Q: What is an administrative penalty?
A: An administrative penalty is a civil monetary penalty in an amount up to $100,000 per violation or deficiency constituting an immediate jeopardy to the health and safety of a patient. These penalties are assessed against general acute care hospitals, acute psychiatric hospitals and special hospitals after an investigation of a facilities non-compliance of licensure. These penalties are assessed and investigations are conducted by the California Department of Public Health, Licensing and Certification Program.

Q: What is an immediate jeopardy?
A: An immediate jeopardy is a situation in which the hospital's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. A situation is an immediate jeopardy at the time it occurred. Correction of the situation does not mean it is no longer an immediate jeopardy. If, when the situation occurred, it was an immediate jeopardy the facility can still be cited for the situation at a later time after the immediate jeopardy has been abated and the department has completed its investigation and evaluation of the situation.

Q: What types of facilities are impacted by the new administrative penalty laws?
A: Only general acute care hospitals, acute psychiatric hospitals, and special hospitals are impacted by these new laws.

Q: When did the CDPH receive the authority to issue administrative penalties for hospitals?
A: The administrative penalties are the first to be issued by the California Department of Public Health under new authority granted by Health and Safety Code, Section 1280.1 (Senate Bill 1312, Statutes of 2006, Chapter 895), which was signed by Governor Arnold Schwarzenegger in 2006 and became effective on January 1, 2007.

Q: Why did it take eight months to issue the first penalties?
A: Because it is a new law, we needed to carefully develop the policies and procedures that will be used to implement the provisions of Senate Bill 1312. The Licensing and Certification Program also met with stakeholders and advocacy groups during the eight months to discuss the new provisions, their implementation, and the impact they would have on hospitals.

Q: What is the fine for an administrative penalty?
A: CDPH has authority to impose administrative penalties for violations that constitute immediate jeopardy to a patient's health and safety up to the following amounts: $50,000 for the first administrative penalty, $75,000 for the second administrative penalty, and $100,000 for the third and every subsequent violation.

Q: What will happen to the fine money? Where does it go?
A: The fines are to be deposited in the Licensing and Certification Program Fund established pursuant to Health and Safety Code section 1266.9. This is a special fund for the Licensing and Certification Program. These fine moneys are tracked and, upon approval by the legislature, are to be used for internal departmental quality improvement activities.

Q: What is the intent of an administrative penalty?
A: The California Department of Public Health expects the enactment of this new statute to lead to improvements in patient safety and healthcare quality for the residents of California.

Q: Will there be an effort to measure this law’s effectiveness in improving patient safety and healthcare?
A: Yes, the Department will evaluate the data collected and be able to compare the number of violations/deficiencies to the number of immediate jeopardy deficiencies issued from year to year in order to determine if the number of violations/deficiencies have changed over time. Hospitals are required to develop plans of corrections for immediate jeopardy situations that are assessed against hospitals.

Q: Prior to administrative penalties, what enforcement actions were available to CDPH to use against hospitals out of compliance with the law?
A: The hospitals are subject to termination from the Centers for Medicare/ Medicaid (federal government) if they are not in compliance with the Conditions of Participation. The hospitals could also have their license revoked if they are not in compliance with the California Code of Regulations. Hospitals are cited for violations/deficiencies to these federal and state standards/regulations during quality of care investigations and surveys and are required to submit plans of corrections to allow them to continue to participate in federal programs and retain their licenses. These avenues for correction will continue; the only difference is that as of January 1, 2007, the Licensing and Certification Program may assess an administrative monetary penalty for these deficiencies.

Q: Who decides what hospital receives an administrative penalty?
A: The recommendation to issue an administrative penalty is made at the Licensing and Certification Program's District Office level by the investigating surveyor and their supervisor after review of the investigation and approval of the determination to issue the administrative penalty. These proposed/recommended penalties are sent to Office of Legal Services and the Licensing and Certification Program Deputy Director for approval and issuance. The Licensing and Certification Program's Deputy Director makes the final decision.

Q: Does a hospital risk losing its license if it receives a certain number of administrative penalties within a certain period of time like nursing homes?
A: No, not at this time. The determination to terminate a license is made after investigations and assessments of a facility's ability and capacity to implement plans of correction to assure the health and safety of patients is protected. The determinations also take into account the severity of the deficiencies/violations that occurred; the ability to implement corrections; and their assurance, through demonstration and assessment, that such occurrences will not happen in the future.

Q: Can a hospital appeal an administrative penalty?
A: Facilities can appeal the administrative penalties by requesting a hearing within ten calendar days of notification. If a hearing is requested, the penalties are to be paid if upheld following appeal. In addition to the penalties, the facility is required to implement a plan of correction to prevent future incidents.

Q: Can CDPH only issue an administrative penalty ONLY for immediate jeopardy?
A: The law allows for a fine of up to $25,000 for violations that do not rise to the level of immediate jeopardy. However, those fines will not take effect until the California Department of Public Health develops regulations for the various potential levels of fines. The California Department of Public Health has not yet estimated how long it will take to develop and adopt the regulations, but the process will include a public comment period.

Q: Isn’t it true that the law also allows up to $50,000 in fines for immediate jeopardy? When and under what circumstances will that happen?
A: Section 1280.3 (a) of the Health and Safety Code provides for the issuance of regulations for the implementation of administrative penalties assessed against hospitals up to the following amounts: $75,000 for the first administrative penalty, $100,000 for the second administrative penalty, and $125,000 for the third and every subsequent violation. In order to
assess these penalty amounts, regulations must be promulgated. At this point in time, the California Department of Public Health has not issued regulations for the implementation of these provisions. The regulatory process will define the types of circumstances, and violations that will be assessed. Public hearings will be held prior to promulgating these regulations.

Q: What is SB 1301?
A: Senate Bill 1301 was enacted in July 2007 due to a heightened awareness of the problem of preventable medical errors in hospitals. The new law’s intent is to promote safety by increasing government oversight and providing public disclosure of medical errors both to the affected patient and public.

Q: What types of facilities must report adverse events?
A: The reporting of adverse events applies to the following types of facilities:
- General Acute Care Hospitals (GACH)
- Acute Psychiatric Hospitals (APH)
- Special Hospitals (SH)

Q: What are the requirements of SB 1301 on hospitals reporting of adverse events?
A: Senate Bill 1301 requires general acute care hospitals, acute psychiatric hospitals and special hospitals to report an adverse event to the California Department of Public Health no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. The Licensing and Certification Program is required to conduct an on-site investigation of all reported adverse events.

Q: What are the penalties assessed for non-reporting of adverse events by hospitals?
A: The California Department of Public Health may assess a civil penalty in an amount not to exceed $100 for each day that the adverse event is not reported following the initial five-day period or 24-hour period.

Q: What is an adverse event?
A: An adverse event is defined as a medical occurrence that caused or is an ongoing threat of imminent danger of death or serious bodily harm at an acute general hospital, acute psychiatric hospital and special hospital. There are 28 “Adverse Events” defined by Senate Bill 1301 and appear under the following headings:

1. Surgical events
2. Product or device events
3. Patient protection events
4. Care management events
5. Environmental events
6. Criminal events
7. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

Q: What are the adverse events defined by SB 1301?
A: There are 28 adverse events defined by the Health and Safety Code, Section 1279.1 (b) (1) – (7) and reflects the following:
1. Surgical events, including the following:
   A. Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
   B. Surgery performed on the wrong patient.
   C. The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.
   D. Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
   E. Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

2. Product or device events, including the following:
   A. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.
   B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
   C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

3. Patient protection events, including the following:
   A. An infant discharged to the wrong person.
   B. Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.
   C. A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

4. Care management events, including the following:
   A. A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.
   B. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
   C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
D. Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.
E. Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.
F. A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

5. Environmental events, including the following:
   A. A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.
   B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.
   C. A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.
   D. A patient death associated with a fall while being cared for in a health facility.
   E. A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

6. Criminal events, including the following:
   A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
   B. The abduction of a patient of any age.
   C. The sexual assault on a patient within or on the grounds of a health facility.
   D. The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

7. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

Q: What is a validation survey?
   A: A validation survey is a certification survey conducted in hospitals to determine if the “Conditions Of Participation (COP)” for participation for federal reimbursement programs (Medicare and MediCal) are being met by the hospital. The hospital must be in compliance with all applicable federal laws and regulations related to the health and safety of patients. These validation surveys are usually conducted at the approval of the federal Centers for Medicare and Medicaid Services (CMS) after an adverse event is reported and investigated and it has been determined that the event is a violation/deficiency of COP.

Q: What is a deemed facility/hospital?
   A: A deemed facility or hospital is a facility that has been determined to meet Medicare "Conditions Of Participation" (federal regulations and laws) by virtue of their accreditation by an accrediting agency. These accrediting agencies are typically provider organizations such as the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission or JCAHO), and American Osteopathic Hospitals (AOH) that have been deemed by CMS to determine their hospital members meet CMS “Conditions Of Participation” through their accreditation process.