Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) on the *Bundled PCI Services in a Non-Hospital Cath Lab (Bundled PCI Services)*

Paul N. Casale, MD, MPH (Lead Reviewer)
Len Nichols, PhD
Grace Terrell, MD
October 10, 2018

In accordance with the Physician-Focused Payment Model Technical Advisory Committee's (PTAC's) Proposal Review Process described in *Physician-Focused Payment Models: PTAC Proposal Submission Instructions*, physician-focused payment models (PFPMs) that contain the information requested by PTAC's Proposal Submission Instructions will be assigned to a Preliminary Review Team (PRT). The PRT will draft a report containing findings regarding the proposal for discussion by the full PTAC. This PRT report is preparatory work for the full PTAC and is not binding on PTAC. This report is provided by the PRT to the full Committee for the proposal identified below.

A. Proposal Information

1. **Proposal Name:** Bundled PCI Services in a Non-Hospital Cath Lab (Bundled PCI Services)

2. **Submitting Organization or Individual:** Clearwater Cardiovascular and Interventional Consultants, MD, PA (CCC)

3. **Submitter's Abstract:**

   "The proposed Bundled PCI Services is a physician-focused payment model (PFPM) designed to give appropriate patients the option for outpatient, non-hospital, same day discharge Percutaneous Coronary Intervention (PCI) procedures at a significantly lower cost than can be offered in a hospital setting. Procedures performed in a non-hospital setting have similar outcomes as hospital-performed procedures while reducing costs and improving patient satisfaction.

   Clearwater Cardiovascular Consultants (CCC) is a 20+ physician cardiovascular medicine group owned by its physician shareholders in Clearwater, Florida. CCC physicians practice at Morton Plant Hospital (MPH) and Mease Hospitals of the BayCare hospital system. CCC has performed over 825 PCIs in its non-hospital outpatient cath lab for managed care plans since January 2016. Unfortunately, lack of a payment model for

non-hospital cardiac cath labs has excluded traditional Medicare patients from this option. However, managed care plans and their patients have participated in this program with exceptional clinical outcomes, outstanding patient satisfaction, and significantly lower costs.

Our proposed Bundled PCI Services will accomplish the following:

- Demonstrate that outpatient PCI services can be safely provided to traditional Medicare beneficiaries in a non-hospital outpatient cath lab with quality outcomes and appropriate utilization, which is similar to the hospital outpatient labs but at a lower cost to the Medicare program and its beneficiaries.
- Provide CMS with a guaranteed discount of $1,285 - $3,105 for the Anchor PCI Procedure.
- Encourage and incentivize Bundled PCI providers to efficiently manage 90-day post procedure costs in the same manner as BPCI Advanced Outpatient PCI participants
- Develop criteria and requirements for PCI Services in Non-hospital Cath Labs that can support national and local coverage determinations.
- Refine Appropriate Use Criteria for PCI Services in a non-hospital cath lab."

B. Summary of the PRT Review

The proposal was received on May 18, 2018. The PRT met between June 20, 2018, and August 10, 2018. A summary of the PRT's findings is provided in the table below.

PRT Rating of Proposal by Secretarial Criteria

Criteria Specified by the Secretary (at 42 CFR§414.1465)	PRT Rating	Unanimous or Majority Conclusion
1. Scope (High Priority)	Does Not Meet	Unanimous
2. Quality and Cost (High Priority)	Does Not Meet	Unanimous
3. Payment Methodology (High Priority)	Does Not Meet	Unanimous
4. Value over Volume	Does Not Meet	Unanimous
5. Flexibility	Meets	Majority
6. Ability to Be Evaluated	Meets	Unanimous
7. Integration and Care Coordination	Does Not Meet	Unanimous
8. Patient Choice	Meets	Unanimous
9. Patient Safety	Does Not Meet	Unanimous
10. Health Information Technology	Does Not Meet	Unanimous

C. PRT Process

The PRT reviewed the CCC proposal as well as an environmental scan and additional data analysis completed by the PTAC contractor for the Office of the Assistant Secretary for Planning and Evaluation (ASPE). ASPE PTAC staff consulted with staff in the Hospital and Ambulatory Policy Group within the Center for Medicare to understand better the way that Centers for Medicare & Medicaid Services (CMS) makes coverage determinations for PCI and services provided by non-hospital cardiac catheterization laboratories (cath labs). The PRT sent questions to the submitter and received written responses. The proposal and other documents, including the submitter questions and written responses, are available on the ASPE PTAC website.

1. Proposal Summary

The overall goal of the Bundled PCI Services model is to provide Medicare fee-for-service (FFS) beneficiaries without exclusion criteria based on clinical complexity the option of undergoing PCI in a non-hospital cath lab. The submitter, CCC, has been performing PCI in its non-hospital cath lab to Medicare Advantage enrollees through ten contracts with Medicare Advantage (MA) plans over the last three years, and they are in the process of developing contracts with seven more MA plans.

The submitter proposes a reduction in Medicare payment for the Anchor PCI procedure due to the lower costs of the non-hospital setting compared to a hospital setting. A global fee (facility fee plus professional fee) is estimated at $10,000 for single-vessel PCI (a $1,285 reduction compared to $11,285 in hospital outpatient departments) and $14,000 for multi-vessel PCI (a $3,105 reduction compared to $17,105 in hospital outpatient departments). In response to questions, the submitters estimated that 85% of PCI conducted in non-hospital cath labs would be single vessel so that the average weighted expected reduction in the global fee would be $1,558.

In addition to these reductions in the global fee, the submitter proposes additional sharing of financial risk in 90-day episode costs by using an approach very similar to the Bundled Payment for Care Improvement (BPCI) Advanced Outpatient PCI model. These steps (detailed on page 9 of the proposal) entail calculation by CMS of a target price for the BPCI Advanced Outpatient PCI episode and then semiannual reconciliation based on the variance between actual costs and the target price. The gross variance has a stop-loss limit of ±$4,000 per episode; the Bundled PCI Provider gains or is responsible for 50% of the "Total Stop Loss Limited Variance per Patient Episode," depending on whether the variance is negative or positive, respectively.

In addition to the patient exclusion criteria that may potentially reduce the risk of complications arising during PCI, the submitter indicates that non-hospital cath labs performing PCI would be required to have close relationships with acute care facilities with cardiac surgery capability and defined transfer procedures in the event of an emergency. The proposal indicated that transport time to surgical backup should be

kept to under 120 minutes but suggested in responses to questions that the transport time to surgical backup should be no more than 30 minutes.

To ensure quality, staff members assisting in the PCI are required to have scrubbed on at least 25 procedures in the previous 12 months (or 5 procedures for someone employed over five years in an interventional cath lab), and the interventional cardiologist would need to be qualified by experience and high volume. Participating non-hospital cath labs would be required to report outcomes to the American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR) for monitoring adherence to clinical practice guideline recommendations, procedure performance standards, and appropriate use criteria. Reported quality measures include appropriate use, outcomes (including complications, death, major adverse cardiac events, other health outcomes), and patient satisfaction.

The submitter proposes that CCC be the initial site for the first year to perform Bundled PCI Services in Medicare FFS beneficiaries as a limited-scale test for developing appropriate criteria for expanding Bundled PCI services to other non-hospital cath lab locations. They propose to expand to at least two additional non-hospital cath labs in year two, with testing over a three- to five-year period to accumulate data to develop criteria for alternative ambulatory facilities to perform PCI.

2. Additional Information Reviewed by the PRT

a) Literature Review and Environmental Scan

ASPE's contractor for PTAC conducted an abbreviated environmental scan that included a review of peer-reviewed literature, as well as a search for relevant grey literature, such as research reports, white papers, conference proceedings, and government documents. The search and the identified documents were not intended to be comprehensive and were limited to documents that meet predetermined research parameters, including a five-year look-back period, a primary focus on United States-based literature and documents, and relevance to the letter of intent. These materials are available on the ASPE PTAC website.

b) Data Analysis

The ASPE PTAC contractor also provided statistics on the geographic distribution of physicians performing cardiac catheterization at non-hospital cath labs, spending on cardiac catheterization by site of service (inpatient hospital, outpatient hospital, and free-standing non-hospital facility), and data on number of physicians performing PCI and number of Medicare FFS beneficiaries receiving PCI by site of service.

c) Public Comments

There were no public comments submitted for this proposal.

d) Other Information

A Notice of Proposed Rulemaking (NPRM) was published in the Federal Register on July 31, 2018 (Link). This NPRM, if approved, means that Medicare would now reimburse ambulatory surgical centers (ASCs)—including non-hospital cath labs—for some procedures (such as CPT code 93458) that the submitter proposed for reimbursement in Table 2 of the proposal.

D. Evaluation of Proposal Against Criteria

Criterion 1. Scope (High-Priority Criterion). Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

PRT Qualitative Rating:	**Does Not Meet Criterion**

Strengths:

- The proposal indicates that cardiologists have historically had only limited participation in Advanced Payment Models (APM), so the Bundled PCI proposal would enable active participation by cardiologists and non-hospital catheterization labs.

Weaknesses:

- Since the Bundled Payment for Care Improvement Advanced demonstrations (BPCI Advanced) being run by the Center for Medicare and Medicaid Innovation include both inpatient and outpatient PCI, cardiologists already have opportunities for participating in bundled payment initiatives.
- Underlying the proposal is a request to change Medicare payment policy to allow reimbursement for PCI to non-hospital-based cath labs, rather than a unique APM.
- The proposal does not include support from a wider set of providers beyond their own organization. Such support would likely be important before embarking on a limited-scale test of this model.
- Current Medicare provisions do not reimburse freestanding non-hospital cath labs for the technical component of cardiac catheterizations, and Medicare does not pay for PCI in these settings. These provisions were reconfirmed in the Federal Register (Vol. 82, No. 239, December 14, 2017, pp. 59412-59413). An NPRM published in the Federal Register on July 31, 2018 (Link) means that ASCs (including non-hospital cath labs) will now be able to be reimbursed by Medicare for some procedures (such as CPT code 93458, which the submitter proposed for reimbursement in Table 2 of the proposal). However, this proposed rule still does not allow Medicare payment for PCI (e.g., CPT code 92928 and other PCI codes) in non-hospital cath labs. The PRT does not expect the PTAC process to result in a reconsideration of Medicare's decision not to reimburse for PCI in ASCs or non-hospital cath labs.

Summary of Rating: The PRT is concerned that this proposal is primarily focused on a "site of service" issue rather than an APM. Bundled payment for PCI is currently a clinical episode in the Center for Medicare & Medicaid Innovation (CMMI) BPCI Advanced Payment Model. This proposal also raises the concern brought up at prior PTAC meetings of limited-scale testing of a model at only one institution.

Criterion 2. Quality and Cost (High-Priority Criterion). Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

PRT Qualitative Rating:	**Does Not Meet Criterion**

Strengths:

- The proposal intends to facilitate receipt of PCI in the least intensive (and therefore least expensive) setting that can provide appropriate care for Medicare beneficiaries who are identified as needing PCI. The submitter indicates that quality would be maintained at lower cost.
- The CMS BPCI Year 3 Evaluation did not find any difference in quality outcomes (measured by readmission rates, emergency department visits, or mortality) for patients undergoing PCI at an institution participating in the BPCI Program versus non-participating institutions, recognizing that all PCIs were performed in hospital-based facilities.

Weaknesses:

- The proposed model appears to rely largely on a site of service differential as the source for savings. In response to questions, the submitter indicated that additional savings including the delivery of more timely care would be achieved because PCI procedures are currently limited to hospital facilities that often operate in excess of capacity. The submitter hypothesized that more timely care reduces the risk of negative outcomes associated with unnecessary delay. However, estimates of savings from more timely care were not provided.
- The CMS BPCI Year 3 Evaluation did not find a reduction in total Medicare payments for BPCI participants versus a comparison group; this lack of effect could be due in part to the relatively low utilization of post-acute care (PAC) services for all patients undergoing PCI.
- While the proposal provides statistics demonstrating that quality of care and patient satisfaction are high for the patients undergoing PCI at the CCC Outpatient (Non-hospital) Cath Lab, there are several concerns:
  - The lower rate of adverse events compared to other patients undergoing PCI in the United States (Figure 2 in the proposal) may be due to selection of relatively healthier patients. The comparison patients in the graph may not have all met the exclusion criteria used by CCC for PCI in a non-hospital cath lab. Movement of patients from hospital to non-hospital settings would not by itself achieve the quality differentials in Figure 2.

- While the rate of adverse events is low for patients undergoing PCI in the CCC outpatient cath lab, the submitters do not provide data that assure high quality by other non-hospital cath labs if the program were to be implemented more broadly.
- While patient satisfaction with CCC services is high and the submitter points out that patients are very dissatisfied when their scheduled PCI procedure is delayed for an emergency patient in a hospital setting, the issue of patient delays or other scheduling issues in the hospital setting can be addressed in other ways.

Summary of Rating: The PRT recognizes that 1) selected patients can receive high-quality PCI in a non-hospital setting, and 2) the resource cost of the non-hospital setting will be lower than hospital settings. However, the care model does not include sufficient provisions to ensure that quality would be similar when expanded to a broader group of non-hospital providers.

Criterion 3. Payment Methodology (High-Priority Criterion). Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.

PRT Qualitative Rating:	**Does Not Meet Criterion**

Strengths:

- The proposal lays out specific steps for Bundled PCI Services that mirror the process used for BPCI Advanced Outpatient PCI participants. The approach enables providers to share in the financial risk of 90-day episode costs.

Weaknesses:

- The underlying issue that the proposal seems to address is a "site of service" issue. This point is reflected by the fact that other than site of service, the payment model follows BPCI Advanced Outpatient.
- The submitter indicates that the costs of hospitalization due to an unanticipated event would be covered under the bundled payment. However, the CMS BPCI Year 3 Evaluation noted that BPCI participants were responsible for medically appropriate hospital admissions following the initial PCI episode even though some admissions were not related to problems with the initial PCI. Financing such care under the proposed Bundled PCI payment might be challenging for non-hospital cath labs with the lower proposed payment.

Summary of Rating: The PRT feels that this proposal largely addresses a site of service constraint against performing PCI in non-hospital ambulatory settings that was reinforced by CMS in 2017 (Federal Register, Vol. 82, No. 239, December 14, 2017, pp. 59412-59413). While consideration of bundled payment for PCI has merit, the ongoing CMMI BPCI

Advanced model will provide an important evaluation of a bundled approach for patients undergoing PCI.

Criterion 4. Value over Volume. **Provide incentives to practitioners to deliver high-quality health care.**

PRT Qualitative Rating:	**Does Not Meet Criterion**

Strengths:

- The intent to provide PCI in a lower cost, less medically intensive setting while maintaining or improving quality is consistent with value over volume.
- The submitter indicated that they follow the ACC appropriate-use criteria in deciding on treatment strategies for patients with stable ischemic heart disease. According to the data provided by the submitters, rates of appropriate use (measured by appropriate-use criteria in Figure 1) for CCC patients are slightly higher than the rates for the comparison U.S. patients (although, as noted earlier, the comparison patients may have worse health status).

Weaknesses:

- The submitter noted that PCI would be appropriate in patients with stable angina if they are symptomatic, have a hemodynamically significant coronary stenosis, and an abnormal functional study. However, they did not describe specific processes for referral of stable angina patients to medical providers for optimization of medical therapy in cases where such treatment is appropriate.
- The proposal reported a high rate of single-vessel PCI (85%). While application of the exclusion criteria results in patients with more stable symptoms, the high rate of single-vessel PCI may indicate that a number of these patients would benefit from optimization of medical therapy rather than undergoing PCI. Specifically, the criteria do not require that the patient has failed maximal medication therapy. In addition, the rate of single-vessel PCI may be driven by a strategy of staged procedures for patients with multi-vessel disease.

Summary of Rating: The PRT feels that value over volume is not demonstrated because of lack of provisions to ensure optimization of medical therapy prior to proceeding with PCI.

Criterion 5. Flexibility. **Provide the flexibility needed for practitioners to deliver high-quality health care.**

PRT Qualitative Rating:	**Meets Criterion**

Strengths:

- Patients who have specific risk factors will not be considered for PCI in a non-hospital cath lab. Cardiologists would be able to perform PCI on patients without those risk factors in a less intensive setting with a focus on same-day discharge.

Weaknesses:

- The required number of procedures for the interventional cardiologist and catheterization laboratory staff to allow participation in this model needs further refinement.

Summary of Rating: While some providers might not want or use the additional setting, the proposal increases flexibility for providers who chose to do PCI in non-hospital cath labs.

Criterion 6. Ability to Be Evaluated. **Have evaluable goals for quality of care, cost, and any other goals of the PFPM.**

PRT Qualitative Rating:	**Meets Criterion**

Strengths:

- The model will use the ACC NCDR CathPCI registry to track outcomes; the registry is currently used by hospital outpatient labs. Sources for other measures include CMS claims data, resource utilization from internal accounting, and patient satisfaction surveys.

Weaknesses:

- The proposal for limited-scale testing involves facilities participating in the model but does not identify a study design with a comparison group.

Summary of Rating: The PRT feels that the submitter identifies appropriate metrics and data sources for evaluation of a limited-scale test.

Criterion 7. Integration and Care Coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

PRT Qualitative Rating: **Does Not Meet Criterion**

Strengths:

- The submitter indicates that by including the non-hospital cath lab in a bundled payment arrangement, they have an enhanced ability to coordinate care for patients.

Weaknesses:

- While the proposal indicates "bundling physician and facility services naturally leads to greater care coordination," the specific mechanisms for improvement in care coordination are not described. The proposal does not clarify how care would be coordinated or provide evidence of benefits from such care coordination. As noted earlier, findings to date from the BPCI Year 3 evaluation have not shown reductions in total payments that might result from better care (though this evaluation focused on inpatient PCI recipients).

Summary of Rating: The PRT feels that despite the greater coordination that accompanies bundled payment from a theoretical perspective, the proposal did not identify how such coordination would occur for patients undergoing PCI in a non-hospital cath lab or how it would be different than for patients undergoing PCI in a hospital-based cath lab.

Criterion 8. Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

PRT Qualitative Rating: **Meets Criterion**

Strengths:

- The proposed model would offer Medicare beneficiaries another option of location for undergoing PCI procedures. The submitters suggest that this location would be less medically intensive (and therefore less costly) than hospital inpatient or outpatient settings and would meet national guidelines for quality and safety.

Weakness:

- For many patients, PCI is performed as an ad hoc procedure at the time of diagnostic cardiac catheterization. If complex coronary anatomy is noted (for example, requiring a rotablator procedure or supported PCI), then the patient would need to undergo a second procedure at the hospital-based cath lab.

Summary of Rating: The PRT recognizes that some patients may prefer to undergo a PCI in a less intensive setting.

Criterion 9. Patient Safety. Aim to maintain or improve standards of patient safety.

PRT Qualitative Rating:	Does Not Meet Criterion

Strengths:

- The proposal indicates that quality (and therefore patient safety) will be maintained by using the same metrics and registries to track outcomes as are currently used for hospital outpatient labs.
- Patients with specific risk factors or certain comorbidities will not be candidates for PCI in a non-hospital cath lab.

Weaknesses:

- The proposal indicates that Bundled PCI has no incentives for the denial of needed care because it does not involve capitation. However, patients at higher risk of complications due to comorbidities that are not listed as exclusions may be deemed as suitable for PCI in a non-hospital cath lab when their risk factors might be better handled in a hospital outpatient setting. Staff and interventionalists working in a non-hospital setting may not have the full complement of ancillary services in the event a significant complication occurs.
- The submitter indicates that "certain cath labs operated by a cardiology practice are in a more suitable position [to perform PCI] than ambulatory surgery centers because of the exclusive cardiovascular focus of these labs and the inherent expertise of their staff." However, the submitter believes that ultimately the model could be applied in a broader set of ambulatory surgery centers once they meet national guidelines. The PRT recognizes that CCC is operated by a cardiology practice and is located on the same campus as Morton Plant Hospital. However, expansion of the model into a wider set of facilities, some of which might be further from a hospital with on-site cardiac surgery, could compromise patient safety.

Summary of Rating: The PRT acknowledges that non-hospital cath labs such as CCC have been able to maintain safety for the patients selected for PCI in their setting to date. However, a broader program that includes Medicare FFS patients may have a higher likelihood of complications.

Criterion 10. Health Information Technology. Encourage use of health information technology to inform care.

PRT Qualitative Rating:	Does Not Meet Criterion

Strengths:

- The model would require the use of health information technology (HIT) to measure and monitor outcomes.

Weaknesses:

- There is no information provided on how the electronic health records (EHR) in the freestanding cath lab will communicate with other EHRs or integrate meaningfully with other providers in care coordination.

Summary of Rating: The PRT feels that the discussion of this issue in the proposal is insufficient and does not identify meaningful attempts at clinical integration to inform care.

E. PRT Comments

The PRT recognizes that CCC, through its historical integration with and proximity to Morton Plant Hospital and Mease Hospitals of the BayCare hospital system, is in a unique position to provide high-quality PCI to patients, including Medicare Advantage patients. With appropriate patient selection, CCC is able to perform PCI in a lower-cost setting that improves efficiency. However, the PRT finds that this proposal to expand PCI more broadly in non-hospital cath labs does not represent a PFPM that meets key scope, quality, cost, and payment criteria, among other criteria.

While acknowledging the potential value of a bundled approach to payment for PCI, efforts along these lines are currently being undertaken by CMMI in the BPCI Advanced Outpatient model. Therefore, the main variation offered by this proposal is related to site of service in a non-hospital setting.

A key concern pertains to the ability to ensure quality and safety for patients undergoing PCI in a range of geographical locations (e.g. urban versus rural). Non-hospital cath labs that are adjacent to (or very close to) hospitals may be most appropriate. It is notable that CMS considered but explicitly decided not to approve payment for PCI in non-hospital settings (both in the 2017 Federal Register as well as the more recent NPRM).

Finally, as noted in more detail above, the PRT is concerned that the proposed model does not provide detail on coordination of care. The proposal lacks specific processes to ensure that patients (in particular, patients with stable angina) initially receive an adequate attempt to optimize medical therapy before proceeding with PCI. The proposal lacks specifics on the coordination of care for the 90 days following PCI. The PRT was not convinced that the quality and outcomes experienced by CCC could easily be extended to Medicare FFS patients among different settings (e.g., urban versus rural).

END OF DOCUMENT