

REPORTING REQUIREMENTS ACROSS AGENCIES

**MASSACHUSETTS COALITION for the
PREVENTION OF MEDICAL ERRORS**

October 2000

July 2001

May 2002

November 21, 2002

April 16, 2004

**CHART 1
REPORTABLE INCIDENTS UNDER HOSPITAL LICENSE**

	BRM	DPH	DMH	OCME (Medical Examiner)	JCAHO	CMS/LTC	FDA
Reportable Incidents	<p>✓DEATHS</p> <ul style="list-style-type: none"> Maternal deaths related to delivery Deaths in the course of, or resulting from, elective ambulatory procedures All deaths or major or permanent impairments of bodily functions (other than those reported above) that are not ordinarily expected as a result of the patient's condition on presentation 	<p>✓DEATHS</p> <ul style="list-style-type: none"> Maternal (during any gestational age, labor or delivery, or within 90 days of delivery) Termination of Pregnancy (within 90 days of termination) Suicide Unknown Causes 	<p>✓DEATHS</p> <ul style="list-style-type: none"> Medico legal (death required by M.G.L. c.38, s 3, to be reported to Medical Examiner) 	<p>✓DEATHS</p> <p>NOTE: Failure to report may result in a \$500 fine and notification to applicable board of registration.</p> <p><u>DEATHS RESULTING from TRAUMA</u></p> <ol style="list-style-type: none"> All homicides. All suicides. All deaths due to or following motor vehicle accidents including motorcyclists, pedestrians, and bicyclists. All deaths from aviation or boating accidents. All industrial or occupational accidents. All deaths from other accidents, including drowning, falls, burns, scalding and inhalation of smoke, electrocution or lightning strike, hurricane or tornado, heat stroke or exposure to cold. All deaths related to drug or narcotic intoxication, chemical poisoning or acute alcohol intoxication. All deaths from asphyxia including aspiration of bolus food, compression of chest or neck and suffocation. All deaths involving children under the age of 18 years old. Deaths where there is a history of a fall or recent injury which may be related to the death. Deaths which because of suspicious circumstance or witness statements may be related to trauma or poisoning. Fractures where death is directly related to the fracture (other than osteoporotic hip fractures in the elderly). Deaths due to unusual or infectious illnesses posing a threat to the public health in the community. <p><u>DEATHS in CUSTODY</u></p> <ol style="list-style-type: none"> All deaths of persons detained in a police holding cell, county jail, or other correction/detention facility. Deaths occurring during or following arrest or altercation with police. All unexpected deaths in a mental hospital, mental health facility, or facility for the mentally retarded, or emotionally disturbed. 	<p>DEATHS</p> <ul style="list-style-type: none"> Inpatient Suicide 	<p>✓DEATHS</p> <ul style="list-style-type: none"> Restraint & Seclusion (behavioral) Blood Transfusion 	<p>✓DEATHS</p> <ul style="list-style-type: none"> Suspected Medical Device Related <p>Deaths must be sent both to FDA and to the manufacturer of the device (or just FDA if the manufacturer is unknown)</p>

SUDDEN INFANT DEATH SYNDROME crib death

1. All infants found dead.
2. Deaths of infants following resuscitation and/or hospitalization who were initially found unresponsive (resuscitated SIDS).

ALL DEATHS OF CHILDREN OUTSIDE OF A HOSPITAL UNLESS THE PATIENT IS IN THE TERMINAL PHASE OF A WELL-DOCUMENTED NATURAL DISEASE AND DEATH WAS EXPECTED.

1. All cases of battered child syndrome, child neglect or cases suspicious of either:
 - a. Accidental deaths in children.
 - b. Deaths from unexpected natural disease occurring outside of a hospital or in a hospital before a definitive diagnosis is made.
2. Fetus, stillbirth or neonates only if there is a history of recent trauma to the mother or alcohol or drug withdrawal syndrome.

PRESUMABLY NATURAL DEATHS

1. Sudden unexpected death of young persons with no diagnosis of a serious medical problem.
2. Sudden unexpected death of a person with a medical condition not expected to cause sudden death.
3. Sudden unexpected death occurring in the course of employment.
4. Maternal death during or following pregnancy, parturition or abortion.

DEATHS FROM NATURAL DISEASE OF PERSONS NOT HAVING AN ATTENDING PHYSICIAN TO CERTIFY THE DEATH.

1. Deaths of persons who have not seen a physician or have not been otherwise treated in the past 30 days.
2. Persons who have an attending physician based in a distant hospital or clinic who is not immediately available to certify the death.

✓ **MAJOR or PERMANENT IMPAIRMENTS**

- Major temporary or permanent impairments that are not ordinarily expected as a result of the patient's condition on presentation

✓ **UNEXPECTED OUTCOMES**

- All serious outcomes or complications that would not ordinarily have been expected to occur, given the patient's condition on presentation. (Diagnostic or Therapeutic Procedures, Medications, Missed or Delayed Diagnoses, Medical Evaluation and

✓ **SERIOUS PHYSICAL**

INJURY/INCIDENT

- Accidents, Incidents, or Unknown Causes (Surgical Errors including retention of foreign object, i.e., sponge or clamp, Medication Errors including I.V. Therapy Errors, Onsite Slips or Falls Requiring Additional Services or Stay, Blood Transfusion Errors, Burns, Electrocutions, Poisonings, Infectious Disease Outbreaks, Equipment Malfunction or User Error)

✓ **SERIOUS PHYSICAL INJURY/INCIDENT**

- Attempted Suicide
- Restraint & Seclusion

DEATHS IN A HOSPITAL OR OTHER MEDICAL FACILITY NOT COVERED IN THE SECTIONS ABOVE

1. Any death within 24 hours of admission to a hospital (not including neonates who live only a few hours);
2. Deaths occurring in emergency rooms or during transport to a hospital;
3. Any sudden and totally unexpected death of a patient in a hospital;
4. Death of a person who was admitted to the hospital in a coma and did not regain consciousness;
5. Deaths of persons who suffered an accident in the hospital which resulted in injury;
6. Deaths during surgery, anesthesia, or medical procedure including deaths in dental offices, doctor's offices, or outpatient surgical facilities.

BONES AND BODY PARTS FOUND OR RECOVERED BY POLICE OR REPORTED TO THE POLICE

✓ **SERIOUS PHYSICAL INJURY or INCIDENT**

- Blood Transfusion Incompatibilities
- Infant Abduction or Discharge to Wrong Family

✓ **INJURY**

- Injury of Unknown Source

✓ **SERIOUS PHYSICAL INJURY**

- Suspected Medical Device Related must be reported to manufacturer or to FDA if manufacturer unknown

Management of Patients including pre-op assessments, Surgery and Anesthesia, Hospital Acquired Infections, Falls and other Accidents, Equipment Performance, Laboratory and Radiological Service, Professional Staff Coverage, House Staff Supervision, Credentialing of Staff, Informed Consent and DNR Requests, Medical Records-keeping by professional staff.

✓WRONG ORGAN, EXTREMITY, BODY PART

- **Invasive Diagnostic Procedure**
- **Surgical Intervention**

✓ Any serious, ordinarily unexpected outcome.

✓MISADVENTURES
• **Not related to patient treatment and not anticipated in normal course of events**

(Fire, Suicide, Serious Criminal Acts, Allegations of Abuse Pending or Actual Staff or Supplier Strike)

- **Discharge of an infant to the wrong family**
- **Presentation of an infant to the wrong mother for breast-feeding.**

✓WRONG PATIENT, SIDE, ORGAN, or EXTREMITY

- **Surgical Errors**

✓CARE OF CERTAIN INFANTS PREMATURELY BORN

✓MISADVENTURES

- **Sexual Assault or Abuse**
- **Physical Assault or Abuse**
- **Felony**
- **Complaint Requiring an Investigation**

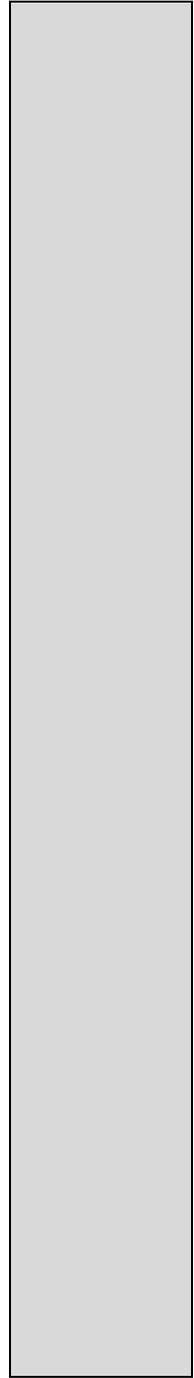
✓MISADVENTURES

- **Infant Abduction**
- **Rape**

✓WRONG BODY PART or PATIENT Surgery

✓MISADVENTURES

- **Mistreatment**
- **Neglect**
- **Abuse**
- **Misappropriation of Resident Property**



(Children born with congenital deformities, birth injuries, or mental retardation)

(a) After the diagnosis in the commonwealth of a congenital anomaly, birth defect, birth injury, or mental retardation (from birth to age 3) which may lead to an incapacity or disability, the physician making the diagnosis shall report the anomaly, defect, injury, or mental retardation to the department on a form to be furnished by the department. Authorized officials or agents of the department may abstract and record information that is required for reporting from the medical records of children under the age of 3 years and their parents

(c) Nothing in this section shall compel any individual to submit to medical or department examination, testing or supervision.

(d) The department shall make rules and regulations to implement this section.

**CHART II
REPORTING INFORMATION**

	BRM	DPH	DMH	OCME	JCAHO	CMS/LTC	FDA
Identification / Time Frame	✓ Semi-Annual	✓ Immediate-telephone ✓ Maternal deaths within 48 hrs. including car accidents, chronic disease, suicides, pregnancy, birth, and post-partum related. ✓ Delivery or Termination of Pregnancy deaths within 90 days of occurrence should be reported within 48 hours of notification. ✓ NOTE: Failure to report may result in a \$500 fine and notification to applicable board of registration. ✓ 7 business days–written report ✓ Congenital Anomaly, birth defect, birth injury, or mental retardation which may lead to an incapacity or disability must be reported within 30 days after diagnosis by the physician making the diagnosis or the facility on behalf of the physician. Reportable up to age 3.	✓ Monthly (30days)	TBD	TBD	✓ CMS=1 bus. day ✓ LTC=5 bus. days	✓ Within 10 days of connecting device to death or injury
Facility	✓	✓	✓	✓	✓	✓	✓
Date & Location	✓	✓	✓	✓	✓	✓	✓
Patient(s) Involved	✓ No names, but DOB, sex, date of adm., adm. dx.	✓	✓ Including Family or Representative	TBD	✓	✓	No name or SS#, but some ID the facility can refer to if FDA calls for follow-up. Age or DOB, gender, and weight are all requested.
Staff Involved (MD/Non)	✓ No names, but type of staff	✓	✓ Appeal Process Available	✓	✓	✓	No names, but type of person (health professional; lay user; patient)

	BRM	DPH	DMH	OCME	JCAHO	CMS/LTC	
Type of Incident	✓	✓	✓	✓	✓	✓	✓
Nature of Incident	✓	✓ Description	✓	✓	✓	✓	✓ Description
Internal Investigation / Root Cause	✓	✓	✓	TBD	✓	✓	No
Root Cause Time Frame	✓	✓	✓ Monthly	TBD	✓	✓ 5 business days	No
Corrective Measures	✓	✓	✓	TBD	✓	✓	No
Report Format	<u>SEMI-ANNUAL</u> -Major Tasks Completed; -Summary Report of Internal Incident Reporting System; -Trending and Follow-up; -General Recommendations <u>ANNUAL</u> -Summary analysis of patient complaints and their disposition; -Names of all full MD licensees who've terminated their relationship with the health care facility; -Any amendments to the PCA Plan and any proposed amendments thereto -The number of major incident reports filed; -The written instructions for the PCA Plan; -Summary information on the handling of impaired physicians	The physician making the diagnosis or the hospital reporting on behalf of the physician shall report the anomaly, defect, injury, or mental retardation to the Department on a form to be furnished by the Department.					
Use Specific Definitions	✓	✓	✓	Yes	No	No	No
Use Specific Codes	✓ Use for Location, Role of Provider and Basis for report	No	No		No	No	Yes, patient problem codes and device problem codes.

**CHART III
DISCLOSURE AND CONFIDENTIALITY**

Agency	Disclosable Information	Confidentiality Issues	State or Federally Mandated
BRM	✓Not subject to subpoena, discovery, or disclosure, or introduction into evidence	✓ Not subject to subpoena, discovery, disclosure, or introduction into evidence	✓State–Medical Malpractice Reform Act of 1986. M.G.L. c. 111, § 203 (d) and M.G.L. c. 112, § 5 and M.G.L. c. 111, § 205
DPH	<p>✓ Incidents entered into password protected electronic database. Hard copies are maintained but are not locked.</p> <p>✓Reports of investigations are available (upon request) 10 days after a hospital has had an opportunity to respond to the deficiencies.</p> <p>✓ Aggregate data without hospital and patient identifiers are available upon request.</p> <p>✓All information in the reporting system, including formal narrative reports and deficiency statements, is available to the general public upon request.</p> <p>✓The contents of reports, records and information regarding birth congenital anomalies, birth defects, birth injury, or mental retardation shall be solely for the use of the DPH and such reports, records and information shall not be open to public inspection or constitute a public record.</p> <p>✓Regarding birth congenital anomalies or mental retardation, the DPH shall collect no more information than it considers necessary and appropriate in order to conduct epidemiological surveys and to develop appropriate preventative treatment and control measures. The commissioner may make such reports, records, or information contained therein available to a researcher performing medical and scientific studies for the purpose of the reduction of morbidity and mortality in the commonwealth, so long as the commissioner and a duly constituted institutional review board first approves that study.</p>	<p>✓DPH will release names of involved hospital personnel and individuals interviewed during an investigation.</p> <p>✓No legal confidentiality protections specifically directed toward reported information or reporters. However, patient specific information and some peer review protected information may not be released.</p> <p>✓ For cases related to birth congenital anomalies, birth defects, birth injury, or mental retardation before abstracting or recording any additional information from an individual’s medical records, department officials shall obtain the approval of a duly constituted institutional review protocol submitted to it by the department. The research protocol shall specify how such records shall be reviewed, how information from them shall be abstracted and reported, the exact information to be recorded, and how the information will be used, maintained and kept confidential.</p> <p>✓The contents of reports, records and information regarding birth congenital anomalies, birth defects, birth injury, and mental retardation shall be solely for the use of the DPH and such reports, records and information shall not be open to public inspection or constitute a public record.</p>	<p>✓Under Massachusetts’ Public Records Law, incident and accident reports are subject to public disclosure because they are not covered by any of the statutory exceptions to the general disclosure requirement.</p> <p>✓Fair Information Practices Act, M.G.L. c. 66A. s 2. M.G.L. c.66, s 10.; M.G.L. Ch4 §7(26)(c).</p> <p>✓Subject to Massachusetts Public Records Law, Including All the Statutory Exemptions to Disclosure. State - 105 CMR 130.331</p> <p>✓Subject to Bargaining Agreements, Civil Service Law and Labor Law Provisions in Effect.</p> <p>✓Birth defects Monitoring Program – Chapter 72 of the Acts of 2002, M.G.L., c.111, Section 67E, Children born with congenital deformities, birth injuries, or mental retardation.</p>
DMH	<p>✓According to the regulations, all parties (see Confidentiality column) may receive a copy of the investigator’s report upon the signing of a non-disclosure statement, where the report includes client specific information.</p> <p>✓According to the regulations, the Department’s Public Log of all complaints and appeals will not include personal identities and will be a public record, available for inspection and copying by members of the public as provided in M.G.L. c.66, s 10. The log will include whether the complaint was substantiated and the outcome of the</p>	<p>✓According to the regulations, any person who is mentioned in a case will have access to the portion of the record in which he or she was mentioned. See mandate.</p> <p>✓According to the regulations, the client or someone acting on behalf of a client or in case of a client death (e.g., next of kin, administrator, executor, and attorney) may have access.</p> <p>✓According to the regulations, any other party defined as the person in charge of facility or program, and the human rights officer and committee.</p>	<p>✓Under Massachusetts’ Public Records Law, incident and accident reports are subject to public disclosure because they are not covered by any of the statutory exceptions to the general disclosure requirement.</p> <p>✓Fair Information Practices Act, M.G.L. c. 66A. s 2. M.G.L. c.66, s 10.</p> <p>✓Subject to Massachusetts Public Records Law, Including All the Statutory Exemptions to Disclosure. State - 104 CMR 32.00</p> <p>✓Subject to Bargaining Agreements, Civil Service Law and Labor Law Provisions in Effect.</p>

	appeal.		
Agency	Disclosable Information	Confidentiality Issues	State or Federally Mandated
OCME	TBD	TBD	✓M.G.L. Ch. 38 § 3; Ch111, § 202
JCAHO	✓During the time the information is possessed by JCAHO, it will not be released to any external entity and its confidentiality will be vigorously defended, if necessary, in the courts. Original sentinel event reports are returned to the organization and all remaining copies are destroyed.	✓During the time the information is possessed by JCAHO, it will not be released to any external entity and its confidentiality will be vigorously defended, if necessary, in the courts. Original sentinel event reports are returned to the organization and all remaining copies are destroyed.	✓No
CMS/ LTC	<p>✓No unauthorized access or dissemination of clinical records is permitted. Hospital staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual. Providers may not withhold information except under limited circumstances including:</p> <ul style="list-style-type: none"> • Information is about a non health care provider and the hospital determines that patient inspection would cause sufficient harm to another individual to warrant withholding. • Inspection could be reasonably likely to endanger the life or physical safety of the patient or anyone else. • The information contains data obtained under a promise of confidentiality (from someone other than a health care provider), and inspection could reasonably reveal the source. • The information is held by an oversight agency and access by the patient could be reasonably likely to impede an ongoing oversight or law enforcement activity. • The information is collected in the course of a clinical trial, the trial is in progress, and an institutional review board has approved the denial of access when consenting to participate. • The information is compiled principally in anticipation of, or for use in, a legal proceeding. • The information is used solely for internal management purposes and is not used in treating the patient or making any administrative determination about the patient, or if it duplicates information available for inspection by the patient. 	<p>✓The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.</p>	<p>✓Confidentiality of Individually-Identifiable Health Information, recommendations of the Secretary of Health and Human Services, pursuant to § 264 of the Health Insurance Portability and Accountability Act of 1996.</p>
FDA	✓Reports are not admissible into evidence in any civil action involving private parties unless the reporter knew the information reported was false.	✓Reports are not admissible into evidence in any civil action involving private parties unless the reporter knew the information reported was false.	✓21 CFR 803, Safe Medical Device Act of 1990
Charts 3 4/21/04			