



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

WASHINGTON STATE
CERTIFICATE OF NEED PROGRAM
Meeting Summary – PCI Rules

WAC 246-310-715, WAC 246-310-720, WAC 246-310-725, and WAC 246-310-745

A meeting regarding the Certificate of Need (CoN) percutaneous coronary intervention (PCI) rules convened on August 3, 2016. The meeting was held at the Department of Health, 111 Israel Road SE, in Town Center 2, Conference Room 158, Tumwater, WA 98501.

PRESENT:

Dennis Hoover, Yakima Valley Memorial
Leif Ergeson, Yakima Valley Memorial
Gail McGaffick, Yakima Valley Memorial
Jody Corona, HFPD (by telephone)
Chris Thomson, CHI Franciscan
Gregory Eberhart, MD, CHI Franciscan
Jonathan Lyons, Skagit Regional Health
Stephen Pentz, Providence
Matthew Moe, Providence
Diane Buelt, Legacy
Vicki Eastridge, Legacy
Jonathan Seib, Yakima Valley Memorial
Mike Leveque, Skagit Valley Hospital
Lisa Robinson, University of Washington Medical Center
Lisa Grundl, HFPD
Chad Knight, PeaceHealth
Richard Petrich, CHI Franciscan
Patty Seib, Yakima Valley Memorial
Zosia Stanley, WSHA
Gavin Keene, WSHA
Frank Fox, Providence
Bill Stauffacher, Legacy
Tom Parker, CHS
Ross C. Baker, Virginia Mason

STAFF PRESENT:

Bart Eggen, CHS Director
Kathy Hoffman, Policy Analyst, OAS
Nancy Tyson, HPF Executive Director
Maura Craig, Policy Analyst, OAS

9:00am – Open Meeting, welcome and introductions

Overview

- Kathy Hoffman – Brief background of PCI rules and rulemaking; brief overview of rulemaking process.
- Discussed revised agenda: meeting structured to concentrate specific blocks of time to each rulemaking petition.
- Purpose and goals for initial meeting: open and begin discussion of issues identified in CR 101 (WSR 16-15-010); overarching goals are patient safety, access, quality and cost control.

Presentations

- Dennis Hoover discussed the Yakima Memorial rulemaking petition (proposing reduction in volume standards for practitioners and institutions performing elective PCI).
 - Outlined and discussed consensus documents;
 - Outlined and discussed petition focus: changes in practice and technology; outcomes in patients receiving elective PCI;
 - Elective PCIs account for less than 25% of all PCI procedures within the state of Washington. (Not just those at hospitals without open heart surgery). There are 18 PCI programs at Washington hospitals that do not perform the current volume threshold of 300 procedures per year, irrespective of the having or not having on-site open heart surgery.
- Richard Petrich discussed the CHI Franciscan rulemaking petition (proposing that the department add language to the existing rule regarding the evaluation of elective PCI CoN applications absent numeric need).
 - Outlined access issues;
 - Outlined concepts and issues regarding of the provision of care in geographic locations with access needs.

Discussion: Yakima Memorial rulemaking petition

- Some representatives were prepared to discuss this petition. Many were in support of the petition as presented.
- Other representatives indicated that they are not in a position to comment at this time, and need additional time to weigh in with internal stakeholders regarding both petitions.
- **Discussion included:**

- Whether there is clinical outcome data available for review: can we look at professional organizations in Washington as a source for clinical outcome data, and would that data affect quality outcomes?
- Distinction between institutional and provider volumes.
- Dennis notes that COAP incorporates quality indicators in data reporting.
- COAP would be helpful for institutional data, but does it also track provider data? Dennis indicates that COAP tracks this, as well.
- Goal is high quality outcomes. With the volume standards that we currently see in Washington facilities, what are some of the clinical outcome data that might be available? Maybe that could help inform us. Review both state and national data. How do we assure quality outcomes?
- ACC/AHA/SCAI Expert Consensus Document standards have been adopted in a number of other states.
- Current data indicates that there is a “large” number of organizations that are not meeting volume standards. So, statewide, what would be the impact of reducing volume standards?
- How do COAP and the state define PCI? Should we limit our definition to DRG or ICD10?
- Many PCI happen during the course of other treatment or procedures – how do we classify and count these?
- Discussed concept of doing a test pack with COAP, looking at Washington outcomes and Washington volumes.
- If we reduce volumes, do we risk patient care and safety?
- Is there a way to get COAP data over time by provider? Yes, but not interpretation or analysis of that data – COAP is neutral. Suggest this information be obtained via data request from the department to COAP.
- Test COAP; look at Washington outcomes vs. Washington volumes; see if reduction of volumes will have an impact on patient care.

Direction Point: Obtain data from COAP to bring back and analyze from a comprehensive perspective with respect to the proposal of reduction in volume standards.

Discussion: CHI Franciscan rulemaking petition

- Discussion regarding what parameters might be used and what criteria might look like if exceptions to numeric need are considered in a large size planning area.
- Assertion that numeric need does not consider unique community characteristics creating access issues – not the “end all” measurement of need. “If there is numeric need, yes but if there is not, let us make an argument.” Opportunity to put forth a case. Targeted at a few communities

in WA that need all the rules re-opened, or need some other avenue to be able to address community need.

- Provider issues – cardiologists are retiring in areas where there might be need but numbers aren't reflecting that.
- What is the overall barrier? Should we increase department latitude? What should we consider beyond step #4 in the methodology? Are there geographic issues that CoN can address? The rule as written does not allow department discretion; should we allow for that? Flexibility is preferred, but there needs to be a fairly applied framework. The overall goal is program consistency and a clear framework for predictable decision making.
- There are other portions of the existing rule that seem to have an arbitrary nature, reducing flexibility in terms of the public interest. If we're going to reduce a number, allow the opportunity for someone to make their case so there isn't an arbitrary lock-out where the department unilaterally denies an application. May go beyond Step 4; may be in general requirements.
- Matthew Moe: Restates Providence opposition for early discussion of language; really need to convene stakeholders before they can weigh in on this because some of this they are hearing for the first time.
- Bart: We're certainly going to have more than just this meeting.
- Group reviews proposed rule language. Providence asserts that it is not taking a position at this point; proposed language is not as "benign as it is being presented."
- Discussion of whether the petition is seeking an "out" clause.
- General discussion of concept language as proposed: definitions of "socio-economic" and "geographic isolation" can be difficult, as are definitions for "catchment" and in this context, "access." How would we clarify and describe these terms?
- Consideration of areas that wouldn't meet volume standards, even absent numeric need (example provided was Forks, WA.) What is the outcome we're looking for?
- Proponents assert that there are essentially two elements to this issue: showing "you don't have access" and then, what standards should apply? Further outcome reporting?
- Some need more time to review petitions and issues. Specificity is needed further down the road; more complicated than it seems.
- Consider overall perspective and CoN statute. Revisit CoN program authority. Need to do a thorough analysis. This is a significant legislative rule.
- Making an exception is a complex issue; application may be too broad. What about considering something narrower? The purpose of the CoN evaluation is safety, safe access. Is this ripe for an exception? When would we want to apply the exceptions?
- Issue of hospitals currently having a hard time meeting volume standards, and additional programs would exacerbate that issue.
- What is the value in the foundational number if we allow exceptions?

- An option may be to look at these on a case by case basis.
- With respect to current proposed language: additional language could be added regarding minimum quality threshold, and within option could be items used to assess reasonableness, ensuring quality and safety.
- Additional analysis is necessary. PCI is a tertiary service, and it is one thing to consider exceptions for a tertiary service versus for instance, exceptions for dialysis providers. Quality is a key factor in this service area.
- Is this the right thing to do? How do we frame it? These are the fundamental questions.
- Providence suggests stakeholder assistance for data elements. Does the department want assistance from stakeholders in data request creation?
- Bart: Steve, send us a name from Providence who could help us with COAP; Jody represents that she's fairly good with COAP data; Dennis is pretty good at COAP. Anyone else? Let's identify a smaller group that Kathy can work with through email regarding what we're thinking about asking COAP.
- Matt: This goes beyond what data COAP can provide us. The DOH data seems to be saying something different than what the COAP data says so there needs to be an agreement in the group what source we're going to use for this analysis. Otherwise we're going to be coming at it from different perspectives.
- Bart: What we're looking at is the count and that's imbedded in the methodology. We're looking at the alignment of outcomes versus volumes.
- Department will do some data coordination; send Kathy an email with a name for her to contact.
- Suggestion for Kathy to notify others who could not attend meeting that department will be doing a data request, please send your contact information or actually post data request to Listserv.
- COAP is voluntary state registry; use data with caution.

Decision Point: Data subcommittee formed. Purpose is to examine data below/just under 200 that support quality outcomes.

- **Kathy Hoffman (department contact)**
- **Someone from Providence who knows is familiar with COAP (Matt?)**
- **Jody Carona**
- **Dennis Hoover**
- **Larry Dean (University of Washington)**
- **Multicare (Frank will follow up)**

Conclusion

- Roundtable: Confirmation that department is open to and interested receiving comments regarding the CR101.
- Kathy will prepare meeting summary and distribute for review.

- Attendees will provide Kathy with contact information for data subcommittee members.
- Next meeting will be scheduled for late September/early October.