

Template: Hospital

Title: Disclosure of Unanticipated Outcomes

Date Developed:

Date Revised:

Approvals: Governing Body; Medical Staff; Administration

I. Hospital Philosophy:

II. Policy Statement:

III. Definition of Terms: [examples]

- Unanticipated outcome
- Adverse event
 - Types of adverse events:
 - Adverse drug event
 - Unintended significant procedural event
 - Preventable adverse event
 - Unpreventable adverse event
- Medical error
- Minor error
- Serious error
- Near miss
- Root cause analysis (RCA)
- Sentinel event
- Significant harm
- Disclosure
- Informed consent

IV. Criteria for Disclosure

V. Defining Personnel Roles

Disclosure Response Team: [examples]

- Risk Manager
- Physician(s)
- Administrators
- Quality Improvement Manager
- Medical Director
- Pharmacists
- Nursing
- Other direct caregivers

VI. Patient Contact Algorithm

- Initial patient contact
- Directing the patient to the appropriate individual(s)

Importance of Maintaining Confidentiality

VII. Investigating the Unanticipated Outcome

- Complete root cause analysis if needed
- Review and communicate details of the investigation with appropriate staff members within *protected* peer review and patient safety “work product” established protocols

VIII. Planning the Disclosure Discussion – Engage professional liability insurer to guide the process and determine the need for legal counsel

- Who
- When
- Setting
- Special needs/accommodations
- Engage professional liability insurer

IX. Disclosure Communication Content

- Description of factors contributing to the outcome if known. If not known, share with the patient that you will look into what happened
- Expression of regrets, apology – if warranted
- Effects on current patient treatment plan – address concerns
- Review actions taken to prevent recurrence – review next steps

X. Documentation of Disclosure Conversation Maintained in Protected File *Outside of Medical Record (Risk Management, Quality)*

- Who
- When
- Description of factors contributing to the outcome
- Information was provided to the patient
- Responses to the patient’s questions
- The patient’s level of understanding
- Planned follow-up
- Who the patient should contact with questions

Medical record documentation should be limited to objective clinical status, medical decision-making, and treatment plans.

XI. Follow-up

- Attachments
- Templates or forms
- Coordinating Policies [Patient Communication; Patient Informed Consent; Patient Confidentiality]

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