

# Greater New Orleans Surgery Center

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## MEDICAL DEVICE PROBLEM REPORTING FDA REQUIREMENTS

Page 1 of 2

Reviewed: August 1, 2001

8/1/03, 6/24/08, 05/01/09

Implemented: August 1, 2001

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**SUBJECT:** Medical device problem reporting – FDA requirements.

**PURPOSE:** Federal regulations require the reporting of medical device problems encountered in various facilities, including ambulatory surgery facilities (referred to as user facilities by the FDA).

**SCOPE:** Administrator or designee.

**DEFINITIONS:** Reportable event.

- A. A “reportable event” refers to an event for which a person has received or become aware of information that reasonably suggests that there is a probability that a device has caused or contributed to a death, serious injury, or serious illness.
- B. What constitutes “serious illness or injury?”
  - a. Is life threatening.
  - b. Results in permanent impairment of a body function or permanent damage to the body structure.
  - c. Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
- C. What does “permanent” mean?

“Permanent means nonreversible impairment or damage.
- D. What does “device” mean?

The Food, Drug and Cosmetic Act defines the term “device” as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory.

**POLICY:** In compliance with the Safe Medical Devices Act of 1990 and subsequent related regulations, the contact person at the surgery center shall be the Administrator for related correspondence related to user facility reporting. In the event of the absence of the Administrator, the Clinical Manager shall be responsible.

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## MEDICAL DEVICE PROBLEM REPORTING FDA REQUIREMENTS

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PROCEDURE: REPORTING EVENTS CAUSING SERIOUS INJURY, ILLNESS OR DEATH.

- A. In the event of a medical device failure or complication involving serious injury, illness or death, an incident report and regulatory report will be completed. The corporate Risk Management Department will review all incident reports.

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# Greater New Orleans Surgery Center

## ADVERSE DRUG REACTIONS

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Reviewed: August 1, 2001

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SUBJECT: Adverse drug reactions.

PURPOSE: To provide a safe environment for patients under the care of personnel of the Surgery Center.

SCOPE: Perioperative staff and physicians.

POLICY: The nursing staff at Greater New Orleans Surgery Center will provide quality care by being aware when adverse drug reactions occur and respond appropriately.

### PROCEDURE:

#### A. General information:

Adverse drug reactions are unwanted and unintended effects of a drug on a patient. The unintended effect may be harmless or it may directly result in a fatality. Adverse drug reactions may be caused by:

1. Idiosyncrasy.
2. Hypersensitivity.
3. Allergy.
4. Overdose.
5. Administration of wrong drug.
6. Potentiation of a chemically reactive combination of drugs.
7. Administration at improper intervals.

#### B. Management:

There are many ways in which drugs may react in the patient to produce unpredictable, unforeseen, harmful and sometimes unexplainable responses. If such an adverse reaction occurs, the following steps should be taken:

1. General:
  - A. Stop the drug immediately if possible.
  - B. Assess airway patency, level of consciousness, vital signs and any other reactions.

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## ADVERSE DRUG REACTIONS

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- C. Notify the physician/anesthesiologist/Clinical Manager immediately of the type of drug, reaction and current status of the patient.
- D. Document type and severity of reaction and treatment.
- E. Continue to monitor vital signs every 5 minutes until stable.
- F. Notify pharmacy consultant.
- G. Prepare an incident report.
- H. Present data to Medical Advisory/Governing Board.
- I. Complete the adverse drug reaction report. (See attached form.)
- J. Notify the appropriate FDA regulatory agency if warranted.

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2. Severe reaction (dyspnea, profound hypotension):

- A. General steps above.
- B. Epinephrine 0.5 mg IV (or IM if no IV yet), total dose over 10 minutes; give incremental doses to avoid overshoot.
- C. Endotracheal intubation for improved ventilation.
- D. Hydrocortisone 100 mg IV push.
- E. Aminophylline 5-9 mg/kg over 20 minutes IV if wheezing.
- F. Benadryl 50 mg slow IV push.
- G. Transfer to PACU for monitoring when stable.

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## ADVERSE DRUG REACTION INVESTIGATION REPORT

Patient Name: \_\_\_\_\_ Age: \_\_\_ Sex: M F

Reaction Onset (MO/DA/Yr): \_\_\_\_\_ Time: \_\_\_\_\_

Diagnosis: \_\_\_\_\_

Describe Reactions(s): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Name of physician notified: \_\_\_\_\_ Date: \_\_\_ Time: \_\_\_\_\_

Vital signs: Temp \_\_\_ Pulse \_\_\_ Resp \_\_\_ BP \_\_\_\_\_

### TREATMENT

Medications:

\_\_\_ mg Epinephrine \_\_\_ PO \_\_\_ IM \_\_\_ IV

\_\_\_ mg Hydrocortisone (SoluCortef) PO \_\_\_ IM \_\_\_ IV

\_\_\_ mg Diphenhydramine (Benadryl) \_\_\_ PO \_\_\_ IM \_\_\_ IV

\_\_\_ mg Narcan

\_\_\_ mg Vitamin K

\_\_\_ mg Other \_\_\_\_\_

INTERVENTION:

\_\_\_ Medication discontinued;

\_\_\_ Dosage change;

\_\_\_ Oxygen;

\_\_\_ CPR;

\_\_\_ Other

### PATIENT OUTCOME

\_\_\_ No effect; \_\_\_ Effected - additional treatment

\_\_\_ Preventable; \_\_\_ Non-preventable; \_\_\_ Death

Patient advised of possibility of future allergic reaction to \_\_\_\_\_

by \_\_\_\_\_ R.N. (drug)

Form completed by: \_\_\_\_\_ Date: \_\_\_\_\_

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## INVESTIGATION BY PHARMACY CONSULTANT

List all medications administered to patient: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Suspected drug: \_\_\_\_\_ Dose: \_\_\_\_\_ Route of adm: \_\_\_\_\_ Time: \_\_\_\_\_

Did reaction abate after stopping drug?: Yes No N/A

By: \_\_\_\_\_ Date: \_\_\_\_\_

Copy of report sent to physician by pharmacist: Yes No

Medical Advisory/Governing Board Findings: Date of Meeting: \_\_\_\_\_

Changes in medical management due to reaction: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Was the reaction due to a known allergy: Yes No

Was the clinical management of the reaction appropriate: Yes No

Are there other problems noted in this case: Yes No

If any of the above items is "Yes", please explain:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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# Greater New Orleans Surgery Center

## PATIENT GRIEVANCES

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Reviewed: August 1, 2001

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SUBJECT: Patient grievances.

PURPOSE: To establish a means for patients to express any grievances regarding their care while at Greater New Orleans Surgery Center.

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SCOPE: All personnel, patients, and caregivers.

### POLICY:

- A. In accordance with the patients rights and responsibilities the facility will inform the patient or representative of their right to file a complaint or grievance.
- B. This right must be supplied in advance of the date of the procedure.
- C. Be in a language and manner, written and verbally that the patient or the patient's representative understands.
- D. The patient complaint information must be posted in writing within the ASC.
- E. The notice must be given to the patient and include the name, address, phone and website of the person in authority at the ASC, the State Agency where a complaint can be filed and the website of the Office of Medicare Beneficiary Ombusman.
- F. The patient or representative must be able to exercise these rights without being subject to discrimination or reprisal
- G. The patient or representative must be able to voice grievances regarding treatment or care that is or fails to be furnished.

### PROCEDURE:

- A. The patient or representative will be contacted before the date of surgery to inform the patient of their rights to file a grievance procedures by the receptionist.
- B. During the call prior to the date of service the receptionist will also advise the patient or representative to review the complaint/grievance in full which are located on the center's website.
  - a. If the patient does not have access to the internet this information will be forwarded to the patient via email, fax or mail (if there is at least 5 days notice).
- C. On the date of surgery the patient or representative will be given a hard copy of this information and will be asked to sign and acknowledgement of receipt.
- D. Once this information is signed by the patient they will not be requested to sign on each additional visit. The only time this will be repeated is in the event of a change of information.

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## PATIENT GRIEVANCES

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# Greater New Orleans Surgery Center

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- E. Patients are also asked a series of questions during their Post-Operative Telephone Call to determine the level of satisfaction, and to provide an opportunity to make suggestions or voice any grievances or complaints.
- F. Patients are also queried through an outside consultant for patient satisfaction data. This information is reviewed at the following quarterly meetings: PIC, Medical Advisory Board and Governing Body meetings.
- G. Once a complaint or grievance has been received it will be immediately forwarded to the Administrator.
- H. The Administrator will log the grievance in the complaint log, initiate a complaint followup and begin investigation, which may be completed by someone other than the Administrator.
- I. All substantiated allegations must be reported to the state and/or local authority.
- J. The investigation process should take no more than one week to compile data and a response of the review will be provided to the complaining party verbally or in writing if requested.

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**Deleted: SCOPE:** All patients having had care at Greater New Orleans Surgery Center.¶  
¶  
**POLICY:** Patient grievances, verbal and written, are reviewed by the nurse manager, business office manager or Administrator.¶  
¶  
**PROCEDURE:** Patient grievances may be verbal or written.¶  
¶  
A. Verbal grievances are written up on a patient complaint form and followed up by appropriate manager.¶  
¶  
B. Written grievances may be found through patient questionnaires, postop phone call, postop follow-up letter or a patient letter. The appropriate department manager reviews these reports. A patient complaint form will be completed. Follow-up phone calls or letters will be made to evaluate the grievance.¶  
¶  
C. A report will be presented to the Medical Advisory Committee/Governing Body.¶  
¶  
D. Follow-up may include but not be limited to revision of policies/procedures, counseling or staff inservices to improve care at the Center. ¶

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# Greater New Orleans Surgery Center

## PATIENT QUESTIONNAIRE/SATISFACTION

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Reviewed: August 1, 2001

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SUBJECT: Patient questionnaire/satisfaction.

PURPOSE: To monitor the quality of patient care and customer satisfaction, each patient is given a patient questionnaire (attached) to complete and return.

SCOPE: Patients at the Greater New Orleans Surgery Center.

POLICY: Before discharge, the patients at the Greater New Orleans Surgery Center will be given a patient comment card/satisfaction sheet to be filled out by them and mailed back to the surgery center (see sample behind policy.)

### PROCEDURE:

A. Returned ~~surveys~~ are reviewed by the Administrator and ~~Clinical Manager~~. Followup telephone calls or letters may be made by either party to further evaluate any complaints or requests made by the patient. If this is a complaint then the complaint policy will be followed.

Deleted: comment cards

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B. A quarterly report will be presented at the Medical Advisory/ Governing Body under performance improvement. The committee will utilize the information received in these questionnaires to evaluate the patient care at Greater New Orleans Surgery Center.

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## PERFORMANCE IMPROVEMENT INDICATORS

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Reviewed: August 1, 2001

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SUBJECT: Performance Improvement Indicators.

PURPOSE: The Performance Indicators report is used to maintain a documentation for indicators and occurrences that may have a detrimental effect of the quality of patient care and to provide a means for tacking the frequency of deviation from the standards of care; therefore, allowing corrective actions to be taken when deemed necessary. Involved are all staff who each day strive to provide the very best care for all patients.

SCOPE: All personnel.

POLICY: A Medical Record checklist shall be completed on each patient's medical record.

Deleted: Performance Indicator sheet

### PROCEDURE:

- A. The Performance Indicators form can be located in each patient's chart.
- B. When an indicator is identified, relevant to a performance improvement project, a form will be provided in the medical record to perform the measurement aspect of performance improvement.
- C. At the end of the day, during the daily chart reviews, the P.I. forms are collected and given to the P.I. coordinator.
- D. The indicators are tallied and reported to the PI team working on the project.
- E. Trends are identified and action is taken to monitor and assess the problem.
- F. The P.I Officer will record the receipt of all forms.

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT ACTIVITIES

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Reviewed: August 1, 2001

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SUBJECT: Performance improvement activities.

PURPOSE: To select major areas of concern and identify methods to assure continuous monitoring.

SCOPE: All personnel.

POLICY: It is the policy of Greater New Orleans Surgery Center to maintain an ongoing Performance Improvement Program in order to provide the highest level of patient care.

### PROCEDURE:

#### A. Safety:

1. Smoking is not permitted in the facility.
2. Gas supply tank pressures are checked daily. Any deficiencies are reported and corrected.
3. Emergency generator is tested quarterly.
4. Ohio Gas System Panels are tested yearly.

#### B. Departmental educational requirements:

1. Mandatory in-services yearly.
  - a. Fire safety,
  - b. Electro-surgical safety,
  - c. Universal precautions/OSHA regulations,
  - d. CPR certification - biannual.
2. In-service is provided on all new equipment prior to use. Records are maintained.
3. Orientation program - formal programs are developed for all new employees.

#### C. Infection control:

1. Traffic patterns are established and adhered to strictly.

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT ACTIVITIES

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2. Proper attire is required before entering the Restricted Areas.
3. Strict cleaning procedures utilizing a germicidal, sporicidal agent are carried out.
4. Compliance with regulations in the disposal of contaminated wastes. Sharps, needles, etc. are placed in hard plastic containers which are closed for disposal.
5. Careful monitoring and record keeping of sterilizer functions.
6. Strict aseptic technique.
7. Utilization of AORN Standards as guidelines.

D. Documentation:

1. Annual review and/or revision of job description.
2. Annual review and/or revision of Policy and Procedure Manual.
3. Daily review of all O/R records for documentation.
4. Quarterly review of statistics relative to caseload.
5. Daily review of Performance Improvement transmittals for follow-up and trending purposes.

E. Communication:

Cooperation and communication with Administrator, Medical Staff and General Partners in providing quality care.

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## PERFORMANCE IMPROVEMENT PROGRAM

<u>Component</u>	<u>Frequency</u>
Performance Indicators	Daily/monthly
Postop calls	Daily
Patient satisfaction questionnaires	Monthly summary
Incident report review Risk Management	Quarterly
PI projects	Ongoing
Infection control audits	Monthly
Inservice program	Ongoing
Emergency Preparedness drills	Annual
Licensure & credentialing review	Ongoing/yearly
Personnel appraisals and evaluations	yearly
Pharmacy	Monthly
Fire and safety	Monthly
Peer Review/ Utilization review	Quarterly
Performance Improvement Council	Quarterly
Adverse Drug Reactions	Quarterly
Cancellations	Monthly/Quarterly

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# Greater New Orleans Surgery Center

## PEER REVIEW/ MEDICAL RECORD/ UTILIZATION REVIEW WORKSHEET GUIDELINES

### RANDOM SAMPLING OF CHARTS FOR REVIEW

INCLUDE ALL REPORTED INFECTIONS, COMPLICATIONS AND RISK MANAGEMENT

5% OR 30 CASES – WHICHEVER IS GREATER PER QUARTER COMPLETED

AREA of review

Indicator

Supporting Data

AREA of review	Indicator	Supporting Data
SURGEON REVIEW	PRE-OP NOTE INCLUDES DIAGNOSIS AND SUFFICIENT INDICATION FOR SURGERY	COMPLETED PRE-OP H&P TO INCLUDE INDICATIONS FOR SURGERY ( PAIN, DECREASED VISION..)
	POST OP PROGRESS NOTE INCLUDES: LISTING OF PROCEDURE, TYPE OF ANESTHESIA, COMPLICATIONS AND PATIENT CONDITION.	A NOTE MUST BE WRITTEN PRIOR TO THE PHYSICIAN LEAVING THE BUILDING. A DICTATED NOTE DOES NOT MEET THE INTENT OF THE INDICATOR.
	PHYSICIAN SIGNATURES PRESENT AND DATED	ALL AREA'S REQUIRING SIGNATURE PRESENT AND DATED.
	PROCEDURE COMPLETED WITHOUT SURGERY RELATED COMPLICATIONS.	NO RECORD OF SURGICAL COMPLICATIONS. (INCORRECT COUNT, RETURN TO SURGERY FOR BLEEDING..)
	POST OP RECOVERY WITHOUT SURGEON RELATED COMPLICATIONS	PATIENT DISCHARGED WITHOUT COMPLICATIONS AND NO COMPLICATIONS NOTED WITH POST OP PHONE CALL.
	IF COMPLICATIONS – APPROPRIATE MANAGEMENT	IF A COMPLICATION OCCURRED, MANAGEMENT OF THE INCIDENT APPROPRIATE.
	APPROPRIATE SETTING FOR SURGERY	THE PATIENT MET FACILITY POLICY FOR ADMISSION AND TREATMENT IN THE SURGERY CENTER.
	APPROPRIATE PRE-OP LABS, X-RAY	APPROPRIATE PRE-OP TESTING ACCORDING TO FACILITY POLICY AND PROCEDURES.
ANESTHESIA REVIEW	ANESTHESIA PRE-OP NOTE ADEQUATE	PRE-OP NOTE DOCUMENTED AND ADEQUATE
	CHOICE OF ANESTHESIA APPROPRIATE	PATIENT MET CRITERIA FOR TYPE OF ANESTHESIA ADMINISTRED.
	EVIDENCE PATIENT RE-EVALUATED POST	REVIEW OF ANESTHESIA RECORD NOTING POST

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	INDUCTION.	INDUCTION MONITORING.
	ANESTHESIA RECORD COMPLETE	ALL SECTION OF ANESTHESIA REPORT COMPLETED. THIS WOULD INCLUDE PRE – INTRA AND POST OP AREAS.
	SIGNATURES PRESENT AND DATED	ALL ANESTHESIA SIGNATURES PRESENT AND DATED – INCLUDES CRNA’S IF PRESENT.
	PROCEDURE COMPLETED WITHOUT INTRA-OP OR POSTOP COMPLICATIONS RELATED TO ANESTHESIA.	NO ANESTHESIA RELATED COMPLICATIONS.
	IF COMPLICATIONS OCCUR, PROPER TREATMENT.	IF COMPLICATIONS OCCURS, COURSE OF TREATMENT WITH IN STANDARDS OF PRACTICE.
	APPROPRIATE CHOICE OF PRESCRIBED MEDICATIONS INCLUDING DOSE AND FREQUENCY.	ALL MEDICATIONS GIVEN OR PRESCRIBED FOR PATIENT WHILE IN FACILITY APPROPRIATE.
	DISCHARGE NOTE PRESENT AND SUFFICIENT.	DISCHARGE NOT PRESENT, ORDER OR RELEASE SIGNED AND DATED.
	LAB REVIEW.	ANY ABNORMAL LAB VALUES ADDRESSED IN ANESTHESIA NOTES.
MEDICAL RECORD REVIEW	PRESENCE OF SOCIO-ECONOMIC DATA -	PT OCCUPATION, RETIRED, MARITAL STATUS, SOCIAL ACTIVITIES, AND ECT.
	PATHOLOGY SPECIMEN NOTATION NO SPECIMEN TO LAB	REVIEW OR RECORD AND PHYSICIAN PROGRESS NOT FOR NOTATION OF PATHOLOGY NOT SENT YES = NO SPECIMEN
	PATHOLOGY SPECIMEN NOTATION – SPECIMEN REMOVED AND SENT TO LAB	YES MEANS THAT A SPECIMEN WAS SENT
	PATHOLOGIST AND SURGEON DIAGNOSIS ARE COMPATIBLE OR AGREE	FINAL PATHOLOGY AND PHYSICIAN IMPRESSION AGREE.
	DISCHARGE – PT RETURNED TO OWN RESIDENCE	YES IF PATIENT RETURNED HOME
	DISCHARGE – PLANNED ADMISSION	IF PRE-OP PREPERATIONS INCLUDED THE FACT THAT THE PATIENT WAS TO BE ADMITTED TO THE HOSPITAL OR FACILITY FOR 23 HOUR CARE – ANSWER YES. IF ADMISSION NOT PLANNED – ANSWER NO.
	LAB REVIEW	IF POTASSIUM ORDERED AND DRAWN – IS IT WITH IN

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		NORMAL LIMITS.
	LAB REVIEW	IF HGB LABEL DRAWN – IS IT WITH IN NORMAL LIMITS
CLINICAL REVIEW	PRE OP, PATIENT INSTRUCTIONS GIVEN AND DOCUMENTED ON CHART. ( CONSIDERATION GIVEN TO CULTURAL, ETHICAL AND LEARNING NEEDS)	INFORMATION PRESENT AND COMPLETE
	ALLERGIES AND/OR ABNORMAL DRUG REACTIONS DOCUMENTED.	INFORMATION PRESENT AND COMPLETE
	PRE OP RECORD AND NURSING ASSESSMENT COMPLETE AND SIGNED BY NURSE. (TO INCLUDE LIST OF PATIENT'S MEDICATIONS)	INFORMATION PRESENT AND COMPLETE
	EVIDENCE OF INFORMED CONSENT, COMPLETE AND SIGNED.	INFORMATION PRESENT AND COMPLETE
	PRE OP DIAGNOSTIC STUDIES ON CHART ( IF ABNORMAL, ADDRESSED)	INFORMATION PRESENT AND COMPLETE
	H&P ON CHART AND SIGNED BY ATTENDING PHYSICIAN AND/OR ANESTHESIOLOGIST.	INFORMATION PRESENT AND COMPLETE
	ALL ENTRIES COMPLETED (PRE OP, INTRA OP AND POST OPERATIVE) WITH APPROPRIATE SIGNATURES , DATED AND AUTHENTICATED IF NEEDED.	INFORMATION PRESENT AND COMPLETE
	VERBAL ORDERS ARE AUTHENTICATED WITHIN TIME FRAME REQUIRED BY LAW.	INFORMATION PRESENT AND COMPLETE
	IF PATIENT INVOLVED IN RESEARCH, CLINICAL TRIALS OR EXPERIMENTATION- DOCUMENTATION OF BENEFITS, RISKS, ALTERNATIVES AND RIGHT TO REFUSE PRESENT.	INFORMATION PRESENT AND COMPLETE
	PATIENT RESPONSE TO TREATMENT RE-EVALUATED AFTER MEDICATIONS AND OR CARE RENDERED.	POST MEDICATION DOCUMENTATION OF AS TO OUTCOME RESULT OF MEDICATION.
	IF TISSUE REMOVED, PATHOLOGY REPORT ON CHART.	INFORMATION PRESENT AND COMPLETE
	OPERATIVE RECORD COMPLETE AND SIGNED	INFORMATION PRESENT AND COMPLETE

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# Greater New Orleans Surgery Center

	BY NURSE.	
	PATIENT DISCHARGED FROM PACU BY PHYSICIAN VISIT & ORDER.	PHYSICIAN SIGNED OFF ON DISCHARGE TO INCLUDE TIME CLEARANCE OF DISCHARGE ESTABLISHED.
	DISCHARGE INSTRUCTIONS INCLUDE USE OF MEDICATIONS, DIET, EXERCISES AND COMMUNITY RESOURCES. ACKNOWLEDGMENT OF PATIENT UNDERSTANDING.	
	POST OP TELEPHONE CONTACT DOCUMENTED (IF UNABLE TO CONTACT, DOCUMENT IN RECORD THE DATE AND TIME CALLS ATTEMPTED AND LETTER SENT TO PATIENT).	

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT GLOSSARY OF TERMS

Page 1 of 2

Reviewed: August 1, 2001

~~8/1/03, 6/24/08, 05/01/09~~

Implemented: August 1, 2001

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- SUBJECT:** Performance improvement glossary of terms.
- AUDIT:** A tool or mechanism used for systematically evaluating the quality of care provided.
- CONCURRENT:** As it happens.
- CRITERIA:** A measurable indicator used to determine if objectives are being met.
- OUTCOME:** The result. The intended or realistically expected correction of the patient's problem by a certain point in time. The end results of nursing care or measurable change of health status of the patient.
- PROCESS:** The sequence of events and activities carried out by the nurse in the delivery of nursing care (nursing activities).
- PROTOCOLS:** Practice guidelines.
- PERFORMANCE IMPROVEMENT:** A continuous process that seeks to reduce systemic defects to as close to zero possible. A program executed to ensure or ascertain the excellence of health care. The program has two major components.
1. Securing measurements and ascertaining degree to which standards are met.
  2. Introduction of changes based on information supplied by measurements.
- End result should be improvement of the total effort and product of the unit or agency.
- RETROSPECTIVE:** Looking backward.
- SENTINEL EVENT:** An important single event that is monitored in addition to other routine indicators.

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT GLOSSARY OF TERMS

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- STANDARD: Something used by general agreement to determine whether a thing is as it should be; an agreed-upon level of excellence; an established norm. An agreed-upon level of excellence; a guideline for practice.
- STRUCTURE: The organizational, physical, fiscal, legal and accreditation parameters in regard to the institution. (The environments in which care takes place.)
- STUDY: A formal, critical investigation of an event or topic.

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT PLAN

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Reviewed: August 1, 2001

8/1/03, 6/24/08, 05/01/09

Implemented: August 1, 2001,

05/18/09

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**SUBJECT:** Performance Improvement Plan.

### **PURPOSE:**

The purpose of the Performance Improvement Program of Symbion Ambulatory Surgery Centers is to insure each facility's ability to carry out its mission and vision. This will include the ability to provide state of the art seamless health care services in cost effective manner. Improved patient health outcomes are the ultimate goal of organizational performance improvement.

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The Performance Improvement Plan of the Greater New Orleans Surgery Center is a method of systematic and objective monitoring which will enable evaluation of the ongoing provision of high quality surgical care services in a cost effective manner. Through this monitoring process, the Greater New Orleans Surgery Center health care team can both document the quality and appropriateness of care and resolve identified problems for the improvement of patient care. Performance Improvement at the Greater New Orleans Surgery Center is a continuous process. The Governing Body has oversight and accountability for the program.

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**SCOPE:** All personnel and Medical Staff.

### **POLICY:**

Through the Performance Improvement Plan, a program shall be established and maintained to assure comprehensive evaluation of the organization and its activities. This program will specify lines of authority, accountability and communication, and it will be designed to assure that patient care is both consistently high in quality and efficient. Performance Improvement is met through a team effort of the entire staff. The organization's plan shall delineate the respective roles of the facility/center's Governing Body, medical leadership, clinical staff, management, and all employees in developing, implementing, evaluating, and coordinating a comprehensive performance improvement program.

### **GENERAL INFORMATION:**

#### **Key Elements**

Each facility's approach to improving performance shall include the following key elements:

- Process design
- Performance measurement
- Performance assessment
- Performance improvement

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT PLAN

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In order to insure that a planned, systematic, organization wide approach to performance improvement is implemented, the following structure has been established:

### PROGRAM SCOPE:

- Ongoing
- Demonstrate measureable improvement in patient health outcomes
- Improve patient safety by using quality indicators or performance measures associated with improved health outcomes and with identification and reduction of medical errors.
- Measure, analyze and track:
  - Quality indicators
  - Adverse patient events
  - Infection control and other aspects of performance (processes of care and services)

### PROGRAM DATA:

- Use quality indicator data in program
- Data must be used to:
  - Monitor effectiveness and safety of services
  - Monitor quality of care
  - Identify opportunities that could lead to improvements and changes in its patient care

### PROGRAM ACTIVITIES:

- Set priorities for performance improvement activities that:
  - Focus on high risk, high volume and problem prone areas
  - Consider incidence, prevalence and severity of problems in areas described above
  - Affect health outcomes, patient safety and quality of care
- Performance improvement activities must:
  - Track adverse patient outcomes
  - Examine their cause
  - Implement improvements
  - Ensure improvements are sustained over time
- The ASC must implement preventative strategies targeting adverse patient events and ensure that all staff are familiar with these strategies.

### PERFORMANCE IMPROVEMENT PROJECTS:

- PI activities must:
  - Reflect the scope and complexity of ASC services and operations in terms of number and scope of distinct PI projects
  - Be documented with reason for implementing the project and description of project results

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT PLAN

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### A. STRUCTURE

1. PERFORMANCE COMMITTEE: The Governing Body of the Greater New Orleans Surgery Center will function as the Performance Improvement Committee. It retains overall authority for the Performance Improvement Plan and Program and has the authority to act on all recommendations from the Administrator and/or Performance Improvement Council to improve or enhance patient care and/or safety. The Performance Improvement Committee approves the Performance Improvement Plan and may delegate responsibilities for carrying out the Performance Improvement Plan to the Administrator and PIC. The physician members of the medical board will approve all criteria utilized in the PI program for review of physician care and/or documentation. The Performance Committee may delegate physician peer review activities to any physician medical staff member(s) it deems appropriate. The Board must ensure that the program is defined, implemented and maintained. It must address the ASC's priorities. All improvements are evaluated for effectiveness. The data collection methods, frequency and details are appropriate. The program expectations for safety are clearly established. Adequate resources are allocated to implement the program.
2. ADMINISTRATOR: The Administrator has the authority to implement the approved Performance Improvement Plan. The Administrator is authorized to independently investigate and resolve any non-physician problems. The Administrator is responsible for supervising all PI activities, participating in the PIC meetings, maintaining pertinent records and compiling and submitting reports of PI activities to the Performance Committee. The Administrator may delegate selected PI activities specified in the PI Plan to the PI coordinator, Clinical Manager, PIC and/or other appropriate staff member.
3. PERFORMANCE IMPROVEMENT COUNCIL (PIC): The PI Council has the authority to monitor, collect data, investigate problems and make recommendations to the Administrator and Performance Committee for resolution based on the approved PI Plan. Its responsibilities include ongoing monitoring of the PI Program for actual or potential problems, assessing the severity of problems concerning priority setting for further action, implementing performance teams, developing and implementing corrective actions, establishing the need and timing of re-studies, conducting re-studies, determining the effectiveness of interventions, submitting reports to the Performance Committee, making recommendations to the Administrator and/or Performance Committee and maintaining a permanent record of its proceedings, findings and recommendations.

B. DESIGN: To achieve a comprehensive review and documentation of ongoing quality improvement, a number of activities will be utilized to assess patient care as well as administrative quality and plant services. Included in these activities are:

1. Staff meetings,
2. Incident reports,
3. Patient satisfaction questionnaire,
4. Services volume,

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT PLAN

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5. Safety review using:
- a. Preventative maintenance contracts
  - b. Standards
    - 1. OSHA
    - 2. AORN
    - 3. Universal precautions
    - 4. ASPAN
    - 5. Orientation program,
    - 6. In-service programs/continuing education profiles,
    - 7. Credentialing of medical, allied health and dental staff,
    - 8. Policy and procedure annual review,
    - 9. Annual employee evaluation,
    - 10. Infection reporting system,
    - 11. Peer review/utilization review,
    - 12. Performance indicator monitoring,
    - 13. Performance improvement projects

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The performance of these activities, the adherence to prescribed policies and the problems encountered will be investigated as necessary in a timely manner by the Performance Improvement Coordinator and will be documented appropriately for quarterly review by the Medical Advisory/Governing Body. Personnel will maintain copies of all reports, worksheets and other data in a manner ensuring strict confidentiality. Such forms, reports and activities sheets will contain no names or will not become a part of any permanent medical record.

### C. MEASUREMENT

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Measurement is the foundation of all performance-improvement activities. Measurement involves the collection of data and forms the basis for determining the level of performance of existing processes and the outcomes resulting from these processes. Measurement will be systematic, relate to relevant dimensions of performance, and be appropriate in scope and focus. The measurement system includes data on:

- processes (goal-directed, interrelated series of actions, events, mechanisms, or steps) and outcomes
- a comprehensive set of performance measures (indicators that measure both quality and quantity)
- patient and customer expectations and satisfaction

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT PLAN

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### D. ASSESSMENT OF INFORMATION

Each facility/center's Performance Improvement Plan shall use appropriate statistical quality control techniques. The assessment of the Performance Improvement Plan shall include at the minimum the following:

- A. Comparison to data over time.
- B. Comparison with practice guidelines in the literature and expert opinions.
- C. Comparison to external databases.
- D. Comparison to company internal databases.

Intensive assessment will occur in the following cases:

- A. When there is undesirable variation.
- B. When there is a sentinel event that triggers concern.
- C. When trends or patterns are identified in the assessment of data.
- D. When the organization's performance varies from recognized standards
- E. When the organization wishes to improve an already good performance.
- F. When there is a significant medication error.
- G. When there is a blood transfusion reaction
- H. When there is an Adverse Drug Reaction

### E. PERFORMANCE TEAMS

Each facility/center shall utilize Performance Improvement Teams (or other equivalent structure) in a systematic process to assess collected data in order to determine:

- A. Whether designed specifications for new processes are met.
- B. The level of performance stability of existing important processes.
- C. The priorities for improving existing processes.
- D. Actions to improve the performance of processes.
- E. Whether changes in the processes resulted in improvement.
- F. Special cause vs. common cause variation.

F. **PERFORMANCE IMPROVEMENT:** At the time action is taken to address a problem, the Medical Advisory Board/Governing Body or PIC will assign the responsibility for follow-up to evaluate whether improvement occurs. The frequency and extent of the follow-up will be determined for each individual circumstance. When appropriate, the assignment for the follow-up may be delegated to another member of the surgery center team who is not a member of either committee.

Management holds the ultimate responsibility for total follow-up and shall participate in all performance improvement activities throughout the year with the submission of a quarterly report to the governing board. Management may also request special meetings of the governing board to discuss any urgent performance improvement problem.

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT PLAN

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G. ELEMENTS OF CARE TO BE EVALUATED: Aspects of care regarding high volume, high risk and problem-prone patients will be given the highest priority. Included in this category are the following patients:

1. High Risk:
  - a. Immuno-suppressed,
  - b. Diabetic,
  - c. TB
  - d. Geriatric,
  - e. Asthmatic,
  - f. Obese,
2. High Volume:
  - a. Cataract
  - b. Endoscopy
  - c. Arthroscopy
3. Aspects of care studies will relate to outcomes involving:
  - a. Medical practice/care,
  - b. Nursing care,
  - c. Administrative interaction and clerical accuracy,
  - d. Level of patient satisfaction.

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H. DOCUMENTATION AND REPORTING:

1. Review of the medical records:

Documentation of the charting relative to quality of care standards/criteria will be reviewed quarterly by randomly selecting 5% of the medical records or 30 charts, whichever is greater. The staff will review charts and report findings to the Medical Advisory /Governing Body. The review will include an assessment of:

- a. Staff members who are negligent in medical records keeping or whose work falls below the medical standards of the community.
- b. Proper utilization of the surgery center.
- c. Appropriateness of care and medical necessity of the cases.
- d. Postoperative pathological diagnosis to determine justification of procedures done.

2. Patient satisfaction:

The Administrator questionnaires daily to determine the level of patient satisfaction with the various elements of the surgery center. It is important to note that patients make suggestions on ways to improve and personalize care. The committee (PIC) will determine how and if such suggestions can be implemented without adversely affecting other areas of care.

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# Greater New Orleans Surgery Center

## PERFORMANCE IMPROVEMENT PLAN

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3. Review all cases of infection in patients treated at the surgery center; develop methods of prevention:
  - a. Refer to postoperative telephone interviews.
  - b. Investigate hospital admissions for surgery center patients to determine if infection was responsible for the admission.
  - c. Refer to returned infection control reports.
  - d. Investigate possible causes of infection.
  - e. Formulate and promote policies concerning infection control.
  - f. Develop and promote in-service education programs for personnel in methods of infection control.
4. Conduct random reviews of medical records for appropriateness of medication and dosage administered at the surgery center.
5. Review information pertaining to medical/surgical equipment currently in use of proposed for use in the surgery center:
  - a. Recommend evaluation for equipment to be considered for use in the center.
  - b. Promote in-service education for personnel pertaining to equipment used in the center.
  - c. Biomedical checks are to be done semi-annually or according to the manufacturer's instructions.
6. Review documentation of performance indicator findings:
  - a. Focus on two indicators per PI Project until expected outcome is reached.
  - b. Determine if corrective action of recurrent problems is adequate.

Findings will be reviewed in the appropriate committee, reported on writing and documented in the minutes.

- I. **RECORD KEEPING:** The secretary will record and maintain a set of minutes from each meeting, dated and signed by the committee chairperson. The agenda for the meeting is as follows:

1. Reading of previous minutes,
2. Approval of minutes,
3. Old business,
4. Chart review,
5. New business.

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## PERFORMANCE IMPROVEMENT PLAN

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The secretary will properly document significant committee findings. Patient medical record number will be used to document deficiencies. The reports and activity sheets will contain no names and will not become part of any permanent medical record.

J. CORRECTIVE ACTION: The course of action resulting from the variation of the established criteria/standard will be as follows:

1. The chairperson will notify each physician by letter of the deficiency.
2. A reasonable number of records pertaining to the deficient physician will be selected for the next quarterly review to determine compliance.
3. If the deficient physician has shown no improvement, the Medical Advisory/Governing Body will take appropriate action as deemed necessary.
4. If a pattern is being established respective to the physician-staff-at-large, an information letter will be mailed to all staff physicians in order to reinforce the need to meet the standard.

In all cases, the process will be an educational one.

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