Department of Health and Senior Services Promulgates Patient Safety Act Rules

Client Advisories

04.21.2008

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On March 3, 2008, the Department of Health and Senior Services published in the New Jersey Register (40 N.J.R. 1094(a)) final rules implementing the Patient Safety Act (N.J.S.A. 26:2H-12.23 to 12.25). This Act became effective on Oct. 15, 2004, and established a medical error reporting system to detect and minimize the occurrence of errors and incorporated patient safety mechanisms to improve the performance of facilities. The Act also contains significant protections of confidentiality and discoverability of committee materials if reported under the Act. There are severe monetary penalties for failing to comply with the regulations.

The regulations became effective on the date of publication, March 3, 2008, for general, special, rehabilitation and psychiatric hospitals, but will not be effective until August 30, 2008, for state psychiatric hospitals, home health agencies, hospices, ambulatory care facilities and residential and outpatient substance abuse treatment facilities; and March 3, 2009, for assisted living residences and comprehensive personal care homes, assisted living programs, long-term care facilities, residential health care facilities and adult and pediatric day health services facilities.

In a very significant provision, the Department has exempted Medicare and/or Medicaid-qualified nursing homes from the mandatory reporting requirements of the regulations if they comply with applicable federal and state reporting laws and regulations on this issue. N.J.A.C. 8:43E-10.6(a)(1).

Central to the purpose of the Patient Safety Act is the recognition and reporting of certain “events.” An “event” is a discrete, auditable and clearly defined occurrence. An “adverse event” is an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable. A “preventable event” is an event that could have been anticipated and prepared against but occurs because of an error or other system failure. And a “serious preventable event” is an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at time of discharge from a health care facility.

Mandatory Reporting. The regulations require mandatory reporting of every serious preventable adverse event ("SPAE"). A prescribed, three-page reporting form is included as Appendix A to the regulations. A Facility must report an SPAE no later than five (5) business days after the facility discovers the occurrence of the event. If the facility fails to submit a report by its due date, it may be subject to severe penalties, which will be imposed from the date following the report's due date until the date it is received as follows: $1,000 per day for general hospitals, with the maximum penalty assessed per event not to exceed $100,000; and $250 per day for all other facilities, with the maximum penalty assessed per event not to exceed $25,000.

Adult and pediatric day health services facilities and other facilities that provide home-based services such as home health care facilities, hospice facilities, assisted living residences, comprehensive personal care homes and assisted living programs, should report only those SPAEs within the control of the facility or directly caused by/related to the services of the facility.

Root Cause Analysis. A facility's obligations do not end with reporting the SPAE, however. No later than 45 days after submission of the initial report, a facility must submit a root cause analysis ("RCA") of every SPAE, using the form attached to the regulations as Appendix B. "Root Cause Analysis" is defined as an in-depth analysis of an adverse event, designed to identify direct and underlying causes of the event, in order to develop corrective actions and reduce the potential for similar events in the future.

Understandably, the RCA will vary based upon the facility type and event involved, but it must involve at least a description of the event including when, where and how it occurred and the adverse outcome for the patient/resident; an analysis of why the event happened; corrective actions taken for patients/residents affected by the event; and how the corrective action(s) will be monitored to assess their impact.

Patient or Resident Safety Committee. Each facility must establish a patient or resident safety committee. In the case of facilities that are part of a system, the patient/resident safety committee may be operated at the system level if there is a representative from each facility on the committee and the patient safety data from each facility remains distinctly identifiable. The patient/resident safety committee may not be a subcommittee of any other committee within the facility or system. Meetings must be held on a quarterly basis or as determined by the committee. Certain specified individuals must be included as members of the patient/resident safety committee. The committee's responsibilities are detailed in Section 8:43E-10.4(d) of the Regulations.

Patient or Resident Safety Plan. One of the principal responsibilities of the patient/resident safety committee is to develop and implement a patient/resident safety plan that includes a process for staff to follow in reporting preventable adverse events or near-misses to the committee; a process for conducting a review and application of evidence-based patient/resident safety practices to reduce the probability of preventable adverse events; policies/procedures for the committee to conduct RCAs of SPAEs and annually, an RCA of at least one near-miss or preventable adverse event; a process for monitoring the impact of changes recommended by the committee; and a process for providing ongoing patient safety training for personnel.

The regulations note that none of the above requirements eliminate or lessen a facility's current federal or state obligation to have a continuous quality improvement program.

Disclosure to Patients or Residents. Facilities must ensure that patients/residents are informed when an SPAE has occurred that affected the patient/resident; or an adverse event related to an allergic reaction (not previously documented in their medical history) has occurred. The facility must inform the patient/resident about the event within 24 hours after the facility discovers the event.

If the facility fails to inform the patient/resident about a serious preventable adverse event, it may be subject to penalties of $1,000 if the facility also failed to report the event to DHSS; and $5,000 for failure to disclose an event to the patient/resident that the facility did report to DHSS.

If the patient/resident has prohibited disclosure of his/her protected health information to any family members under federal HIPAA regulations (45 CFR § 164.522), the facility must not disclose information to a family members who is not a guardian or does not have a medical power of attorney. (See N.J.A.C. 8:43E-10.7(e)).

Voluntary, Anonymous Reporting. The regulations encourage health care professionals and health care facility employees to submit anonymous reports regarding near-misses and preventable adverse events that are not subject to mandatory reporting. Facilities must inform employees and health care professionals of the option to file such anonymous reports through information available in their safety training programs and by posting it in accessible locations.

Protection from Discovery. Discoverability protection is provided for any documents, materials or information received by DHSS and DHS under these regulations. Those documents, materials or information shall not be subject to discovery or admissible as evidence or otherwise disclosed in civil, criminal or administrative proceedings; considered a public record; or used in adverse employment actions.

The same protection exists for documents, materials and information (e.g., minutes and RCAs) developed by the facility exclusively during the process of self-critical analysis of preventable events, near-misses, adverse events or SPAEs. Similarly, the discoverability protection exists for oral statements and documents representing the disclosure to a patient/resident of an SPAE or adverse allergic event as well as the entry in the medical record of such disclosure.

The discoverability protections also cover individuals who participate in patient/resident safety committee meetings or perform responsibilities for that committee. Those individuals cannot be required to testify as to any matters regarding knowledge gained from responsibility or participation on the committee.
These discoverability protections do not limit a facility's right to take disciplinary action against those professionals exhibiting recklessness, gross negligence or willful misconduct or when evidence exists from similar cases that demonstrate a pattern of significant substandard performance resulting in SPAEs.

Finally, the regulations clarify that these provisions do not affect the availability, discoverability, admissibility or use of documents, materials or information otherwise available from other sources.
The foregoing is merely an overview. The regulations implementing the Act are extremely complex, detailed and comprehensive. Careful review with competent counsel is strongly recommended.

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