PCI Rulemaking

Updates, Recommendations, & Proposed Next Steps from the External PCI Group Collaboration Sessions

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PCI Rulemaking | External Group Collaboration

Participants To-Date:

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Please note that this remains an open offer for anyone who would like to partner between the Department's PCI Workgroup meetings to discuss key topics and offer questions and/or recommendations. We are glad to invite others into these optional touch-base meetings.

Agenda Topics

- Updates & Recommendations for Four Key Topics
  - Data Source
  - Numeric Need Methodology
  - Non-Numeric Need
  - Planning Area Definitions
- Proposed Next Steps & Future Topics for Workgroup Discussion

Topic #1: Data Source
Recommendations & Next Steps

Progress Update from External PCI Collaboration Group

Following the Oct. 1 PCI Rule Workshop, the External PCI Collaboration Group …

- Reviewed & discussed the answers we received to the questions asked about the COAP data. These areas included:
  - Participation in COAP
  - Cost to access COAP data
  - Scope of COAP data for full spectrum of CN needs
  - COAP vs. CHARS volume analysis
- Based on the information that was gathered, prepared recommendations about COAP as a single data source, including identifying the data elements that are needed and type of data access that is preferred
- Completed additional analysis and discussion regarding the differences in volume counts between the COAP vs. CHARS/survey models. Prepared a summary assessment & recommendation

Recommendation: Adopt COAP as the Single Data Source

Requested Scope of COAP Data

- **Data Frequency:** Quarterly
- **Historical Data:** 5 years of historical data, plus an archive going forward that continues to maintain COAP data reports
- **Data Elements**
  - PCI procedure volumes (including the ability to filter by emergent vs. elective)
  - Procedure quarter & year
  - Patient age group (e.g. 15-64, 65+)
  - Patient zip code
  - Facility name

Data Access

- *Prefer* electronic access to the data directly from COAP (e.g. Web site login or similar). *Minimum*: Willing to work with a flat file from COAP that is posted by the Department its site.

Remaining Questions

- Will the Department codify in WAC (or elsewhere) that hospitals must participate in COAP reporting? Can the Department require CN-approved facilities to report data to COAP? (Note: This has implications for the completeness of the data set & accuracy of the need models).
- What will be the cost for access to the COAP data for both facilities and other parties (e.g. consultants / analysts)?

Update: CHARS + Survey vs. COAP

- **Issue**: Differences exist when comparing the CHARS + Survey and COAP volume counts in the PCI need models.
- **Assessment**: Based on further analysis, the differences appear to be a result of three factors: (1) Differences in PCI definitions, (2) double-counting on some surveys that included both inpatient & outpatient PCIs, and (3) differences in counting patients vs. procedure volumes.
- **Recommendation**: Anchoring to a single data source (COAP) should result in greater consistency in PCI definitions and decrease the potential for reporting errors.

2023-2024 Percutaneous Coronary Intervention Numeric Need Methodology											
	Using CHARS and CN Survey Data					Using COAP Data					Difference: (COAP - CHARS/Survey)
Planning Area	Total PSA PCIs	2022 Use Rate	2027 Projected Net Need	Projected Need/200	# of New Programs	Total PSA PCIs	2022 Use Rate	2027 Projected Net Need	Projected Need/200	# of New Programs	Total PSA PCIs
PSA 1	1420	2.12	28	0.14	0	898	1.36	-633	-3.16	0	-522
PSA 2	580	1.94	95	0.48	0	624	2.09	77	0.38	0	44
PSA 3	441	3.26	-75	-0.37	0	336	2.48	-29	-0.15	0	-105
PSA 4	532	2.17	159	0.79	0	565	2.30	177	0.89	0	33
PSA 5	957	1.77	9	0.04	0	813	1.52	-8	-0.04	0	-144
PSA 6	1366	2.98	342	1.71	1	1431	3.12	234	1.17	1	65
PSA 7	796	2.35	485	2.43	2	802	2.37	455	2.27	2	6
PSA 8	904	2.20	-553	-2.76	0	761	1.86	-543	-2.72	0	-143
PSA 9	1685	1.60	-35	-0.18	0	1617	1.54	83	0.42	0	-68
PSA 10	1148	1.27	-771	-3.85	0	1170	1.30	-975	-4.87	0	22
PSA 11	1515	2.19	408	2.04	2	1656	2.40	420	2.10	2	12
PSA 12	589	2.95	431	2.15	2	598	2.99	344	1.72	1	9
PSA 13	1279	3.87	207	1.04	1	963	2.92	175	0.88	0	-316
PSA 14	793	4.07	-253	-1.26	0	560	2.87	-122	-6.12	0	-233

Topic #2: Need Methodology
Recommendations & Next Steps

Progress Update from External PCI Collaboration Group

Following the Oct. 1 PCI Rule Workshop, the External PCI Collaboration Group …

- Reviewed & discussed the key questions, issues, and discussion points that we raised during the Oct. 1 meeting. This included reflecting on the questions and clarifications asked by the Department
- Continue to evaluate current state vs. alternative numeric need methodologies. As a reminder, those alternatives included:
  - Proposed Alternative #1: Effectively Elective Only
  - Proposed Alternative #2: Acute Care Style
  - Proposed Alternative #3: Constrained Supply Style
  - Proposed Alternative #4: Benchmark Supply Model
  - Proposed Alternative #5: Statewide Use Rate
- Based on additional discussion and analysis, recommend eliminating Alternative #2, #3 and #5 from the list
- Prepared a simplified side-by-side analysis of three options: (1) Current State, (2) Alternative #1: Effectively Elective Only, and (3) Alternative #4A and 4B: Benchmark Supply Model

PCI Need Model Alternatives Analysis

	PCI Type	DOH Model	Proposed Alternative #1 - Effectively Elective only	Proposed Alternative #4 - Benchmark Supply Model
Demand (Forecast Year)	**Emergent**	Planning area residents only, all WA facilities	Resident + non-resident cases in Base Year, all facilities within PA	Planning area residents only, all WA facilities
	Elective	Planning area residents only, all WA facilities	Planning area residents only, all WA facilities	Planning area residents only, all WA facilities
Supply (Base Year)	**Emergent**	Resident + non-resident cases, CN-Approved facilities within PA	Resident + non-resident cases, all facilities within PA	Benchmark level of emergent + elective PCIs (e.g. 300 or 500)
	Elective	Resident + non-resident cases, CN-Approved facilities within PA	Resident cases, CN-Approved facilities within PA	Benchmark level of emergent + elective PCIs (e.g. 300 or 500)

PCI Need Model Alternatives Analysis

	DOH Model	Proposed Alternative #1 - Effectively Elective only	Proposed Alternative #4 - Benchmark Supply Model
Pros	Status-quo so not disruptive. Reflective of actual practice of CN-Approved facilities in a planning area. Relatively easy to model and understand.	Adjusts for in- and out-migration of emergent cases. W/o population growth, emergent S&D "cancel out." Thus, reflects capacity and demand for resident elective cases only. Need estimates closer to DOH model.	Solves mismatch of supply and demand by replacing supply with some to-be-agreed upon benchmark. Model is straightforward and can be "calibrated" to reduce disruptive impacts on need estimates.
Cons	Mismatch between supply and demand; Does not adjust for migration on e demand-side	Accounts for emergent PCI in and out-migration, but assumes all residents prefer planning area providers for elective PCIs. "Locks in" migration patterns for emergent PCI cases, and omits in-migration of elective cases for capacity calculation. Model is complex	Benchmark is inherently arbitrary and depending on choice of benchmark, will have disruptive impact on need model.

PCI Need Model Alternatives Analysis

		DOH Model	ALT #1 - Effectively Elective only	ALT #4A - Benchmark Supply Model (300 PCIs Per Program)	ALT #4B - Benchmark Supply Model (500 PCIs Per Program)
PCI PA #1	Adams, Ferry, Grant, Lincoln, Pend Oreille, Spokane, Stevens, Whitman, Asotin	0	0	4	2
PCI PA #2	Benton, Columbia, Franklin, Garfield, Walla Walla	0	0	1	0
PCI PA #3	Chelan, Douglas, Okanogan	0	0	0	0
PCI PA #4	Kittitas, Yakima, Klickitat East	0	0	1	0
PCI PA #5	Clark, Cowlitz, Skamania, Wahkiakum, Klickitat West	0	0	0	0
PCI PA #6	Grays Harbor, Lewis, Mason, Pacific, Thurston	1	1	2	0
PCI PA #7	Pierce East	2	1	2	1
PCI PA #8	Pierce West	0	0	1	0
PCI PA #9	King East	0	1	1	0
PCI PA #10	King West	0	1	1	0
PCI PA #11	Snohomish	2	1	4	2
PCI PA #12	Skagit, San Juan, Island	2	1	1	0
PCI PA #13	Kitsap, Jefferson, Clallam	1	1	5	4
PCI PA #14	Whatcom	0	0	2	1
Sum across planning areas		8	7	25	10

Topic #3: Non-Numeric Need
Recommendations & Next Steps

Progress Update from External PCI Collaboration Group

Following the Oct. 1 PCI Rule Workshop, the External PCI Collaboration Group …

- Recognize that any numeric need model comes with its strengths and weaknesses and may not adequately address access in every Planning Area. It's likely not possible to create a perfect numeric need model that addresses every unique issue throughout the State
- Therefore, there has been dialogue that updating the PCI rules to include an avenue for non-numeric need could be helpful and warrants discussion
- Currently, there are other examples of non-numeric need in the WACs for other types of CNs (e.g. Acute, Hospice, ASF, and Dialysis)
- Via our External PCI Collaboration Group meetings, we have made progress on beginning to draft WAC verbiage for discussion
- **Next Steps:** Continue working in partnership to discuss the key non-numeric need issues and editing text for proposed WACs

Questions for Department

- Based on the Department's experience as analysts who must evaluate non-numeric need in other types of applications, what would you want to see in a PCI numeric need proposal?
- What are the things that you like about other non-numeric need WACs that you have found help?
- What are the challenges that you face with non-numeric need models? What would you want to see codified that would help you?

Example #1 (DRAFT – WORK in PROGRESS)

(1) The Department may grant a certificate of need for a new elective percutaneous coronary intervention program in a planning area where there is not numeric need.

(a) The Department will consider if the applicant meets the following criteria:

(i) All applicable review criteria and standards with the exception of numeric need have been met;

(ii) The applicant commits to serving Medicare and Medicaid patients; and

(iii) The applicant demonstrates the ability to address at least one of the following non-numeric criteria. Applicants must include empirical data that supports their non-numeric need application. This information must be publicly available and replicable. The non-numeric need criteria are:

(1) Demonstration an applicant's PCI request would significantly reduce planning area resident travel times to PCI programs.

(2) Demonstration an applicant's request would substantially improve access to communities where identifiable health status disparities or different disease burdens are prevalent.

(3) Demonstration an applicant's request would improve access in a PCI Planning Area that lacks a CN-approved elective PCI provider or wherein an existing emergency-only provider that has operated for more than X years, seeks to add elective, and all other providers are meeting the minimum volume standards.

(4) Demonstration an applicant's request is consistent with a significant change in PCI treatment practice and promotes cost containment. *

(5) (5) Demonstration an applicant's request will improve cost-effectiveness and efficiency by alleviating capacity constraints at an affiliate hospital's catheterization laboratory (ies) and/or inpatient beds where PCIs are currently performed. The applicant must also demonstrate the cumulative annual planning area resident PCI volumes performed by the applicant and any affiliate PCI program(s) will be sufficient to support the minimum volume standard for the applicant and its affiliate PCI program(s). An affiliate PCI program is defined as a health care facility's CN-approved PCI program that is owned and operated by the same system as the applicant.

DRAFT ONLY
Work in progress

***RULEMAKING WORKSHOP NOTE: The fourth non-numeric criteria is a placeholder and is only applicable if a PCI site of care change is implemented as a result of PCI rulemaking. If no changes are made to site of care, then (4) should be eliminated, as it isn't applicable to hospital-based PCI programs.**

Example #2 (DRAFT – WORK in PROGRESS)

(1) The Department may grant a certificate of need for a new elective percutaneous coronary intervention program in a planning area where there is not numeric need.

(a) The Department will consider if the applicant meets the following criteria:

(i) All applicable review criteria and standards with the exception of numeric need have been met;

(ii) The applicant commits to serving Medicare and Medicaid patients; and

(iii) The applicant demonstrates the ability to address a minimum of one non-numeric criteria. Applicants must include empirical data that is replicable to support their non-numeric application. The non-numeric criteria are:

(1) Proposes to serve a geographic area that is underserved as determined by [insert additional requirements here]

(2) Proposes to provide access to a specific population or populations that are underserved and for which documented data on health status disparities or different disease burdens exist

(3) Proposes to provide access in a PCI Planning Area that lacks a CN-approved elective PCI provider or wherein an existing emergency-only provider that has operated for more than X years, seeks to add elective, and all other providers are meeting the minimum volume standards.

(4) [Ability to generate significant cost savings]*

(b) The Department has the sole discretion to grant or deny application(s) submitted under this subsection.

DRAFT ONLY
Work in progress

***RULEMAKING WORKSHOP NOTE: The fourth non-numeric criteria is a placeholder and is only applicable if a PCI site of care change is implemented as a result of current PCI rulemaking. If no changes are made to site of care, then (4) should be eliminated, as it isn't applicable to hospital-based PCI programs.**

Next Steps for External PCI Collaboration Group

Following the Oct. 29 PCI Rule Workshop, the External PCI Collaboration Group proposes to …

- Continue working in partnership to discuss the key non-numeric need issues and editing text for proposed WACs

    - **Tiebreaker.** Should the non-numeric need criteria include reference to a Tiebreaker? (e.g. “If more than one applicant applies in a planning area, the Department will utilize the Tiebreaker to consider which facility’s location provides the most improvement in geographic access (WAC 246-310-750).”)

    - **Data.** Continue to discuss the type of data that would be needed to support a non-numeric need application. Need to establish the appropriate level of rigor

    - **Geographic Access.** Continue to refine & edit the criteria pertaining to geographic access, dispersion of programs, etc.

    - **Health Equity.** Continue to refine & edit the criteria pertaining to the type of populations to be served

Topic #4: Planning Area Definitions

Update

Progress Update from External PCI Collaboration Group

Following the Oct. 1 PCI Rule Workshop, the External PCI Collaboration Group …

- Discussed whether changes should be made to the current PCI Planning Area definitions and, if so, how the new definitions should be established (e.g. what factors should inform a new definition)

- Discussed the interrelationship between key variables: (1) Data source & availability of key data, (2) Numeric need methodology, and (3) Non-numeric need methodology

- **Recommendation:** Maintain the current PCI Planning Area definitions, only if non-numeric need is codified into the WACs. If non-numeric need is not included, then the PCI Planning Area definitions will need to be revisited.

Proposed Next Steps & Future Topics for External PCI Group Collaboration Sessions

Proposed Next Steps & Future Topics

Request for the Department

- **Schedule additional PCI Rule Workshops.** The timeline will help the External PCI Collaboration Group establish the cadence of our meeting schedule to continue make ongoing, meaningful progress on working through key issues and drafting recommendations and questions for discussion.

Proposed Next Steps & Future Topics

Based on our prior PCI External Workgroup meeting, several topics remain unresolved. Examples of these include but are not limited to:

Topic	Description
Projected Need for Programs	Within the numeric need methodology, should rounding be utilized when calculating the # of new programs? (e.g. Currently, if the projected need in 0.95 in a Planning Area, the need model will say there is no need for a new program. Should this be changed to round and identify the need for an additional program?)
Concurrent Review Cycle	Should we consider eliminating the elective PCI concurrent application cycle and allow applicants to apply at any time?
State Health Plan	Due diligence is required to ensure that no PCI remnants remain in the State Health Plan and that all relevant pieces are migrated to the WACs and RCWs.
Border Communities	How should we address the methodology for border communities? Are additional refinements needed to the proposed alternatives for the Numeric Need Methodology? Are the issues adequately addressed if Non-numeric Need is codified into the WACs?
Tiebreaker	Need to review the current Tiebreaker WACs and evaluate its role alongside the proposed changes for the Numeric and Non-numeric Need models

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Questions?