

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1315 Session of
1993

INTRODUCED BY DeLUCA, TIGUE, LYNCH, COLAIZZO, PETRONE,
CAPPABIANCA, MELIO, PISTELLA, ROONEY, TRELLO, LAUGHLIN,
LINTON, TRICH AND BELARDI, APRIL 21, 1993

REFERRED TO COMMITTEE ON HEALTH AND WELFARE, APRIL 21, 1993

AN ACT

1 Providing for reportable events in medical treatment and for
2 powers and duties of the Department of Health; and imposing
3 duties on health care practitioners and health care
4 facilities.

5 The General Assembly of the Commonwealth of Pennsylvania
6 hereby enacts as follows:

7 Section 1. Short title.

8 This act shall be known and may be cited as the Reportable
9 Events in Medical Treatment Act.

10 Section 2. Definitions.

11 The following words and phrases when used in this act shall
12 have the meanings given to them in this section unless the
13 context clearly indicates otherwise:

14 "Administrator." The chief executive officer, chief
15 operating officer or administrator of a health care facility or
16 an individual owning, directing or controlling a health care
17 facility.

18 "Attending physician." The physician who acted as the

1 attending physician at the time a reportable medical event
2 occurred.

3 "Department." The Department of Health of the Commonwealth.

4 "Health care facility." A general or special hospital,
5 including tuberculosis and psychiatric hospitals; rehabilitation
6 facilities; skilled nursing facilities; kidney disease treatment
7 centers, including freestanding hemodialysis units; intermediate
8 care facilities; and ambulatory surgical facilities, both profit
9 and nonprofit. The term includes those facilities operated by an
10 agency of State or local government, but shall not include an
11 office used exclusively for private or group practice by
12 physicians or dentists; a program which renders treatment or
13 care for drug or alcohol abuse or dependence, unless located
14 within, by or through a health care facility; a facility
15 providing treatment solely on the basis of prayer or spiritual
16 means in accordance with the tenets of any church or religious
17 denomination; or a facility conducted by a religious
18 organization for the purpose of providing health care services
19 exclusively to clergymen or other persons in a religious
20 profession who are members of the religious denominations
21 conducting the facility.

22 "Health care practitioner." A licensed, certified or
23 registered practitioner of the healing arts.

24 "Reportable medical event." An unusual incident occurring in
25 the treatment of a patient which is unexpected or out-of-the-
26 ordinary or incidents investigated by the facility under
27 regulations issued by the Secretary of Health. Reportable
28 medical events may include, but are not limited to, unexpected
29 massive bleeding, tearing or perforation of blood vessels or
30 body organs, obstruction of airways, inadvertent penetration of

1 body cavities, anaphylaxis, overdose of drugs, medication or
2 chemicals, sudden collapse, shock or coma.

3 "Responsible party." The family member, guardian or other
4 individual designated by the patient as responsible to receive
5 information concerning or in making decisions on behalf of a
6 patient, when necessary.

7 "Risk manager." The individual designated by a health care
8 facility or administrator to administer the facility's internal
9 risk management program or an individual appointed by the health
10 care facility, or its administrator, to receive information
11 regarding reportable medical events.

12 "Secretary." The Secretary of Health of the Commonwealth.

13 "Substantiated reportable medical event." A reportable
14 medical event, the occurrence of which is established by clear
15 and convincing evidence to the satisfaction of the risk manager,
16 and one which both the risk manager and the attending physician
17 agree poses a clear risk of harming the patient.

18 Section 3. Reporting.

19 (a) Health care practitioners.--It shall be the duty of each
20 health care practitioner charged with the care or involved in
21 the care of a patient in a health care facility at the time a
22 reportable medical event occurs to:

23 (1) Complete and file an incident report in accordance
24 with the health care facility's standard operating procedures
25 for any reportable medical event of which the health care
26 practitioner becomes aware as promptly as possible after a
27 reportable medical event, but no later than 48 hours from the
28 time the health care practitioner becomes aware or is
29 notified of the event.

30 (2) Inform the patient's attending physician of the

reportable medical event's occurrence through the use of incident reports in accordance with the health care facility's standard operating procedures.

(b) Attending physicians.--As soon as possible after receiving information under subsection (a)(2), the attending physician shall document the facts relevant to the reportable medical event in the patient's chart, stating when the attending physician became aware of the event and describing subsequent orders for treatment, as it relates to the event. If the patient's attending physician causes a reportable medical event, the attending physician shall comply with the reporting requirements of subsection (a).

(c) Investigation.--If a risk manager receives notice of a reportable medical event, the risk manager shall:

(1) Ensure compliance with subsection (a).

(2) Investigate the reportable medical event, which may include interviewing the health care practitioners involved and any other appropriate individuals and determining whether clear and convincing evidence suggests that the incident occurred.

(d) Substantiation.--The risk manager shall complete the review of a reportable medical event and determine whether clear and convincing evidence indicates that the reportable medical event has occurred. After this determination has been made, the risk manager and the attending physician shall then determine whether the reportable medical event poses a clear risk of harming the patient in accordance with the definition of a "substantiated reportable medical event" under section 2.

Section 4. Notification.

The risk manager shall ensure that the patient involved is

1 notified of a substantiated reportable medical event. If the
2 patient is a minor or is incapacitated, the risk manager and the
3 attending physician shall notify the patient's responsible
4 party. If notification might harm the physical or mental health
5 of the patient or if the patient cannot be located, the facts of
6 the events and rationale for nonnotification shall be documented
7 in the patient's medical record. The attending physician shall
8 notify the health care facility of the date and time the
9 physician intends to notify the patient or responsible party for
10 the patient of the substantiated reportable medical event so
11 that the facility can ensure that a member of its administration
12 or designee, or both, and its risk manager are present when the
13 patient or responsible party is notified of the event. The
14 attending physician shall document the status of patient
15 notification or the reasonable attempts which were made to
16 locate and notify the patient.

17 Section 5. Enforcement.

18 The department shall have the authority to review reports of
19 substantiated reportable medical events and to determine
20 compliance with this act. The department may conduct unannounced
21 surveys whenever it receives any complaint or has other
22 reasonable grounds to believe that the requirements of this act
23 have not been met.

24 Section 6. Immunity from liability.

25 (a) Making a report.--Notwithstanding any other provision of
26 law, no person making a report under this act shall be held, by
27 reason of making the report, to have violated any criminal law
28 or to be civilly liable under any law, unless the information
29 provided in the report is false and the person providing the
30 information knew that the information was false.

1 (b) Performance of duty.--No individual who, as a member,
2 employee, agent, officer or director of a health care facility
3 shall be held, by reason of the performance of any duty,
4 function or activity authorized or required under this act, to
5 have violated any criminal law or be civilly liable under any
6 law as a result of performing any duty, function or activity,
7 unless the duty, function or activity was motivated solely by
8 malice toward a person affected by the action.

9 Section 7. Reports and confidentiality.

10 (a) Reports confidential.--Reports generated by reason of
11 this act shall remain confidential. This includes the
12 identification of the patient, the person reporting an event and
13 the health care practitioners involved. No person may be
14 required to testify in any civil action as to the contents of a
15 report.

16 (b) Annual report.--The department shall annually compile a
17 listing of all substantiated reportable medical events in health
18 care facilities throughout this Commonwealth. The substantiated
19 reportable medical event report shall include the name of the
20 health care facility where the incident occurred, the date of
21 the incident and a description of the circumstances surrounding
22 the occurrence of the substantiated reportable medical event.
23 The report shall also include recommendations from the
24 department, when applicable, to describe how the event could be
25 prevented in the future. The annual report of all substantiated
26 reportable medical events shall be distributed to every health
27 care facility risk manager by the department upon release of the
28 publication.

29 (c) Civil, administrative or criminal proceedings.--This act
30 is not intended to nor shall it be construed to prohibit any

1 person from testifying during any civil, administrative or
2 criminal proceeding regarding that person's knowledge of the
3 medical treatment provided to a patient who is the subject of a
4 report generated under this act.

5 Section 8. Penalties.

6 The department may assess an administrative penalty of \$1,000
7 against a health care facility that intentionally or negligently
8 violates this act. The assessment under this section is subject
9 to 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure
10 of Commonwealth agencies) and Ch. 7 Subch. A (relating to
11 judicial review of Commonwealth agency action).

12 Section 9. Effective date.

13 This act shall take effect in 60 days.