

June 7, 2024

Eric Hernandez, CN Program Manager
Washington State Department of Health
Certificate of Need Program
111 Israel Rd. S.E.
Tumwater, WA 98501

RE: PCI rulemaking – Recommended Changes on WAC 246-310-700, WAC 246-310-705, and WAC 246-310-710

Dear Mr. Hernandez:

Thank you for allowing Providence to have the opportunity to participate in the upcoming PCI rulemaking workshops. In preparation for the first workshop on June 10, we are writing to offer several recommendations for WAC 246-310-700, WAC 246-310-705, and WAC 246-310-710 for consideration.

WAC 246-310-700: No recommended changes.

WAC 246-310-705: Providence recommends the following changes:

WAC 246-310-705 (5)

"Percutaneous coronary interventions (PCI)" means invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. PCI interventions are defined in WAC 246-310-745 (4). 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.~~

Rationale for Proposed Change: Currently, the PCI definition is duplicated in WAC 246-310-705 (5) and WAC 246-310-745 (4). Our proposed change would eliminate this duplication and simplify the rules by relying upon a single definition for PCIs in WAC 246-310-745 (4). If the definition of PCIs needs to be updated in the future, the consolidation of the PCI definition into WAC 246-210-745 (4) would allow such updates to be made with greater ease, would reduce confusion about where to find the PCI definition that should be relied upon for need models and CN applications, and would decrease the potential for misalignment between WACs.

WAC 246-310-710: Providence recommends three changes:

1. Align the PCI Application Review Period with the General Timeline for Certificate of Need Application¹
The general application review period is a total of 90 days, while the PCI review period is a total of 135 days.

¹ <https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/certificate-need/review-process>

Rationale for Proposed Change: Aligning the PCI review period with the general timeline would reduce the overall time to complete the application process and would create alignment and consistency across CN efforts.

- In WAC 246-310-710, codify in the Concurrent Review Cycle timeline when the PCI numeric need model will be published. We recommend the draft PCI numeric need model be published on October 15 (or the next working day) with the final version published on October 31 (or the next working day).

Rationale for Proposed Change: Currently, there is no set date by when the Department releases the PCI numeric need model in preparation for the annual PCI concurrent review cycle. The lack of a consistent deadline for publishing the PCI numeric need model drives unpredictably within the CN process and can hinder the ability of potential applications to evaluate and make an informed decision to file a CN application to establish a new PCI program. Establishing a consistent date by when the PCI need models will be made available will assist health care facilities in having the appropriate timeline for internal planning when considering whether to submit an elective PCI application.

- Reduce the Beginning of Review Preparation period from 15 days to 7 days.

Rationale for Proposed Change: The original Beginning of Review period was established during a time when the CN Program relied upon mailing notices and application materials via mail. With the shift to electronic notification via e-mail and use of online storage sites (such as Box), 15 days is no longer necessary and could be shortened in order to streamline the overall process.

In the table below, we summarize our three recommendations for WAC 246-310-710. Please see sections highlighted in both yellow and bold.

PCI Numeric Need Model Forecast	PCI numeric need model published	Draft numeric need model published on October 15 or the first working day after October 15. Final numeric need model published on October 31 or the first working day after October 31.
Application Submission Period	Letters of Intent Due	First working day through last working day of January of each year.
	Initial Application Due	First working day through last working day of February of each year.
	End of Screening Period	Last working day of March of each year.
	Applicant Response Due	Last working day of April of each year.
Department Action	Beginning of Review Preparation	May 1 through May 7
Application Review Period	35 -Day Public Comment Period (includes public hearing if requested)	Begins May 8 of each year or the first working day after May 8 .
	10 -day Rebuttal Period	Applicant and affected party response to public comment.
	45-day Ex Parte Period	Department evaluation and decision.

We greatly appreciate the opportunity to provide recommendations in this rulemaking process. We look forward to working with the Department and community stakeholders as we jointly modernize the PCI rules. Please contact me if you have any questions at Lisa.Crockett@providence.org.

Sincerely,



Lisa Crockett
Vice President, System Strategy & Planning
Providence