



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
Office of Health Care Quality
Bland Bryant Building • Spring Grove Center
55 Wade Avenue • Catonsville, Maryland 21228

To: All Maryland Hospitals

From: Carol Benner
Director

Subject: Patient Safety Regulations

Date: March 10, 2004

On March 15, 2004 the Maryland Patient Safety Regulations (COMAR 10.07.06) will become effective. The regulations will require all Maryland Hospitals to develop a patient safety program that shall include:

- A supportive environment within the hospital to encourage internal reporting of near misses and adverse events
- Mandatory reporting to the Office of Health care Quality of Level I adverse events and submission of a root cause analysis for that event
- Communication with patients or their families when an adverse event occurs
- Inter- hospital communication when a hospital receives a patient whose care at another hospital resulted in an adverse event.

Each hospital must develop a written patient safety plan and submit it to the Office of Health Care Quality by June 1, 2004. Patient safety plan requirements can be found in the regulations (COMAR 10.07.06) which are posted on the OHCQ website. Be sure to include the name and contact information, including telephone number and email, of the individual who will be designated to manage patient safety activities within the hospital. After review of the hospital's Patient Safety Plan, OHCQ staff will provide written notification of the hospital's compliance with COMAR 10.07.06 or if necessary will request additional information.

Effective March 15, 2004, all Level I Adverse Events (those events where death or serious disability occurs) must be reported to OHCQ. Reports must be filed within five working days of the hospital's knowledge that a Level I Adverse Event has occurred. Reports

should be sent to Renee Webster, Assistant Director for Hospitals and Ambulatory Care. Reports can be made by:

- Telephone (410) 402-8090,
- Fax (410) 402-8167, or
- Email (rwebster@dhmh.state.md.us)

We have prepared a form that will serve as a guideline for the type of information to be reported. It can be downloaded from the OHCQ website www.dhmh.state.md.us/ohcq/ .

Please note that information identifying staff and other individuals who were involved in the adverse event is not required unless there is a direct relationship between the adverse event and deliberate or gross negligence of an individual. We will work with you to ensure that in these rare situations, appropriate referrals and actions are taken.

Within 60 days of notification to OHCQ, the hospital must conduct a root cause analysis and submit the root cause analysis (RCA) including action plan to OHCQ for review. OHCQ will accept the RCA in either electronic or hard copy format. OHCQ staff will review the RCA and will notify the hospital in writing regarding the results of the review.

Over the years, Maryland has taken positive and constructive steps to ensure that efforts to improve care and safety are indeed that. Although these regulations may pose a challenge, please be assured that we will work with you and the Maryland Hospital Association to work through implementation issues as they arise. If you have questions, please bring them to our attention.

Please contact Renee Webster with any of your concerns or questions at (410) 402-8090 or email her at rwebster@dhmh.state.md.us

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