



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

TO: Martin Mueller, Assistant Secretary, Health Services Quality Assurance
FROM: Certificate of Need Tertiary Services Review Team¹
SUBJECT: 2015 tertiary services review
DATE: August 18, 2015

EXECUTIVE SUMMARY

Beginning in January 2015, the Department conducted a review of proposed changes to its list (the “List”)² of tertiary services. This memorandum represents the end of the process as laid out in rule and therefore, the conclusion of the Review Team’s work.

External input revolved around two services: first, there were proposals to add Neonatal intensive care nursery and/or obstetric services level IV (“NICU Level IV”) to the List; second, there were proposals to both remove elective therapeutic cardiac catheterization (Elective PCI) from the List and reduce minimum volume standards for institutions and individual providers that perform Elective PCI.

The services and procedures that fall under NICU Level IV fit all of the Department’s criteria for tertiary services. Additionally, the Department adopted Level of Care Guidelines in 2013 that recommended the addition of Level IV to the pre-existing levels. Finally, there was no external opposition to the addition of Level IV to the List.

¹ Participation in the review was sought from all divisions. The review team consisted of Steve Saxe, Community Health Systems; Bart Eggen, Construction Review/Certificate of Need Program; Janis Sigman, Certificate of Need Program; Blake Maresh, Health Professions and Facilities; Katherine Hoffman, Office of the Assistant Secretary; Kyle Karinen, Office of Legal Services; and Laurie Soine, ARNP, Nursing Care Quality Assurance Commission (Commission member).

² For ease of reference, we will be using informal designations throughout. In the body of the memorandum, where appropriate, there will be an initial citation to the relevant statute or rule.

The services and procedures that fall under Elective PCI fit a majority of the Department's criteria for tertiary services. Elective PCI was the focus of a majority of the external input and the Team discussion. The proposals for removal of Elective PCI and against removal could not be reconciled. After review of the material submitted, the Review Team concluded the while the clinical landscape around Elective PCI has changed since the initial adoption of the List in 1991, a majority of the factors for inclusion remain.

In summary, the Review Team recommends:

1. NICU Level 4 should be added to the List; and
2. No other changes should be made to List.

Part I of this memorandum describes the process used by the Team and briefly lays out the statutory and administrative rule structure that underlies tertiary services. Part II describes the input received regarding NICU Level 4 and Team's conclusions regarding adding it to the List. Part III describes the input received regarding elective PCI and the team's conclusions regarding removing it from the List.

Part I – Process and underlying statutes and rules

In addition to construction, development, or other establishment of new health care facilities, the Department has been charged by the Legislature with implementing rules that guide the provision of tertiary services.³ The Legislature defines tertiary services in statute as “a specialized service that meets complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.”⁴ The Department identifies specific services and procedures using a set of seven base factors that are identified in rule:

- (a) Whether the service is dependent on the skills and coordination of specialties and subspecialties. Including, but not limited to, physicians, nurses, therapists, social workers;
- (b) Whether the service requires immediate access to an acute care hospital;
- (c) Whether the service is characterized by relatively few providers;
- (d) Whether the service is broader than a procedure;
- (e) Whether the service has a low use rate;

³ RCW 70.38.105(4)f).

⁴ RCW 70.38.025(14).

(f) Whether consensus supports or published research shows that sufficient volume is required to impact structure, process, and outcomes of care; and

(g) Whether the service carries a significant risk or consequence.⁵

(Hereinafter, the Criteria)

The seven factors listed are not conjunctive and the rule does not call for one factor to be weighted more heavily than the others. Therefore, the Team considered one factor alone could mean the service was tertiary even if the other factors did not.

The Certificate of Need Program (Program) is required to periodically conduct a review of the services it has identified as tertiary services.⁶ By rule, the review has three phases. The first period announces to interested parties that a review will to be conducted and offers an opportunity to submit materials for the Department to consider. This period is two months in length and ended on February 27.

Four groups submitted materials. The materials largely focused on two areas: (1) adding NICU Level IV; and (2) either removing Elective PCI or reducing the volume thresholds necessary for a Certificate of Need. The Program disseminated the materials received via the Program listserv and on the DOH website to interested parties shortly after February 27.

Beginning March 16, Program accepted comments on the materials submitted over a thirty-day period. (This is referred to as the “comment period” in rule.)

There were nine comments submitted. Eight of the nine revolved around Elective PCI.⁷

Between April 16 and June 15, the Team conducted an internal review of all materials submitted to the Department. (This is referred to as the “consideration period” in rule.) All seven members reviewed the materials submitted along with the relevant statutes, rules and two pieces of supplemental reference material.⁸ The Team also regarded this period as an opportunity to correspond with interested parties to clarify unresolved issues. As detailed in Part III, there was a short exchange with a group who advocate removing Elective PCI from the List.

The time period after June 15 until now has been dedicated to finishing the review, meeting to make sure all members were in consensus and preparing this memorandum.

⁵ WAC 246-310-035(2). The Department is required by rule to review these factors at least every three years to make ensure they continue to accurately define tertiary services.

⁶ WAC 246-310-035(3).

⁷ The ninth was submitted by the Washington State Hospital Association (WSHA). WSHA did not take a substantive position regarding either NICU Level IV or Elective PCI, but endorsed the Program’s review of tertiary services and the process the Program chose to use.

⁸ Respectively: (i) Washington State Level of Care Guidelines for Perinatal and Neonatal Care, February 2013; and (ii) Chapter 14: Certificate of Need, Washington Health Law Manual, 3rd edition, 2010.

Part II – NICU Level 4

The List currently contains two services that relate to neonatal and obstetric care: Level II and Level III.⁹ In 2013, the Department through the Perinatal Advisory Committee convened a technical workgroup to review the level of care guidelines for perinatal and neonatal care.¹⁰ That workgroup was precipitated by an American Academy of Pediatrics recommendation to use uniform, nationally applicable definitions and consistent standards of service. The resulting guidelines essentially split Level III into two parts, the latter of which was designated Level IV. Currently, there are thirteen institutions that are designated Level III providers. Of those, the Program has determined four are also providing services that would fit under the Level IV designation.

The guidelines are self-explanatory, but the most concise summary is that a Level IV institution is a Level III institution with certain additions that allow for care of the small population of the most ill neonates.

Specifically, a Level IV institution must have: (a) an on-site roster of pediatric medical and surgical subspecialists as well as pediatric anesthesiologists; (b) a multi-disciplinary team for management of orthopedic and neurological anomalies; (c) surgical capabilities that contemplate repair of complex conditions that may require cardiopulmonary bypass, extracorporeal membrane oxygenation (ECMO), dialysis, tracheostomy and similar procedures; (d) a neuro-developmental follow-up program; (e) quality improvement program with comparison to national benchmarks for other Level IV institutions; and (f) a training and educational relationship with referring hospitals.

In applying the factors to determine whether NICU Level IV is a tertiary service, it is important to note that all of the care provided under NICU Level IV is already a tertiary service under the current Level III. However, a brief review showed that this care fits the Criteria:

a. Dependent on skills and coordination of specialty and subspecialty providers. No less than twenty-two medical subspecialties and no less than thirteen surgical subspecialties could be involved in NICU Level IV care.

b. Acute care hospital access. NICU Level IV care always requires immediate access to a hospital.

⁹ WAC 246-310-020(1)(d)(i)(B), (C).

¹⁰ Note the 2013 Guidelines did not add a Level IV for obstetrics.

c. Few providers. Only four institutions in Washington are currently providing care equivalent to NICU Level IV.

d. Service broader than a procedure. The advocates for inclusion of NICU Level IV interpret this factor to rely on diagnosis –related groups, and the Team endorsed that approach. The primary advocate for inclusion conducted a survey of its “recent Level IV cases.” The survey revealed less than seventeen separate DRGs. Without further data, it is not possible to verify this result as a representative sample. However, the wide range of medical and surgical subspecialties that fall under the Guideline definitions make this at the very least a plausible representative sample. Therefore, NICU Level IV is broader than a procedure.

e. Low use rate. Data submitted indicates a volume of approximately 1.4% of all births in 2013 meet criteria for NICU Level IV. While the definition of “low” in the Criteria is vague, the Team believed 1.4% of all births represents a commonsense threshold for a low use rate.

f. Volume correlated to structure, process and outcomes. This factor was non-conclusive. There does not appear to be consensus or published research.

g. Significant risk or consequence. Data submitted indicates a mortality rate of 15% which is slightly less than double the next highest tertiary service mortality rate, heart transplants. “Significant risk or consequence” is not more specifically defined in rule. Additionally, there is no quantitative factor of how often a specific risk or consequence must occur in order to be relevant to a discussion of significance. Even with those limitations in mind, the Team believed a 15% mortality rate would be toward the far end of a more specific definition.

The Team regards the addition of NICU Level IV as an administrative housekeeping item. The adoption of the 2013 Guidelines was non-controversial and the Program already has the technical capability to add this item. Potential rule-making to add NICU Level IV will also require some revision of the Level III as parts of the definition will no longer be applicable.

Part III Elective PCI

The List includes Elective PCI as part of a larger definition that includes open heart surgery:

“Open heart surgery and/or elective therapeutic cardiac catheterization including elective percutaneous transluminal coronary angioplasty (PTCA). Open heart surgery includes the care of patients who have surgery requiring the use of a heart lung bypass machine. Therapeutic cardiac catheterization means passage of a tube or other device into the coronary arteries or the

heart chambers to improve blood flow. PTCA means the treatment of a narrowing of a coronary artery by means of inflating a balloon catheter at the site of the narrowing to dilate the artery[.]”¹¹

No party submitted material concerning open heart surgery and therefore the Team did not consider open heart surgery as part of its review. Additionally, there were several comments received in both the initial phase of the review and the comment period that endorsed a reduction in institutional and individual practitioner volume standards. The current volume standards are three hundred (300)¹² and seventy-five (75)¹³, respectively. While there is academic research that supports reconsidering those volume standards¹⁴, the Team believed this issue fell outside the scope of whether the service should be on the List generally.

Elective PCI is by its very definition an outlier on the List because an institution does not need a Certificate of Need in order to perform PCI on emergent cases. Emergent cases are arguably more complex than those deemed elective. The Department’s rationale when the List was originally put into rule in 1991 was the risk of transport in emergent cases outweighed the benefit in requiring an institution to have a Certificate of Need in order to provide the care. So while it may not seem intuitive to require a Certificate of Need for arguably more complex cases, there is an underlying rationale and the Team endorses absent compelling clinical data to the contrary.

Notably, unlike any other tertiary service, there are both statutes and rules that apply to Elective PCI and no other tertiary service. As outlined above, tertiary services require a Certificate of Need. Removal from the List would normally remove the legal requirement to receive a Certificate of Need from the Program in order to provide Elective PCI. However, in 2007, the Legislature added a statute that requires a Certificate of Need for Elective PCI without regard to tertiary service designation in hospitals that do not otherwise provide on-site cardiac surgery.¹⁵ This consideration did not directly impact the Team’s application of the Criteria to Elective PCI, but it is worth noting as another way in which Elective PCI is different than other tertiary services.

Application of the Criteria:

¹¹ WAC 246-310-020(1)(d)(i)(E).

¹² WAC 246-310-720(1).

¹³ WAC 246-310-725.

¹⁴ See Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures, Journal of the American College of Cardiology, Vol. 62, No. 4 (2013), Section 2.8.3, page 374.

¹⁵ RCW 70.38.128.

a. Dependent on skills and coordination of specialty and subspecialty providers.

Elective PCI requires a highly specialized team of interventional cardiologists, nurses, lab technicians and imaging staff. The advocates for removal stressed that this factor was applicable to many acute care services and some of those services were considered tertiary and some were not. The Team acknowledged that may be the case, however the plain language of the factor is easily met nonetheless in the case of Elective PCI.

b. Acute care hospital access. All parties that applied the factors acknowledged that Elective PCI requires access to an acute care hospital and the Team agreed.

c. Few providers. Currently, ten of Washington’s hospitals are performing Elective PCI without also performing open heart surgery. No matter how the data is reviewed, applying a standard definition of “few”, there are not few providers of Elective PCI in Washington State.

d. Service broader than a procedure. Here it is important to note the List refers specifically to “elective therapeutic cardiac catheterization.” The Department has adopted rules that define “percutaneous coronary interventions” as “invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:

- (a) Bare and drug-eluting stent implantation;
- (b) Percutaneous transluminal coronary angioplasty (PTCA);
- (c) Cutting balloon atherectomy;
- (d) Rotational atherectomy;
- (e) Directional atherectomy;
- (f) Excimer laser angioplasty;
- (g) Extractional thrombectomy.

The Team interpreted this latter definition to be a subset of the broader definition found in the List. Advocates for and against both agreed that, at a minimum, six DRGs applied to Elective PCI. Advocates for maintaining Elective PCI on the List felt that another twelve DRGs also applied and those DRGs represented a minimum of fourteen separate ICD-9 procedure codes. In reviewing the submitted material, the Team again believed DRGs were an adequate way to gauge the variety in the service and when coupled with ICD-9 procedure codes and the need for substantial coordination between multi-disciplinary providers both pre- and post-procedure, there was sufficient support to say the service was broader than a procedure.

e. Low use rate. Material submitted differed on what could be categorized as a low use rate. No matter which statistical method is chosen, the parties agreed that PCI is used at a rate higher than four of the other tertiary services, but lower than two of the other tertiary services. If the number of discharges is adjusted to only represent truly elective procedures, the use rate falls further. Again, the Criteria does not offer much guidance, but the Team felt that so long as the use rate was in line with other tertiary services, it was appropriate to say Elective PCI has a low use rate.

f. Volume correlated to structure, process and outcomes. There is substantial and conclusive research that supports the conclusion that volume standards are a necessary aspect to maintain structure, process and outcomes of care.¹⁶

g. Significant risk or consequence. Elective PCI carries a lower mortality risk than almost all other tertiary services. However, it is an interventional cardiac procedure associated with significant life-threatening risks including stroke, heart attack, rupture of a coronary artery. As detailed previously, this factor does not call for an evaluation of how often a risk or consequence must occur to count. However, the risks to a patient are certainly significant and therefore the Team believed this factor was also met. Additionally, the Team noted the lifelong consequences of Elective PCI in the lives of patients, including use of antiplatelet medications as support for this factor.

Six of the factors from the Criteria were clearly met. There are valid, substantive arguments on both sides of the issue. However, in light of the Program's statutory mandate to "promote, maintain, and assure the health of all citizens in the state, provide accessible health services, health manpower, health facilities, and other resources while controlling increases in costs, and recognize prevention as a high priority in health programs,"¹⁷ the Team found that the first, second and seventh factors were particularly important in the case of Elective PCI. All of those factors support inclusion. Therefore, the Team concluded there was substantial support for leaving Elective PCI on the List.

¹⁶ Id. Fn 14.

¹⁷ RCW 70.38.015(1).