

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED _____ (Y/N)
ADOPTED AS AMENDED _____ (Y/N)
ADOPTED W/O OBJECTION _____ (Y/N)
FAILED TO ADOPT _____ (Y/N)
WITHDRAWN _____ (Y/N)
OTHER _____

1 Committee/Subcommittee hearing bill: Health Innovation
2 Subcommittee

3 Representative Pigman offered the following:

4
5 **Amendment**

6 Remove lines 66-138 and insert:

7 At a minimum, the rules must require the following:

8 1. Cardiologists must be experienced interventionists who
9 have performed a minimum of 50 interventions annually, averaged
10 over 2 years, that were performed in institutions performing
11 more than 200 total intervention procedures annually and more
12 than 36 primary intervention procedures annually.

13 2. The hospital must provide a minimum of 36 primary
14 interventions annually in order to continue to provide the
15 service.

16 3. The hospital must offer sufficient physician, nursing,
17 and laboratory staff to provide the services 24 hours a day, 7

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18 days a week.

19 4. Nursing and technical staff must have demonstrated
20 experience in handling acutely ill patients requiring
21 intervention based on the staff members' previous experience in
22 dedicated interventional laboratories or surgical centers. In
23 order for experience acquired at a dedicated interventional
24 laboratory at a hospital without an approved adult open-heart-
25 surgery program to qualify, the cardiac interventional
26 laboratory must have, throughout the training period:

27 a. Had an annual volume of 200 or more percutaneous
28 coronary intervention procedures;

29 b. Achieved a demonstrated success rate of 95 percent or
30 greater for percutaneous coronary intervention procedures;

31 c. Experienced a complication rate of less than 5 percent
32 for percutaneous coronary intervention procedures;

33 d. Experienced required emergent coronary artery bypass
34 grafting on less than 2 percent of the patients undergoing a
35 percutaneous coronary intervention procedure; and

36 e. Performed diverse cardiac procedures, including, but
37 not limited to, balloon angioplasty and stenting, rotational
38 atherectomy, cutting balloon atheroma remodeling, and procedures
39 relating to left ventricular support capability.

40 5. Cardiac care nursing staff must be adept in hemodynamic
41 monitoring, operation of temporary pacemakers, intra-aortic
42 balloon pump management, management of indwelling arterial and
43 venous sheaths, and identifying potential complications.

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44 6. Hospitals implementing the service must first undertake
45 a training program of 3 to 6 months' duration, which includes
46 establishing standards and testing logistics, creating quality
47 assessment and error management practices, and formalizing
48 patient-selection criteria.

49 7. The applicant must certify that the hospital will use
50 at all times the patient-selection criteria for the performance
51 of primary angioplasty at hospitals without adult open-heart-
52 surgery programs issued by the American College of Cardiology
53 and the American Heart Association.

54 (b) For a hospital seeking a Level I program,
55 demonstration that, for the most recent 12-month period as
56 reported to the agency, it has provided a minimum of 300 adult
57 inpatient and outpatient diagnostic cardiac catheterizations or,
58 for the most recent 12-month period, has discharged or
59 transferred at least 300 inpatients with the principal diagnosis
60 of ischemic heart disease and that it has a formalized, written
61 transfer agreement with a hospital that has a Level II program,
62 including written transport protocols to ensure safe and
63 efficient transfer of a patient within 60 minutes. However, a
64 hospital located more than 100 road miles from the closest Level
65 II adult cardiovascular services program does not need to meet
66 the 60-minute transfer time protocol if the hospital
67 demonstrates that it has a formalized, written transfer
68 agreement with a hospital that has a Level II program. The
69 agreement must include written transport protocols to ensure the

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70 safe and efficient transfer of a patient, taking into
71 consideration the patient's clinical and physical
72 characteristics, road and weather conditions, and viability of
73 ground and air ambulance service to transfer the patient.
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