

Ensuring Patient Safety Through Effective Compliance

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What is Neglect?

- Neglect defined in civil context
- Neglect defined in criminal context
- Intent issues
- Discharge planning process

PA Neglect of Care Dependent Persons (Act 28, 18 Pa. C.S. 2713)

- Criminalizes neglect cases.
- Offenses graded as either a 1st degree felony or 1st degree misdemeanor. A Felony-1 is punishable by a maximum of more than 10 years in prison, and a Misdemeanor-1 is punishable by a maximum of no more than 5 years in prison. The degree of bodily injury determines the grading of the offense.

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Neglect By Caregivers

- A caregiver is guilty of neglect of a care-dependent person if he: (1) intentionally, knowingly or recklessly causes bodily injury or serious bodily injury by failing to provide treatment, care, goods or necessary to preserve the health, safety or welfare of a care-dependent person

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Neglect By Caregiver

- (2) Intentionally or knowingly uses a physical restraint or chemical restraint or medication on a care-dependent person, or isolates a care-dependent person contrary to law or regulation, such that bodily injury or serious bodily injury results.

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Compassion Fatigue

- Defense to neglect (Wisconsin case)?
- Who is responsible?
- Who should intervene?

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Reporting Issues Hypothetical #1

- TKR - LEFT KNEE
- Pre-Operative Identification of site
- Operating room set up for TKR on right knee
- Is this reportable in PA?
- Is this reportable elsewhere?

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Hypothetical #2 – MEDICATION ERROR

- ICU: S/P Lung –lobectomy
- Heparin dosage is given in ICU
- Patient transferred to Med/Surg floor
- Heparin dosage given again
- Non-lethal overdose
- Is this reportable in PA?
- Is this reportable elsewhere?

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Hypothetical #3 Major Oops!

- Med/Surg Floor
- Yellow ID Band re: code status (Full Code)
- Agency Nurse
- No Facility Specific Training
- Pt. stops breathing
- No Code called
- Is this reportable in PA?
- Is this reportable elsewhere?

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Who Do You Report To?

- PSO – Patient Safety Organization (Voluntary)
- In PA--PA Department of Health (MCARE – ACT 13)
- Joint Commission
- FDA – Medication Events
- National Physician Data Bank
- Medical Device Reporting

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Pennsylvania -MCARE

Medical Care Availability and Reduction of Error Act

- The Pennsylvania Safety Authority, an independent State agency, has established a mandatory statewide Pennsylvania Patient Safety Reporting System for serious events within twenty-four hours. The system requires the reporting of both actual adverse events and near misses. Healthcare workers can also submit anonymous reports

PA. Stat. Ann. Tit. 40 Sec. 1303.308 (2003)

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Pennsylvania MCARE

- A serious event is an event, occurrence or situation involving the clinical care of a patient in a medical facility that either:
 - A) resulted in the patient's death, or
 - B) resulted in an unanticipated injury.

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Pennsylvania

Pennsylvania identified instances of underreporting by comparing hospitals and matching against other data sources.

"Pennsylvania identified reporting disparities by analyzing the number of reports per hospital for every 1000 patient days. It found a wide range of reports across hospital, with the top 25 % of reporting hospitals submitting 36 to 302 adverse events per 1,000 patient days, and the bottom 25% of hospitals reporting 0 to 8 events per 1,000 patient days. State staff theorized that this range could be explained by hospitals' differing interpretations of events; systems for identifying events; cultures regarding patient safety; and/or patient case mix, which can affect rates of serious events."

Pennsylvania Safety Authority, "2007 Annual Report," April 29, 2008, o. 32. Available online at: http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2007.pdf. Accessed on May 7, 2008

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Pennsylvania

Pennsylvania uses adverse event reports to produce quarterly bulletins that examine a range of patient safety issues and typically include clinical reminders, best practices anecdotes, policy alerts, and reporting guidance.

Pennsylvania Patient Safety Advisory. Available online at http://www.psa.state.pa.us/psa/cwp/asp?a=1293&q=445966&psaN_av=1. Accessed on June 9, 2008.

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What is Reported? Model 1: "Everything"

- What is the effect of transparency?
- What is disclosure: the release of, transfer of, provision of access to, or divulging in any other manner of, patient safety work product by a entity or natural person, other than a workforce member of, or a physician holding privileges with, the entity holding the patient safety work product.
- Example: Beth Israel

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What is Reported? Model 2: "Too little"

- Failure to report
 - Deliberate under-reporting
 - Risks:
 - Loss of privacy protections
 - Fraud and abuse charges
 - Bad publicity
 - Surveys, investigations of violations
 - Fines
 - Litigation

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What is Your Role?

Do you know....

- What is reported?
- How do you know whether everything that should be reported is reported?
- What remedies do you have?
- What "fix" have you made?
- How do you test the "fix"?
- "Bad" doctors and Peer Review

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What are "Never Events"?

Never events are a specific list of serious events that the National Quality Forum deemed "should never occur in a health care setting." These events are divided into six categories:

1. Surgical events
2. Product or device events
3. Patient protection events
4. Care management events
5. Environmental events
6. Criminal events

National Quality Forum, NQF, "Serious Reportable Events in Healthcare, 2006 Update," 2007 pp. vi. And 6.

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The Patient Safety and Quality Improvement Act of 2005

- Creation of voluntary program through which health care providers can share information relating to patient safety events
- Creates Patient Safety Organizations (PSOs)
- Establishes network of databases
- Requires reporting of findings annually in AHRQ's National Health Quality/Disparities Report

Source: William Munier, MD, MBA, **PSO Update: Final Rule & Common Formats**,
December 16, 2008

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Purpose of the Rule

- The purpose of the Patient Safety Act was to "create a voluntary system through which providers could share sensitive information relating to patient safety events without fear of liability, which should lead to improvements in patient safety and in the quality of patient care."

Patient Safety and Quality Improvement Final Rule, 42 CFR Part 3, Vol. 73, No. 226/Friday November 21, 2008, (pp. 70732-70814)

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Patient Safety Organizations

- What is a PSO?
 - public or private entity—for profit or not-for-profit
 - ineligible orgs: health insurance issuers or their components; accrediting & licensing bodies; regulators including their agents (e.g. QIOs)
- 68 in country
- PSQIA final rule went into effect January 19, 2009

Source: Munier, supra.

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General PSO Requirements

1. Makes effort to improve patient safety.
2. Collects and analyzes patient safety work product.
3. PSO uses its analysis to provide information such as protocols or best practices on improving patient safety.
4. PSO uses patient safety work product to encourage a culture of safety and to minimize risk to patients.
5. PSO implements procedures to keep patient safety work product confidential.
6. PSO provides sufficient security measures for patient safety work product.
7. PSO utilizes qualified staff.
8. PSO operates a patient safety evaluation system and provides feedback to providers on the patient safety evaluation.

Source: Final Rule

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Who Has To Report?

- **Providers:**
An individual or entity licensed or otherwise authorized under State law to provide health care services including:

Source: Final Rule

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Who is a Provider?

- An individual or entity licensed or otherwise authorized under State law to provide health care services including:
- (1)(i)
 - Hospital
 - Nursing facility
 - Comprehensive outpatient rehabilitation facility
 - Home health agency
 - Health center
 - Clinical Laboratory
 - Hospice program
 - Renal dialysis facility
 - Ambulatory surgical center
 - Pharmacy
 - Physician or health care practitioner office (including group practice)
 - Long term care facility
 - Behavior health residential treatment facility

Source: Final Rule

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Who is a Provider?

- (1)(ii)
 - Physician
 - Physician assistant
 - Registered nurse
 - Nurse practitioner
 - Clinical nurse specialist
 - Certified registered nurse anesthetist
 - Certified nurse midwife
 - Psychologist
 - Certified social worker
 - Registered dietician or nutritional professional
 - Physical or occupational therapist
 - Pharmacist
 - Other health care practitioner

Source: Final Rule

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Who is a Provider?

- (2)
 - Agencies
 - Organizations
 - Individuals within Federal State, local or Tribal governments that deliver health care
 - Organizers engaged as contractors by the Federal State, local or Tribal governments to deliver health care practitioners employed or engaged as contractors by the Federal State, local or Tribal governments to deliver health care

Source: Final Rule

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Who is a Provider?

- (3) A parent organization of one or more entities described in paragraph (1)(i) of this definition or a Federal, State, local or Tribal government unit that manages or controls one or more entities declared in paragraphs (1)(i) or (2) of this definition.

Source: Final Rule

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Operational Activities

- PSO must have at least 2 bona fide contracts with different providers for the purpose of reviewing patient safety work product within the first 24-month period from the date of its initial listing and every 2-month period thereafter.
- NOT a health insurance provider or component thereof

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What is Reported?

- 26 states have hospital adverse event reporting systems
- Events resulting in death
 - All 26 states use this criteria for at least one reportable event
- Events resulting in long term harm or permanent disability
 - 23 states use this criterion for at least one reportable event
- Events resulting in harm and likely to require additional medical care
 - 24 states use this criterion for at least one reportable event
- Events not resulting in identifiable physical harm
 - 23 states use this criteria for at least one reportable event
- Near misses (PA only)

DHHS, OIG Adverse Events in Hospitals: State Reporting Systems, December 2008, p.9.

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Patient Safety Work Product

- Patient safety work product

"(A) In general.--Except as provided in subparagraph (B), the term 'patient safety work product' means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements--

(i) which--

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

Source: Final Rule

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What is NOT Patient Safety Work Product?

- A patient's medical record
- Billing information
- Discharge information
- Information collected, maintained or developed separately or exists separately from a patient evaluation system

Source: Final Rule

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What is NOT Patient Safety Work Product?

- Information collected to comply with external obligations including:
 - State incident reporting requirements;
 - Adverse drug event information to the FDA;
 - Certification or licensing records for compliance with health oversight agency requirements;
 - Reporting to National Practitioner Data Bank of physician Disciplinary Actions;
 - Complying with required disclosures by particular providers or suppliers pursuant to Medicare conditions of participation or conditions of coverage; or
 - Provision of access to records by Protection and Advocacy organizations as required by law.

Source: Final Rule

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What Does That Mean?

- Information collected through peer review, risk management and subsequently reported to a PSO
- Aggregate data from multiple providers
- De-identified data
- Immediate feedback and assist in making changes to system to avoid future reoccurrences

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PSQIA—Final Rule

- Permits a provider & PSO to establish a functional reporting system
- Requires notification to affected providers of improper disclosure of Patient Safety Work Product and/or security breaches
- Protects information that is collected within a “patient safety evaluation system” for reporting to a PSO

Source: Munier, *supra*.

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Enforcement

- Patient identifiers never revealed
- Breach of confidentiality similar to breach in HIPAA ---HHS Office of Civil Rights

Source: Final Rule

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Do PSO Recommendations Create a New Standard of Care?

The rule declines to address this issue finding that standard of care is "a function of courts and entities that have jurisdiction over the issue for which standard of care is relevant. The introduction of patient safety work product as information that may help establish a standard of care is highly unlikely given the limited disclosure permissions. For this reason, we make no modifications in the final rule."

Source: Final Rule

I am not so sure....

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References:

- Patient Safety and Quality Improvement: Final Rule, 42 CFR Part 3, Vol. 73, No. 226/Friday November 21, 2008, (pp. 70732-70814)
- www.AHRQ.org
- MCARE, P.L. No. 154, No. 13, chapter 3, §§ 302 and 313(a)
- DHHS, OIG Adverse Events in Hospitals: State Reporting Systems, December 2008
- CMS Medicare News, Medicare Fact Sheet, "CMS Improves Patient Safety for Medicare and Medicaid by Addressing 'Never Events'", August 4, 2008
- FDA: <http://www.fda.gov/cder/aers/default.htm>. Accessed February 25, 2009
- http://usatoday.com/news/health/2008-09-22-supplements-adverse-events_N.htm. Accessed February 25, 2009.