

April 13, 2015

Certificate of Need Program  
Tertiary Service Review  
Attn: Kyle Karinen, Office of Legal Services  
Washington State Department of Health  
P.O. Box 47873  
Olympia, WA 98504-7873

RE: Proposal to delete elective therapeutic cardiac catheterization including percutaneous coronary intervention from the list of defined tertiary services.

Dear Mr. Karinen:

I am a practicing board certified interventional cardiologist who takes care of patients for elective heart procedures and during the course of life threatening heart attacks at all hours of the day. I understand that there is proposal, submitted by Mr. Jonathan Seib on behalf of CHI Franciscan Health Highline Medical Center, Capital Medical Center, Yakima Valley Memorial Hospital, Legacy Salmon Creek Medical Center, and Walla Walla General Hospital (“the 5-hospital group”) to delete elective therapeutic cardiac catheterization, including general percutaneous coronary interventions (PCI) and elective percutaneous coronary angioplasty, from the list of defined tertiary services found in WAC 24-310-020(1)(d)(i).

I am concerned about this proposal and respectfully disagree with this possible change. Based on findings from clinical studies and recommendations from the American College of Cardiology (ACC), American Heart Association (AHA), and Society of Cardiac Angiography and Interventions (SCAI) 2013 Clinical Competence Statement, in my opinion, percutaneous coronary interventions (“PCI”) procedures are a tertiary service, as defined in WAC 246-310-035, and as such should be Certificate of Need (“CN”) regulated, as currently.

I understand that in the proposal, the 5-hospital group makes a number of claims and assertions, but all are founded on the proposition that “there is no correlation between volume and outcomes for Elective PCI”.<sup>1</sup> This opinion is at odds with current clinical literature and recommendations, which has found just the opposite, that is, higher per-facility and per-operator PCI volumes lead to improved patient outcomes.

The 5-hospital group includes as supporting evidence the 2013 ACCF/AHA/SCAI Clinical Competence Statement . However, this Statement *directly contradicts* the claims made by the 5-hospital group. Specifically, the ACCF/AHA/SCAI report concludes that there is a volume quality relationship at institutions performing less than 200 PCIs annually as detailed in section 2.8.1.1: RELATIONSHIP OF INSTITUTIONAL VOLUME TO PROCEDURAL OUTCOME in this document. This document states:

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<sup>1</sup> Seib Policy & Public Affairs LLC. Proposal to Remove Elective PCI from the Listing of Tertiary Services Identified in Certificate of Need Rules. February 26, 2015. 9.

“Overall, the preponderance of data suggests that hospitals in which fewer coronary interventions are performed have a greater incidence of adverse events, notably death and CABG surgery for failed intervention, than hospitals performing more procedures.... An institutional volume threshold <200 PCIs annually appears to be consistently associated with worse outcomes.... Accordingly, the writing committee recommends a minimum institutional volume threshold of 200 PCIs per year.”<sup>2</sup>

The ACCF/AHA/SCAI further concludes that facilities performing fewer than 200 PCI procedures annually “that are not serving isolated or underserved populations” are questionable, should be closely monitored for performance, and facilities that “cannot maintain satisfactory volumes should close.”<sup>3</sup> Further, it states that “interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency.”<sup>4</sup>

In my opinion, the findings and recommendations are unequivocal and directly contradicts the 5-hospital’s assertion there is no positive association between PCI volume and quality. Further, while the 5-hospital group claims more PCI providers means better access, the clinical literature states the opposite--more providers simply lower volumes across each provider; this necessarily increases costs per unit of service, and most importantly, reduces the likelihood of good outcomes.

PCI facility and operator volumes are, in fact, positively associated with improved patient outcomes. CN regulation of elective PCI programs prevents too many facilities from offering PCI procedures in markets where there is no demonstrated need. This helps prevent programs operating with too few cases and spreading declining PCI volumes across too many facilities that have neither the volume nor the experience to handle potential life threatening complications of PCI.

I recommend the Department of Health retain PCIs as a tertiary service, as presently. This is the best approach to insure providers and programs operate with sufficient volumes to ensure the best possible outcomes for our patients.

Please feel free to contact me at (253) 572 – 7320 if you have any questions.

Sincerely,



Tobias Lee, MD, FACC

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<sup>2</sup> Harold et al. ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures: A report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). J Am Coll Cardiol 2013. 374.

<sup>3</sup> Ibid., 380.

<sup>4</sup> Ibid., 381.