



*State of New Jersey*

**DEPARTMENT OF HEALTH AND SENIOR SERVICES**

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RICHARD J. CODEY  
*Acting Governor*

CLIFTON R. LACY, M.D.  
*Commissioner*

December 8, 2004

TO: Hospital CEO's

FROM: Marilyn Dahl  
Deputy Commissioner, Health Care Quality & Oversight

Subject: Change in Process for Mandatory Reporting -Patient Safety

The "Patient Safety Act," P.L. 2004, c.9, (N.J.S.A. 26:2H-12.23-12.25), signed into law on April 27, 2004 and effective on October 24, 2004, establishes a statutorily mandated reporting system for certain adverse events that occur in any health care facility licensed pursuant to N.J.S.A. 26:2H-1 et seq.

General hospitals have been required by rule for a number of years to report a wide range of events to the Department. With the Patient Safety Act now in effect, the Department is developing proposed new rules which should appear for formal public comment in the New Jersey Register in early 2005. The Department has been consulting informally with representatives of all types of health care facilities in the development of the rule proposal.

However, effective February 1, 2005, in advance of the adoption of new rules, the Department will require general hospitals to use the Patient Safety Act's mandatory reporting standards, as well as a new process for reporting serious preventable adverse events. The requirement will apply not only to the general hospital's main campus, but also to all ambulatory care and satellite facilities that are on the hospital license. It is the Department's view that this early adoption of the new process will be beneficial to both hospitals and the Department. Completion and submission of the new reporting forms and accompanying documentation will afford general hospitals the benefits and confidentiality protections specified in the Patient Safety Act.

This new Patient Safety Act mandatory reporting process will replace the one articulated in the May 5, 2003 memorandum from Commissioner Lacy to hospital CEOs. (For reference purposes, we have enclosed a copy of the memorandum.)

1. Hospitals will notice few changes in what types of events must be reported to the Department. The types of Serious Preventable Adverse Events, (care management events, environmental events, product or device events, surgery-related events and patient protection events) previously set forth in Section 2 of the May 5, 2003 memorandum are generally consistent with the requirements of the Patient Safety Act, and continue to be subject to mandatory reporting, with one notable difference. Hospitals must continue to report post-operative death for all patients undergoing same-day surgery, but for inpatients undergoing surgery, post-operative death must be reported only for those patients who were ASA Class I. However, the separate reporting form and process that governed anesthesia-related events in the past are being discontinued. In addition, any event that meets the statutory definition of a serious preventable adverse event must be reported, even if it is not readily covered by any category on the attached reporting form.

*Please note, however, that other types of reportable events covered in the May 5, 2003 memorandum and not subject to the Patient Safety Act must continue to be reported according to existing procedures previously established by the Department. These events include physical plant and operational interruptions, communicable diseases, and alleged criminal activities.*

2. Hospitals will notice major changes in how reporting will occur, as well as the type of follow-up actions to be taken by both hospitals and the Department.
  - a. Patient Safety Act reportable events occurring in general hospitals shall be reported by fax, utilizing the attached standardized reporting form and instructions.
  - b. Timeframes for reporting are being expanded from within three hours of the event to two business days after discovery (but no later than five days after occurrence).
  - c. Reports shall be submitted to the Health Care Quality Assessment Program, not, as is currently the case, to the Acute Care Survey Program.
  - d. Follow-up by the hospital will consist of submission within 45 days of a root cause analysis (RCA) of the reported event, including recommendations/actions taken with respect to preventing future occurrences of similar events.
  - e. Follow-up by the Health Care Quality Assessment Program will consist of evaluation of the RCA in terms of best practices in patient safety, as well as identification of information that is important to share with other health-care facilities on a de-identified basis, in order to reduce the likelihood of similar events statewide. Only in exceptional cases meeting the statutory standards will cases be referred for potential enforcement action by the

survey and licensure programs. This approach is consistent with the Department's intent to take a broad quality improvement rather than a strictly regulatory compliance approach to patient safety issues.

Hospitals are reminded that the law provides confidentiality protection for documents, materials and information received by the Department concerning serious preventable events, near-misses, preventable events and adverse events and limits the admissibility and discoverability of the information received by the Department.

By January 5, 2005, please return the enclosed form identifying the person in your hospital who will serve as the point of contact between the Department and the hospital on implementing this new process. The form should be returned to:

Frances Prestianni, Ph.D.  
Program Manager  
Health Care Quality Assessment  
Division of Health Care Quality & Oversight  
Department of Health and Senior Services  
25 Scotch Road, Suite 10  
Ewing, NJ 08628

Additionally, if you or your staff have any technical questions concerning the reporting requirements, please contact Dr. Prestianni at 609-530-7473.

Thank you for your cooperation in this effort to improve safety for patients in New Jersey hospitals.



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DEPARTMENT OF HEALTH AND SENIOR SERVICES

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Contact Information for Patient Safety Reporting Initiative

Table with 2 columns: Field Name (Hospital Name, License Number, Name, Title, Street Address, City, State, Zip, Telephone Number, Fax Number, Email) and Input Area. Includes a footer row: Please submit this information before January 5, 2005 to:

Patient Safety Reporting Initiative
Frances Prestianni, Ph.D.
Program Manager
Health Care Quality Assessment
Division of Health Care Quality & Oversight
Department of Health and Senior Services
25 Scotch Road, Suite 10
Ewing, New Jersey 08628
Tel: 609-530-7473

Form may be faxed to 609-530-4850