Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 07 HOSPITALS

Notice of Proposed Action

The Secretary of Health and Mental Hygiene proposes to repeal in its entirety Regulation **.25** under **COMAR 10.07.01 Acute General Hospitals and Special Hospitals** and to adopt new Regulations **.01- .16** under a new chapter **COMAR 10.07.06 Hospital Patient Safety Program.**

Statement of Purpose

The purpose of this action is to strengthen accountability of hospitals for certain events that cause death or other harm to patients and strengthen the internal reporting and evaluation systems within hospitals**.**

In 2001,the Maryland General Assembly expressed concern over patient safety in Maryland hospitals and asked the Maryland Health Care Commission, in consultation with the Department, to review activities and to make recommendations for improvements. One initiative of The Patient Safety Coalition was to revise risk management regulations for hospitals.

Comparison to Federal Standards

(Check one option)

☐ There is no corresponding federal standard to this proposed regulation.

Or

There is a corresponding federal standard to this proposed regulation, but the proposed regulation is not more restrictive or stringent.

Or

☑ In compliance with Executive Order 01.01.1996.03, this proposed regulation is more restrictive or stringent than corresponding federal standards as follows:

(1) Regulation citation and manner in which it is more restrictive than the applicable federal standard:

42 CFR 482.21 requires a hospital to have an ongoing patient safety plan for reducing medical errors. No directions or guidelines are provided for the plan. No external reporting of adverse events is required. The proposed regulations are consistent with the federal regulations but provide guidelines with emphasis on internal reporting and investigation of adverse events. Hospitals are expected to use investigation results to make system changes to prevent or reduce medical errors. The proposed regulations require hospitals to report investigation results to the Department for monitoring and trending purposes.

(2) Benefit to the public health, safety or welfare, or the environment: In addition to the benefits mentioned above, hospitals will be required to notify the patient or the patient's family whenever a final outcome of care differs significantly from an anticipated outcome.

(3) Analysis of additional burden or cost on the regulated person:

JCAHO requires all accredited hospitals to conduct a root cause analysis of events. The analysis report may be used to satisfy the State's reporting requirement. All of Maryland's hospitals are accredited by JCAHO.

(4) Justification for the need for more restrictive standards:

In 1999, the Institute of Medicine released a report indicating that there may be up to 100,000 deaths per year due to medical errors. The 2001 Legislature asked the Maryland Health Care Commission in consultation with the Department, to review patient safety in Maryland hospitals and to make recommendations for improvements. As a result, hospital risk management regulations have been revised and strengthened. The proposed regulations are consistent with the CMS, JCAHO, and other national standards.

Impact Statements

Part A

(Check one option)

Estimate of Economic Impact

The proposed action has no economic impact.

Or

☑ The proposed action has an economic impact.

Complete the following form in its entirety.

I. Summary of Economic Impact. Although the proposed requirements are not new to hospitals, the increased oversight will probably cause increased review of patient

safety activities by hospitals. Hospitals may experience a minimal increase in administrative costs.

		Revenue (R+/R-)	
I.	Types of Economic Impacts.	Expenditures (E+/E-)	Magnitude
	A. On issuing agency:	NONE	
	B. On other State agencies:	NONE	
	C. On local governments:	NONE	
		Benefit (+) Cost (-)	Magnitude
	D. On regulated industries or trade groups:	(-)	MINIMAL
	E. On other industries or trade groups:	NONE	
	F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

II.D. Although the proposed requirements are not new to hospitals, the increased oversight will probably cause increased review and scrutiny of patient safety activities by hospitals. Hospitals may experience a minimal increase in administrative costs as a result of the proposed regulations. The JCAHO requires accredited hospitals to conduct a root cause analysis of events. The analysis report may be used to satisfy the State's reporting requirement. Note: All hospitals in Maryland are accredited by JCAHO.

The proposed $500 fine for hospitals that violate the regulations is not new to hospitals. It has existed in the hospital risk management statute (Health-General Article, §19-319) since the

late l980s and it is included in COMAR 10.07.01.25 that is being repealed as part of this action. There will be no additional economical impact as a result of this proposal.

Part B

(Check one option)

Economic Impact on Small Businesses

☑ The proposed action has minimal or no economic impact on small businesses.

Or

The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Regulations Coordinator, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 521, Baltimore, Maryland 21201, or fax to (410) 333-7687, or email to regs@dhmh.state.md.us, or call (410) 767-6499 or 1-877-4MD-DHMH, extension 6499. These comments must be received by

Part C

(For legislative use only; not for publication)

A. Fiscal Year in which regulations will become effective: 2004

B. Does the budget for fiscal year in which regulations become effective contain funds to implement the regulations?

Yes No ☑ N/A

C. If "yes", state whether general, special (exact name), or federal funds will be used:

D. If "no", identify the source(s) of funds necessary for implementation of these regulations: The Department can absorb the additional workload required by the regulations by shifting resources.

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

1a. The intended beneficiaries are patients who seek care at hospitals.

1c. Hospitals are not considered to be small businesses. The changes strengthen accountability of hospitals for certain events that cause death or harm to patients and strengthen the internal reporting and evaluation systems within hospitals.

Although the proposed requirements are not new to hospitals, the increased oversight will probably cause increased review and scrutiny of patient safety activities by hospitals. Hospitals may experience a minimal increase in administrative costs as a result of the proposed regulations. The JCAHO requires accredited hospitals to conduct a root cause analysis of events. The analysis report may be used to satisfy the State's reporting requirement. Note: All hospitals in Maryland are accredited by JCAHO.

10.07.01 Acute General Hospitals and Special Hospitals

Authority: Health-General Article, §§[19-307.2] 19-308 and 19-319,

Annotated Code of Maryland

10.07.01 Hospital Patient Safety Program

Authority: Health-General Article,

[.25 Risk Management Program.

A. General.

(1) On or before January 1, 1988, each hospital shall have in effect a risk management program that meets the requirements of this regulation.

(2) The purpose of this regulation is to provide a safer environment for patients by requiring hospitals to:

(a) Identify incidents;

(b) Investigate and evaluate incidents in a timely manner;

(c) Take appropriate action to prevent reoccurrence of the incident; and

(d) Provide for a process by which the concerns of patients can be addressed.

B. Duties of Hospital.

(1) The hospital shall identify an individual as risk management coordinator who shall:

(a) Coordinate risk management activities;

(b) Monitor all incidents related to patient care; and

(c) Provide for flow of information among quality assurance, credentialing, peer review, and any risk management committee.

(2) The hospital shall establish:

(a) Risk management education programs for all staff; and

(b) An internal staff committee structure to conduct review and evaluation of risk management activities in accordance with this regulation.

(3) The board of directors of a hospital shall:

(a) Adopt a statement that indicates commitment of the board to a hospital-wide risk management program; and

(b) Provide for a mechanism for reporting risk management activities to the board of directors.

(4) Before a committee can operate or review risk management activities under this regulation, a hospital shall require that the committee meet the requirements for a medical review committee under Health Occupations Article, § 14-501 et seq., Annotated Code of Maryland.

C. Risk Management Program Requirement--Incident Reporting.

(1) In accordance with this section, the risk management program shall include a hospital-wide incident identification and reporting process.

(2) The incident identification and reporting process shall:

(a) List and describe incidents that shall be reported;

(b) Designate a hospital representative to whom the incident shall be reported;

(c) Provide a time frame within which the incident shall be reported; and

(d) Require that a person employed by the hospital or appointed to the medical staff and who is aware of an incident shall report the incident in accordance with this regulation.

D. Risk Management Program Requirement--Review and Evaluation.

(1) In accordance with this section, the risk management program shall include a process for review and evaluation of incidents.

(2) The incident review and evaluation process shall provide for:

(a) Investigation of incidents;

(b) Identification of trends among incidents;

(c) Referral of incidents and trend summaries to evaluation committees when further action is necessary; and

(d) Referral of incidents that require further action to medical staff credentialing and peer review committees for appropriate action.

E. Risk Management Program Requirement--Information Sharing. The risk management program shall require that the quality assurance programs share information about incidents.

F. Risk Management Program Requirement--Documentation. Actions taken by the quality assurance and medical staff credentialing and peer review committees shall be documented in committee minutes.

G. Risk Management Program Requirement--Patient Complaint Program.

(1) In accordance with this section, the risk management program shall include a formal written program for addressing patient complaints.

(2) The hospital shall provide patients with information regarding the hospital's patient complaint program including:

(a) The name of the hospital's representative that the patient may contact if the patient wishes to make a complaint; and

(b) The hospital representative's phone number or address.

(3) The hospital's representative shall treat the complaining patient with dignity and courtesy and due regard for the person's privacy.

(4) The hospital's representative shall provide the patient with information about the complaint including:

(a) Who in the hospital the patient may contact for information regarding the complaint;

(b) The procedure for investigating the complaint; and

(c) When the patient can expect a response or resolution to the complaint.

(5) The hospital's representative shall document the complaint and any action taken concerning the complaint or the hospital function complained about.

H. Risk Management Program Requirement--Records. In accordance with these regulations, the hospital shall maintain records concerning the operation of its risk management program.

I. Documentation.

(1) On or before December 1, 1987, the hospital shall send to the Secretary a written description of its risk management program which includes:

(a) The name of the risk management coordinator;

(b) The board policy statement relevant to risk management activities;

(c) A description of the incident identification and reporting process;

(d) A list of incidents that must be reported;

(e) A description of the incident review and evaluation process; and

(f) A description of the formal written patient complaint process.

(2) The hospital shall notify the Secretary of any change in its risk management program related to the description required by this section within 30 days of the effective date of the change.

J. Plan of Correction.

(1) If the Department notifies a hospital that the risk management program of the hospital does not meet the requirements of this regulation, the hospital shall submit a plan indicating the steps the hospital shall take to meet the requirements of this regulation.

(2) The plan shall be sent to the Secretary within 30 days after the Department notifies the hospital that the hospital does not meet the requirements of this regulation.

K. Penalties. If a hospital fails to have in effect a risk management program in accordance with these regulations, then the Secretary may impose upon the hospital the following penalties:

(1) Delicensure of the hospital; or

(2) A fine of $500 for each day that the hospital is in violation of these regulations.**]**

Final Draft submitted for publication. To obtain the official regulations with an effective date of March 15, 2004, visit www.dsd.state.md.us

COMAR 10.07.06 Hospital Patient Safety Program

Authority: Health-General Article, §§19-308 and 19-319,

Annotated Code of Maryland

ALL NEW MATERIAL

.01 Purpose.

The purpose of this chapter is to provide a safe environment for patients by requiring hospitals to:

A. Identify adverse events;

B. Encourage reporting of near-misses;

C. Assess and prioritize near-misses and adverse events based on level of disability or potential disability to patients;

D. Determine the appropriate hospital response based on level of disability or potential disability;

E. Conduct a root cause analysis of:

(1) All level 1 events;

(2) All level 2 events; and

(3) If warranted, any near-miss or other adverse event;

F. Conduct an appropriate investigation of adverse events and near-misses that do not require or warrant a root cause analysis;

G. Provide a process by which the concerns of patients can be addressed; and

H. Provide a process to notify a patient or, if appropriate, a patient's family, whenever an outcome of care differs significantly from an anticipated outcome.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Action plan" means a written document that includes:

(a) Specific measures to correct problems or areas of concerns;

(b) Specific measures to address areas of system improvement;

(c) Time frames for implementation of any specific measures; and

(d) Title of responsible individual to monitor implementation and effectiveness.

(2) "Adverse event" means an unexpected occurrence related to an individual's medical treatment and not related to the natural course of the patient's illness or underlying disease condition.

(3) " Department" means the Department of Health and Mental Hygiene.

(4) "Level 1 adverse event" means an adverse event that results in death or serious disability.

(5) "Level 2 adverse event" means an adverse event that requires a medical intervention to prevent death or serious disability.

(6) "Level 3 adverse event" means an adverse event that does not result in death or serious disability and does not require any medical intervention to prevent death or serious disability.

(7) "Medical review committee" has the meaning stated in Health Occupations Article, §1-401 et seq., Annotated Code of Maryland.

(8) "Near-miss" means a situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

(9) "Patient safety program" means an ongoing, proactive program for identifying risks to patient safety and reducing medical errors which is one component of the hospital-wide risk management program.

(10) "Root cause analysis" means a medical review committee process as defined under Health Occupations Article, §1-401 et seq Annotated Code of Maryland, for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or near-misses.

(11) "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual and lasts more than 7 days or still present at the time of discharge.

.03 Patient Safety Program.

A. General.

On or before March 15, 2004, a hospital shall have in effect a patient safety program that meets the requirements of this chapter.

B. Duties of the Hospital.

(1) The hospital shall identify an individual as patient safety coordinator who shall:

(a) Coordinate patient safety activities;

(b) Facilitate assessment and determination of the appropriate response to reported near-misses and adverse events related to patient care;

(c) Monitor root cause analyses and any actions resulting from a root cause analysis; and

(d) Provide for flow of information among quality assurance, credentialing, peer review, and any patient safety committee.

(2) The hospital shall establish:

(a) Patient safety education programs for all staff; and

(b) An internal staff committee structure in accordance with Health Occupations Article, §1-401, Annotated Code of Maryland to conduct a review and evaluation of patient safety activities in accordance with this chapter.

(3) The governing board of a hospital shall develop a process to review the hospital's patient safety program and to determine the effectiveness of the hospital's patient safety program.

(4) Before a committee can operate or review patient safety activities under this chapter, a hospital shall require that the committee meet the requirements for a medical review committee under Health Occupations Article, §1-401 et seq., Annotated Code of Maryland.

.04 Near-Miss and Adverse Event Reporting and Determination of Appropriate Response.

A. The hospital shall develop and encourage a supportive environment that permits spontaneous identification, open discussion, and timely and accurate reporting of near-misses and adverse events.

B. The hospital shall establish a clear and well-defined near-miss and adverse event identification and reporting process that shall:

(1) Encourage reporting of near-misses and require reporting of adverse events;

(2) List and describe examples of adverse evens that shall be reported;

(3) Designate a hospital representative to whom a near-miss is encouraged to be reported or to whom an adverse event shall be reported;

(4) Provide a time frame within which the near-miss is encouraged to be reported or within which an adverse event shall be reported;

(5) Require that an individual employed by the hospital or appointed to the medical staff and who is aware of an adverse event shall report the adverse event in accordance with this chapter;

(6) Develop a procedure to coordinate receipt of all adverse events and near-misses and to prioritize adverse events and near-misses based on level of disability or potential disability; and

(7) Develop a procedure to assign an appropriate response to level 1 and level 2 adverse events, other adverse events, and near-misses.

.05 Procedures for Level 1 and 2 Adverse Events And Certain Near-Misses.

A. When a level 1 or 2 adverse event, or near-miss that warrants a root cause analysis occurs, the hospital shall:

(1) Provide immediate care to the patient;

(2) Identify any immediate corrective action to prevent reoccurrence;

(3) Identify and report the event in accordance with the hospital's reporting process;

(4) Complete a root cause analysis within 60 days of the time that the hospital has knowledge of the occurrence;

(5) Develop and implement an action plan to correct any systems problems;

(6) Share any pertinent information with quality assurance or other medical review committees; and

(7) Aggregate data to determine patterns or trends.

B. All patient safety activities shall be conducted by a medical review committee established under Health Occupations Article, §1-401, Annotated Code of Maryland.

.06 Root Cause Analysis.

A. The hospital shall appoint an interdisciplinary root cause analysis team that shall include:

(1) Individuals who have knowledge of the event or near-miss;

(2) Representatives of hospital leadership; and

(3) Individuals with expertise in the subject matter of the event.

B. The root cause analysis team shall interview and permit participation of individuals who were directly involved in the event or near-miss and allow the individual to participate in the root cause analysis as appropriate.

C. The root cause analysis shall examine the cause and effect of the event through an impartial process through:

(1) Analysis of human and other factors;

(2) Analysis of related processes and systems;

(3) Analysis of underlying cause and effect systems through a series of "why" questions;

(4) Identification of risks and possible contributing factors; and

(5) Determination of improvement in processes or systems.

D. A root cause analysis shall:

(1) Be internally consistent; and

(2) Include consideration of relevant literature and best practices.

E. The hospital shall provide feedback including changes to hospital policy or procedure resulting from the root cause analysis to hospital employees and staff who were involved in the event or near-miss and to other employees or staff who would benefit from the feedback.

.07 Procedures for Level 3 Adverse Events and Certain Near-Misses.

A. If the event is not a level 1 or 2 event or near-miss that warrants a root cause analysis, the hospital shall conduct an evaluation of the event to determine any problem area and corrective action.

B. All events shall be aggregated by type and level to determine any patterns or trends.

C. The hospital is encouraged to evaluate and trend all near-misses to determine any system problems.

D. The hospital shall monitor the results and effectiveness of all action plans.

.08 Information Sharing.

The patient safety program shall require that the quality assurance, and other medical review committees share information and take any appropriate action concerning near-misses and adverse events.

.09 Reports To the Department.

A. A hospital shall report any level 1 adverse event to the Department within 5 days of the hospital's knowledge that the event occurred.

B. A hospital shall submit the root cause analysis and action plan for the level 1 adverse event to the Department within 60 days of the hospital's knowledge of the occurrence.

C. Any root cause analysis and any other medical review committee information submitted to the Department and the identity of individuals appointed to the interdisciplinary root cause analysis team are confidential under Health Occupations Article, §1-401, Annotated Code of Maryland and may not be discoverable, disclosable, or admissible as evidence in any civil action or available under the Maryland Public Information Act.

D. If the Department receives a complaint alleging a level 1 adverse event, the Department may accept the root cause analysis as a hospital's internal investigation under Health-General Article, §19-309(b), Annotated Code of Maryland.

.10 Documentation.

Actions taken by the quality assurance and medical staff credentialing and peer review committees shall be documented in committee minutes.

.11 Patient Complaint Program.

A. In accordance with this regulation, the patient safety program shall include a formal written program for addressing patient complaints.

B. The hospital shall provide patients with information regarding the hospital's patient complaint program including:

(1) The name of the hospital's representative that the patient may contact if the patient wishes to make a complaint; and

(2) The hospital representative's phone number or address.

C. The hospital's representative shall treat the complainant with dignity and courtesy and due regard for the individual's privacy.

D. The hospital's representative shall provide the complainant with information about the complaint including:

(1) The hospital representative that the patient may contact for information regarding the complaint;

(2) The procedure for investigating the complaint;

(3) The length of time in which the complainant can expect a response or resolution to the complaint; and

(4) Notice that the patient may contact the Department at a specified telephone number or address with any complaint.

E. The hospital's representative shall document the complaint and any action taken concerning the complaint or the hospital function complained about.

F. Patient Safety Program Requirement- Notice to Patients and Families of Unanticipated Outcomes. The hospital shall inform the patient and, when appropriate,

the patient's family whenever a final outcome of care differs significantly from an anticipated outcome.

.12 Interhospital Notification Of Level 1 or Level 2 Adverse Events.

A. A hospital that admits a patient with a condition resulting from a level 1 or level 2 adverse event that the hospital perceives may be related to care that was provided at another Maryland hospital and that appears to be unknown to the other hospital at the time of discharge shall notify and provide any necessary information to the appropriate medical review committee at the hospital where the adverse event allegedly occurred.

B. The hospital where the event allegedly occurred shall conduct a root cause analysis and provide notice to the Department in accordance with this chapter.

C. The hospital where the event allegedly occurred shall notify the patient or the patient's family in accordance with this chapter.

D. All communication that occurs in accordance with §A-B of this provision is confidential under Health Occupations Article, §1-401, Annotated Code of Maryland.

.13 Records.

The hospital shall maintain records that document the operation of its patient safety program.

.14 Documentation.

A. On or before March 15, 2004, the hospital shall send to the Secretary a written description of its patient safety program that includes:

(1) The name of the patient safety coordinator;

(2) The board policy statement relevant to patient safety activities, including the process to review the hospital's patient safety program and to determine the effectiveness of the hospital's patient safety program;

(3) A description of the near-miss and adverse event identification and reporting process;

(4) A list of examples of adverse events that shall be reported;

(5) A description of the process for determining which near-misses warrant a root cause analysis to be conducted;

(6) A description of the near-miss and adverse event review, prioritization, evaluation, and root cause analysis process;

(7) A description of the process used to provide notification to a patient, and, when appropriate, to a patient's family whenever an outcome of care differs from an anticipated outcome; and

(8) A description of the formal written patient complaint process.

B. The hospital shall notify the Secretary of any change in its patient safety program related to the description required by this regulation within 30 days of the effective date of the change.

.15 Plan of Correction.

A. If the Department notifies a hospital that the patient safety program of the hospital does not meet the requirements of this chapter, the hospital shall submit a plan indicating the steps the hospital shall take to meet the requirements of this chapter.

B. The plan shall be sent to the Secretary within 30 days after the Department notifies the hospital that the hospital does not meet the requirements of this chapter.

.16 Penalties.

If a hospital fails to have in effect a patient safety program in accordance with this chapter, then the Secretary may impose on the hospital the following penalties:

A Revocation of the hospital's license; or

B. A fine of $500 for each day that the hospital is in violation of this chapter.

END ALL NEW MATERIAL

NELSON J. SABATINI

Secretary of Health and Mental Hygiene