

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL
No. 2443 Session of
2006

INTRODUCED BY KILLION, BASTIAN, ADOLPH, BAKER, BARRAR, BUNT,
CALTAGIRONE, CAPPELLI, CLYMER, CRAHALLA, CREIGHTON, DeWEESE,
FREEMAN, GEIST, HARHAI, HENNESSEY, HERSHEY, KAUFFMAN,
LaGROTTA, LEVDANSKY, MARKOSEK, MILLARD, MUSTIO, PERZEL,
PICKETT, PYLE, ROBERTS, ROSS, SATHER, SAYLOR, E. Z. TAYLOR,
TURZAI, WATSON, YOUNGBLOOD, BALDWIN, FLEAGLE, THOMAS, GANNON,
WALKO, HARPER, SOLOBAY, SAINATO AND DALEY, FEBRUARY 8, 2006

AS AMENDED ON THIRD CONSIDERATION, IN SENATE, JUNE 12, 2006

AN ACT

1 ~~Amending the act of June 13, 1967 (P.L.31, No.21), entitled "An~~ <—
2 ~~act to consolidate, editorially revise, and codify the public~~
3 ~~welfare laws of the Commonwealth," providing for continuation~~
4 ~~of demonstration projects for cardiac care.~~
5 AMENDING THE ACT OF JULY 19, 1979 (P.L.130, NO.48), ENTITLED "AN <—
6 ACT RELATING TO HEALTH CARE; PRESCRIBING THE POWERS AND
7 DUTIES OF THE DEPARTMENT OF HEALTH; ESTABLISHING AND
8 PROVIDING THE POWERS AND DUTIES OF THE STATE HEALTH
9 COORDINATING COUNCIL, HEALTH SYSTEMS AGENCIES AND HEALTH CARE
10 POLICY BOARD IN THE DEPARTMENT OF HEALTH, AND STATE HEALTH
11 FACILITY HEARING BOARD IN THE DEPARTMENT OF JUSTICE;
12 PROVIDING FOR CERTIFICATION OF NEED OF HEALTH CARE PROVIDERS
13 AND PRESCRIBING PENALTIES," PROVIDING FOR CONTINUATION OF
14 DEMONSTRATION PROJECTS FOR CARDIAC CARE.

15 The General Assembly of the Commonwealth of Pennsylvania
16 hereby enacts as follows:

17 ~~Section 1. The act of June 13, 1967 (P.L.31, No.21), known~~ <—
18 ~~as the Public Welfare Code, is amended by adding a section to~~
19 ~~read:~~

20 ~~Section 1002.1. Continuation of Demonstration Projects for~~
21 ~~Cardiac Care. Any hospital that is subject to the provisions of~~

~~this act, which also operates a demonstration project for percutaneous coronary intervention, shall, upon expiration of the demonstration project period initially approved by the Department of Health, receive permanent approval of the service operated under the demonstration project in accordance with the conditions as initially approved, unless otherwise agreed to in writing by the hospital. Nothing in this section shall prevent the Department of Health from promulgating regulations regarding percutaneous coronary intervention.~~

~~Section 2. This act shall take effect in 60 days.~~

SECTION 1. THE ACT OF JULY 19, 1979 (P.L.130, NO.48), KNOWN AS THE HEALTH CARE FACILITIES ACT, IS AMENDED BY ADDING A SECTION TO READ:

~~SECTION 822. CONTINUATION OF DEMONSTRATION PROJECTS FOR CARDIAC CARE. ANY HOSPITAL THAT OPERATES A DEMONSTRATION PROJECT FOR PERCUTANEOUS CORONARY INTERVENTION SHALL, UPON EXPIRATION OF THE DEMONSTRATION PROJECT PERIOD INITIALLY APPROVED BY THE DEPARTMENT, RECEIVE APPROVAL TO CONTINUE IN THE DEMONSTRATION PROJECT IN ACCORDANCE WITH THE CONDITIONS AS INITIALLY APPROVED, UNLESS OTHERWISE AGREED TO IN WRITING BY THE HOSPITAL, EXCEPT THAT THE DEPARTMENT, AFTER CONSULTATION WITH THE PENNSYLVANIA CHAPTER OF THE AMERICAN COLLEGE OF CARDIOLOGY, MAY REQUIRE HOSPITALS PARTICIPATING IN THE DEMONSTRATION PROJECT TO PARTICIPATE IN A STUDY OF THE DEMONSTRATION PROJECT BY AN ACADEMIC INSTITUTION ACCEPTABLE TO THE HOSPITAL AND THE DEPARTMENT.~~

~~SECTION 822. CONTINUATION OF DEMONSTRATION PROJECTS FOR CARDIAC CARE.~~

~~(A) APPROVAL.--ANY HOSPITAL THAT OPERATES A DEMONSTRATION PROJECT FOR PERCUTANEOUS CORONARY INTERVENTION MUST, UPON~~

1 EXPIRATION OF THE DEMONSTRATION PROJECT PERIOD INITIALLY
2 APPROVED BY THE DEPARTMENT, RECEIVE APPROVAL TO CONTINUE IN THE
3 DEMONSTRATION PROJECT IN ACCORDANCE WITH THE CONDITIONS AGREED
4 TO BY THE DEPARTMENT, IF THE HOSPITAL PERFORMS 200 PROCEDURES OR
5 MORE ANNUALLY OR IS DETERMINED BY THE DEPARTMENT TO BE WITHIN
6 RANGE OF PERFORMING 200 PROCEDURES IN THE NEXT 12 MONTHS.

7 (B) LOWER VOLUME.--A HOSPITAL WHICH OPERATES A DEMONSTRATION
8 PROJECT FOR PERCUTANEOUS CORONARY INTERVENTION THAT PERFORMS
9 FEWER THAN 200 PROCEDURES ANNUALLY AND WHICH IS NOT DETERMINED
10 BY THE DEPARTMENT TO BE WITHIN RANGE OF PERFORMING 200
11 PROCEDURES IN THE NEXT 12 MONTHS MAY CONTINUE ITS ELECTIVE
12 PERCUTANEOUS CORONARY INTERVENTION PROGRAM IN ACCORDANCE WITH
13 ALL OF THE FOLLOWING REQUIREMENTS:

14 (1) THE HOSPITAL SHALL FOLLOW A PROSPECTIVE, RIGOROUS
15 PROTOCOL FOR CASE SELECTION DEVELOPED BY A HOSPITAL WITH
16 CARDIAC SURGERY CAPACITY.

17 (2) ALL PHYSICIANS PERFORMING PERCUTANEOUS CORONARY
18 INTERVENTIONS AT THE HOSPITAL WITHOUT CARDIAC SURGICAL BACKUP
19 SHALL RECEIVE OR HAVE RECEIVED FORMAL INTERVENTION TRAINING
20 AT A HOSPITAL WITH OPEN-HEART SURGERY AND MAINTAIN PROCEDURAL
21 VOLUMES COMPLIANT WITH THE AMERICAN COLLEGE OF CARDIOLOGY
22 GUIDELINES. THE PHYSICIAN MUST PERFORM AT LEAST 75
23 PERCUTANEOUS CORONARY INTERVENTIONS PER YEAR. THE
24 PERCUTANEOUS CORONARY INTERVENTIONS CAN BE PERFORMED AT ANY
25 COMBINATION OF FACILITIES.

26 (3) ALL PHYSICIANS PERFORMING PERCUTANEOUS CORONARY
27 INTERVENTIONS AT THE HOSPITAL WITHOUT CARDIAC SURGICAL
28 CAPACITY SHALL BE CREDENTIALLED AND ROTATED THROUGH THE
29 CATHETERIZATION LAB AT A HOSPITAL WITH CARDIAC SURGERY
30 CAPACITY.

1 (4) THE HOSPITAL SHALL ENSURE THAT OVERSIGHT OF ITS
2 PROGRAM IS PROVIDED BY INTERVENTIONALIST CARDIOLOGISTS WHO
3 REGULARLY PRACTICE AT A HOSPITAL WITH CARDIAC SURGERY
4 CAPACITY, WHO SHALL PROVIDE ASSISTANCE IN ACCORDANCE WITH ALL
5 OF THE FOLLOWING:

6 (I) A REVIEW OF ALL POLICIES AND PROCEDURES FOR THE
7 OPERATION OF THE CARDIAC CATHETERIZATION LABORATORY AND
8 PERCUTANEOUS CORONARY INTERVENTION PROGRAM, WITH
9 RECOMMENDATIONS FOR CHANGES, IF NECESSARY.

10 (II) AN OPERATIONS REVIEW OF THE CATHETERIZATION
11 LABORATORY AND PERCUTANEOUS CORONARY INTERVENTION PROGRAM
12 EVERY SIX MONTHS.

13 (III) PARTICIPATION IN QUARTERLY PEER REVIEW OF ALL
14 ELECTIVE CASES AND SELECTED PRIMARY CASES.

15 (IV) TRAINING OF ALL NEW STAFF AT THE HOSPITAL
16 WITHOUT CARDIAC SURGICAL BACKUP IN THE CATHETERIZATION
17 LABORATORY, AND PERIODIC RETRAINING, AS NECESSARY.

18 (5) THE HOSPITAL SHALL HAVE IN PLACE A TRANSFER
19 AGREEMENT WITH ONE OR MORE HOSPITALS WITH CARDIAC SURGERY
20 CAPACITY FOR EMERGENCY TRANSFER OF PATIENTS FROM THE
21 CATHETERIZATION LABORATORY, IF NECESSARY.

22 (6) THE HOSPITAL SHALL IMPLEMENT THE SAME PROTOCOLS FOR
23 BOTH PREELECTIVE AND POSTELECTIVE PERCUTANEOUS CORONARY
24 INTERVENTION CARE WHICH ARE UTILIZED BY THE HOSPITAL WITH
25 CARDIAC SURGERY CAPACITY.

26 (7) A TESTED TRANSPORT PROTOCOL WHICH INCLUDES
27 HELICOPTERS AND GROUND AMBULANCES WITH INTRA-AORTIC BALLOON
28 PUMP CAPABILITY FOR HEMODYNAMIC SUPPORT SHALL BE ESTABLISHED.

29 (8) WHEN WEATHER CONDITIONS PREVENT THE USE OF THE
30 TRANSPORT SYSTEM, ALL ELECTIVE PERCUTANEOUS CORONARY

1 INTERVENTIONS SHALL BE CANCELED, UNLESS CANCELLATION WILL
2 RESULT IN PATIENT HARM.

3 (9) THE HOSPITAL MUST TRACK THE OUTCOMES OF PATIENTS AT
4 6 AND 12 MONTHS AFTER EACH PERCUTANEOUS CORONARY INTERVENTION
5 AND YEARLY THEREAFTER, FOR TWO YEARS, TO ASSESS MAJOR ADVERSE
6 CARDIOVASCULAR EVENTS.

7 (10) THE HOSPITAL MUST PARTICIPATE IN THE AMERICAN
8 COLLEGE OF CARDIOLOGY NATIONAL CARDIOVASCULAR DISEASE
9 REGISTRY. CARDIOLOGISTS FROM THE HOSPITAL WITH CARDIAC
10 SURGERY CAPACITY WILL REVIEW A SAMPLE OF CASE REPORTS FROM
11 THE PRIOR 12 MONTHS TO DETERMINE THE ACCURACY OF REPORTING.
12 IN ADDITION TO THE REQUIREMENT OF THIS PARAGRAPH, THE
13 HOSPITAL WITHOUT CARDIAC SURGICAL BACKUP MAY PARTICIPATE IN
14 AN INDEPENDENT STUDY OF ELECTIVE PERCUTANEOUS CORONARY
15 INTERVENTION CASES TO EVALUATE OUTCOMES FOR ELECTIVE
16 PERCUTANEOUS CORONARY INTERVENTIONS AT DISCHARGE, AND AT 6
17 AND 12 MONTHS.

18 (C) GENERAL REQUIREMENTS.--ALL HOSPITALS SUBJECT TO THIS
19 SECTION SHALL COMPLY WITH ALL OF THE FOLLOWING:

20 (1) THE HOSPITAL SHALL USE A PATIENT CONSENT FORM FOR
21 ALL ELECTIVE PERCUTANEOUS CORONARY INTERVENTIONS THAT
22 INCLUDES THE FOLLOWING STATEMENT:

23 "THE PENNSYLVANIA DEPARTMENT OF HEALTH AND THE AMERICAN
24 COLLEGE OF CARDIOLOGY RECOMMEND THAT PATIENTS UNDERGO
25 ELECTIVE ANGIOPLASTY PROCEDURES IN A HOSPITAL WITH ONSITE
26 OPEN-HEART SURGERY SERVICES."

27 A LIST OF HOSPITALS WHICH PROVIDE ONSITE OPEN-HEART SURGICAL
28 SERVICES WITHIN A 50-MILE RADIUS OF THE HOSPITAL SHALL BE
29 ATTACHED TO THE CONSENT FORM.

30 (2) THE HOSPITAL SHALL REPORT WITHIN 24 HOURS AND IN A

1 MANNER PRESCRIBED BY THE DEPARTMENT, ANY TRANSFER MADE BY THE
2 HOSPITAL TO ANY OTHER HOSPITAL AS A RESULT OF THE PERFORMANCE
3 OF AN ELECTIVE PERCUTANEOUS CORONARY INTERVENTION.

4 (3) THE DEPARTMENT MAY TERMINATE A PERCUTANEOUS CORONARY
5 INTERVENTION PROGRAM SUBJECT TO THIS SECTION IF THE
6 DEPARTMENT DETERMINES THAT THE HOSPITAL HAS DEMONSTRATED
7 NEGATIVE OUTCOMES THAT SERIOUSLY JEOPARDIZE PATIENT SAFETY,
8 IN ACCORDANCE WITH THIS ACT.

9 (4) THE HOSPITAL SHALL NOTIFY ITS LIABILITY INSURANCE
10 CARRIER THAT IT IS PROVIDING ELECTIVE PERCUTANEOUS CORONARY
11 INTERVENTION SERVICES WITHOUT ONSITE AVAILABILITY OF OPEN-
12 HEART SURGICAL SERVICE.

13 (D) PERMANENT APPROVAL.--THE DEPARTMENT MAY DETERMINE AT ANY
14 TIME THAT CONTINUATION OF THE DEMONSTRATION PROJECT IS NO LONGER
15 NECESSARY TO ALLOW FOR THE PROVISION OF PERCUTANEOUS CORONARY
16 INTERVENTIONS IN HOSPITALS WITHOUT CARDIAC SURGICAL BACKUP AND
17 MAY PERMANENTLY APPROVE SUCH SERVICES AT THAT TIME. THE
18 DEPARTMENT SHALL ISSUE A DECISION REGARDING A DETERMINATION
19 UNDER THIS SUBSECTION NO LATER THAN TWO YEARS FROM THE EFFECTIVE
20 DATE OF THIS SECTION AND ANNUALLY THEREAFTER.

21 SECTION 2. THIS ACT SHALL TAKE EFFECT IMMEDIATELY.