefits, complications prognosis and goals if he/she is mentally impaired by virtue of medication or abused substances. If a patient has been given an anesthetic agent, the patient is incapable of giving consent until 24 hours after administration of the anesthetic agent.
 - a. If the physician will attest in the medical record that the patient received sufficient information and did consent to the treatment prior to receiving the medication, the proposed treatment may proceed without a Form #232 being signed.
 - b. If the physician cannot document that sufficient information was given prior to the administration of the medication, the treatment will be delayed until the patient is capable of understanding and consenting.
 - c. Sterilization/therapeutic abortion may not proceed unless a Form #232 is signed prior to pre-operative medication.
4. Minors. Except in emergency cases, the consent of a parent, Legal Guardian, or person acting in place of the parents is required in providing medical or surgical treatment to an individual under age eighteen (18). The assent of the minor, as appropriate for age, should be sought in conjunction with obtaining parental consent and the minor's assent, or lack thereof, should be documented in the medical record. If the minor does not assent, Clinical Ethics consultation should be considered.
 - a. Minor Living at Home but Parent Unavailable: If a minor requires medical and/or surgical care and the parents are temporarily unavailable, the physician should obtain consent from the minor's nearest available adult relative or person with a written delegation of parental rights acting in place of the parents. The medical record should reflect the fact that attempts were made to contact the minor's parents. In addition to providing discharge instructions to the responsible adult, a copy of relevant discharge instructions should be mailed to the minor's parents at their home address.
 - b. Minor's Parents are Divorced or Legally Separated: If the parents are legally separated or divorced, the court will have awarded custody. If parents have joint legal custody, then either parent may consent. If one parent has been awarded legal custody of the minor, then that parent's consent should be obtained. In the event of a dispute, the parents should be required to produce a written Judgment of Divorce and the Department of Legal Affairs must be contacted immediately.
 - c. Parental Refusal of Treatment: If, in the opinion of the attending physician, a minor requires medical treatment and the parents refuse to consent, a court order may be obtained under the Child Abuse and Neglect Act. Contact the Department of Legal Affairs immediately.
 - d. Minor Not Living at Home and Without Legal Guardian: If a minor is not living with his/her parents and does not have a Legal Guardian, consent to routine non-surgical medical care may be obtained from the Circuit Court – Family Division or the Michigan Department of Human Services. If a question arises in this circumstance, the Department of Legal Affairs should be contacted.
 - e. Minor Lives in Foster Home or Residential Care Facility
 - i. Consent for minors in foster care depends upon the nature of the proposed treatment and the type of placement as follows:

Type of Care	Type of Placement	Who May Consent
Routine, non-surgical care (other than contraceptive treatment, services, or devices)	Involuntary placement by Court	Court, child placing agency, Michigan Department of Human Services, or the residential care provider to which they have delegated such authority in writing
Routine, non-surgical care (other than contraceptive treatment, services, or devices)	Voluntary placement by parent/Legal Guardian	Parent/Legal Guardian
Emergency medical or surgical care	Involuntary placement by Court	Court, child placing agency, Department of Human Services, or the residential care provider to which they have delegated such authority in writing
Emergency medical or surgical care	Voluntary placement by parent/Legal Guardian	Residential care provider to which parent must delegate such authority in writing
Non-emergent, elective surgery	Voluntary or Involuntary placement	Parent / Legal Guardian OR If parental rights have been permanently terminated, then the Court or Department of Human Services

- ii. Although the consent of the parent or Legal Guardian is typically required for minors prior to commencing treatment, Michigan law permits a minor in some instances to consent to medical or surgical treatment on his/her own behalf.
- f. Emancipated Minors: Emancipation means a parent is no longer legally responsible for a minor. It occurs in the following instances:
 - i. Where a minor is legally married.
 - ii. During the period when a minor is on active duty with the Armed Forces of the United States.
 - iii. For the purpose of consenting to routine, non-surgical medical care or emergency care, when the minor is in the custody of a law enforcement agency and the minor's parent or Legal Guardian cannot be promptly located.
 - iv. Upon entry of an emancipation order by the Circuit Court – Family Division
- g. Substance Abuse, Venereal Disease or HIV: Minors may consent to medical advice or treatment for substance abuse, venereal disease or HIV (AIDS, ARC) without parental consent.
 - i. Substance Abuse: The minor must consent for a treating physician to inform the parents of treatment.
 - ii. Venereal Disease or HIV: A treating physician may inform the parents of treatment, even if the minor specifically requests that the physician not inform his/her parents of the treatment.
- h. Birth Control Information and Devices: Minors may obtain birth control information, medication and devices without parental consent.
- i. Mental Health Services: Minors over the age of 14 may seek and receive outpatient mental health services, excluding pregnancy termination referral services and the use of psychotropic drugs, without parental consent for up to twelve (12) sessions or four (4) months.
- j. Abortions: A minor may not obtain an abortion without the written consent of one (1) parent or the minor's Legal Guardian, unless the Circuit Court – Family Division has entered a written order waiving the parental consent requirement. A parent's written

consent or the Court's order waiving parental consent must be included in the medical record together with the written consent of the minor.

- k. Prenatal and Pregnancy Related Health Care: A minor female may seek and consent to prenatal and pregnancy related health care and to the provision of health care for her child without the consent of her parents.
 - i. Prenatal and pregnancy related "health care" is defined by law as "only treatment or services intended to maintain the life and improve the health of both the minor and the minor's child or fetus." Prior to treatment, the Hospital or physician is required to inform the minor that while the physician is not obliged to notify the spouse, parent, Legal Guardian, or putative father of the child, the law does not prevent such notification.
 - ii. The physician, for medical reasons, may inform the spouse, parent, Legal Guardian, or putative father of the child regardless of the minor's consent or lack thereof.
 - iii. The medical record should reflect the fact that the minor has been informed that notification of others regarding her treatment may occur.
- l. Blood Donation: A person 17 years of age or over may donate blood in a voluntary and non-compensatory blood program without the necessity of obtaining the permission or authorization of a parent or Legal Guardian.
- m. Sterilization: The law is silent as to whether a married minor may consent to be sterilized without spousal or parental consent. The Department of Legal Affairs should be contacted in all cases involving sterilization of minors. For the patients who are Medicaid recipients, federal regulations prohibit funding for any person under age 21.

3.5. MEDICAL MARIHUANA (SEE FULL CORPORATE POLICY #210)

This policy provides an overview of the Michigan Medical Marihuana Act and guidance for our healthcare workers. For detail of application and guidelines, see full Policy #210.

3.6. MEDICALLY NON-BENEFICIAL OR POTENTIALLY HARMFUL INTERVENTIONS (CORPORATE POLICY #318)

There are occasions when treatment interventions requested by a patient, family, or surrogate decision maker (patient advocate or legal guardian) are believed by the patient's attending physician to be medically inappropriate or harmful. Such interventions may include medications, dialysis, blood transfusions, cardiopulmonary resuscitation, ventilator support or artificial nutrition and hydration.

While a physician is never obligated to initiate or continue inappropriate or harmful interventions, the families of some patients feel that they are obligated to demand what they consider to be life-prolonging interventions, no matter what the clinical status of the patient is. In some cases the medical facts are disputed. In many cases there is conflict over which values should take precedence in determining the proper management of a patient's final days or weeks of life.

Contemporary medical ethics has guiding principles, which include respect for autonomy, beneficence, non-maleficence, and justice. With regard to non-beneficial or harmful treatment:

Autonomy refers to the principle that a patient's value preference and choices among health care alternatives should be respected. Respect for autonomy does not require that patient or their surrogate be offered an intervention that is not indicated.

Beneficence implies that an action is done for the benefit or good of the patient. If an intervention cannot be expected to enhance the good or welfare of the patient, then it is

not offered. An intervention may have a measureable effect on some part of the patient without being beneficial.

Non-maleficence means to do no harm. Most medical interventions have some risk of harm. An intervention may be offered if its intent is not to inflict harm, and if the balance between benefit and harm is favorable.

Justice requires the fair and non-wasteful use of resources. Non-beneficial treatment efforts use healthcare resources that are better used in other ways.

The following procedure will be followed when a patient, family or surrogate decision maker request medically non-beneficial interventions. There should be a discussion between the physician and patient / surrogate explaining the rationale behind withholding the non-beneficial medical intervention, and providing reassurance that the patient will continue to receive appropriate nursing and comfort care.

The capacity of the patient to make his / her own medical decisions must be established and documented. A Clinical Ethics consultation may be requested to help ensure that a values conflict will be identified early and courses of action presented that are consistent with the patient's values.

- A. If the patient / surrogate continues to request / demand non-beneficial treatment, the attending physician should arrange and attend a meeting which includes, as appropriate, the patient, the patient's family members, a family-selected advisor (if desired), the surrogate decision maker, consulting physicians, nurse manager and a primary nurse. A member of the Clinical Ethics Consultation Service can be asked to attend, if desired. At this meeting the history, medical facts, diagnoses, prognosis, patient preferences, and other pertinent information should be thoroughly reviewed. There should be time for a response to all questions. The goals of care should be delineated with reference to the patient's values and beliefs. The result of this discussion should be summarized in the patient's medical record.
- B. If there is no resolution of the disagreement over treatment following the guidelines in A, the attending physician should request the opinion of additional consultants, as indicated by the clinical condition of the patient; this may include a palliative care specialist. If there is persistent disagreement with the attending physician over the goals of care or treatment plan, the attending may attempt to transfer care within the institution or, if that is not possible, attempt to transfer the patient to another institution.
- C. If transfer of the patient to another physician is not possible, and there remains irresolvable disagreement about the appropriateness of a particular treatment and the goals of care, an order will be written for Clinical Ethics consultation.
- D. The attending physician will notify the Physician-in-Chief, and provide an adequate synopsis of the case; the Physician-in-Chief must acknowledge receipt of that notification. Should the Physician-in-Chief be unavailable, the Chief Medical Officer or another Beaumont Health System Physician-in-Chief may substitute. In order to assure that appropriate legal concerns are addressed, it is the responsibility of the Physician-in-Chief, or his / her covering representative, to contact Legal Affairs.
- E. When consulted, the Clinical Ethics Consultation Service will interview all identified concerned parties recommend a course of action. When the patient is incompetent and the family refuses to participate in this process and / or appears to be not acting in the best interests of the patient, Legal Affairs may be asked to pursue the appointment of a guardian to participate in these discussions on the patient's behalf.
- F. The attending physician will have authority to order the discontinuation or withholding of a medically non-beneficial intervention, if consistent with the recommendations of the Ethics Consultation team, and with concurrence of the Physician-in-Chief.

3.7. ORGAN DONATION FOLLOWING CARDIAC DEATH (DCD) (CORPORATE POLICY #310)

Patients or their surrogate decision makers (surrogates) have the right to accept or reject medical treatment, including the right to forego life-sustaining treatment. Patients and their surrogates in a designated order of priority also have the right to make anatomical gifts (gifts of the whole body or specified organs and tissues).

It is consistent with the mission of Beaumont Health System and ethically appropriate for patients and their surrogates to consider Organ Donation Following Cardiac Death (DCD), and for Beaumont Health System to support patients and their surrogates in making the choice whether to donate or not to donate organs and tissues.

This policy defines DCD as organ recovery from patients who are pronounced dead on the basis of irreversible cessation of circulatory and respiratory functions. It is intended to provide surrogates with an additional option for donation, which complies with the patient's previously expressed wishes or the authorized surrogate's directives, as long as the surrogate's directives are not contrary to the patients previously expressed views. This option is offered to a surrogate **ONLY AFTER** the surrogate in conjunction with the medical staff has chosen to forego life-sustaining treatment.

The goals of this DCD policy are to:

1. Demonstrate respect for the wishes of patients and / or surrogates regarding organ donation.
2. Recover organs that can be transplanted, when consistent with the wishes of patients / surrogates, thereby meeting the needs of patients currently awaiting organ transplantation, and the needs of dying patients and their surrogates who may find satisfaction in making a gift of life.
3. Maintain the integrity and quality of organ and tissue recovery through DCD.
4. Support surrogates / families of patients in the decision making process and in the organ and tissue recovery process through DCD.
5. Support Beaumont Health System's staff participating in organ and tissue recovery through DCD.

Appropriate candidates for DCD are limited to those patients who meet the following criteria:

- The patient has a non-recoverable illness or injury that has caused neurological devastation and / or other body system failure resulting in ventilator dependency.
- The patient / appropriate surrogate decision maker, in conjunction with the medical staff, has decided to withdraw life-sustaining treatment.
- In the opinion of the health care team, cardiopulmonary death will likely occur within ninety (90) minutes following withdrawal of life-sustaining treatment.
- The patient's level of central nervous system (CNS) incapacitation is not due to the influence of CNS depressant drugs, metabolic coma or body temperature <32.2C.

The decision to remove life support is separate and distinct from and must be made prior to and independently of the decision to donate organ(s) and / or tissue(s).

If the patient is not competent to consent to the removal of life support, the appropriate surrogate decision maker for the purpose of consenting to the removal of life support is a court appointed guardian, patient advocate acting under a Durable Power of Attorney for Health Care or family member, in the order of priority and as described in Policy #307 "Guidelines for Withdrawing or Withholding Life Sustaining Treatment".

This policy should in no way undermine or impede the process of declaring appropriate patients dead by reason of irreversible cessation of spontaneous brain function, in accordance with Policy #317 "Determination of Death by Neurological Criteria (Brain Death)."

The well-being of the patient will remain the primary responsibility of the attending physician and the health care team. The comfort and needs of the patient will be continually evaluated and addressed.

Appropriate decision makers for purposes of DCD are an adult patient of sound mind, or the following surrogates in the following order of priority: patient advocate with authority stated in the patient advocate designation to the extent of the stated authority, spouse, adult child, either parent, adult sibling, guardian of the person of the patient, or other individual with authority to dispose of the patient's body. A surrogate in a lower priority may make a donation if a person in a higher priority is not available or not capable. Such a surrogate may make a donation only if the surrogate has no knowledge of the patient's unwillingness to donate or of the unwillingness of any person in the same or a higher priority. A donation made by a surrogate in a higher priority is not revocable by a person in a lower priority.

Procedure

Gift of Life of Michigan (Gift of Life) will be notified by the Bereavement Representative or designee of all imminent deaths as provided in Policy #311, "Anatomical Gifts."

The Gift of Life Coordinator will consult with the health care team to determine the suitability of the patient for DCD. No tests or procedures will be performed on the patient without approval of the attending physician and / or intensivist, who will approve only those tests or procedures ordinarily undertaken for the patient's comfort or to treat the patient's underlying disease. No tests or procedures that ordinarily require consent of a patient or surrogate will be performed without the consent of the patient or surrogate.

If the patient's condition does allow for DCD, the Gift of Life Coordinator, with the knowledge of the attending physician and / or intensivist, will work with the health care team to develop an appropriate plan to discuss the option of DCD with the surrogate.

A hospital chaplain and / or designee will be on-site to support the surrogate / family and serve as an advocate for the surrogate / family in the process of informed consent. A Gift of Life Family Support Person may be asked to assist by the chaplain and / or designee in this support.

If the patient's condition does not allow for DCD or if the patient / surrogate does not consent to DCD, withdrawal of life-sustaining treatment and care of the patient will be conducted in accordance with Policy #307 "Guidelines for Withdrawing or Withholding Life Sustaining Treatment."

It is the responsibility of the Bereavement Representative (Royal Oak) and Nurse Manager / Administrative Representative (Troy & Grosse Pointe), in conjunction with the Gift of Life Coordinator, to contact the Medical Examiner (ME) in cases that are within the jurisdiction of the ME. Any restrictions of donation by the ME will be discussed with the surrogate / family at this time.

Any ethical issue or concern raised by any staff member, surrogate or family member will be addressed in accordance with Policy #309, "Clinical Ethics," If the ethical issues and / or concerns are justified, or the surrogate with priority does not consent following consultation or withdraws consent previously given, DCD will not proceed.

If the ethical concerns are related to the staff member's personal beliefs regarding DCD, the staff member may choose to not participate in the process based on Human Resource Policy #268, "Staff Deference."

Consent For DCD

The surrogate will be approached about the possibility of DCD ONLY AFTER a decision to withdraw life-sustaining treatment has been agreed to by the patient / appropriate surrogate decision maker and the attending physician. The decision about withdrawal of treatment and the decision about DCD must be made independently of one another.

The Gift of Life Coordinator will approach the surrogate / family of patients who meet the criteria for DCD. A member of the health care team will be present and serve as the advocate for the patient and surrogate / family. The Gift of Life of Michigan Coordinator will provide:

- An explanation of DCD and the opportunity for donation.
- An explanation of the medical and ethical rationale for DCD.
- A clear statement that the surrogate is free to agree to or refuse donation.
- An explanation of where and how support will be withdrawn and of the measures used to maintain patient comfort
- A period of time for questions about the donor process.
- A period of time for the surrogate to consider the decision.
- An explanation of any additional procedures needed for DCD, including premortem procedures that may not be for the benefit of the patient (e.g., use of drugs, cannulation, bronchoscopy, liver biopsy, and other similar procedures), and their risks and complications and measures used to maintain patient comfort.
- Documentation of the surrogate's decision.

If the surrogate consents to DCD, the routine consent forms and process of donor evaluation will be followed by the Gift of Life Coordinator, in accordance with Procedure #311-1, "Anatomical Gift Requests."

A plan for the withdrawal of life sustaining treatment will be discussed with the surrogate and family during the consent process. The attending physician or designee and Gift of Life Coordinator will explain the procedures for withdrawal of treatment and answer any questions of the surrogate and family. The plan for withdrawal should keep three primary goals in mind: 1) the patient's comfort, 2) the ability to successfully recover organs for transplantation, and 3) meeting the needs of the surrogate and family to grieve and spend appropriate time with the patient. The health care team will support this process through flexible visiting by the surrogate and family with the patient. The chaplain will play a key role in this process by advocating for and serving the needs of the surrogate and family. The Chaplain and / or designee may request assistance from a Gift of Life Family Support Person.

If the patient should sustain cardiac arrest before the decision to withdraw life-sustaining treatment has been made by the attending physician and surrogate and documented, any pre-existing orders as to CPR control will be followed.

If the patient should sustain cardiac arrest after the decision to withdraw life-sustaining treatment has been made by the attending physician and patient / appropriate surrogate decision maker and documented, but before the process of informed consent concerning DCD has been completed, the patient will not undergo CPR. Comfort measures and ventilatory support, if any, will be continued until further decisions are made.

Patient Management After Consent

To facilitate organ recovery, the patient must be maintained on a ventilator and hemodynamically supported for organ perfusion until withdrawal of ventilatory support. The Gift of Life Coordinator will work in conjunction with the hospital medical staff to request medical consultations and laboratory studies to determine the suitability of the organs for transplantation.

Comfort measures will be provided during any testing period and during withdrawal of life support, in accordance with applicable standards of practice for the care of persons undergoing the same or similar types of procedures who are not candidates for DCD. Palliative care will remain the primary goal of patient care during this period. Families should be permitted to consent to, or refuse to consent to, the use of measures to restore circulation and oxygenation to the organs of a candidate for DCD if cardiovascular arrest occurs during testing. Surrogate / family support will continue during this period

Results from studies related to the suitability of organs for transplantation will be expedited as soon as possible. The surrogate / family will be informed of the approximate wait for these studies to be completed.

If the studies reveal that the patient cannot serve as an organ donor, the surrogate / family will be informed. They will also be informed of the continued option for tissue donation. The chaplain and / or designee will provide support during this reporting phase. The surrogate may refuse to continue with tissue donation at this point. The surrogate's right to refuse will be explained and any decision to refuse will be supported.

If the studies confirm the patient's suitability as an organ donor, the surrogate / family will be informed. The Gift of Life Coordinator will review the plan agreed to earlier regarding withdrawal of life-sustaining treatment and DCD.

Withdrawal of Life Sustaining Treatment and Pronouncement of Death

The patient and surrogate / family will be transferred to the designated area (preop / PACU / OR) with the patient being mechanically ventilated and monitored by the critical care team.

When the transplant team has been assembled (See: Organ Retrieval Procedure), and has performed any procedures preparatory to transplantation as explained in the consent process (See: Consent for DCD), the transplant team will withdraw from the area where the patient is being treated, and will have no role in the continuing care of the patient. The critical care team will be responsible for withdrawal of mechanical ventilation in accordance with the procedures in Policy #307, "Guidelines for Withdrawing or Withholding Life Sustaining Treatment," and will be responsible for all medical care of the patient until the patient is pronounced dead.

Death will be pronounced by the attending physician or his / her physician designee. The physician certifying death will not be involved as a part of the organ / tissue transplant or recovery team. No steps will be taken to intentionally hasten the death of the patient.

The Bed Coordinator – Royal Oak & Troy, Admitting – Grosse Pointe will assign and hold the patient's critical care bed for the patient in the event the patient does not expire within ninety (90) minutes after termination of support (See: Care When DCD is Not Successful).

Organ Retrieval Procedure

After suitability has been determined and consent obtained, the Gift of Life Coordinator will assemble a transplant team and inform the Operating Room staff. The transplant team will arrive at the hospital and follow procedures in accordance with the organ donation protocol.

Criteria for declaring death prior to donation of organs after cardiac death are as follows: Death may only be declared after a five (5) minute waiting period following the cessation of circulation [defined as the absence of sufficient cardiac activity to generate a pulse or blood flow (not necessarily the absence of all electrocardiographic activity)], during which time the patient must have no respiratory effort (apneic) and be completely unresponsive. It is highly recommended that cessation of circulation be documented with absent blood pressure via an arterial pressure catheter. If the placement of an arterial catheter is not feasible, a zero blood pressure should be documented in addition to absent pulses in the femoral, carotid or brachial arteries by Doppler. An attending physician must certify in writing that these criteria were met for a full five (5) minutes before declaration of death; upon such declaration of death, surgical recovery of organs may commence.

After surgical recovery of organs, the surrogate / family may wish to view the body of the deceased. The surrogate / family should be allowed to view the body prior to transfer to the morgue. This viewing will take place in the isolation room in PACU on the second floor, North Tower (Royal Oak), in ENDO, Room 9 (Troy), or the Critical Care Unit (Grosse Pointe). Hospital staff should support this request in a sensitive manner and as similar requests are handled in relation to other deaths in the Operating Room area.

Release of the body to a funeral home or Medical Examiner will take place in a manner consistent with Policy #495 "Expiration of a Patient"

Care When DCD Is Not Successful

A discussion with the patient's family members about possible contingencies in the O.R. must be conducted before the patient's transfer to the O.R. This discussion must include the time frame allowed for the patient to expire after withdrawal of life sustaining treatment. This time frame is based on a determination of predicted organ viability after life sustaining treatment is withdrawn and in no case will this time frame exceed ninety (90) minutes. When organ donation is not possible, the attending physician will be notified to provide continuing medical care for the patient, and the patient will be returned to the unit from which the patient was transferred to the O.R.

The critical care unit receiving the patient will be informed by the Bed Coordinator – Royal Oak and Troy and Admitting – Grosse Pointe. The staff from that unit will be prepared to continue palliative care for the patient and support of the surrogate / family. The attending physician may transfer the patient to a non-critical care bed, consistent with the patient's medical needs and bed availability.

The Gift of Life Coordinator and the chaplain and / or designee will inform the surrogate / family in person, or at a previously agreed upon telephone number, if the surrogate / family has chosen to leave the hospital.

The chaplain or designee will continue to provide support for the patient and surrogate / family during the continuing care of the patient.

Care of the Surrogate / Family

Care of the surrogate / family is a primary responsibility of Beaumont Health System's health care team, including a hospital chaplain. The chaplain will serve in the role of primary patient / surrogate / family advocate, and will support the surrogate / family through the process of informed consent for DCD, encourage communication and provide spiritual and emotional care.

Additional support may be provided through access to the surrogate's / family's own clergy person(s), which is welcomed and encouraged. The chaplain or designee will facilitate contact with the surrogate's / family's own clergy person(s), and may request assistance from a Gift of Life Family Support Person.

The chaplain and / or designee will provide reports from surgery for those who consent to DCD. In the event that DCD is not successful and the patient is moved back to a nursing unit bed, the chaplain and / or designee will provide support for the family / surrogate throughout the dying process.

Care of Beaumont Health System's Staff

DCD requires that all staff involved receive adequate training in the protocol and unique medical aspects of DCD. Training will be the responsibility of the Organ and Tissue Donation Committee (Royal Oak), Department of Education (Troy & Grosse Pointe) and Gift of Life of Michigan working in conjunction with the nursing / surgical unit directors and medical staff involved.

DCD may present some staff members with a conflict of conscience. Staff must be allowed to forego participation in DCD in a manner consistent with Policy #302, "Staff Deference."

DCD may cause emotional distress for staff. Opportunity for debriefing and discussion will be offered following each case of DCD. Spiritual Care Services (Royal Oak & Grosse Pointe) and Pastoral Care (Troy) will be responsible for providing this opportunity within 72 hours of the completion of any donation or attempted donation through DCD.

Reports of staff response to DCD will be made to the Chair of the Organ and Tissue Donation Committee.

Beaumont Health System's Quality Review Of Organ And Tissue Recovery Through DCD

Review of cases will include the following:

- Interviews with ICU staff, attending physician or his / her designee, OR staff, chaplain, and Gift of Life Coordinator. The focus of the interview will be on overall satisfaction with the process, as well as inquiring into any improvements that might be made. The Chair of the Organ and Tissue Donation Committee or his / her designee is responsible for these interviews.
- A follow-up phone call to the surrogate / family will be made within eight weeks by the chaplain or designee who was the surrogate's / family's advocate during the decision-making and / or donation process. This call will focus on overall satisfaction with care of the patient and surrogate / family.
- The DCD Nurse coordinator will present the rate of successful transplantation of organs recovered through DCD at the Organ and Tissue Donation Committee.
- A brief summary of each organ donation case will be presented to the Institutional Ethics Committee (IEC) at its monthly meetings by the Organ Donation Coordinator. The information presented will include feedback from interviews with ICU staff, the attending physician, spiritual care, other staff, immediate family members, and the Gift of Life Coordinator.

Related Policies

Policy 495 - Expiration of a Patient

Policy 268 - Staff Deference

Policy 307 - Guidelines for Withdrawing or Withholding Life Sustaining Treatment

Policy 308 - End of Life Care

Policy 309 - Clinical Ethics

Policy 311 - Anatomical Gifts

Policy 317 - Determination of Death by Neurological Criteria (Brain Death)

3.8. PATIENT RIGHTS AND RESPONSIBILITIES ISSUES (CORPORATE POLICY #313)

Patient Rights

1. A patient will not be denied appropriate care on the basis of race, religion, color, national origin, gender, age, disability, marital status, sexual orientation, height, weight, or source of payment.
2. A patient has the right to confidential treatment of their Protected Health Information (PHI) as outlined in Policy 314 – Confidentiality and Release of PHI. A patient has the right to inspect, obtain a copy and request to amend (by placing additional information, not by deleting or changing information) their PHI subject to limitations under HIPAA and other applicable laws. A patient has the right to receive notice of Hospital Privacy Practices and receive an accounting of who has had access to their PHI. A patient has the right to file a complaint with the Beaumont Compliance Office, or with the U.S. Secretary of the Department of Health and Human Services about how their PHI was handled.
3. A patient has a right to courtesy, respect, dignity, responsiveness, and timely attention to his or her needs. The effectiveness and safety of care, treatment and services does not depend on the patient's ability to pay.
4. A patient is entitled to privacy, to the extent feasible, in treatment and in caring for personal needs with consideration, respect and full recognition of his or her dignity and individuality.
5. A patient is entitled to receive adequate and appropriate care, and to receive, from the appropriate individual within the hospital, information about his or her medical condition, proposed course of treatment, and prospects for recovery, in terms that the patient can understand, unless medically contraindicated as documented in the medical record by the attending physician or a mid-level provider to whom the physician has delegated the performance of medical care services.
6. A patient is entitled to obtain the most effective pain relief that may safely be provided. A pain management plan will be established for each patient as appropriate taking into account the patient's medical condition, comfort, age, setting and /or environment. The patient and / or family will receive information about pain, pain assessment and the use of drugs or other methods of pain relief, if applicable.
7. Patients and / or the families of patients (with the patient's approval) have the right to participate in decisions regarding treatment and course of therapy. Support at the end of life will be provided to foster comfort and dignity by managing pain, addressing the treatment of primary and/or secondary symptoms, and attending to the spiritual, cultural, psychosocial and continuing care needs of both the patient and family through a Hospice Consult, Palliative Care Consult, Spiritual Care Services, Social Work or a representative of the patient's ethnic culture (arranged by Social Work). The patient and family have the right to participate in the plan for the care setting at the end of life. Recognizing the importance of family support at the end of life, a family friendly environment will be encouraged through the involvement of family members in direct patient care as appropriate and relaxation of visiting restrictions to the extent possible.
8. A patient has the right to formulate advance directives and to have hospital staff comply with these directives (see Corporate Patient Care Policy #494 for recommendations in the ambulatory setting).
9. A patient is entitled to refuse treatment to the extent provided by law and to be informed of the consequences of that refusal. When a refusal of treatment prevents the hospital

or its staff from providing appropriate care according to ethical and professional standards, the relationship with the patient may be terminated upon reasonable notice.

10. When a patient needs protective services (eg, guardianship or advocacy services, conservatorship, or child or adult protective services), the hospital provides resources to help family and courts determine the patient's needs for such service. The hospital maintains a list of names, addresses and telephone numbers of patient advocacy groups, such as a state authority or a protection and advocacy network. The hospital gives the list of patient advocacy groups when requested.
11. A patient is entitled to information concerning any research or experimental procedure proposed as part of his or her care and shall have the right to refuse to participate or withdraw from research without jeopardizing his or her care.
12. A patient is entitled to receive and examine an explanation of his or her bill regardless of the source of payment and to receive, upon request, information relating to financial assistance available through the hospital.
13. A patient or his or her legal representative has the right to make informed decisions regarding his or her care. A patient is entitled to know who is responsible for and who is providing his or her direct care, is entitled to receive information concerning his or her continuing health needs and alternatives for meeting those needs, and to be involved in the development and implementation of his or her plan of care and discharge plan, as appropriate. The patient's right to participate in care is not to be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.
14. A patient is entitled to associate and have private communications and consultations with his or her physician, attorney, or any other person of his or her choice and to send and receive personal postal mail unopened on the same day the hospital receives it, unless medically contraindicated or disruptive to hospital operations as documented by the attending physician in the medical record. A patient's civil and religious liberties, including the right to available choices, shall not be infringed and the hospital shall encourage and assist in the fullest possible exercise of these rights. A patient may meet with, and participate in the activities of social, religious, and community groups at his or her discretion, unless medically contraindicated or disruptive to hospital operations as documented by the attending physician in the medical record.
15. A patient has the right to receive care in a safe setting and to be free from all forms of abuse, neglect, harassment or coercion. A patient is entitled to be free from any form of seclusion or restraint not medically necessary or that is used as a means of coercion, discipline, convenience or retaliation by staff. All use of seclusion or restraints must be authorized in writing by a physician for a specified and limited time, implemented in the least restrictive manner possible and removed at the earliest possible time.
16. A patient is entitled to have a family member or representative of his or her choosing and the patient's own physician promptly notified of his or her admission to the hospital.
17. A patient, and / or his or her legal representative, is entitled to be informed in advance of providing or discontinuing patient care and of his or her patient rights.
18. A patient is entitled to be free from performing services for the hospital that are not included for therapeutic purposes in the plan of care.
19. A patient is entitled to information about the hospital rules and regulations affecting patient care and conduct.
20. The hospital provides interpreting and translation services as necessary to afford patients with vision, speech, hearing or cognitive impairments an equal opportunity to

participate in or benefit from hospital goods, services, facilities, advantages and accommodations.

21. A patient must give informed consent for photographs or other images of the patient for purposes other than treatment.
22. The above rights may be exercised on the patient's behalf, if the patient is incapable of rendering a decision by the patient's surrogate. This may be a court-appointed guardian, advocate appointed under a durable power of attorney for health care, or next of kin in order of priority, or by a parent or guardian of a minor.

Patient Responsibilities

1. A patient is responsible for following the hospital rules and regulations affecting patient care and conduct.
2. A patient is responsible for providing a complete and accurate medical history.
3. A patient is responsible for making it known whether he or she clearly comprehends a contemplated course of action and the things he or she is expected to do.
4. A patient is responsible for following the recommendations and advice prescribed in a course of treatment by a physician when there is mutual understanding and agreement about the treatment.
5. A patient is responsible for providing information about unexpected complications that arise in an expected course of treatment.
6. Patients are strongly encouraged to discuss end-of-life decisions with their family and physicians and make their wishes known. Such a discussion might include writing an advance directive.
7. Patients are strongly encouraged to be committed to health maintenance through health-enhancing behavior. Illness can often be prevented by a healthy lifestyle, and patients must take personal responsibility when they are able to avert the development of disease.
8. A patient is responsible for being considerate of the rights of other patients and hospital personnel and property.
9. A patient is responsible for providing the hospital with accurate and timely information concerning his/her sources of payment and the ability to meet financial obligations.
10. Patients are expected to treat hospital staff, visitors and other patients with respect and to refrain from language and behavior that is offensive, abusive or intimidating.
11. Patients who display serious behavior problems may be asked to agree to a list of behavioral expectations. Failure to sign or comply may result in discharge from the Hospital.

3.9. REFUSAL OF BLOOD OR BLOOD PRODUCTS ON GROUNDS OF PERSONAL BELIEFS (CORPORATE POLICY #304-1)

Patients have the right to refuse care, treatment, or other services in accordance with law and regulation. When patients are not able to make decisions for themselves; a surrogate decision maker may refuse care, treatment, and other services in accordance with law and regulations.

A competent, adult patient who knowingly and contemporaneously refuses the transfusion of blood or blood products may be admitted and treated at William Beaumont Hospital. The patient must sign Form #7488, "Refusal of Blood Transfusion and Release" (available

through Forms Library) if refusing blood. Grosse Pointe uses form # 610-49 "Refusal to permit treatment / procedure/ medication". Questions concerning competent, adult patients whose beliefs prohibit the transfusion of blood or blood products should be handled according to this policy.

ALL CASES involving minor patients, incompetent patients, whether minor or adult, and pregnant females, whether minor or adult, where transfusion of blood or blood products is declined, must be referred to the Department of Legal Affairs.

Definitions:

Competent Adult: A competent adult is one who is eighteen (18) years of age or older and can understand his/her medical condition and proposed treatment, risk and benefits of proposed course of treatment and non-treatment, prospects for treatment, and significant alternative treatment.

Incompetent Adult: An incompetent adult is one who cannot understand his/her medical condition, proposed treatment and alternative treatments.

3.10. TERMINAL ILLNESS

A physician who has diagnosed a patient as having a reduced life expectancy due to a terminal illness and is recommending medical treatment for the patient shall inform the patient or the patient's surrogate of the following rights and options:

1. to designate a patient advocate to make medical treatment decisions in the event the patient becomes unable to do so;
2. to decide whether to receive, refuse, continue or discontinue medical treatment;
3. to choose palliative care, including hospice care and pain management; and
4. to choose pain and symptom management as an essential part of medical treatment.

This information must be provided orally and in writing. Distribution to the patient or the patient's surrogate of the information summary prepared by Michigan Department of Community Health satisfies the obligation to inform.

3.11. WITHDRAWING OR WITHHOLDING LIFE SUSTAINING TREATMENT (CORPORATE POLICY #307)

Patients with Decision-Making Capacity

Adult patients are presumed to have the capacity to decide about their treatment unless demonstrated otherwise.

Decision-making capacity requires the patient to have the ability to make and communicate a decision that reflects an understanding and appreciation of the nature and consequences of the proposed and alternate actions and to evaluate them in relation to personal preferences and priorities.

The attending physician has the responsibility for determining each patient's decision-making capacity. If the attending physician is uncertain about the patient's decision-making capacity, the physician will request a consultation from another staff physician, preferably a psychiatrist or a neurologist or from a fully licensed psychologist and / or consult another staff physician to assist in defining the patient's decision-making capacity.

If a patient with decision-making capacity chooses a non-resuscitation or limited support alternative, this is the patient's choice and it may not be overridden by contrary view of either his / her attending physician or family members. When the patient's physician

disagrees with the patient's decision, it remains the physician's responsibility to write the order according to the patient's wishes or arrange for transfer of care to another physician.

The patient's decision shall remain in effect if the patient subsequently becomes incapacitated and if the anticipated outcome has not changed significantly.

Patients Without Decision-Making Capacity

If, in the judgment of the attending physician, the patient is incapable of making informed decisions, the physician should consult the surrogate decision maker.

The surrogate decision maker may be an individual named in advance by the patient to act in this capacity, next of kin, or guardian. The surrogate should make decisions of care based on the patient's wishes.

Procedure For Withdrawing or Withholding Life Sustaining Treatment For All Patients

- A. Before concurring in a request to withdraw or withhold life-sustaining treatment, the attending physician may desire to seek consultation concerning questions of diagnosis, prognosis, and alternative therapies. Although such consultations are not required, their utilization in this process is encouraged. In addition, the physician may want to seek other consultation or distribute educational materials to the patient or to the patient's family.

An attending physician must document in the patient's medical record:

- 1) Patient's medical condition and prognosis,
- 2) Discussion the physician had with the patient / surrogate decision maker regarding the patient's condition, prognosis and alternative treatment modalities, and
- 3) Patient's / surrogate's decision maker's ultimate decision and rationale for that decision. The physician of record must be notified and concur with a decision to withhold or withdraw life sustaining treatment or a clinical ethic consultation should be initiated.

Consultations and any material provided to the patient and / or family should be documented in the medical record.

Approval of next-of-kin to withdraw or withhold life-sustaining treatment from a medically competent, adult patient is not required. Objection of surrogate decision maker / family members is not sufficient to overrule the informed decision of a medically competent adult patient.

The surrogate decision maker should, however, be informed of the patient's decision and of the physician's intent to comply with that decision unless the patient requests that his / her decision be kept confidential.

- B. If the attending physician and patient / surrogate decision maker disagree as to the course of treatment, consultation with another physician is encouraged. If the disagreement is not resolved, a clinical ethics consultation may be requested. (See Patient Care – Corporate Manual, Policy #309 "Clinical Ethics"). If the disagreement between physician and patient / surrogate decision maker cannot be resolved, the attending physician should make appropriate arrangements to transfer the patient to another physician within the Hospital or to another health care facility willing to honor the patient's / surrogate decision maker's treatment decisions. If it is impossible to transfer the patient to another physician or facility, it is the patient's / surrogate decision maker's option to sign out against medical advice.

During the period that the disagreement remains unresolved, treatment should continue. If the conflict remains unresolved, the attending physician must contact Medical Administration or the Department of Legal Affairs.

The attending physician remains responsible for the patient until the care is formally transferred to another physician.

- C. In the following cases, the attending physician may not withdraw or withhold treatment, or transfer the patient until an attending physician has discussed the case with the Department of Legal Affairs:
 - 1) A pregnant adult;
 - 2) An adult with minor children as dependents;
 - 3) A patient who is a prisoner referred for medical care;
 - 4) A patient who is a victim of an act or omission out of which prosecution might arise;
 - 5) No Legal guardian, DPOA for Health Care, or qualified family member (spouse, adult child, parent, adult sibling) available;
 - 6) The patient's parent is a minor; or
 - 7) The patient has never been competent.
- D. To ensure adequate communication regarding a patient's / surrogate decision maker's treatment decisions only the attending physician or his / her designee may order withdrawing or withholding life sustaining treatment where death is likely to follow. This must be a written order. The attending physician should ensure appropriate control of symptoms after withdrawal of an intervention and appropriate support of family members at the bedside leading up to and following the death of the patient.
- E. For patients without decision-making capacity the attending physician or designate should inquire about and document review of the following:
 - 1) The existence of current Letters of Guardianship evidencing the appointment of a legal guardian by the Probate Court.
 - 2) The existence of a Durable Power of Attorney for Health Care authorizing an individual to act as patient advocate, that is, to make decisions on the patient's behalf when the patient is no longer capable of making them for himself/herself. By law, the patient advocate cannot make decisions to withhold or withdraw life-sustaining treatment unless the Durable Power of Attorney for Health Care contains a statement that the patient understands withdrawing or withholding treatment could result in death and specifically authorizes the patient advocate to make such decisions. A Durable Power of Attorney for Health Care is binding in Michigan.
 - 3) The existence of a Living Will or other written document expressing the patient's wishes regarding withholding or withdrawing life sustaining treatment that the patient signed when he/she was competent. Although a Living Will is not authorized by statute in Michigan, it does provide evidence of the patient's intentions concerning these matters.
 - 4) Any oral directives that the patient might have given to a family member, friend or other health care provider regarding life sustaining treatment.
 - 5) The patient's philosophical and / or religious beliefs, if appropriate.
- F. If the wishes of the patient without the decision-making capacity cannot be determined, and the attending physician has reason to question whether the surrogate decision maker is acting in the patient's best interest, withdrawing or withholding life-sustaining treatment may be delayed until further appropriate information / consultation is obtained, including consultation with Legal Affairs as appropriate, and consultation with

the Clinical Ethics Consultation Service is encouraged.

- G. An attending physician must document in the incompetent patient's medical record:
- 1) The patient's medical conditions and prognosis,
 - 2) That the attending physician has reviewed any available written Advance Directive, or
 - 3) The discussions that the attending physician has had with the legal guardian, patient advocate or family regarding the patient's condition, prognosis and alternative treatment modalities and
 - 4) Consent of the legal guardian, patient advocate or family to the withdrawal or withholding of life sustaining treatment.
- H. The decision to withhold or withdraw treatment from an Incompetent Patient who is Terminally Ill or Permanently Unconscious must be made by the patient's attending physician, and consultation with others as appropriate is encouraged when there are questions about diagnosis, prognosis, or alternative therapies. A decision to withhold or withdraw treatment should be supported by the other physicians caring for the patient. Their consultation and agreement with the plan to withhold or withdraw treatment should be included in the record. In the event of differences of opinion among the staff, consultation with the Clinical Ethics Consultation Service is encouraged.

Additional Requirements In Withdrawing or Withholding Life Sustaining Treatment From a Minor

- A. Generally, under Michigan law, a person less than age 18 is considered to be a minor whose parents are the principal decision makers regarding medical treatment decisions. However, if the attending physician and parents believe the minor child possesses the maturity to participate in a decision to withdraw or withhold life-sustaining treatment, that participation should be allowed. In assessing the minor child's maturity, the attending physician and parents should consider the factors enumerated in the initial paragraphs of this policy.
- 1) Only an attending physician may order and act upon an order to withdraw or withhold life-sustaining treatment when death is likely to immediately follow (e.g., withdrawal of a ventilator). In such instances the attending physician may not delegate this responsibility to the resident staff and / or nursing staff.
 - 2) If the parents of a minor are divorced or separated and do not agree about a decision to withdraw or withhold life sustaining treatment, the Department of Legal Affairs should be consulted.
- B. Emancipated Minors. An emancipated minor may participate in his / her medical treatment decisions and consent to withdrawing or withholding life sustaining treatment. For this purpose, the emancipated minor is treated as an adult.

A minor, defined as a person less than 18 years of age, is emancipated in each of the following circumstances:

- 1) When a minor is validly married;
- 2) When a minor is on active duty with the United States Armed Forces;
- 3) When the Family Division of Circuit Court has entered an order of emancipation.

An emancipated minor may validly participate in and consent to treatment decisions. Refer to the Sections pertaining to the adult patient (above). **GOVERNING POLICY**

This policy is to be considered the governing policy of Beaumont Hospitals. All previous policies not in conformity with this policy are no longer valid.

SECTION IV: DEATH OF PATIENTS

4.1. DETERMINATION OF DEATH BY NEUROLOGICAL CRITERIA (BRAIN DEATH) (CORPORATE POLICY #317)

This policy will detail the medical practice parameters at Beaumont Hospitals for the determination of death by neurological criteria.

Definition

The Michigan "Determination of Death Act" of 1992 defines death as follows:

An individual, who has sustained either of the following, is dead:

- Irreversible cessation of circulatory and respiratory functions.
- Irreversible cessation of all function of the entire brain, including brain stem.

A determination of death shall be made in accordance with accepted medical standards.

General

1. Death by neurological criteria (Brain death) is diagnosed by clinical criteria, at times supported by ancillary studies as outlined below. Ancillary studies are not required to establish brain death and are *not* a substitute for neurologic examination.
2. Two (2) full clinical neurologic examinations, each including an apnea test, by two different physicians, as outlined below, must be performed and documented on the age-appropriate "Determination of Death by Neurological Criteria" form. The first examination determines that the patient has met the accepted neurologic examination criteria for brain death. The second examination confirms brain death based on an unchanged and irreversible condition.
3. No member of the transplant team and no physician caring for an intended recipient may participate in either exam or certify the patient's death.
4. The decision to certify brain death must be independent of decisions regarding the appropriateness and feasibility of organ or tissue donation.
5. Irreversibility of loss of brain and brain stem functions is recognized when the cause of the patient's unresponsive state is established by clinical evaluation and appropriate investigations, and is sufficient to account for the loss of function of the entire brain. The possibility of recovery is excluded by observation as outlined below and an unchanged second clinical examination.
6. The first brain death examination should be done at least 4 hours after the initial brain insult to allow for stabilization time. In children, assessment of neurologic function may be unreliable immediately following resuscitation after cardiopulmonary arrest or other acute brain injuries. It is reasonable to defer the neurological examination to determine brain death for ≥ 24 hours in children if dictated by the clinical judgment of the treating physician in such circumstances.
7. The recommended observation periods between the first and second examinations are age-specific as outlined below.
8. Ancillary studies are not required to establish brain death except in one of the following situations:
 - a. A portion of the clinical examination, including apnea testing, cannot be fully performed due to the underlying medical condition of the patient.

- b. If a neurodepressant drug alters the clinical examination, in which case a brain perfusion test must be done.
- c. The etiology of coma is not certain or there is uncertainty about the results of the neurologic examination.
- d. To reduce the observation period between the two (2) clinical examinations. In this instance, the second clinical examination is to be performed after the results of the supporting ancillary study are documented in the medical record by the radiologist or by the neurologist, neurosurgeon, or intensivist performing the clinical examination.

If the ancillary study supports the diagnosis, a second clinical examination and apnea test should be performed and components that can be completed must remain consistent with brain death. If the ancillary study is equivocal, a waiting period of 24 hours should be observed before further clinical re-evaluation or repeat ancillary study is performed. Supportive patient care should continue during this time period.

9. Ancillary studies are classified in two categories:
 - a. Brain perfusion tests that include: Conventional four-vessel cerebral contrast angiography, cerebral perfusion scintigraphy, magnetic resonance angiography (MRA), CT angiography (CTA) with CT perfusion, or transcranial Doppler ultrasound. A brain perfusion scan must be done if a neurodepressant drug alters the clinical examination. Conventional four-vessel cerebral contrast angiography is the gold standard for determining absence of cerebral blood flow (CBF). This test can be difficult to perform in infants and children. Radionuclide CBF determinations to document the absence of CBF remain the most widely used brain perfusion scan to support the clinical diagnosis of brain death in infants and children. Radionuclide CBF testing must be performed in accordance with guidelines established by the Society of Nuclear Medicine and the American College of radiology. MRA, CTA, perfusion MRI and transcranial Doppler have not been studied sufficiently nor validated in infants and children and cannot be recommended as ancillary studies to assist with the determination of brain death in children at this time.
 - b. Electroencephalography (EEG) is acceptable if there is no concern about neurodepressant drugs. The EEG should show no electrocerebral activity during a 30-minute period using techniques for brain death examination in accordance with standards established by the American Electroencephalographic Society. The presence of EEG artifacts should not exclude the diagnosis of brain death as long as there is no discernible electrocerebral activity.
10. The two Beaumont Hospital forms "Determination of Death by Neurological Criteria – Adults" (form #4695) and "Determination of Death by Neurological Criteria – Pediatrics" (form #9) must be consistent with this policy and should include documentation of the cause of coma and results of any ancillary studies if performed.
11. The documented CPR status will be followed during the neurological examinations for determination of brain death as discussed with the family or next of kin.
12. Brain death is not the only circumstance in which termination of artificial life support is medically appropriate (See: Guidelines for Withdrawing or Withholding Life Sustaining Treatment, policy #307).

Age-Specific Requirements

Adult patients (18 years of age or older)

Only a neurologist, neurosurgeon or intensivist may perform the brain death examination.

1. Recommended observation periods between the two examinations are:
 - 6 hours for direct structural cerebral damage (intra-cerebral hemorrhage, stroke, trauma, etc.)
 - 12 hours for non-direct, non-structural cerebral damage (hypoxic-ischemic encephalopathy).
2. Ancillary studies are optional and not required to establish brain death unless:
 - A portion of either of the two (2) required clinical examinations, including apnea testing, cannot be fully performed due to the underlying medical condition of the patient.
 - The clinical examinations are altered by a neurodepressant drug, in which case a brain perfusion test is required.
 - The etiology of the coma is not certain or there is uncertainty about the results of the neurologic examination.
 - To reduce the observation period between the two (2) examinations. In this instance, the second clinical examination is to be performed after the results of the supporting ancillary study are documented in the medical record by the radiologist or by the neurologist, neurosurgeon, or intensivist performing the clinical examination.

If applicable, documentation of the need for, as well as the results of, the ancillary study performed must be included on the "Determination of Death by Neurological criteria – Adults" (form #4695)

Pediatric patients (less than 18 years of age)

Only a neurologist, neurosurgeon, intensivist, or neonatologist may perform the brain death examination.

1. Determination of brain death in term newborns (37 weeks gestational age), infants and children is a clinical diagnosis based on the absence of neurologic function with a known irreversible cause of coma. Two (2) examinations, including apnea testing with each examination, separated by an observation period are required.
2. Recommended age-specific observation periods between the two examinations:
 - Term newborns (37 weeks gestational age) to 30 days of age: 24 hours
 - Infants and children >30 days to 18 years of age: 12 hours
 - Adults (18 and older): 6 hours for direct, structural cerebral damage (intra-cerebral hemorrhage, stroke, trauma, etc.) and 12 hours for non-direct, non-structural cerebral damage (hypoxic-ischemic encephalopathy).
 - The first examination determines the patient has met the accepted neurologic examination criteria for brain death. The second examination confirms brain death based on an unchanged and irreversible condition.
 - Assessment of neurologic function following cardiopulmonary resuscitation or other severe acute brain injuries in children should be deferred for 24 hours or longer if there are concerns or inconsistencies in the examination.
3. Ancillary studies are optional and not required to establish brain death unless:
 - A portion of the clinical examination, including apnea testing, cannot be fully performed due to the underlying medical condition of the patient.

- The clinical examination is altered by a neurodepressant drug, in which case a brain perfusion test is required.
- The etiology of the coma is not certain or there is uncertainty about the results of the neurologic examination.
- To reduce the observation period between the two (2) examinations. In this instance, the second clinical examination is to be performed after the results of the supporting ancillary study are documented in the medical record by the radiologist or by the neurologist, neurosurgeon, intensivist, or neonatologist performing the clinical examination.

If applicable, documentation of the need for, as well as the results of, the ancillary study performed must be included on the "Determination of Death by Neurological Criteria – Pediatrics" (form #9)

Clinical Criteria for Determination of Brain Death in Adult and Children

Clinical Criteria Relating to Determination of Brain Death

1. The proximate cause of the patient's unresponsive state should be established, should be sufficient to account for the loss of brain and brain stem functions, and should be irreversible.
 - a. Reversible conditions should be excluded, such as:
 - Acute intoxication or poisoning.
 - Severe electrolytes, acid-base, or metabolic disorders.
 - Severe hypothermia, 32° C (90°F) or lower.
 - Severe hypotension (< 5th percentile for age for children or systolic blood pressure < 90 mm Hg for adults).
 - Cardiogenic shock
 - Administration of neuromuscular blocking agents.
 - Administration of high dose sedatives, hypnotics, anesthetics or barbiturates for control of elevated intracranial pressure or status epilepticus.
 - Presence of reversible peripheral neuropathy (i.e. Guillain-Barre).

If any of the above conditions exist, they should be treated and corrected prior to the initiation of brain death examinations.
 - b. A clinical diagnosis of brain death can be made in patients who received sedatives, hypnotics, anesthetics or barbiturates if:
 - Drug levels (e.g. barbiturates) are in the therapeutic range and below clinically-significant neurodepressant levels, or
 - At least four times the elimination half-life of the medication has elapsed, or the effect of the medication was reversed.
 - In the case of a patient receiving a neuromuscular blocking agent, the peripheral nerve stimulation test is normal.

Clinical Examination Criteria

1. A core body temperature of ≥ 35 degrees Celsius (95 degrees Fahrenheit) should be achieved and maintained during examination and testing to determine brain death.
2. Coma characterized by absence of spontaneous or induced cerebral motor response to painful stimulation that is applied within the *cranial nerve* distribution. Decerebrate and decorticate responses or seizures are absent.
3. Absence of pupillary light reflexes (fixed pupils) and the pupil size is mid-position (4mm) or dilated (up to 9mm).

4. Absence of corneal reflexes.
5. Absence of spontaneous eye movements.
6. Absence of eye movements in response to vestibular stimulation by cold caloric testing (50 ml ice water each side; 5 minute interval between sides).
7. Absence of eye movements in response to oculoccephalic reflex testing.
8. Absence of gag reflex in response to stimulation of posterior pharynx.
9. Absence of cough reflex in response to deep bronchial suctioning.
10. Absence of spontaneous respiration at a $pCO_2 \geq 60$ mmHg and an increase in pCO_2 of ≥ 20 mmHg above pre-apnea test level. Evident respiratory acidosis at the completion of the apnea test. The apnea test should be done using the apneic diffusion oxygenation technique to prevent hypoxia performed with a 10cmH₂O peep valve. The body temperature should be at 35°C or higher before the apnea test. The patient should be monitored during the exam with an arterial line. The certifying physician must continuously observe the patient for any respiratory effort throughout administration of the test.

Clinical Observations Still Compatible with the Diagnosis of Brain Death

These manifestations are occasionally seen and should not be misinterpreted as evidence for brain stem function.

1. Spontaneous 'spinal' movements of limbs (not to be confused with pathologic flexion or extension response)
2. Respiratory-like movements (shoulder elevation and abduction, back arching, intercostals expansion without significant tidal volumes)
3. Sweating, blushing, tachycardia
4. Normal blood pressure in the absence of pharmacologic support
5. Absence of diabetes insipidus (i.e. normal osmolar control mechanism)
6. Deep tendon reflexes, triple flexion responses or Babinski's reflex, all of which may be spinally-mediated reflexes
7. Facial myokymias

Certification of Death by Neurological Criteria

1. The two physicians who perform the neurological examinations for determination of brain death must:
 - a. Document their findings on the age-appropriate "Determination of Death by Neurological Criteria" form.
 - b. They should document the cause of the coma, the reasons for and the results of any ancillary studies, if performed. They should document the date and time of each clinical examination and sign the form.
 - c. Upon confirmation of brain death following two (2) documented clinical examinations for determination of death by neurological criteria, a No CPR / Do Not Call the CPR Team order will be written in the medical record. If the patient is a consented organ donor and family has consented to full CPR status for the purpose of keeping the organs viable, this will be documented in the medical record.
2. If the patient's condition is within the described criteria, the patient is pronounced dead by the physician who performed the second clinical examination. The date and time of death are the date and time of completion of the second clinical examination. The

completed form must be entered in the patient's medical record.

3. The pronouncing physician must inform the family or the next of kin that the patient has died. Mechanical ventilation and other supportive measures should be withdrawn unless organ donation is requested (see policy 311 "Anatomic Gift Requests") or there are other documented reasons for maintaining ventilatory support for a brief time, except in rare cases not to exceed 24 hours. If the patient's family objects to the use of neurological criteria for death, an Ethics Consultation should be requested before withdrawal of life support.

4.2. ANATOMIC GIFT REQUESTS (CORPORATE POLICY #311)

State Statute for Donation of Anatomical Gifts

The next of kin of any decedent with organ(s), tissue or body suitable for medical school study or organ transplantation must be asked to consent to a gift of all or any physical part or the decedent's body, unless the decedent or the next of kin has previously indicated opposition to organ, tissue, or body donation.

Organ and Tissue Procurement Agreement

Beaumont Hospital utilizes the services of the Gift of Life (GOL) and the Midwest Eye-Banks (MEB) to facilitate compliance with related statutes and regulations, and to assist with identification of potential organ and tissue donors. GOL must be promptly notified of all deaths or imminent deaths. The GOL Procurement Coordinator, accompanied by appropriate Hospital staff, will request consent by potential donors' families for organ donation; and under medical supervision, will assist in conducting or directing all necessary donor evaluation and supportive care; will coordinate the recovery of organs, tissues, and corneas / eyes by qualified surgical teams; and will arrange for the preservation and distribution of organs, tissue, and corneas to transplant centers.

Only designated requesters at the Hospital may request consent to the donation of tissue or corneas. A designated requester is an individual who has been trained and certified by GOL and / or MEB, as applicable to approach families for the purpose of obtaining consent to organ, tissue and cornea donation.

Organ and Tissue Donation Committee

A hospital may establish an Organ and Tissue Donation Committee to meet regularly to monitor and evaluate related issues. Organ and tissue donation protocol(s) may be obtained from any such the committee.

4.3. AUTOPSY PROCEDURES

Because the information from autopsies is an essential part of medical education and the advancement of knowledge, every member of the Staff shall use best efforts to secure permission for an autopsy on any patient who dies in the Hospital. All autopsies shall be performed by a hospital pathologist or by a physician to whom the duty may be delegated, or a qualified pathologist assistant directly supervised by a pathologist, but no autopsy shall be performed without written consent of the next of kin. Please contact the Chair of the Autopsy Service (248-898-9060) at Royal Oak or the Chief of Pathology and Laboratory Medicine Department (248-964-4100) at Troy, or (313-343-1615) at Grosse Pointe for any specific questions concerning the autopsy protocol.

Autopsy Consent Procedure

Written consent for autopsy must be obtained by the attending physician or designate from the person who is the legal custodian of the body and responsible for its proper disposal. The right to grant permission for autopsy rests with the next of kin. Definition of next of kin is in the following order of priority:

1. Surviving spouse
2. Adult children (one should be certain that there is no disagreement between the surviving children).
3. Surviving parents
4. Siblings and their descendants
5. Grandparents
6. Uncles and aunts
7. Cousins

If there is more than one survivor of equal degree of kinship, one signature is sufficient if the survivor who signs the permission form is also the one who assumes custody of the body for purposes of burial. All adult children have equal rights, and the eldest has no prerogative in this regard. If the next of kin cannot come to the Hospital to sign the permission form, he or she can grant permission for autopsy by telegram / FAX. Oral permission (e.g. by telephone) is not acceptable unless confirmed by telegram / FAX.

A separated but not divorced spouse is still considered next of kin and may give consent if he/she assumes responsibility for burial. A divorced spouse has no claim by kinship on the body. Unless the next of kin has been declared legally incompetent by the Probate Court, he/she shall be permitted to sign the autopsy permit. Common-law partners have no legal standing as next of kin. A friend who assumes responsibility for burial has no legal authority to grant permission for an autopsy.

Major relatives of deceased minors (under 18 years of age) are considered next of kin in the following order of priority:

1. Surviving husband or wife (if under 18 years of age, right to grant autopsy permission is inherent because he or she is then an emancipated minor).
2. Parents (one should be certain that there is no disagreement between the surviving parents).
3. Legal guardian
4. Brothers and sisters
5. Grandparents
6. Uncles and aunts

Autopsy Restriction

"No restrictions" on the autopsy permit means that the pathologist may remove or examine all parts of the body, as indicated medically to determine the cause of death or the nature of the disease. Restrictions specified by the family should be listed on the autopsy permit (e.g. "examination limited to thorax and abdomen").

Autopsy - General Policies

There is no charge for autopsies on patients who die after being admitted to the Hospital.

Autopsies are not performed routinely on patients who are dead on arrival (DOA) and who have not recently been hospitalized at Beaumont. Special permission for an autopsy on

such patients should be obtained from the pathologist on duty before any promises are made to the family members.

No promises should be made to families or undertakers regarding time of release of body without first consulting the pathology department. Also, no promises should be made regarding direct reporting of findings by the pathology department to families. Reports will be sent routinely to the physician of record.

Autopsy Permit for Stillborn Fetuses and Newborns

Consent for autopsy must be obtained from the parents of newborn infants who die after birth in the Hospital. There should not be disagreement between parents. Newborns, regardless of size, will receive a complete postmortem examination. Pertinent clinical information must be provided. Stillborns of 21 weeks gestation (greater than 20 full weeks) or, if gestational age is unknown, less than 400 gm. will also receive appropriate gross and microscopic examination. Autopsy consent, burial transit permit and fetal death certificates must be obtained. Pertinent clinical information should be provided.

Embryos and immature fetuses (less than 20 full week's gestation) are processed as routine surgical pathology specimens unless the parents request, in writing, that no examination or only limited external examination be performed.

Karyotyping is not considered to be a part of the autopsy. It must be requested by the clinician with a proper request form. A fee for cytogenetics will be charged.

Guidelines for Requesting Autopsy

The following guidelines have been developed for physicians to follow when considering which patients should be autopsied:

1. Deaths in which an autopsy may help explain unknown and unanticipated medical complications.
2. Death in which the cause is not known with certainty on clinical grounds.
3. Cases in which an autopsy may help allay concerns of the family and / or the public regarding the death, and provide reassurance to them regarding the same.
4. Deaths occurring in patients who have participated in clinical trials (protocols) approved by institutional review boards.
5. All obstetric deaths.
6. All neonatal and pediatric deaths
7. Deaths at any age in which it is felt that autopsy would disclose a known or suspected illness that may also have a bearing on survivors or recipients of transplant organs.
8. Deaths known or suspected to have resulted from occupational or environmental hazards.
9. Sudden, unexpected, or unexplained deaths in the Hospital that were apparently natural and not subject to a forensic medical jurisdiction.
10. Unexpected or unexplained death occurring during or following any dental, medical, or surgical diagnostic or therapeutic procedure.
11. Natural deaths that are ordinarily subject to a forensic jurisdiction, such as deaths in which the patient sustained or apparently sustained an injury while hospitalized.
12. Deaths of organ / tissue transplant recipients who have received a non-living related transplant within 60 days prior to death.
13. Cases of special interest to either the family or attending physician.

Hours of Operation

Autopsies are performed daily until 3pm (1pm on weekends) at Royal Oak and Grosse Pointe, and until 11:00 a.m. daily at Troy. Later requests are performed the next day, except under unusual circumstances.

4.4. MEDICAL EXAMINER CASES (SEE FULL CORPORATE POLICY #495)

Deaths of all persons who die as the result of accidents, violence or suspected foul play, or who have not been seen by a physician during the previous 48 hours, must be reported to the Oakland County Medical Examiner's Office (phone 248-858-5097), for deaths at Royal Oak or Troy, and to the Wayne County Medical Examiner' (phone 313-833-2569) for deaths at Grosse Pointe, and the full details presented to him for his consideration. If the Medical Examiner relinquishes authority in the case, an autopsy permit can then be obtained from the next of kin and an autopsy performed by the Hospital, guided by the usual considerations. The denial by the Medical Examiner's office should be noted on the chart, including the name of the medical examiner or his representative, the time and date of such denial, along with a brief explanatory statement.

Cases reportable to the Medical Examiner include:

- death by violence (stabbing, shooting, drowning, falls, etc.)
- prisoner (dying while in custody)
- accidental deaths (autos, burns, drowning, falls, etc.)
- deaths under suspicious circumstances (including unidentified persons)
- deaths resulting from administration of drugs
- deaths occurring in operating room, therapeutic procedures, anesthesia, etc.,
- sudden and unexpected deaths from causes unknown (where deceased was in apparent good health, i.e.: SIDS, or in restraint or seclusion with no apparent cause of death)
- a person who has not been seen by a physician within 48 hours prior to death
- any death within 24 hours of admission (Wayne County / Grosse Pointe only)

A person, however, who has been seen by a physician within 48 hours of death is not a Medical Examiner's case, unless the death falls within one of the categories enumerated above.

In case of chronic illness, a physician need not have been in attendance within 48 hours prior to death if he can be reasonably certain that death resulted from the chronic illness; however, he should examine the body before signing the death certificate to satisfactorily determine that no other complicating disease or foul play caused death.

In any Medical Examiner's case, a body may not be removed until after notice of death is given to, and permission for removal given by, the Medical Examiner.

Failure to give proper notice to the Medical Examiner is a misdemeanor, punishable by law. In the case of doubt, report to the Medical Examiner for his determination.

SECTION V: RESEARCH

The Research Institute (RI) at Beaumont Hospitals (BH) has the obligation and duty to protect patients, research participants, staff, protected health information (PHI) and data generated from performance of research associated with BH facilities. The authority of the RI is established by the RI Bylaws, which outline RI's purpose and responsibilities and are approved by RI Board of Governors and BH Board of Directors. The Physician-in-Chief and Vice President of Research serves as the Institutional Official (IO) for the Human Investigation Committee (HIC) and Animal Care Committee (ACC). The departments within Research Administration, including the Offices of the Medical and Administrative Directors, Research Accounting, Research Compliance, Research Education and the Clinical Research Quality & Process Improvement Program, Grant Development, and the Research Oversight Committees (HIC, ACC, Biosafety Committee, Research Institute Compliance Committee) work together to provide oversight and advise investigators and staff on matters of compliance, assurance of human subject protection, animal welfare, and research integrity in order to assure the highest standards in research conduct are maintained.

Research Administration Approval of Research Projects

All research projects at BH, regardless of type (clinical, animal, bench or outcomes) and funding source, must be given final approval by Research Administration. No research project may begin without this approval.

The Offices of the Medical and Administrative Directors

The Physician-in-Chief and Vice President (VP) of Research serves as the IO for the HIC and the ACC. The IO signs, on behalf of BH, the Federal Wide Assurance (FWA) committing to comply with federal regulations for human subjects research (45 CFR 46) and the Animal Welfare Assurance (AWA) committing to comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. The Medical and Administrative Directors of the RI, and the Director of Research Finance, are the Authorized Signatories for all contracts and confidentiality disclosure agreements and grant proposal submissions for BH. For more information, contact the RI Medical Director at 248-551-8550 or the RI Administrative Director at 248-551-1105.

HIC Oversight of Human Subjects Research Projects

Health and Human Services (HSS) and the Food and Drug Administration (FDA) regulations mandate all research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) prior to implementation of the research. The oversight shall include, but is not limited to, ethical, scientific, and financial issues. The Human Investigation Committee (HIC) serves as the BH's IRB of record. BH adheres to 45 CFR 46 Subpart D and does not allow enrollment of prisoners into research trials.

The level of HIC review a research project will undergo is based on the type of research project submitted. The HIC will determine the level of review once the submission is received. The criteria for initial HIC review includes determining the level of risk to participants, the potential benefits, the informed consent and authorization process, use of PHI, and safeguarding the subject. The types of HIC review include:

- Exempt review
- Expedited review
- Full board review

The HIC will conduct continuing review of research at intervals appropriate to the degree of risk involved in the study, but not less than once per year, and will have authority to observe, or have a third party observe, the consent process and the research being conducted. Any changes to the research protocol must be reported to, and approved by, the HIC prior to the change being implemented. The only exception is a change necessary to eliminate apparent immediate risk or injury to study subjects. The HIC will also review reports of Unanticipated Problems, Protocol Deviations, and Data Safety Monitoring Boards, and will conduct periodic audits of individual studies to ensure the safety and welfare of subjects and appropriate study record maintenance.

Scientific Evaluation

Before the HIC can review a protocol involving the use of human participants in research, the protocol must be reviewed for scientific merit by the principal investigator's department. Departments may conduct scientific review in different ways. The Department Chief must certify by signing the HIC Application Form that a scientific review has been completed. In addition to scientific review, the department is responsible for certifying appropriate support will be provided to conduct the study.

HIC oversight is required of all individuals and projects considered to be "engaged in research." For additional information on study submission requirements, including information on Exempt and Quality Assurance / Quality Improvement projects, contact the HIC Office at 248-551-0662, or review the HIC policy listing available on the RI website at Inside Beaumont.

HIPAA and Research

The Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) have made provisions to the Health Insurance Portability and Accountability Act (HIPAA) that establish the conditions under which protected health information may be used for research. In order to protect patient confidentiality rights when patient information is viewed via charts, computer databases or other recorded information sources when developing protocols or recruiting and locating potential subjects, a Waiver of Authorization must be approved, in advance, by the HIC. The Waiver of Authorization form is available on the RI website at Inside Beaumont.

Research data generated from research conducted at Beaumont, whether identifiable or de-identified, belongs to Beaumont. Investigators are not authorized to remove research data from Beaumont.

Research data including any form of Protected Health Information (PHI) may not be shared outside of Beaumont without prior authorization from subject informed consent(s) or an approved Limited Data Use Agreement between Beaumont Research Institute and the recipient. For more information contact Chair, Human Investigation Committee, 248-551-0662 or Manager of Human Investigation Committee, 248-551-0653.

ACC Oversight of Animal Care and Use

The ACC oversees all aspects of live animal activities on Beaumont Hospitals premises. The Committee assures the humane care, use and treatment of animals according to the standards and regulations of the United States Department of Agriculture Animal Welfare Act. All research and education involving live animals must be reviewed and approved by the ACC before the animals are requested and prior to the initiation of any other activities. For additional information on animal study submissions requirements, contact the ACC Office at 248-551-0666, or review the available policies on the RI website at Inside Beaumont.

Pre-Clinical Research

All pre-clinical (bench) research must be reviewed by the Physician-in-Chief and Vice President of Research, prior to project initiation. For further information, contact Research Administration at 248-551-8550 or 248-551-1105.

Research Accounting

Each research project must have a budget prepared and approved by Research Accounting, regardless of funding source. For unfunded studies, a budget must be prepared with all of the true costs to the Hospital identified. Budgeted expenses for unfunded studies must receive approval from the appropriate Department Chief and Research Administration. For externally sponsored studies, there must be a clinical trial agreement negotiated with the study sponsor by Research Accounting and a representative of Legal Affairs. All research funding must be directed through the Research Institute. As part of the budget process, Research Accounting staff is also responsible for identifying any non-Division 08 personnel who will be working on a study and ensuring that approval is given by the appropriate Hospital Administrators in order for the staff to participate. Questions may be directed to the Director of RI Financial Services, 248-551-2476.

Research Patient Billing

The Research Institute is committed to appropriately billing all patient care provided as part of research participation. Research Billing Coordinators are responsible for receiving and tracking grant forms related to patient visits, processing research charges through the Hospital billing system and conducting research billing compliance audits. For more information, contact the Director of Research Regulatory and Billing, 248-551-7366 or Research Patient Billing Coordinators, 248-551-2132.

Research Compliance Committee (RICC)

The RICC shall provide oversight and review of research activities to assure their conduct adheres to applicable legal and financial guidelines. All investigators and their research projects are subject to Federal and local regulations in addition to the Research Institute policies and procedures. The RICC is responsible for developing and updating the Research Institute Compliance Plan. The plan is designed to assure compliance with the regulations, policies and procedures and includes the review and management of key personnel Conflict of Interest Disclosures and the monitoring of educational strategies and activities. For more information, contact the Director of Research Regulatory and Billing, 248-551-7366.

Research Education and the Clinical Research Quality and Process Improvement Program (CRQIP)

Because of the many regulations and potential risks associated with research and the Research Institute's commitment to ensuring the protection of our research subjects, all investigators and key personnel must complete the applicable mandatory education requirements as determined by Research Administration. Examples of mandatory education include Human Subjects Protection ("Collaborative Institutional Review Board Training Initiative" or "CITI" on-line training), Packaging and Shipping of Laboratory Specimens, Research Compliance, Research Patient Billing, Research Services, etc.

Audits and monitoring visits of clinical research studies are conducted under the CRQIP. These audits are conducted to assure studies are conducted in accordance with Federal regulations governing human subjects research, good clinical practices and Beaumont Hospitals RI policies for the purposes of identifying areas for process improvement. Audits

are conducted routinely as part of the RI Compliance Plan, in response to concerns raised by the HIC or RICC and as part of special monitoring foci. The principal investigator of each investigator-initiated research project is required to contact CRQIP monitors after the enrollment of the first subject. For further information, contact the Administrative Nurse Manager of Research Education and Process Improvement, 248-551-1535.

Grant Proposals

Beaumont requires that all proposals, pre-proposals, concept papers, letters of intent, contracts and subcontracts submitted to external agencies requesting funds and / or committing Hospital resources (e.g., personnel, space, funds, equipment and facility use, etc.) for the purpose of research activities, be reviewed and approved by the RI Authorized Signatories prior to submission, even when the sponsoring agency allows direct electronic submissions from the investigator. In order to obtain RI approval, a copy of the complete and final proposal must be submitted to the RI Grants Development Representative at least five (5) business days prior to the sponsor's deadline. For additional information, contact the RI Grants Development Manager, 248-551-5071.

Biosafety Committee

The Biosafety Committee assures safe and ethical use of recombinant DNA molecules and potentially infectious or toxic agents in research at Beaumont. Any investigation involving DNA or potentially pathogenic organisms must be evaluated and approved by the Biosafety Committee prior to approval by the HIC or ACC, and if required, by appropriate State or Federal regulatory agencies prior to implementation. For further information please refer to the policy entitled "Gene Therapy Research #214" available on the RI website at Inside Beaumont. Information and submission requirements of the Biosafety Committee can be obtained by contacting the Chair of the Biosafety Committee at 248-551-3170 or 248-551-2560.

SECTION VI: MEDICAL / HOSPITAL ADMINISTRATION RULES & POLICIES

6.1. ACTIVITY GUIDELINES

Minimum Meeting Attendance Guidelines

As defined in the Bylaws, each member of the Staff (except Emeritus-Retired, Honorary-Consulting, Pediatric Newborn Associate and Affiliate Staffs) is expected to attend one of the three regular Staff Meetings at the Hospital(s) where they hold Staff Membership. In addition, all Members of the Attending and Associate Staffs are strongly encouraged to attend 50% of the meetings designated as required by their respective Department or Section. Attendance at meetings of another Beaumont Hospital staff will not fulfill these requirements. Attendance at a specially arranged Joint Meeting can be used to fulfill these requirements.

Minimum Hospital Activity Guidelines

To provide a basis for assessing the quality of physician practices all members of the Active Staff (Attending and Associate categories) shall be expected to have a minimum of twelve (12) Hospital admissions, consultations, or operative / invasive procedures (inpatient / outpatient) per twelve (12) month period

Exception: Members of the Attending or Associate Staffs in the Departments of Allergy, Dermatology, and Psychiatry shall be required to have only six (6) Hospital admissions, consultations, or procedures per year.

Exception: Members of the Ambulatory Staff are expected to have at least six (6) patients per year admitted to Beaumont Hospitals with inpatient care provided by their designated hospitalist. This will allow a quality assessment to be performed by the Physician Practice Assessment Service of specific outpatient records of patients admitted to the Hospital.

Those physicians who are members of the Attending or Associate Staffs of more than one of the Beaumont Hospitals may meet the minimum Hospital activity guidelines by a combined total of the above described activity at any of the Beaumont Hospitals.

Reappointment Considerations

Attendance at Department and Section Meetings will be one of the criteria considered in connection with applications for reappointment to the Medical Staff. Non-participation may result in modification of the Staff member's clinical privileges.

Hospital activity guidelines will be used as one of the criteria for reappointment to the Medical Staff and / or modification of clinical privileges. Physicians not meeting Hospital Activity Guidelines may, at the Department Chief's discretion, undergo a quality assessment process equivalent to the usual review of inpatient admissions, consultations or procedures. This equivalent review may entail a review of outpatient records.

Members of the Ambulatory Staff must undergo review of at least six (6) office records of patients admitted to Beaumont Hospital in the previous two years and demonstrate improved compliance with any previously cited office assessment deficiencies.

6.2. COMMUNICATION OF MEDICAL STAFF POLICIES AND CREDENTIALING MATERIAL

In order to promote rapid, reliable and comprehensive delivery of key information salient to credentialing matters and patient care, each physician and mid-level provider (employed and private) will be provided with an Outlook e-mail account. Each physician and mid-level provider shall be responsible for the matters and information delivered to that account by Medical Administration and Central Credentialing and for checking it at least once every seven days.

6.3. DISASTER PLAN / DISASTER ASSIGNMENTS

The Hospital will maintain a written plan for the care of mass casualties coordinated with the Inpatient and Ambulatory Services of the Hospital, which may be modified. All members of the Attending Staff, Associate Staff and House Staff must fulfill Staff disaster assignments. Failure to fulfill this assignment will be reported to the Medical Executive Board and may be grounds for declining reappointment to the Staff.

6.3.1. PROTOCOL FOR ALLOCATION OF SCARCE CRITICAL CARE RESOURCES

Please see Infection Control Corporate Policy #3.6 for guidance about allocation of scarce critical care resources during a pandemic influenza emergency when it is determined that a state of emergency exists requiring an alternate standard of care. In such an emergency, declared by a competent authority under Beaumont's Emergency Operations Plan, patients with the best chance of survival through the use of medically necessary scarce resources will have the highest priority for access to those resources. A mechanism for determining this priority can be found in the above-mentioned policy.

6.4. IDENTIFICATION BADGES

It is imperative that physicians and Mid-level Providers wear their identification badges while reviewing patient charts and while visiting patients, so that they may be readily identified as physicians or Mid-level Providers by other Hospital staff.

6.5. INFORMATION SECURITY (SEE FULL CORPORATE POLICY #358)

6.6. CODE OF BUSINESS AND ETHICAL CONDUCT (SEE FULL CORPORATE POLICY #350)

6.7. PHYSICIAN HEALTH

Matters Relating to Physician Health Are Separate From the Medical Staff Disciplinary Function

Beaumont has an obligation to protect patients from harm, and accordingly the Medical Staff, approves the development of an improved process / program that will provide education about physician health, address prevention of physical, psychiatric, or emotional illness. This process/program will also facilitate the means to obtain confidential diagnosis, treatment, and rehabilitation of physicians who may suffer from a potentially impairing condition

The purpose of this process / program will be to assist and rehabilitate, rather than discipline, to aid a physician in retaining or regaining optimal professional functioning, consistent with protection of patients. If, at any time, during the diagnosis, treatment, or rehabilitation phase of the process it is determined that a physician is unable to safely

perform the privileges he or she had been granted, the matter will be forwarded to the Medical Executive Board leadership for handling and follow up.

The following elements are to be addressed:

1. Education of the Medical Staff and other organization staff about illness and impairment recognition issues specific to physicians;
2. Self-referral by a physician and referral by other organization staff;
3. Referral of the affected physician to the appropriate professional internal or external resources for diagnosis and treatment of the condition or concern;
4. Maintenance of the confidentiality of the physician seeking referral or referred for assistance, except as limited by law, ethical obligation, or when the safety of a patient is threatened;
5. Evaluation of the credibility of a complaint, allegation, or concern;
6. Monitoring of the affected physician and the safety of patients until the rehabilitation or any disciplinary process is complete; and
7. Reporting to the Medical Staff leadership instances in which a physician is providing unsafe treatment.

In Michigan, the Health Professional Recovery Program (HPRP) was established by the Legislature in 1993 to meet the needs of health professions for a confidential, non-disciplinary approach to support recovery from substance abuse/chemical addiction or mental illness. The HPRP is designed to encourage impaired health professionals to seek a recovery program before their impairment harms a patient or damages their careers through disciplinary action. The HPRP is supported by the licensing boards, as well as professional societies and associations throughout the State. The HPRP is administered by a private contractor under the direction of the Health Professional Recovery Committee (a multi-disciplinary committee) and the Office of Health Services in the Michigan Department of Consumer & Industry Services. Beaumont has had an excellent working relationship with this Program since its inception.

6.8. PROFESSIONAL CONDUCT POLICY

Objective

A good working relationship among all members of the health care team is necessary in order to provide and maintain quality patient care. The relationship among members of the Medical Staff and with professional and non-professional personnel must reflect mutual respect in order to avoid threats to patient care and disruption of Hospital operations.

Policy

Members of the Medical Staff shall strive to achieve a professional environment in which all Staff members and Hospital employees are treated with respect. Disruptive or inappropriate behavior by a Staff member that impedes the harmonious interaction of health care personnel at Beaumont Hospital is unacceptable. Any Staff member or Hospital employee who observes disruptive or inappropriate behavior by a Staff member may report the incident to his or her immediate supervisor or Medical Administration. Disruptive or inappropriate behavior by a Staff member may result in disciplinary action.

Definitions: Appropriate / Disruptive / Inappropriate Behavior

"Appropriate behavior" means any reasonable conduct to advocate for patients, to recommend improvements in patient care, to participate in the operations, leadership or

activities of the organized Medical Staff, or to engage in professional practice including practice that may be in competition with the Hospital.

“Disruptive behavior” means any abusive conduct including sexual or other forms of harassment, or other forms of verbal or non-verbal conduct that harms or intimidates others to the extent that quality of care or patient safety could be compromised.

“Inappropriate behavior” means conduct that is unwarranted and is reasonably interpreted to be demeaning or offensive. Persistent, repeated inappropriate behavior can become a form of harassment and thereby become disruptive, and subject to treatment as “disruptive behavior.”

Disruptive or inappropriate behavior includes, but is not limited to, the following:

1. Verbal comments or physical gestures directed at Staff members or Hospital personnel or others, which exceed the bounds of fair criticism or professional comment, including profane language or non-constructive criticism;
2. Verbal comments directed at Staff members, Hospital personnel, patients or others, which a reasonable person would find to be threatening, belittling or intimidating, or behavior that suppresses input by other members of the health care team;
3. Unsolicited physical contact, or threats of physical contact, throwing objects or otherwise acting with violence toward Staff members or Hospital personnel, patients or others;
4. Written comments or illustrations in patient medical records or other official documents (except incident reports and other mechanisms established by the Hospital for documenting and resolving complaints and problems) impugning the quality of care being provided, or impugning the character of Staff members or Hospital personnel or others are inappropriate;
5. Sexual harassment, innuendo or improprieties;
6. Rudeness or a refusal to respond to questions or requests regarding patient care;
7. Negative or disparaging comments to patients, or patients’ family members, Hospital personnel or others about the character or professional capabilities of Staff members or Hospital personnel;
8. Negative, disparaging, or degrading comments to Staff members, Hospital personnel, patients or patient family members or others, including such comments regarding their ethnic or racial background;
9. Failure to adequately address safety concerns or patient care needs expressed by another member of the health care team;
10. Deliberate failure to adhere to organizational policies without evidence to support an alternative;
11. Retaliation against any member of the health care team who has reported a violation of the any law, regulations, Medical Staff Bylaw, or Hospital Rule, Regulation or Policy or who is participating in an investigation of the same.