
By: **Delegates Shriver and Donoghue**
Introduced and read first time: February 22, 2001
Assigned to: Rules and Executive Nominations

A BILL ENTITLED

1 AN ACT concerning

2 **Patient Safety Improvement Act of 2001**

3 FOR the purpose of requiring the Maryland Health Care Commission to establish a
4 Patient Safety Information Collection Program; providing for the purposes of the
5 Program; requiring the Commission to take certain actions under the Program;
6 authorizing the Commission to contract out the administration of the Program;
7 requiring the Commission to implement a system for the mandatory,
8 collaborative, and confidential reporting of egregious and nonegregious medical
9 errors involving health care practitioners in the State that lead to adverse
10 medical events in health care facilities in the State; requiring the Commission to
11 define certain terms by regulation; authorizing the Commission to contract out
12 the administration of the system; requiring the Commission to establish certain
13 methods for reporting medical errors and implement a campaign publicizing
14 those methods; prohibiting certain personnel actions against certain employees
15 who disclose certain information or seek certain remedies; providing for the
16 confidentiality of certain information reported or collected; requiring the
17 adoption of regulations; requiring an annual report; defining certain terms; and
18 generally relating to patient safety and the reporting of medical errors.

19 BY adding to
20 Article - Health - General
21 Section 19-139 through 19-141 to be under the new part "Part IV. Patient
22 Safety"
23 Annotated Code of Maryland
24 (2000 Replacement Volume)

25 **Preamble**

26 WHEREAS, Recent studies have indicated that medical errors may result in
27 44,000 to 98,000 deaths in United States hospitals annually; and

28 WHEREAS, Deaths from errors in the prescription and administration of
29 medications may claim as many as 7,000 lives annually, exceeding the number of
30 deaths attributed annually to workplace injuries; and

1 WHEREAS, Medically induced injuries and death not only represent a major
2 public health problem -- resulting not only in death, permanent disability, and
3 unnecessary suffering -- but also in economic costs and a loss of trust in the medical
4 profession; and

5 WHEREAS, Although medical errors may be more easily detected in hospitals,
6 they occur in other health care settings as well; and

7 WHEREAS, A 1999 report of the Committee on Quality Health Care in America,
8 sponsored by the Institute of Medicine of the National Academy of Science, stated that
9 "the health care delivery system is rapidly evolving and undergoing substantial
10 redesign, which may introduce improvements, but also new hazards"; and

11 WHEREAS, The report's recommendations included the establishment of a
12 mandatory reporting system for adverse medical events, the encouragement of
13 voluntary reporting efforts, modifications of legal and confidentiality requirements to
14 promote reporting and analysis, and the development of performance standards by
15 health care organizations and health care professionals to focus greater attention on
16 patient safety; and

17 WHEREAS, Many of the recommendations and methods of implementation
18 offered by the report have critical significance for the delivery of health care in the
19 State of Maryland; now, therefore,

20 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
21 MARYLAND, That the Laws of Maryland read as follows:

22 **Article - Health - General**

23 **PART IV. PATIENT SAFETY.**

24 19-139.

25 (A) IN THIS SECTION, "PROGRAM" MEANS THE PATIENT SAFETY
26 INFORMATION COLLECTION PROGRAM ESTABLISHED UNDER THIS SECTION.

27 (B) THE COMMISSION SHALL ESTABLISH A PATIENT SAFETY INFORMATION
28 COLLECTION PROGRAM.

29 (C) THE PURPOSES OF THE PROGRAM ARE TO:

30 (1) MAXIMIZE PATIENT SAFETY;

31 (2) REDUCE MEDICAL ERRORS;

32 (3) IMPROVE THE QUALITY OF HEALTH CARE BY IMPROVING SYSTEMS
33 THAT REPORT, COLLECT, ANALYZE, AND DISSEMINATE INFORMATION RELATING TO
34 MEDICAL ERRORS AND PATIENT SAFETY;

1 (4) ENCOURAGE A CULTURE OF BLAME-FREE REPORTING OF MEDICAL
2 ERRORS; AND

3 (5) IMPROVE PUBLIC ACCESS TO INFORMATION RELATING TO MEDICAL
4 ERRORS AND PATIENT SAFETY THAT IS NOT OTHERWISE RESTRICTED.

5 (D) (1) THE COMMISSION SHALL:

6 (I) IDENTIFY AVAILABLE INFORMATION THAT IS USEFUL FOR
7 MAXIMIZING PATIENT SAFETY, REDUCING MEDICAL ERRORS, AND IMPROVING
8 HEALTH CARE QUALITY, INCLUDING INFORMATION AVAILABLE FROM FEDERAL,
9 STATE, AND LOCAL AGENCIES;

10 (II) EVALUATE EXISTING REPORTING REQUIREMENTS;

11 (III) DEVELOP RECOMMENDATIONS FOR THE GENERAL ASSEMBLY
12 FOR STANDARDIZING, CONSOLIDATING, AND SUPPLEMENTING EXISTING DATA
13 REPORTING REQUIREMENTS, AND ELIMINATING DUPLICATIVE AND UNNECESSARY
14 DATA REPORTING REQUIREMENTS, IN A MANNER THAT SATISFIES THE PURPOSES OF
15 THIS PART IV;

16 (IV) COORDINATE THE DATA COLLECTION AND REPORTING
17 ACTIVITIES OF THE PROGRAM WITH THE ACTIVITIES OF:

18 1. THE OFFICE OF HEALTH CARE QUALITY IN THE
19 DEPARTMENT OF HEALTH AND MENTAL HYGIENE;

20 2. THE FEDERAL GOVERNMENT AND OTHER STATES; AND

21 3. OTHER PROGRAMS FOR IMPROVING PATIENT SAFETY OR
22 HEALTH CARE QUALITY, INCLUDING THE PROGRAMS OF THE NATIONAL FORUM FOR
23 HEALTH CARE QUALITY MEASUREMENT AND REPORTING; AND

24 (V) DEVELOP PROGRAMS TO ENSURE THE VALIDITY OF STATEWIDE
25 DATA REPORTING SYSTEMS, INCLUDING THE USE OF RANDOM AUDITS TO ENSURE
26 COMPLIANCE.

27 (2) THE COMMISSION SHALL:

28 (I) ANALYZE AND USE THE INFORMATION COLLECTED UNDER
29 THIS SECTION TO RECOMMEND STATEWIDE GOALS FOR MEDICAL SAFETY;

30 (II) TRACK THE PROGRESS OF HEALTH CARE PROVIDERS IN
31 MEETING GOALS FOR MEDICAL SAFETY; AND

32 (III) USE THE INFORMATION COLLECTED UNDER THIS SECTION IN
33 REPORTING ON THE PERFORMANCE OF HEALTH CARE PROVIDERS AND HEALTH
34 CARE PRACTITIONERS IN THE STATE UNDER THIS PART IV.

35 (E) THE COMMISSION SHALL PROMOTE:

1 (1) THE DEVELOPMENT AND DISSEMINATION OF REGIONAL AND
2 STATEWIDE PERFORMANCE INFORMATION; AND

3 (2) CONSISTENT WITH STATE LAW, EFFORTS BY HEALTH CARE
4 ORGANIZATIONS, INSURERS, HEALTH PLANS, HEALTH MAINTENANCE
5 ORGANIZATIONS, HEALTH CARE PROVIDERS, AND HEALTH CARE PRACTITIONERS TO
6 PARTICIPATE IN VOLUNTARY, COOPERATIVE EFFORTS TO IMPROVE PATIENT SAFETY
7 AND HEALTH CARE QUALITY.

8 (F) THE COMMISSION SHALL:

9 (1) REVIEW AND PROMOTE RESEARCH TO ASSIST HEALTH CARE
10 PROVIDERS AND HEALTH PLANS IN:

11 (I) IDENTIFYING SYSTEMIC PROBLEMS IN HEALTH CARE THAT
12 LEAD TO MEDICAL ERRORS OR THE IMPAIRMENT OF PATIENT SAFETY OR HEALTH
13 CARE QUALITY;

14 (II) IDENTIFYING APPROPRIATE QUALITY IMPROVEMENT
15 STRATEGIES; AND

16 (III) DEVELOPING AND ADOPTING HEALTH CARE BEST PRACTICES;
17 AND

18 (2) SERVE AS A CLEARING HOUSE OF INFORMATION FOR HEALTH CARE
19 PROVIDERS OF QUALITY IMPROVEMENT STRATEGIES AND BEST PRACTICES.

20 (G) (1) THE COMMISSION MAY CONTRACT WITH ONE OR MORE PRIVATE
21 ENTITIES TO PERFORM THE RESPONSIBILITIES MANDATED UNDER THIS SECTION.

22 (2) AN ENTITY CONTRACTED UNDER THIS SECTION SHALL BE SUBJECT
23 TO ALL LAWS RELATING TO CONFIDENTIALITY.

24 (H) THIS SECTION MAY NOT BE INTERPRETED TO:

25 (1) RESTRICT PUBLIC ACCESS TO INFORMATION CURRENTLY
26 AVAILABLE OR PERMITTED BY ANY OTHER LAW OR REGULATION; OR

27 (2) EXCEPT UNDER THE EXPRESS TERMS OF THIS SECTION, AUTHORIZE
28 THE DISCLOSURE OF OTHERWISE CONFIDENTIAL INFORMATION.

29 19-140.

30 (A) (1) ON OR BEFORE JULY 1, 2002, IN COLLABORATION WITH HEALTH
31 CARE PROVIDERS AND HEALTH CARE PRACTITIONERS, THE COMMISSION SHALL
32 ADOPT REGULATIONS IMPLEMENTING A SYSTEM FOR THE MANDATORY,
33 COLLABORATIVE, AND CONFIDENTIAL REPORTING OF EGREGIOUS AND
34 NONEGREGIOUS MEDICAL ERRORS INVOLVING HEALTH CARE PRACTITIONERS IN
35 THE STATE THAT LEAD TO ADVERSE MEDICAL EVENTS IN HEALTH CARE FACILITIES
36 IN THE STATE.

1 (2) IN DEVELOPING THE SYSTEM, THE COMMISSION SHALL DEFINE BY
2 REGULATION:

3 (I) "EGREGIOUS MEDICAL ERROR", TAKING INTO CONSIDERATION
4 THE 1999 RECOMMENDATIONS OF THE NATIONAL ACADEMY OF SCIENCE'S
5 INSTITUTE OF MEDICINE AND THE RECOMMENDATIONS OF THE NATIONAL FORUM
6 FOR HEALTH CARE QUALITY MEASUREMENT AND REPORTING; AND

7 (II) "ADVERSE MEDICAL EVENT", INCLUDING IN THE DEFINITION:

8 1. AN UNANTICIPATED DEATH;

9 2. SURGERY ON THE WRONG PATIENT OR WRONG BODY
10 PART; AND

11 3. A SERIOUS INJURY NOT ANTICIPATED IN THE NATURAL
12 COURSE OF AN ILLNESS, DISEASE, OR TREATMENT.

13 (3) THE PURPOSE OF THE SYSTEM SHALL BE TO OBTAIN INFORMATION
14 THAT IS USEFUL FOR MAXIMIZING PATIENT SAFETY, REDUCING MEDICAL ERRORS,
15 AND IMPROVING THE QUALITY OF HEALTH CARE.

16 (4) THE SYSTEM SHALL REQUIRE THE REPORTING OF EGREGIOUS AND
17 NONEGREGIOUS ERRORS BY TELEPHONE AS SOON AS REASONABLY POSSIBLE AFTER
18 THE ERROR IS IDENTIFIED.

19 (5) THE SYSTEM SHALL COMPLY WITH ANY REPORTING REQUIREMENTS
20 IMPOSED UNDER FEDERAL LAW OR REGULATION AND SHALL COORDINATE WITH
21 FEDERAL REPORTING SYSTEMS IN CARRYING OUT THE PURPOSES OF THIS SECTION.

22 (6) THE SYSTEM SHALL INCLUDE PEER REVIEW AND AN INVESTIGATIVE
23 PROCESS THAT DOES NOT EXCEED 45 DAYS FOR EACH INVESTIGATION.

24 (7) THE COMMISSION MAY CONTRACT WITH ONE OR MORE PRIVATE
25 ENTITIES TO ADMINISTER THE SYSTEM.

26 (8) THE SYSTEM SHALL INCLUDE AN AUDITING PROCESS TO ENSURE
27 COMPLIANCE.

28 (B) THE COMMISSION SHALL ESTABLISH, FOR THE REPORTING OF
29 EGREGIOUS AND NONEGREGIOUS MEDICAL ERRORS:

30 (1) A TOLL-FREE TELEPHONE NUMBER AND A TOLL-FREE FACSIMILE
31 NUMBER;

32 (2) A MEANS FOR REPORTING BY A WEB-BASED TOOL OR ELECTRONIC
33 MAIL; AND

34 (3) A VOICE MESSAGING SYSTEM.

1 (C) EXCEPT AS OTHERWISE SPECIFICALLY AUTHORIZED UNDER LAW,
2 INFORMATION COLLECTED BY THE COMMISSION UNDER THIS SECTION SHALL BE
3 KEPT CONFIDENTIAL AND MAY NOT BE:

4 (1) SUBJECT TO DISCLOSURE UNDER §§ 10-611 THROUGH 10-624 OF THE
5 STATE GOVERNMENT ARTICLE; OR

6 (2) EXCEPT IN A DISCIPLINARY ACTION BY THE DEPARTMENT OF
7 HEALTH AND MENTAL HYGIENE AND THE APPROPRIATE LICENSING OR
8 REGISTRATION BOARD INITIATED AS A RESULT OF INFORMATION RECEIVED
9 THROUGH A PROCESS OTHER THAN THE REPORTING UNDER THIS SECTION,
10 DISCOVERABLE OR ADMISSIBLE IN ANY CIVIL OR ADMINISTRATIVE ACTION.

11 (D) THE COMMISSION SHALL DEVELOP A PUBLIC INFORMATION CAMPAIGN
12 WHICH SHALL INCLUDE A NOTICE SUITABLE FOR POSTING THAT INFORMS HEALTH
13 CARE PRACTITIONERS, NURSES, MEDICAL PERSONNEL, AND STAFF OF THE ADDRESS,
14 TELEPHONE NUMBERS, AND ELECTRONIC MAIL ADDRESS FOR REPORTING
15 EGREGIOUS AND NONEGREGIOUS MEDICAL ERRORS.

16 (E) (1) A SUPERVISOR OR HEAD OF A HEALTH CARE FACILITY MAY NOT
17 TAKE OR REFUSE TO TAKE ANY PERSONNEL ACTION AS A REPRISAL AGAINST AN
18 EMPLOYEE WHO:

19 (I) DISCLOSES INFORMATION THAT THE EMPLOYEE REASONABLY
20 BELIEVES EVIDENCES AN EGREGIOUS OR NONEGREGIOUS MEDICAL ERROR; OR

21 (II) FOLLOWING A DISCLOSURE UNDER ITEM (I) OF THIS
22 PARAGRAPH SEEKS A REMEDY UNDER PARAGRAPH (2) OF THIS SUBSECTION.

23 (2) THE COMMISSION SHALL ESTABLISH REMEDIES FOR A VIOLATION
24 OF THIS SUBSECTION.

25 19-141.

26 BEGINNING APRIL 1, 2002, THE COMMISSION SHALL ANNUALLY REPORT THE
27 ACTIVITIES OF THE COMMISSION UNDER THIS PART IV AND THE COMMISSION'S
28 FINDINGS AND RECOMMENDATIONS FOR ANY CHANGES TO THE PROGRAM OR
29 SYSTEMS IMPLEMENTED UNDER THIS PART IV TO THE GOVERNOR AND, SUBJECT TO
30 § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY.

31 SECTION 2. AND BE IT FURTHER ENACTED, That, on or before April 1,
32 2002, the Commission shall adopt regulations to implement the provisions of §§
33 19-139 and 19-140 of the Health - General Article as implemented by this Act.

34 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
35 July 1, 2001.