

Never Events and Immediate Jeopardy Managing the Process

HASC/ DWT Compliance Seminar
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Overview of Presentation

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Overview

- **Never Events – California Style**
- **Reporting Obligations**
- **Immediate Jeopardy**
- **Managing the Investigation, the Survey Process and Appeals**



Overview

- **Scope of presentation will focus on California law and the Department of Public Health enforcement of reporting of adverse events and surveys citing hospitals for immediate jeopardy**



Overview

- “Never 28” events are also subject to –**
- **Reporting to other agencies and payors**
 - **Proposed federal rules for reporting to patient safety organizations are pending comment and final review**
 - **Possible sentinel event**
 - **Possible Medical Staff investigation**
 - **Risk management implications**
 - **Limitations on billing health plans and other payors**



Overview

Limits on billing Medicare

- **“Present on Admission” indicator reporting required as of October 1, 2007**
- **2007 – CMS will not assign a case to a higher DRG based on the occurrence of 8 selected conditions if acquired during patient stay (eff. Oct. 2008)**
- **April 2008 – list to be expanded 9 more conditions**
- **Not applicable (so far) to CAHs, Rehab and Psych hospitals or other non-IPPS hospitals**
- **Resource: www.cms.hhs.gov/HospitalAcqCond/**



Never Events

California Style

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Never Events

- Obligations apply to acute, psychiatric and special hospitals
- List of events are set in statute
- Some differences or nuances between NCF and statutory lists
- DPH may clarify the statutory language in regulations; e.g., “low risk pregnancy”, the “wrong person” (as in, “an infant discharged to the wrong person”), “after surgery”, “on the grounds of the facility.”
- Resource: Cal. Health & Safety Code Sections 1279.1, 1279.2, 1279.3 and 1280.4



Never Events

Surgical Events

- **Surgery performed on the wrong body part** (*inconsistent with informed consent signed by the patient, excluding emergency situations*)
- **Surgery performed on the wrong patient**
- **Wrong surgical procedure** (*inconsistent with informed consent signed by the patient, excluding emergency situations*)
- **Unintended retention of foreign object**
- **Death during or within 24 hours of surgery of a normal healthy patient**



Never Events

Product or Device Events

Death or serious disability associated with -

- **Use of contaminated drugs, devices or biologics** (*when contamination is result of generally detectable contaminants*)
- **Use or function of device** (e.g., *catheter, drain, specialized tube, infusion pump or ventilator*) in patient care if device used or functions other than as intended
- **Intravascular air embolism** (*excluding deaths relating to neurosurgical procedures with high risk of intravascular air embolism*)



Never Events

Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with patient disappearance exceeding 4 hours (*excluding adults with competence or decision-making capacity*)
- Patient suicide, or attempted suicide, associated with serious disability (*excluding self-inflicted injuries causing the admission*)



Never Events

Care Management Events

Death or serious disability associated with -

■ **Medication error, including –**

- Wrong drug or dose
- Wrong patient
- Wrong time
- Wrong rate
- Wrong preparation
- Wrong route of administration

■ **Excludes reasonable differences in clinical judgment on drug selection or dose**



Never Events

Care Management Events

Death or serious disability associated with -

- **Hemolytic reaction due to administration of ABO-incompatible blood/blood products**
- **Labor or delivery of low-risk pregnancy**
(including events within 42 days post-delivery, excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy)



Never Events

Care Management Events

Death or serious disability associated with -

- **Hypoglycemia (*if onset occurs in the hospital*)**
- **Failure to identify/treat hyperbilirubinemia in newborns within 28 days of birth**
- **Stage 3 or 4 pressure ulcers acquired after admission (*excluding progression from Stage 2 to 3 if Stage 2 identified on admission*)**
- **Spinal manipulative therapy**



Never Events

Environmental Events

- **Death or serious disability associated with the electric shock (*excluding planned events*)**
- **Any incident in which an oxygen or other gas line contains the wrong gas or is contaminated by a toxic substance**
- **Death or serious disability associated a burn from any source**
- **Death from a fall**
- **Death or serious disability associated with the use of restraints of bedrails**



Never Events

Criminal Events

- **Care ordered or provided by someone impersonating any licensed provider**
- **Patient abduction (any age)**
- **Sexual assault within or on grounds of the hospital**
- **Death or serious injury of patient or staff member from a physical assault within or on grounds of the hospital**



Never Events

Catchall Events

- **Any adverse event or serious or adverse events that cause the death or serious disability of a patient, personnel or visitor**



Never Events

- Some “adverse events” --
 - require death or serious disability
 - others do not require any adverse impact
- **“Serious disability”** is defined as a physical or mental impairment that substantially limits one or more major life activities or loss of bodily function, if the impairment or loss continues more than 7 days or present at discharge, or a loss of a body part





Reporting Never Events

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Reporting Obligations

- An adverse event must be reported to Licensing -
 - Within 5 days after detection of the event, or
 - Within 24 hours after detection of the event if the event is an ongoing urgent or emergent threat to the health, welfare or safety of patients, personnel or visitors
- Reporting of adverse events does not supersede separate obligation to report “unusual occurrences” to Licensing



Reporting Obligations

- Failure to report an adverse event in a timely manner is subject to a fine of \$100 a day for each day the report is overdue
- Failure to report is subject to an appeal that must be filed within **10** days of Licensing action



Reporting Obligations

- **Obligation to inform the patient or his/her representative of the adverse event by the time of the report to Licensing**



Reporting Obligations

- **Obligation to report also includes “unusual occurrences” [Title 22, Cal. Code of Regs. § 70737]:**
 - Epidemic outbreak, poisoning, fire, major accident, disaster, catastrophe
 - Any unusual occurrence that threatens the welfare, safety or health of patients, personnel or visitors
- **Report “as soon as reasonably practical,” either by “telephone or by telegraph” to DPH/local health officer**




Reporting of Adverse Events

- **328 adverse events reported between July 1 and Nov. 27, 2007**
 - **38% -- Stage 3 or 4 ulcer**
 - **18% -- Foreign objects**
 - **10% -- Other adverse events or series of adverse events**
- **One assessment for late reporting**

Source: Kathleen Billingsley, R.N., Presentation, December 2007





IMMEDIATE JEOPARDY

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Immediate Jeopardy

- **Licensing must conduct an onsite survey within 2 business days of receiving --**
 - **Any report of an adverse event, or**
 - **Any other report involving a hospital of an imminent threat danger of death or serious bodily harm**
- **The investigation must be completed within 45 days**



Immediate Jeopardy

- Survey may or may not result in a finding of “immediate jeopardy”
- “Immediate jeopardy” defined as “a situation in which the licensee’s noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient”

Resource: Cal. Health & Safety Code Sections 1280.1 and 1280.3



Immediate Jeopardy

- **Immediate jeopardy may be related to --**
 - **The report of an adverse event;**
 - **Any other report to Licensing (such an unusual occurrence that is not an adverse event);**
 - **Finding made by a surveyor during the course of a survey, whether due to a complaint or planned or during the course of a certification survey**
- **Immediate jeopardy identified during a survey will continue in effect until removed by Licensing (in one case, up to 20 days)**



Immediate Jeopardy

- Findings of immediate jeopardy reported in the standard licensing survey form (2567)
- The finding of immediate jeopardy is usually stated on the first or second page of the statement of deficiencies
- The survey does not include the amount of the administrative penalty
- Survey may trigger a validation survey



Immediate Jeopardy

Finding of “immediate jeopardy”

- Submission of an acceptable plan of correction; and
- Imposition of a administrative penalty up to \$25,000 per violation
 - Current policy to impose \$25,000 for each confirmed violation
 - Will increase to range of \$17,500 to \$50,000 when regulations adopted
- Penalty for any hospital under common governance with a health plan must take into consideration of DMHC investigation or fines



Immediate Jeopardy

- DPH will issue a press release identifying hospitals and events identified as constituting “immediate jeopardy”
- Licensing will post on the DPH website the statements of deficiencies for surveys finding “immediate jeopardy”
www.cdph.ca.gov/certlic/facilities/Pages/Counties.aspx
- DPH may also issue a press release and publicize cases without finding of immediate jeopardy



Immediate Jeopardy

- To date, 23 surveys have been posted involving 18 hospitals (one survey was later removed from the website)
- One hospital cited 3 times, four hospitals cited twice
- Cases include community, teaching, specialty, public and private hospitals



Immediate Jeopardy

Examples of surveys finding immediate jeopardy

- Patient death due to defective bed rails
- Medication errors (14 cases)
- Refrigeration controls and storage (2 cases)
- Physical and verbal abuse of a patient by a physician (triggered a validation survey)
- Emergency patient assessment and transfer



Immediate Jeopardy

Examples of immediate jeopardy surveys --

- Psychiatric unit elopement (2 cases, one later removed from the DPH website) – inadequate staffing or failure to deliver care in a safe manner
- Failure to maintain on-call roster and ensure physician inpatient coverage
- Failure to maintain adequate nurse staffing for emergency triage assessment



Immediate Jeopardy

- Most common case for finding immediate jeopardy
- Several cases involve administration and monitoring of “black box” medications
- DPH issued Hospital Alert in November 2007 on “black box” warnings
- DPH also initiated monitoring on the implementation of Medication Error Reduction Plans submitted by hospitals to DPH



Immediate Jeopardy

- **DHS is in the process of hiring 150 new surveyors**
- **Will include surveyors in all CALS surveys by end of 2008**
- **Focus will include compliance with both state regulations and federal certification standards**



IMMEDIATE JEOPARDY

Managing the Process and Appeals

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Managing the Process

Compliance begins before an adverse event or an immediate jeopardy

- **Adoption of reporting and investigation policy**
- **In-service of board, management, medical staff and hospital personnel**
- **In-service of new personnel during orientation**
- **Identification and management of areas of risk (e.g., medication errors)**
- **Learn from errors**



Managing the Process

- **Effective and timely internal reporting of adverse or other reportable events**
 - Designate key position to receive reports
 - Advise management
 - Manage public relations
 - Coordinate timely report to patient
- **Timely reporting of adverse or other reportable events to DPH**



Immediate Jeopardy

- **Timely internal investigation of reports**
 - Form an internal investigation team
 - Involve compliance and risk management
 - Consider use of legal counsel
- **Interview personnel involved in the occurrence of events – direct and indirect (including supervisors and physicians)**
- **Immediate commencement of corrective action (do not wait for the surveyor)**



Immediate Jeopardy

Survey Process --

- **Licensing interviews of staff**
 - **Cases on the DPH website report staff statements (often in quotes), including understanding of hospital policies, the facts of the event and a personal assessment of the risk or danger of the event**



Immediate Jeopardy

Survey Process –

- If “immediate jeopardy” identified and confirmed with supervisor, surveyor will advise hospital management
- Immediate jeopardy will also be reaffirmed at the exit conference



Immediate Jeopardy – Appeals

- **A hospital may appeal –**
 - The alleged deficiency,
 - The alleged failure to correct a deficiency,
 - The reasonableness of the deadline to correct a deficiency; or
 - The amount of the administrative penalty
- **Appeal must be filed with DPH within 10 working days (unclear if from the date of letter or date of receipt of the letter)**
- **Hearing is conducted in accordance with the Administrative Procedure Act**



Questions and Answers



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