

Department of Health Analysis: Proposed Rules for Percutaneous Coronary Interventions Without On-Site Surgery

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In May 2008, the Department of Health filed a proposed rule regarding the criteria for granting a certificate of need to a hospital to perform elective percutaneous coronary interventions without the availability of open heart surgery services at the hospital, as currently required. The proposed rule was the result of an extensive process of analysis and stakeholder participation. This paper describes that process and the basis for the standards the rule establishes

1. The Rule Making Process

In 2007, the legislature adopted Substitute House Bill 2304. The bill directed the Department of Health to:

- Contract for an independent evidence-based review of the circumstances under which elective PCI should be allowed in Washington at hospitals that do not otherwise provide on-site cardiac surgery.
- Adopt rules allowing PCI at hospitals that do not provide on-site cardiac surgery
- Adopt rules that protect the minimum number of procedures (volume) the University of Washington must maintain to train cardiologists.

On June 21, 2007, the Department of Health held an initial stakeholder meeting to validate the statement of work for the independent evidence-based review. Through a competitive contracting process, Health Management Associates (HMA) was chosen to conduct the independent review. Their report, submitted in September 2007, recommended that elective PCI should not be performed in hospitals without on-site cardiac surgery. However, recognizing the legislative mandate in SHB 2304, the report provided an in-depth analysis of available and reputable literature regarding PCI procedures with and without on-site cardiac surgery.

In September 2007, the department convened a stakeholder meeting to review the findings of the report. The stakeholders elected to form a group which met five times between November 2007 and March 2008. A final stakeholder report was submitted to the department on April 9, 2008, identifying agreed upon recommendations and differing positions.

The final stakeholder report listed several areas that had general agreement between stakeholders and the HMA report. The proposed rule incorporates these areas of consensus, including:

- applicant responsibility to demonstrate need,
- consideration of potential volume and staffing impact on existing providers and the UW training program,
- assurance that facility teams are experienced and qualified,
- physician's annual volumes,
- existence of transfer agreements with cardiac surgeons and facilities,
- prearranged policies and mode of transportation for transfer, and

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- Existence of a quality improvement program.

A chart setting out the HMA recommendations and stakeholder agreements appears on page 4 below.

There is not consensus on all aspects of the proposed rule. The major disagreements are over 1) the minimum number of procedures that a new PCI program would require; 2) the method for proving need for the services; and 3) the boundaries of planning areas. The department's rationale is discussed below.

2. Designation of Planning Areas

The proposed rule creates twelve designated planning areas. Pierce and Snohomish Counties each comprise an area. King County is divided into east and west areas. The remaining nine areas are comprised of three or more counties (or parts thereof).

The department's based its decision to propose these twelve planning areas on the following considerations, which the stakeholder group supported:

- PCI is a tertiary service where facility and physician volumes combine to create effective and safe programs.
- Planning area populations that could support at least one elective program.
- Geographic or transportation barriers need to be minimized for new or existing programs, and planning areas should be clearly defined geographic areas.
- Planning areas need to consider existing counties.

In defining the designated planning areas, the department: took the following steps:

- Identified county boundaries.
- Included entire zip code boundaries.
- Identified population densities.
- Identified natural geographic characteristics and major transportation routes.
- Examined patient utilization for general acute care services.

We considered adopting the 54 planning areas used in general acute care hospital planning. While these planning areas would continue to meet the planning needs for general acute care facilities, this approach was rejected because the planning areas were not consistent with the underlying rationale for tertiary service planning areas. PCI is a tertiary service. We also considered the four historical health service planning areas. We determined these areas were too large and would not support improving access to this tertiary service.

3. Minimum Volume Standards

SHB 2034 required the department to set the minimum volume standards for elective PCI programs. The department evaluated the volume standards proposed by the HMA report and the stakeholder group report. The proposed rule sets the annual facility volume standard at 300 procedures performed by the end of the third year of operation. Physician volume standard is proposed at seventy-five procedures performed per year.

The department based its decision to set the minimum volume at 300 procedures on graded evidence in the HMA report and patient safety considerations. The HMA report recommended facility volumes of 300 procedures by the end of year 2 and 400 by the end of year 3. The proposal for requiring 300 procedures per year after the 3rd year of operation aligns with the HMA recommendation for year two. We concluded an annual volume of 300, combined with quality assurance standards, is the least burdensome volume that assures patient safety.

The stakeholders recommended a range of 200 to 400 as the minimum number of procedures per year. Some of the stakeholders have referred to an article by the Society for Cardiovascular Angiography and Interventions to support a recommendation of 200 as the safe minimum volume for a program. That article also recommends that facilities performing 150 procedures should be closed, and that all facilities should strive for 400 per year. As discussed above, the department concluded a minimum volume of 300 would be the least burdensome while still providing for patient safety.

The HMA report recommended a minimum volume for physicians of 75 procedures per year was. This standard was supported by the stakeholder group.

4. Proof of Need

The proposed rule uses actual volumes for existing programs when calculating the need for a planning area. Our rationale for this approach is based on patient safety concerns and the legal requirement to consider the “need of the population served” as one of the criteria considered when making a certificate of need determination. (RCW 70.38.115.) Some stakeholders proposed determining need by shifting market share within a planning area. We felt this duplication of service could negatively impact cost, access, and quality of care.

HMA & Stakeholder Agreements:

Health Management Associates Recommendations:	Stakeholders Final Report:
1. Applying programs must prove unmet need in the community served.	The burden to demonstrate need is on the applicant.
2. Applying programs must report on the impact of new program on volume of procedures at existing programs.	Applicant must identify the potential impact on existing PCI providers.
3. Applying programs must report on the impact of new program on staffing at existing programs.	Applicant must identify the potential impact on existing PCI providers.
4. Participation in a well powered, national, multi-site study assessing outcomes of elective PCI with and without on-site surgery.	Applicant must report Clinical Outcomes Assessment Program (COAP) required data.
5. Applying programs must report on the impact of new programs on the Cardiology and Interventional Cardiology training programs at the University of Washington.	Applicant must identify the potential impact on the University of Washington PCI program. University of Washington is held at actual or 400, whichever is greater.
6. Catheterization labs must be staffed with qualified, experienced technicians and nurses.	Ensure medical teams are experienced and qualified.
7. Programs must have experienced Interventional Cardiologists who meet certification and annual operator volumes of 75 PCI.	Physicians who perform PCI in hospitals that do not have surgical backup must achieve annual operator volumes of 75 PCI.
8. Hospitals without on-site cardiac surgery must have rigorous patient and lesion selection guidelines.	Work group discussed these issues and agreed that patient selection guidelines are always important regardless of setting.
9. Programs without on-site surgery must have a signed agreement with backup surgical hospital and associated cardiac surgeons for 24/7 emergency transfers.	Hospitals without surgical backup must have a written transfer agreement with a partnering surgical hospital and associated cardiac surgeons for 24/7 emergency services.
10. Emergency transport in fully equipped vehicle by ACLS certified, experienced staff.	Prearranged mode of transportation to facilitate emergency transfers.
11. Programs will conduct ongoing QI evaluation of outcomes.	Promote continuous quality improvement.