table. The report must include the time periods after the administration of the vaccine within which the vaccine-related illness, disability, injury or condition, the symptoms and manifestation of such illness, disability, injury or condition, or death occurs, and the manufacturer and lot number of the vaccines; and

2. The occurrence of any contraindicating reaction to a vaccine that is specified in the manufacturer’s package insert.

**REPORTING MECHANISM**

The agency that must be advised of an adverse reaction will depend on whether the vaccine or toxoid was privately or publicly purchased. If there is an adverse reaction to a privately purchased vaccine or toxoid, reports are to be made directly to the FDA on its Vaccine Adverse Event Report System (VAERS) form. If the adverse reaction is due to a publicly purchased vaccine, the reaction should be reported to the local health department in charge of immunizations. For further information regarding reporting requirements, hospitals may contact their county health department or:

California Department of Public Health
Immunization Branch
850 Marina Bay Parkway
Richmond, CA 94804
(510) 620-3737

For further information about reporting adverse reactions to vaccines and the VAERS form, go to www.vaers.hhs.gov.

**K. PESTICIDE POISONING AND RELATED INJURIES OR ILLNESSES**

Health and Safety Code Section 105200 requires a physician who knows, or has reasonable cause to believe, that a patient is suffering from pesticide poisoning or a disease or condition caused by a pesticide must promptly report this to the local health officer. The report must be made:

1. By telephone within 24 hours; and

Failure to comply with this reporting requirement may subject the physician to a civil penalty of $250.

1. This requirement is broader than the Labor Code reporting requirement described in X. “Vaccines,” page 4.18 and applies outside of the occupational injury context.
2. As used in Health and Safety Code Section 105200, the term “physician” means a “physician and surgeon” and does not include the other practitioners described in X. “Vaccines,” page 4.18.

**L. BURNS AND SMOKE INHALATION INJURIES**

**STATUTORY DUTY**

Health and Safety Code Section 13110.7 requires the director of every burn center that examines, treats, or admits a person with a burn or smoke inhalation injury or a person who suffers a burn-related death to file a report with the state fire marshal.

For the purposes of this law, “burn center” means an intensive care unit in which there are specially trained physicians, nursing, and support personnel and the necessary monitoring and therapeutic equipment needed to provide specialized medical and nursing care to burned patients.

**CONTENTS AND TIME OF THE REPORT**

The report must describe the injury or death at the time of the examination or treatment, at the time the patient is discharged from the burn center or at the time of the patient’s death.

The report must be made on the “Burn Center Report (BR-1)” developed by the state Fire Marshal. This form can be obtained from:

Office of the State Fire Marshal
California Burn Registry
P.O. Box 944246
Sacramento, CA 94244-2460
Attn: CAIRS Unit
(916) 445-8435

**FAILURE TO COMPLY**

Violation of the law requiring reports may result in a misdemeanor conviction which is punishable by a fine of not less than $100 nor more than $500, or by imprisonment for not more than six months or both [Health & Safety Code Section 13112].

**III. REPORTS UNDER THE SAFE MEDICAL DEVICES ACT OF 1990**

The Safe Medical Devices Act requires hospitals and other providers to report incidents involving medical devices (including restraints) that have or may have caused or contributed to the serious injury or death of a patient [21 U.S.C. Section 360i(b)]. In addition to the individual reports required, hospitals must provide the FDA with annual summaries of the individual reports made during the preceding year (see below). Regulations implementing the reporting requirements are found at 21 C.F.R. part 803. Detailed information about this reporting requirement may be found at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.
A. WHEN AND TO WHOM REPORTS OF ADVERSE EVENTS MUST BE MADE

INDIVIDUAL REPORTS:
Hospitals and other health care providers ("device user facilities") must make individual (per-incident) reports when they receive or otherwise become aware of information reasonably suggesting that a medical device has or may have caused or contributed to the death or serious injury of a patient. Reports of individual adverse events are to be made on FDA Form 3500A, also known as the "MEDWATCH" form," or an electronic equivalent approved by the FDA [21 C.F.R. Section 803.11]. (See "Forms to be Used," page 20.15.) The information required is specified in the MEDWATCH form and described in 21 C.F.R. Section 803.32.

Reports of deaths are made to the FDA and to the device manufacturer if the identity of the manufacturer is known [21 C.F.R. Section 803.30(a)(1)].

Reports of serious injury are made to the device manufacturer if the identity of the manufacturer is known; if the identity of the manufacturer is not known, the report must be made to the FDA [21 C.F.R. Section 803.30(a)(2)].

Reports must be made as soon as practicable but no later than 10 work days after becoming aware of the information. ("Work day" means Monday through Friday, excluding federal holidays.)

Adverse events need not be reported if there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Information which leads the qualified person to this determination must be contained in the medical device reporting (MDR) event file [21 C.F.R. Section 803.20(c)(2)].

ANNUAL REPORTS
Annual summaries of individual reports must be made to the FDA by January 1 of each year using FDA Form 3419, "Medical Device Reporting Semianual User Facility Report," or an electronic equivalent as approved by the FDA. If no reports were submitted to the FDA or device manufacturers during the previous year, the hospital need not submit an annual report. [21 C.F.R. Section 803.33]

WHERE TO SUBMIT REPORTS
All reports made to the FDA (individual reports and annual reports) should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
P. O. Box 3002
Rockville, MD 20847-3002

Each report and its envelope must be specifically identified — e.g., as "User Facility Report" or "Annual Report." [21 C.F.R. Section 803.12]

DEFINITIONS
"Become aware" means that an employee of an entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred. Device user facilities are considered to have "become aware" when medical personnel who are employed by, or otherwise formally affiliated with (e.g., medical staff), the facility, obtain information about a reportable event [21 C.F.R. Section 803.3]. This requirement means that hospitals and other covered providers must provide appropriate training and notice to those employees and other personnel whose knowledge of reportable events will trigger the facility's obligation to report, as well as the time clock (10 work days) for making such reports.

In making reports, facilities must provide all information specified in the law that is "reasonably known" to them. This includes information found in documents in the possession of the device user facility and any information that becomes available as a result of reasonable follow-up within the facility. However, a device user facility is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably known to it [21 C.F.R. Section 803.30(b)]. (There may, of course, be other reasons to conduct such investigations, and in such instances the information discovered would be considered to be reasonably known to the facility. The medical device reporting law, however, does not require such investigations.)

"Caused or contributed" means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of failure, malfunction, improper or inadequate design, manufacture, labeling or user error [21 C.F.R. Section 803.3].

The reporting obligations apply to "device user facilities," which includes hospitals, ambulatory surgical facilities, nursing homes, and outpatient diagnostic and treatment facilities (but not physicians’ offices) [21 C.F.R. Section 803.3].
“Serious injury” means an illness or injury that:

1. Is life threatening;
2. Results in permanent impairment of a body function or permanent damage to the body structure; or
3. Necessitates medical or surgical intervention to preclude impairment of a body function or permanent damage to a body structure [21 C.F.R. Section 803.3].

FORMS TO BE USED

Forms may be obtained from:

Food and Drug Administration
Division of International and Consumer Education
Center for Devices and Radiological Health
10903 New Hampshire Ave., Bldg.66, Rm. 4621
Silver Spring, MD 20993-0002
(800) 638-2041
www.fda.gov/medwatch/getforms.htm
email: DICE@fda.hhs.gov


QUESTIONS

The FDA asks that questions about reporting be mailed or faxed to the FDA at the following address:

Food and Drug Administration
Reporting Systems Monitoring Branch (HFZ-533)
Center for Devices and Radiological Health
Medical Devices Reporting Inquiries
1350 Piccard Drive
Rockville, MD 20850
Phone: (240) 276-3464
Fax: (240) 276-3454

The FDA prefers that questions be faxed; however, questions about medical device reporting may also be asked by phone, (240) 276-3464. To report a public health emergency, call the FDA office of Emergency Operations at (866) 300-4374 and follow with an email to emergency.operations@fda.hhs.gov or a fax to (301) 847-8544.

DISCLAIMERS

A report or other information submitted by a reporting entity under this law, and any release by the FDA of that report or information, does not necessarily reflect an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a reportable event. [21 C.F.R. Section 803.16]

B. RESTRAINTS

FDA regulates restraint devices as it regulates other medical devices. Thus, hospitals and other device user facilities must report incidents involving restraints that have or may have caused or contributed to the serious injury or death of a patient.

For purposes of this reporting law, it should be noted that the FDA uses a different definition of restraint than does the Centers for Medicare & Medicaid Services Conditions of Participation or California law. The FDA defines a “protective restraint” as:

a device, including but not limited to a wristlet, ankle, vest, mitt, straight jacket, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient’s movements to the extent necessary for treatment, examination, or protection of the patient or others [21 C.F.R. Section 880.6760].

Whereas the CMS definition of restraint could include a geri-chair, a tray table, a side rail, a sheet, or even a staff member holding a patient, the FDA definition does not. Therefore, this reporting requirement is somewhat more narrow than the CMS reporting requirement for deaths associated with seclusion or restraints discussed under VI. “Reporting Requirements Related to Restraint or Seclusion,” page 20.21.

C. REQUIRED POLICIES AND PROCEDURES

Hospitals must develop and implement written policies and procedures that provide for the following:

1. Timely and effective identification, communication and evaluation of events that may be subject to medical device reporting requirements;
2. A standardized review process/procedure for determining when an event meets the criteria for reporting to the FDA; and
3. Timely transmission of complete medical device reports to the FDA and/or the device manufacturer.

The policies and procedures must also include documentation and record keeping requirements as described under “Required Documentation” below, including information that was evaluated to determine if an event was reportable [21 C.F.R. Section 803.17].
**REQUIRED DOCUMENTATION**

Facilities must establish and maintain medical device reporting (MDR) event files. MDR event files must be prominently identified as such and filed to facilitate timely access. The files may be written or electronic, and may incorporate references to other information, such as medical records or engineering reports, in lieu of copying and maintaining duplicates in this file. MDR event files must include the following:

1. Information related to adverse events, including all documentation of the hospital’s deliberations and decision-making processes used to determine if a device-related death, serious injury or malfunction was or was not reportable under this part; and

2. Copies of all Safe Medical Devices Act forms and other information related to the event that was submitted to the FDA or manufacturer.

MDR event files must be retained for two years following an adverse event. Hospitals must permit FDA employees to access, copy and verify the records noted above [21 C.F.R. Sections 803.13, 803.17 and 803.18].

**D. REQUEST FROM FDA FOR ADDITIONAL INFORMATION**

The FDA may determine that protection of the public health requires additional or clarifying information for the medical device reports submitted to the FDA under this law. In these instances, and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible, the agency will notify the reporting entity in writing of the additional information that is required.

Any request from the FDA must state the reason or purpose for which the information is being requested, specify the due date for submitting the information and clearly identify the reported event. All verbal requests will be confirmed in writing by the FDA. [21 C.F.R. Section 803.15]

**E. DEVICE TRACKING**

Device manufacturers and distributors are required to develop formal schemes for tracking specified (“tracked”) medical devices [21 U.S.C. Section 360i(e)]. Hospitals, licensed practitioners, retail pharmacists and other types of device user facilities are considered “final distributors” [21 C.F.R. Section 821.3].

Under the regulations, a final distributor must provide the manufacturer with specified information at the time that it purchases a tracked device [21 C.F.R. Section 821.30(a)] and at the time that a tracked device is implanted in or provided to a patient [21 C.F.R. Section 821.30(b)].

At the time that the device is implanted in or provided to the patient, the hospital must provide to the device manufacturer the following information:

1. The name and address of the final distributor (i.e., the hospital itself).

2. The unique device identifier (UDI), lot number, batch number, model number or serial number of the device, or other identifier used by the manufacturer to track the device.

3. The name, address, telephone number and Social Security number (if available) of the patient receiving the device unless not released by the patient (see “Patient Confidentiality Rights” below).

4. The date the device was provided to the patient or for use in the patient.

5. The name, mailing address and telephone number of the prescribing physician.

6. The name, mailing address and telephone number of the physician regularly following the patient if different from the prescribing physician.

7. When applicable, the date the device was explanted, and the name, mailing address and telephone number of the explanting physician, the date of the patient’s death, or the date the device was returned to the manufacturer, permanently retired from use or otherwise permanently disposed of.

[21 C.F.R. Section 821.30(b)]

**PATIENT CONFIDENTIALITY RIGHTS**

A patient receiving a device subject to tracking may refuse to release, or refuse permission to release, his or her name, address, telephone number and Social Security number, or other identifying information for the purpose of tracking [21 CFR Section 821.55]. FDA guidance states that hospitals must document the refusal and the forwarding of such documentation back to the device manufacturer.

**DEVICE TRACKING RECORDS**

Hospitals must permit FDA employees to access, copy and verify device tracking records, as well as all other records and information related to the events and persons identified in such records [21 C.F.R. Section 821.50]. In addition, hospitals must make any records required to be kept by the device tracking law available to the manufacturer of the tracked device for audit upon written request by an authorized representative of the manufacturer [21 C.F.R. Section 821.30(d)].

Device tracking records must be maintained for the useful life of the tracked device. The useful life of a device is the time a device is in use or in distribution for use. A
In response to media attention on medical errors, the California Legislature passed, and the Governor signed, legislation requiring general acute care hospitals, psychiatric hospitals, and special hospitals to report specified adverse events to CDPH. This reporting requirement became effective July 1, 2007. [Health and Safety Code Sections 1279-1, 1279-2, 1279-3 and 1280-4]

Effective Jan. 1, 2012, outpatient settings must also report adverse events. “Outpatient settings” are defined as:

1. Any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in Health and Safety Code Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered, have the probability of placing a patient at risk for loss of the patient’s life-preserving protective reflexes. A clinic or ambulatory surgery center that does not meet this definition — i.e., does not use general anesthesia — is not subject to this reporting requirement.

2. Facilities that offer in vitro fertilization, as defined in Health and Safety Code Section 1374.55(b).

Outpatient settings do not include, among other settings, any setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient’s life-preserving protective reflexes.

[Health and Safety Code Sections 1248 and 1248-15]

CDPH has confirmed that distinct-part nursing facilities (DP-NFs) need not report adverse events under this law. However, other reporting requirements may apply (for example, the “unusual occurrences” reporting requirement may apply).

A. TYPES OF EVENTS THAT MUST BE REPORTED

For purposes of this reporting requirement, “adverse event” includes the surgical events, product or device events, patient protection events, care management events, environmental events, criminal events, and one other item described below. The term “serious disability,” which is used in many places in the list of adverse events, means:

- a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from an inpatient health facility, or the loss of a body part.

The list of adverse events includes the following.

SURGICAL EVENTS

1. Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. This 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.

2. Surgery performed on the wrong patient.

3. 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. This 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.

4. 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.

5. 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.

PRODUCT OR DEVICE EVENTS

1. 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.

2. 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 requirement, “device” includes, but it not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

3. 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.