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May 18, 2018

Physician-Focused Payment Model Technical Advisory Committee
c/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy
200 Independence Ave. S. W.
Washington, D. C. 20201
PTAC@hhs.gov

Re: Bundled PCI Services in a Non-hospital Cath Lab (Bundled PCI Services)

To: The Physician Focused Payment Model Technical Advisory Committee

Dear Committee Members,

Clearwater Cardiovascular and Interventional Consultants, M.D., P.A. (CCC) is pleased to present this proposal of Bundled PCI Services, a program to migrate appropriate Percutaneous Coronary Intervention (PCI) services from higher cost hospital facilities to lower cost non-hospital cath labs with bundled physician and facility service pricing and 90 day post procedure risk sharing.

CCC has provided PCI Services in a non-hospital cath lab to over 825 managed care patients since 2016, resulting in excellent outcomes, high patient satisfaction, and significantly lower cost. CCC is seeking to provide similar services to appropriate Medicare patients.

My contact information is shown below. We look forward to working with you to lower costs and improve outcomes for these patients.

Sincerely,

Frederic R. Simmons, Jr. CPA
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**BUNDLED PCI SERVICES IN A NON-HOSPITAL CATH LAB
(Bundled PCI Services)**

Advanced Alternate Payment Model

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Table of Contents

Description	Page
Abstract	IV
I. Model Description	1
II. Response to Criteria	
1. Scope of Proposed APM	10
2. Quality and Cost	12
3. Payment Methodology	14
4. Value over Volume	16
5. Flexibility	17
6. Ability to be Evaluated	18
7. Integration and Care Coordination	19
8. Patient Choice	20
9. Patient Safety	20
10. Health Information Technology	21
11. Supplemental Information	22

Appendices

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.

I Model Description

It was estimated in 2017 that 92.1 million US adults suffer from at least one type of cardiovascular disease (CVD). CVD and stroke accounted for 14% of total health expenditures from 2012 to 2013, more than any other major diagnostic group. The annual direct and indirect cost of CVD and stroke in the United States was an estimated \$316.1 billion during that same time period. (1)

Percutaneous coronary intervention (PCI), also known as coronary angioplasty, is a nonsurgical procedure that improves blood flow to the heart. PCI requires cardiac catheterization, which is the insertion of a catheter tube and injection of contrast dye, usually iodine-based, into the coronary arteries. Access is usually introduced via the groin (transfemoral) or the wrist (transradial). PCI opens coronary arteries that are narrowed or blocked by the buildup of atherosclerotic plaque. PCI may be used to relieve symptoms of coronary heart disease or to reduce heart damage during or after a heart attack. (2)

PCI procedures represent a high cost for the U.S. healthcare system. Approximately 600,000 patients undergo PCI procedures annually at a cost of \$10 billion. Of the 600,000 PCIs performed annually, virtually all were performed in the hospital setting either as outpatient or inpatient. (3) We propose that a significant number of hospital outpatient same-day discharge (SDD) PCI procedures could be performed in a non-hospital cath lab at a significant cost savings and potential improvement in outcomes and patient satisfaction.

We propose Bundled PCI Services as a PFPM to allow qualified non-hospital cardiac cath labs to perform PCI on appropriate patients at a global bundled price (physician professional and facility fees) for the Anchor PCI Procedure of \$10,000 for a single-vessel PCI with a drug eluting stent and \$14,000 for a two-vessel PCI with a drug eluting stent. This price will guarantee CMS a savings for the Anchor PCI procedure of \$1,285 for a single-vessel PCI and \$3,105 for multi-vessel PCI, as compared to national prices for the combined facility fee and professional fee in a hospital outpatient lab. We estimate that 70% of PCI cases in the Outpatient Lab are one-vessel cases and 30% are two-vessel cases.

We are also proposing Bundled PCI participants share in the financial risk of 90-day post-procedure cost for up to 20% of the total episode costs in the same manner as BPCI Advanced Outpatient PCI Participants share in the risk for the hospital outpatient PCI procedures.

In December of 2017, CMS considered requests for additional codes to allow PCI in Ambulatory Surgery Centers (ASCs). These requests were denied, stating that there is a concern for a significant safety risk for Medicare populations in the ASC setting. (4) However, CCC has performed these procedures for managed care patients in its non-hospital cath lab for over two years with proven patient safety and excellent outcomes. We believe certain cath labs operated by a cardiology practice are in a more suitable position than ambulatory surgery centers because of the exclusive cardiovascular focus of these labs and the inherent expertise of their staff. By working with dedicated cardiac labs, CMS benefits from a specialized team who often performs these procedures in hospital-owned facilities, and who already abide by the same reporting and appropriate-use criteria. As the program expands, benchmarks could evolve to include ASCs as well as non-practice owned outpatient labs.

We propose that this model begin with CCC and its established non-hospital cath lab (Initial Model Participant) as a limited scale test case for developing appropriate criteria in other locations. In year two, we expect to expand to at least two additional non-hospital labs. Testing would take place over an approximate three to five-year period to accumulate the required data to consider alternative ambulatory facilities to perform PCI. CCC is in a unique position to assist with this process due to its demonstrated experience managing outpatient cardiac catheterization laboratories, as well as the history of our non-hospital cath lab.

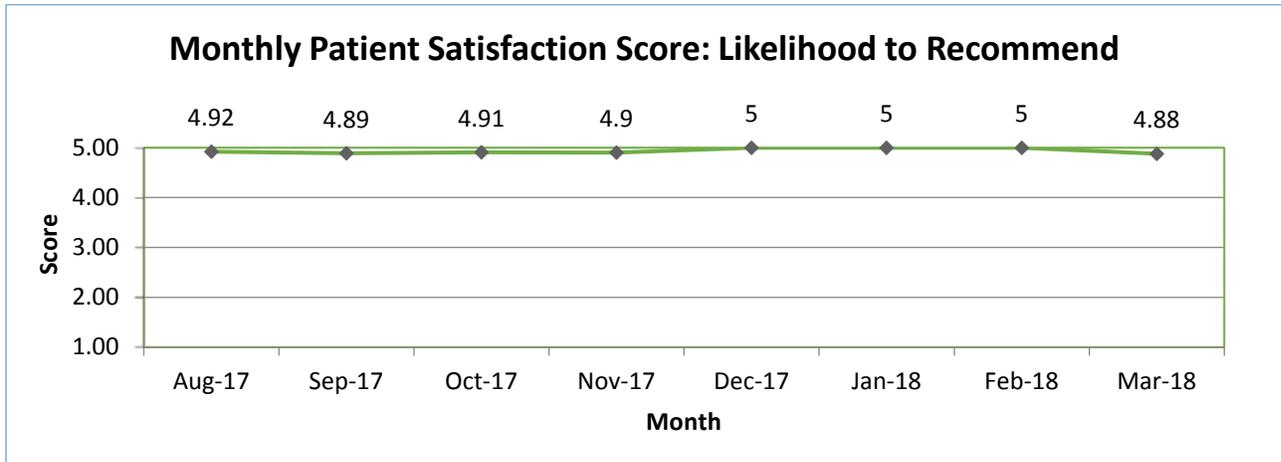
Prior to January 1, 2016, CCC physicians provided PCI services at a hospital outpatient cardiac catheterization laboratory owned by Morton Plant Hospital (MPH) located in the Heart and Vascular Pavilion on the MPH campus close to the emergency room (Hospital Outpatient Lab). The services were provided under Medicare place of service (POS) 22. CCC managed and staffed the Hospital Outpatient Lab.

On January 1, 2016, the Outpatient Cath Lab was acquired from MPH by CCC (CCC Outpatient Lab) and began providing diagnostic cardiac angiography services to Medicare patients and diagnostic cardiac angiography and PCI services to managed care patients under Medicare POS 11. However, the facility, physicians and non-physician staff performing the procedures remained the same. Table 1 is a comparison of the CCC Outpatient Cath Lab when it was operated as an MPH outpatient lab under POS 22 to the current operations as a physician office-based outpatient lab operated under POS 11.

Table 1 – Hospital Outpatient Lab vs. CCC Outpatient Lab		
Comparison	Hospital Outpatient Lab POS 22	CCC Outpatient Lab POS 11
Facility	Same	Same
Physicians Performing Procedure	Same	Same
Non-Physician Staff	Same	Same
Equipment	Same	Same
Supplies	Same	Same
Technology	Same	Same
Medical Director	Same	Same
Accreditation	The Joint Commission	AAAHC(2)
PCI registry reporting	NCDR	Same
Patient Convenience	Variable	Very Good
Patient Satisfaction	? (1)	Excellent
Cost	Higher	Lower
(1) The hospital outpatient lab does not survey patient satisfaction specific to its cath labs.		
(2) Accreditation Association for Ambulatory Health Care, Inc.		

CCC has been surveying patient satisfaction since August 2017. For the key survey question of the likelihood to recommend the CCC Outpatient Cath Lab to family and friends on a scale of 1 – 5, with 1 being “Would not recommend,” 3 being “Would probably recommend,” and 5 being

“Would definitely recommend,” the CCC Outpatient Cath Lab has an average score of 4.96 as shown below:



CCC is **not** currently providing PCI services to Medicare patients in the CCC Outpatient Cath Lab. Instead, we send these cases to the hospital lab, even though CCC’s outpatient lab physicians, staffing, equipment, workup, recovery, and quality of care are the same as the hospitals, and CCC can document very high patient satisfaction.

In 2017, compared to other outpatient PCI facilities, the CCC Outpatient Lab exceeds most key National Cardiovascular Data Registry (NCDR) metrics (5), including appropriate use criteria and adverse events, as outlined in Figures 1 – 4, below.

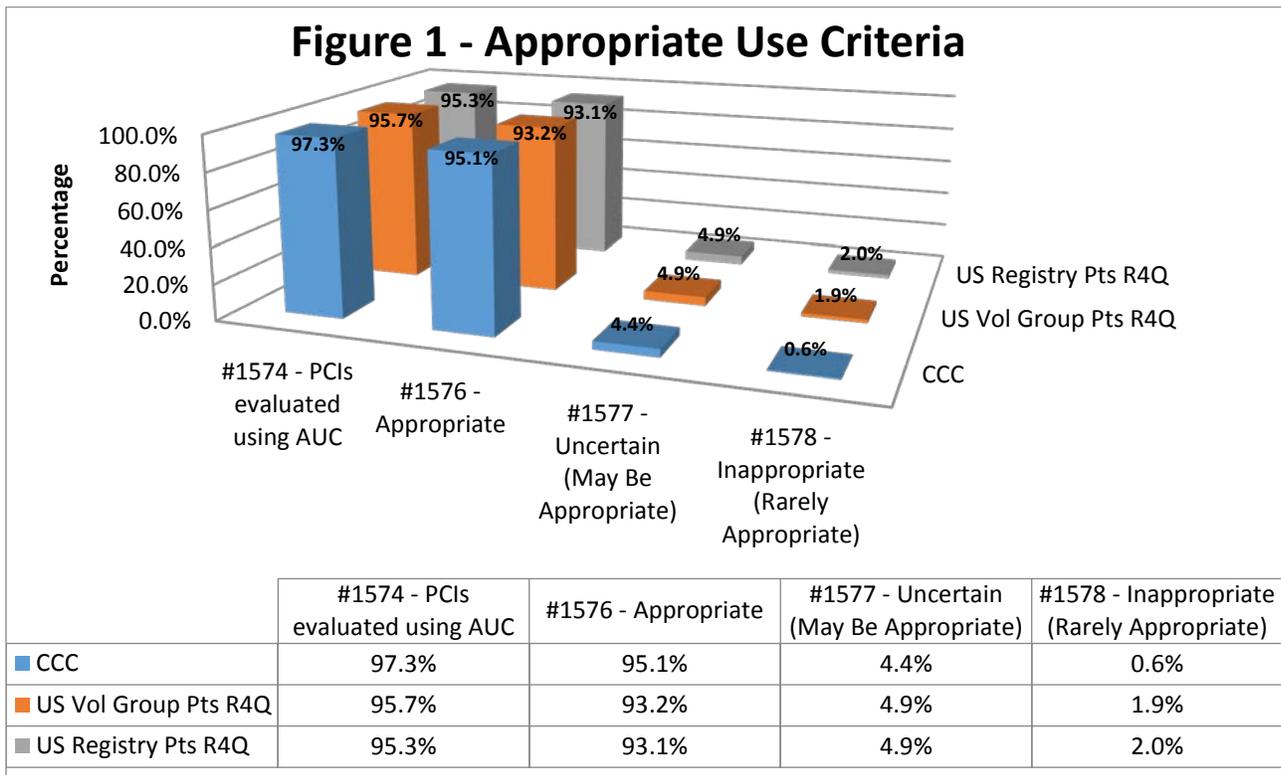
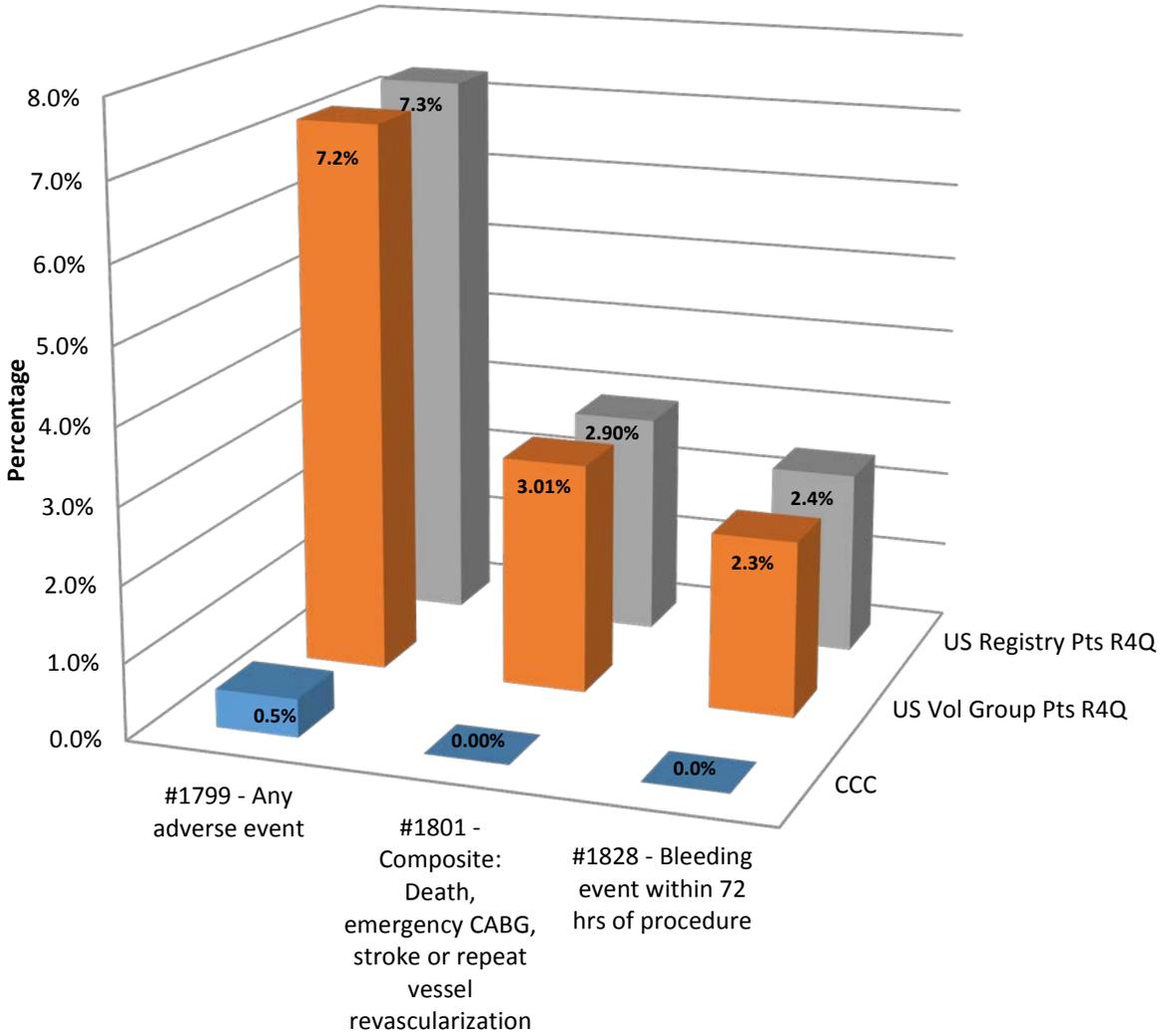
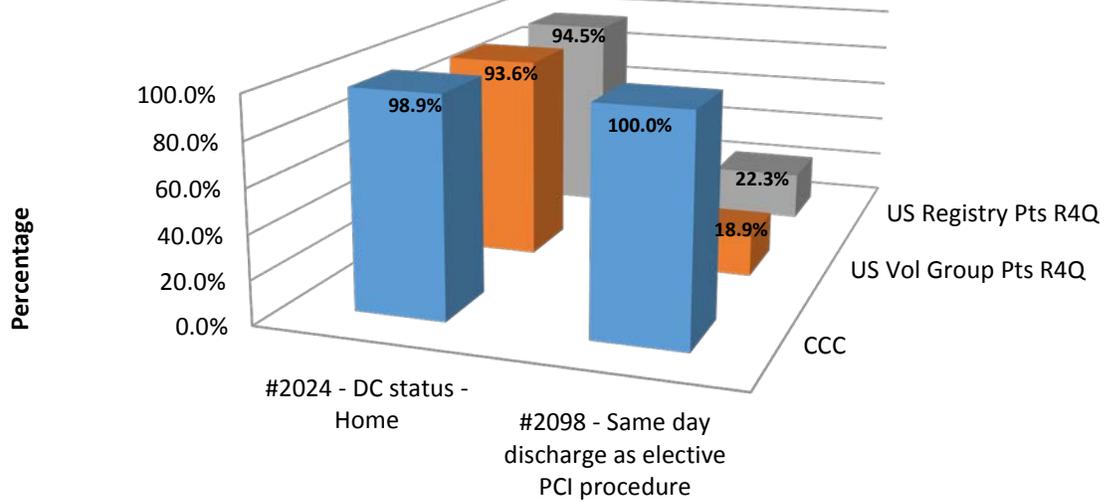


Figure 2 - Adverse Events



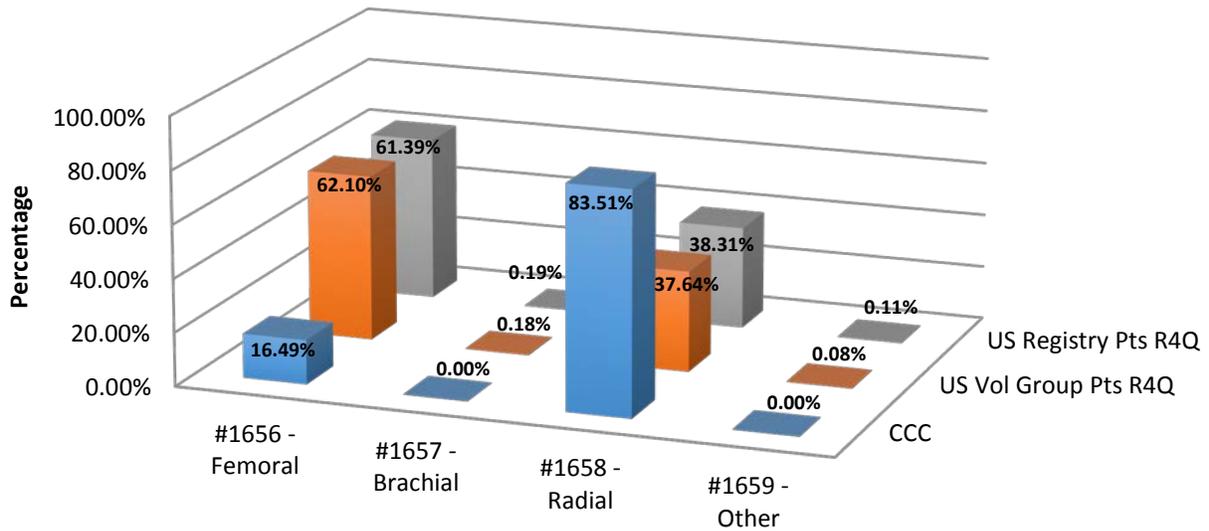
	#1799 - Any adverse event	#1801 - Composite: Death, emergency CABG, stroke or repeat vessel revascularization	#1828 - Bleeding event within 72 hrs of procedure
■ CCC	0.5%	0.00%	0.0%
■ US Vol Group Pts R4Q	7.2%	3.01%	2.3%
■ US Registry Pts R4Q	7.3%	2.90%	2.4%

Figure 3 - Discharge Status



	#2024 - DC status - Home	#2098 - Same day discharge as elective PCI procedure
■ CCC	98.9%	100.0%
■ US Vol Group Pts R4Q	93.6%	18.9%
■ US Registry Pts R4Q	94.5%	22.3%

Figure 4 - Arterial Access Site



	#1656 - Femoral	#1657 - Brachial	#1658 - Radial	#1659 - Other
■ CCC	16.49%	0.00%	83.51%	0.00%
■ US Vol Group Pts R4Q	62.10%	0.18%	37.64%	0.08%
■ US Registry Pts R4Q	61.39%	0.19%	38.31%	0.11%

While CCC cannot currently provide these services to Medicare patients, managed care plans and their members benefit from this option. From January 1, 2016, through April 30, 2018, CCC performed over **825** PCIs for managed-care patients in the CCC Outpatient Lab. We estimate **\$1,500 - \$10,000** per case cost savings to the managed-care companies, compared to the cost had the services been provided in the hospital outpatient POS 22 setting. The total estimated savings is over **\$4,000,000**.

A recent study states that shifting current hospital practices from the transfemoral interventional approach (TFI) with non-same day discharge (NSDD) to transradial intervention approach (TRI) with same day discharge (SDD) by 30% could save a hospital performing 1,000 coronary interventions \$1,000,000 (\$3,689 per case) each year. Of the 600,000 PCI procedures performed each year in the United States, one-half are eligible for SDD. The study concluded that a 30% conversion from the current pathway of TFI NSDD to TRI SDD could potentially save U.S. hospitals approximately \$332,000,000 annually based on a per-case savings of \$3,689. (3) Migrating those 90,000 cases which could be converted from hospital outpatient to an appropriate non-hospital lab as outlined in this proposal would save an additional **\$1,831** per case for Medicare, which totals up to **\$164,900,000** annually. Studies also show that PCI procedures have an outstanding safety profile, and SDD is safe and cost effective. (6) The rates of in-hospital mortality, stroke, and emergency coronary artery bypass grafting after elective PCI are 0.66%, 0.2%, and 0.3%, respectively, with little to no difference in SDD and NSDD. The evidence supporting the safety and efficacy of outpatient PCI in properly selected patients is indisputable. (7)

Below is a comparison of what Medicare currently pays (national average) at a Hospital Outpatient Lab (Table 2) versus what Medicare would pay for the Anchor PCI procedure if performed in the CCC Outpatient Cath Lab under Bundled PCI Services (Table 3). (8) (9)

Table 2 – Current Medicare Payment Under Hospital Outpatient Lab POS 22		
APC/CPT Code	Description	Rate
Single Vessel PCI with Drug Eluting Stent		
5193	Level 3 Endovascular Procedure	\$ 10,510
92928 (1)	Angioplasty and Stent Single Major Coronary Artery	\$ 620
93458	Catheter placement in coronary artery(s) for coronary angiography with left heart catheterization (2)	\$ 155
Total		\$ 11,285
Two Vessel PCI (separate vessels) With Drug Eluting Stents		
5194	Level 4 Endovascular Procedure	\$ 16,019
92928 (1)	Angioplasty and Stent Single Major Coronary Artery	\$ 620
92928 (1)	Angioplasty and Stent Single Major Coronary Artery (2)	\$ 311
93458	Catheter placement in coronary artery(s) for coronary angiography with left heart catheterization (2)	\$ 155
Total		\$ 17,105

- (1) For the above and below examples we use CPT code 92928 as the Anchor Procedure as it is the most often used code. However, any CPT code in Table 4, below could be the Anchor Procedure
- (2) Multiple Procedure Discount 50%

Table 3 – Anchor Procedure Weighted Average Cost Savings

Procedure	Weight	Anchor Procedure Rate		Savings	
		Hospital Outpatient (POS 22)	Bundled PCI Services/ Physician Office (POS 11)	Difference	Weighted Average Difference
Single Vessel PCI	70%	\$11,285	\$10,000	\$1,285	\$ 900
Two Vessel PCI	30%	\$17,105	\$14,000	\$3,105	\$ 931
Weighted Average	100%	\$13,031	\$11,200		\$1,831

Table 4 – Anchor Procedures

CPT Code	Description
92920	Percutaneous transluminal coronary angioplasty, single major artery or branch
92928	Percutaneous trans catheter placement of intra-coronary stent, with coronary angioplasty when performed; single major coronary artery or branch
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft

Quality of care and appropriate patient selection are the most important factors for allowing non-hospital cath labs to perform these procedures. CCC has developed criteria to identify appropriate patients for outpatient PCI. These policies are similar to other hospital-owned labs as follows:

- Scheduled and ad-hoc percutaneous coronary interventions may be performed on patients with stable angina (CCS Class I, II, and III) by appropriately-credentialed Clearwater Cardiovascular Consultants interventionalists, when initiated at or before 3pm, and when performed in compliance with established ACC/AHA/SCAI Appropriate Use Criteria (AUC) for coronary revascularization. These procedures are subject to established criteria for admission to the department, and in accordance with the following additional exclusion criteria:
 - Electrical and/or hemodynamic instability
 - Acutely decompensated heart failure
 - Severe left ventricular dysfunction, with ejection fraction less than 25%
 - Significant co-morbid conditions exist, such that overnight observation is necessary or predicted
 - Advanced therapeutic procedures, such as coronary atherectomy, are anticipated
 - Chronic total occlusions
 - Unprotected Left Main lesions

- Bifurcation lesions necessitating the use of two guide wires, with intended stenting of both vessels
 - Presence of thrombus
 - Degenerated vein grafts
2. A cardiologist must remain within the physical confines of the Heart and Vascular Pavilion building for five hours beyond completion of the procedure, or until the patient is discharged.
 3. A minimum of two members of the cath lab support team (to include the scrub tech) must have documented competency for PTCA/coronary stent procedures. To initially demonstrate this, an individual must have successfully scrubbed 25 such procedures in the previous 12-month period. Alternatively, an individual with documented five years of prior employment working within an interventional cath lab may initially demonstrate this by satisfactorily co-scrubbing five such procedures.

In addition to patient-specific criteria, sites performing Bundled PCI Services will require close relationships with acute care facilities with surgical backup, and defined transfer procedures in the event of an emergency. As non-hospital cath labs will reduce cost, it is anticipated they will have a significant volume of PCI procedures. As recommended for hospital facilities currently performing this procedure without on-site surgical backup, transport time should be kept under 120 minutes. (10) It is important to note that the site offered for this test case is on campus at an acute care facility with surgical backup. The CCC Outpatient Lab is located 350 yards from the hospital emergency room. However, recent studies show no difference in 30-day mortality between sites with and sites without on-site surgery. One study showed high-volume facilities performing only elective PCIs that were staffed by high-volume interventionalists had a lower mortality than facilities with less volume but with on-site surgery backup. (10)

Facilities participating in Bundled PCI Services will be required to report their outcomes to the National Cardiovascular Data Registry (NCDR) and outliers could be eliminated from the program. The American College of Cardiology NCDR is a reputable and dependable source for tracking this information and already does this using the CathPCI Registry. This powerful tool captures the data that measure adherence to ACC/AHA clinical practice guideline recommendations, procedure performance standards, and appropriate use criteria for coronary revascularization. (11) Patient satisfaction will be measured for Bundled PCI Services Providers and compared to HCAPS patient satisfaction survey results. Bundled PCI Service providers will be required to report appropriate use results, outcomes, complications, and patient satisfaction quarterly and feedback will be provided to participants as soon as practical after the data can be analyzed, benchmarked and reported. By collecting and reporting these data, we will have evidenced-based quality measures to evaluate.

Outcomes to be measured include:

- Death
- Major adverse cardiac events (MACE)
- Myocardial infarction (MI)
- PCI for in stent restenosis within 90 days

- Stroke

Complication rates to be measured include:

- Sentinel events
- Falls
- Infections
- Return to surgery/lab
- Serious vascular complications
- MI
- Stroke

The proposed bundled payment for the Anchor Procedure provides Medicare with a guaranteed savings of between \$1,285 (one vessel PCI) and \$3,105 (multi-vessel PCI) compared to national rates for the Anchor Procedure performed in a hospital outpatient department (POS 22). Shared financial risk for the outpatient lab and the providers is evident by the bundled payment. If the costs exceed the fixed reimbursement, the providers would face unreimbursed costs.

We are also proposing Bundled PCI Services participants share in the financial risk of 90-day episode costs in a similar manner as BPCI Advanced Outpatient PCI Participants share in the risk for the hospital outpatient PCI procedures (90-Day Episode Risk Sharing) calculated specifically as follows:

- A. CMS calculates a target price for Bundled PCI 90-day episode costs in the same way CMS calculates the target price for BPCI Advanced Hospital PCI episodes (Target Price)
- B. CMS conducts a semiannual reconciliation comparing the actual costs per patient episode to the Target Price and calculates the variance between the actual cost and the Target Price for each patient episode (Gross Variance per Patient Episode)
- C. CMS limits the Gross Variance per Patient Episode to +/- \$4,000 per patient episode (Stop-Loss Limited Variance per Patient Episode)
- D. CMS will sum all the Stop Loss Limited Variance per Patient Episodes in the semiannual reconciliation to calculate the total Stop Loss Limited Variance per Patient Episode (Total Stop Loss Limited Variance per Patient Episode)
- E. If the Total Stop Loss Limited Variance per Patient Episode is positive, CMS shall pay the Bundled PCI Provider fifty percent (50%) of the Total Stop Loss Limited Variance per Patient Episode
- F. If the Total Stop Loss Limited Variance per Patient Episode is negative, the Bundled PCI Provider shall pay CMS fifty percent (50%) of the Total Stop Loss Limited Variance per Patient Episode
- G. If the Total Stop Loss Limited Variance per Patient Episode is negative and the Bundled PCI Provider does not pay CMS fifty percent (50%) of the Total Stop Loss Limited Variance per Patient Episode within sixty (60) days of receiving notification from CMS, CMS shall have the option of deducting any unpaid amounts from future Medicare payments to the Bundled PCI provider

These financial risks are feasible for both large and small practices as these risks are the same as under BPCI Advanced Outpatient PCI. Shared financial risks help ensure only appropriate patients are included for outpatient PCI. If Bundled PCI Services providers select patients that do

not meet the inclusion/exclusion criteria due to inappropriate risk, both the outpatient lab and the providers will have potential financial fallout for inappropriate patient selection.

As a result of cost savings for Medicare, ACOs will naturally gravitate towards outpatient PCI procedures due to the lower price point and potentially better outcomes. The reporting mechanisms in this proposal support accountability for the quality, outcomes, and cost of delivery of cardiovascular care, offering a natural partnership for communities in cost sharing payment models, a priority for both CMS and the American College of Cardiology. (12) CCC has experienced this migration with commercial ACOs and with a Medicare ACO for cardiovascular procedures excluding PCI.

Historically, cardiologists have been limited in their participation in APMs due to several factors. Many cardiologists are unfamiliar with these programs, and bonus payments available in current federal programs may not offset the burden of reporting. Many physicians report that claims-based metrics are unreliable, too general, and delivered too infrequently or too late to be actionable. Employed cardiologists are often unaware of their APM (or even ACO) participation, and performance feedback often goes to the employer, not the cardiologist. They may not perceive changes to their operations or practice if these changes are administratively driven. (13) Bundled PCI encourages partnership between the labs and the providers, allowing those providers a simple and effective way to participate in an APM.

Phase 2 of Bundled Payments for Care Improvement (BPCI) program included several cardiovascular episodes. So far, no BPCI cardiovascular episodes have had significant differences in payments relative to the comparison group for the inpatient stay bundles plus services furnished during the 90-day post-hospital discharge. (14) Interestingly, BPCI Advanced includes only three outpatient clinical episodes with one being PCI. However, CMS has indicated "... In the first two years of the model, the anchor procedure will trigger an outpatient clinical episode when it occurs in an outpatient hospital department only. So, anything paid under the outpatient prospective payment system, such as Ambulatory Surgery Centers and freestanding facilities, are not currently included to start in model years, 1 and 2." (15)

CCC compensates its providers using a system compliant with Stark Law, the Federal Anti-kickback statute and the Internal Revenue Service guidelines. Specifically, our compensation system does not take into account the volume or value of referrals for services including technical fee services or Bundled PCI Services. All of the physicians of CCC are W-2 employees paid under this physician compensation system. As other practices and centers join Bundled PCI, they would be required to comply accordingly.

II Response to Criteria

1 – Scope of Proposed PFPM

Criterion 1 of 10. Scope of Proposed PFPM (High Priority Criterion): The proposal aims to broaden or expand CMS' APM portfolio by either: (1) addressing an issue in payment policy in a new way, or (2) including APM Entities whose opportunities to participate in APMs have been limited.

The goal of this section is to explain the scope of the PFPM by providing PTAC with a sense of the overall potential impact of the proposed model on physicians or other eligible professionals and beneficiary participation. Proposals should describe the scope and span of the payment model and discuss practice-level feasibility of implementing this model as well as clinical and financial risks.

Bundled PCI Services will expand CMS's APM offerings by:

- Moving appropriate PCI services from higher cost hospital inpatient and hospital outpatient locations to lower cost qualified non-hospital cath labs
- Allowing interventional cardiologists and their broader groups to participate in an APM
- Expanding bundling into the non-hospital arena as it does not require a hospital-admission or hospital-performed procedure as an anchor like the original BPCI or BPCI Advanced program
- Expanding patient and provider options and access for PCI procedures

Information Items:

- *Related to physician or other eligible professionals' practices:*
 - *What types of physician or other eligible professionals' practices would be able to participate in this payment model?*

Cath labs that provide services billed under POS 11 may be operated by independent physicians and/or hospital integrated physician groups. As such, both independent physicians and hospital employed physicians may provide services under this payment model. Private cardiology practices and interventional cardiologists would be eligible for this payment model -- a group that historically has not been able to participate on such a large scale.

- *How many physician or other eligible professionals' practices or numbers of physicians or other eligible professionals have expressed interest and willingness to participate in the model if it is approved?*

As the model expands, we anticipate several other practice-owned labs will request inclusion, and CCC will work with CMS to develop and refine recommended guidelines for other outpatient cath labs to qualify. So far, all potentially qualified outpatient labs CCC has contacted about the proposals have expressed great interest in participation.

- *How many physicians or other eligible professionals and patients could participate if the model was expanded to scale?*
- *How would the payment model work for physicians or other eligible professionals who are employed and for those that are independent, and what changes in compensation might be necessary for employed physicians or other eligible professionals, if applicable?*

If the APM is expanded to scale, all independent and employed physicians will be able to participate services Bundled PCI Services either directly or with their partner facilities. Once enough cases are completed and reported under Bundled PCI Services, CMS will have the data and tools it needs to determine if, when, and how to allow appropriate PCI services to be delivered to Medicare beneficiaries in the most cost-effective environment.

Participation in Bundled PCI Services would not necessitate a change in physician compensation.

- *Has the model been implemented by other payers, and if so, what was the experience?*

CCC has provided the Anchor Procedure from this model for all of its major managed care payers. These managed care plans and their members have experienced greater access to high-quality appropriate PCI services at a lower cost and with high patient satisfaction.

- *Are the costs or financial risks associated with the payment model feasible for small practices?*

The cost and financial risks would be feasible for practices of all sizes. The proposed model would encourage partnership between providers and local labs in order to allow smaller practices without their own lab to participate.

- *Related to patient population(s):*
 - *What is the size of the population anticipated to benefit from the model in its initial stages and if the model were expanded to scale?*

As outlined in the overview, we anticipate approximately 90,000 cases per year would be appropriate for this model once it is scaled. Based on the managed care contracts in place, we expect our test site(s) to complete at least 350 Medicare cases per year.

- *How are patients expected to benefit and how would they be protected against unintended consequences? For example, what protections would be in place to protect against the denial of needed care, overutilization, or less than optimal patient outcomes?*

Bundled PCI is not based on capitation and has no incentives for the denial of needed care. If a patient is not an appropriate candidate for Bundled PCI Services, the patient would be referred to a hospital lab rather than have care denied. Overutilization will be addressed by the AUC criteria and less than optimal patient outcomes will be addressed by the financial deterrent of a bundled payment, accompanied by the 90 Day Episode Risk Sharing. Bundled PCI Services would be governed by the current Appropriate Use Criteria (AUC) through NCDR which should also address potential overutilization.

- *What are the overall anticipated impacts on Medicare spending?*

Overall, Medicare spending would decrease due to cost savings and risk sharing as more fully described in this proposal.

- *What are the expected spillover effects on Medicaid, CHIP, TRICARE/VA, or private health spending, or on those beneficiaries/enrollees, if any?*

Medicaid, Tricare/VA, and private supplemental insurance would also benefit from the cost savings and decreased copayments if the program is expanded to these payers.

2 – Quality and Cost

The proposal is anticipated to (1) improve health care quality at no additional cost, (2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost.

The goal of this section is to better understand the “value proposition” that will be addressed by the proposed PFFM. Please describe how the components of the value proposition will be achieved. For example, how will clinical quality, health outcomes, patient experience, and health care cost management be addressed within the model and how will performance be measured? Please describe any current barriers to achieving desired value/quality goals and how they

would be overcome by the payment model. Please identify any novel clinical quality and health outcome measures that will be included in this proposed model. In particular, measures related to outcomes and beneficiary experience should be noted.

This model clearly meets the goal for PFPs -- reducing spending without reducing the quality of care, by migrating appropriate PCI cases to the most cost-effective facilities. Appropriate use and clinical quality (outcomes) will be measured through the NCDR system. The patient experience will be measured through patient satisfaction surveys.

Information Items:

- *How is care delivery expected to improve in order to achieve savings or improve quality, including:*

- *Where and by how much will health care services or costs be reduced, and/or*

As outlined above, the proposal would expand access and patient choice and decrease costs for appropriate Anchor PCI procedures by an estimate of \$1,285 for a single vessel PCI and \$3,105 for multi-vessel PCI.

- *If quality will be improved beyond a baseline, how and by how much will quality be improved? If quality will not be improved, how will quality be maintained?*

Quality will be maintained by using the same metrics and registries to track outcomes as are currently used for hospital outpatient labs.

- *What are the nature and magnitude of barriers and risks to the model's success and how will they be overcome?*

The barrier to success is the lack of an avenue for reimbursement for Medicare patients. As the Anchor Procedure component of this model is now in place for CCC managed care payers, it is a natural extension for a demonstration project for CMS.

- *What metrics will be used to assess performance under the model including the impact of the model on total cost of care, and will any of the metrics include patient-reported outcome measures or measures of beneficiary experience of care?*
- *What approach will be used to develop any innovative metrics proposed for inclusion in the model, such as specialty-specific measures or patient-reported outcome measures, and how will this approach leverage existing measures, standards, value sets, etc.?*

As outlined above, specific metrics are already in use to assess costs, appropriate use, patient outcomes, and patient satisfaction for hospital outpatient labs. These metrics include CMS claims data, resource utilization from internal accounting, NCDR metrics, and patient satisfaction surveys. 90-Day Episode Risk Sharing will be measured in the same manner as BPCI Advanced Outpatient PCI.

Results from applying Bundled PCI Services will help refine recommendations to CMS for non-hospital cath lab PCI inclusion/exclusion criteria. Results will also assist in developing recommendations to CMS for establishing criteria which non-hospital cath labs will be required to meet in order to provide PCI services to Medicare patients.

- *What approach will be used to incorporate data from multiple sources to support total cost of care, resource utilization, or clinical quality metrics?*

Data will be incorporated from:

- Anchor procedure cost from claims data
- 90-day post procedure costs in the same manner as BPCI Advanced Outpatient PCI

- Resource utilization from our internal accounting
- Appropriate use from AUC through NCDR
- Clinical quality metrics from NCDR PCI registry and our internal outcome tracking
- Patient satisfaction from patient satisfaction surveys
- *What approach to electronic reporting of and timely feedback on performance measures will be used? How will the approach take into account capturing and sharing data from the EHRs of all clinicians who provide relevant care for the attributed patient population, aggregation and calculation of measures, and provision of timely feedback to support performance improvement?*

NCDR reporting is an important element of the proposal, which is currently in use for hospital-based PCIs. The registry data is tracked outside the EMR.

- *What level of monitoring or auditing will be required?*

By using an existing data registry that already outlines benchmarks, auditing will be greatly simplified.

- *Are there any prior or planned statistical analyses to estimate the impact of the model on spending and quality of care?*

As shown in Table 3, we project Anchor Procedure Medicare savings of \$1,285 for a single vessel PCI and \$3,105 for multi-vessel PCI.

3 – Payment Methodology

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 PFPM cannot be tested under current payment methodologies. *The goal of this section is to better understand the payment methodology for the proposed model, including how it differs from both existing payment methodologies and current alternative payment models. Include in your description how the proposed PFPM will incorporate the performance results in the payment methodology. Please describe the role of physicians or other eligible professionals in setting and achieving the PFPM objectives, as well as the financial risk that the entity/physicians will bear in the model. Please also differentiate between how services will be reimbursed by Medicare versus how individual physicians or other eligible professionals might be compensated for being a part of this model. Finally, a goal of this section is to better understand any regulatory barriers at local, state, or federal levels that might affect implementation of the proposed model.*

Information Items:

- *Payment methodology:*
 - *How would entities be paid under the proposed model, including the amount of new payments (e.g., per beneficiary per month, shared savings payments, etc.), and what is the methodology for calculating such payments?*

For the Anchor Procedure, we propose a global bundled price (physician professional and facility fees) of \$10,000 for a single vessel PCI with a drug eluting stent and \$14,000 for a two-vessel PCI with a drug eluting stent. We also propose 90-Day Episode Risk Sharing in a similar manner as BPCI Advanced Outpatient PCI

- *Will the proposed model include other payers in addition to Medicare, and if so, is a different payment methodology needed for those payers?*

CCC has successfully provided the anchor procedure from the Bundled PCI Services model for managed care payers for the since January 1, 2016.

- *How will the model enable entities to sustain the expected changes in care delivery over time?*

Over time, payments can be adjusted to sustain the expected changes in care in a similar manner that is currently used for the Medicare Physician Fee Schedule or the Hospital Outpatient Prospective Payment System.

- *How are the targets for success defined, and what are the penalties for failure?*

Clinical success will be defined based on the reported outcomes, quality metrics, and patient satisfaction outlined above. Penalties for failure would result in exclusion from the payment model. Financial success will be defined as the ability of Bundled PCI Services Providers to manage the 90-day post procedure cost at or below the CMS determine target price.

- *What methodology will be used for risk adjustment (if relevant)?*

Risk adjustment methodology through 90-Day Episode Risk Sharing would be the similar to BPCI Advanced Outpatient PCI.

- *How does the payment methodology differ from current Medicare payment methodologies/Center for Medicare and Medicaid Innovation (CMMI) models for physicians or other eligible professionals and why cannot it be tested under current payment methodologies/CMMI models?*

The barriers in the current payment system that make this payment methodology necessary result from the lack of technical facility fee reimbursement in the Medicare Physician Fee Schedule for PCI services in non-hospital settings. Currently, in the Medicare program, outpatient PCI services are paid separately for the physician professional fee under the Medicare Physician Fee Schedule and for the hospital outpatient facility fee through the Medicare Hospital Outpatient Prospective Payment System. However, the proposed bundle would eliminate that barrier while incorporating shared risk and lower cost to Medicare and its beneficiaries.

- *What degree of financial risk will the entity and its physicians or other eligible professionals bear as a consequence of this proposed model (i.e., will physicians be at financial risk for their portion of care within the framework of the model, and how will this be determined)?*

The providers of Bundled PCI Services will assume risk by:

- Fixed cost -- If costs exceed the fixed reimbursement, which is lower than hospital reimbursement, participating labs would lose money
- 90-Day Episode Risk Sharing -- providers will be responsible for managing cost in the 90 day post procedure in a similar manner as BPCI Advanced for hospital outpatient PCI
- *Where relevant, how will the model address:*
 - *Establishing the accuracy and consistency of identification/coding of diagnoses/conditions?*

AUC would drive appropriate coding of diagnoses and conditions for patients who qualify.

- *Clinical appropriateness of the payment unit (e.g., procedure or other treatment for which payment would be made)?*

Bundled billing, AUC, and the 90-Day Episode Risk Sharing would again deter from overutilization and drive providers to only use this option when it is clinically appropriate.

- *Accurately assigning claims for payment to particular episodes of care?*

Anchor Procedure services would be billed under one of the following codes:

- 92920 – Percutaneous transluminal coronary angioplasty, single major artery or branch
- 92928 – Percutaneous trans catheter placement of intra-coronary stent, with coronary angioplasty when performed; single major coronary artery or branch
- 92937 – Percutaneous transluminal revascularization of our through coronary artery bypass graft

Atherectomy procedures which are included in BPCI Advanced Outpatient PCI would be excluded from this proposal.

- *Barriers that make a new payment methodology necessary:*
 - *Are there any barriers in the current payment system that prevent or discourage the change in care delivery?*

As outlined above, the current lack of a facility fee or global payment for PCI in a non-hospital cath lab and the exclusion of non-hospital PCI from BPCI Advanced prevents the performance of these procedures for Medicare beneficiaries.

- *Are you aware of any barriers that exist in state or federal laws or regulations (such as current coverage limitations in Medicare or state-specific scope of practice limitations)?*

Some states may require a certificate of need to establish a new cardiac cath lab. We are not aware of any other barriers.

- *If no barriers exist, why is the proposed model the appropriate solution?*

The proposed model will drastically reduce costs while providing patients with proven outcomes, quality, and satisfaction.

- *Will the proposed model have an impact if regulatory barriers (if present) are not addressed?*

Not applicable.

4 – Value over Volume

The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

The goal of this section is to better understand how the model is intended to affect practitioners' behavior to achieve higher value care through the use of payment and other incentives. PTAC acknowledges that a variety of incentives might be used to move care towards value, including financial and nonfinancial ones; please describe any unique and innovative approaches to promote the pursuit of value including nonfinancial incentives such as unique staffing arrangements, patient incentives, etc.

The Bundled PCI Services program is a fixed payment model with providers bearing the risk for costs through 90-Day Episode Risk Sharing. The combination of a fixed payment that is lower than any alternative together with strict AUC, outcome results, accreditation and the 90 Day Episode Risk Sharing clearly aligns the incentive for high-value care.

Information Items:

- *What financial incentives will be provided to encourage physicians and other eligible professionals to deliver high-value health care?*

Providers will have a financial incentive to treat appropriate patients in the outpatient setting because this program expands access and choice for the patient while allowing the physicians to participate in the technical fee component of the Bundled PCI Services reimbursement. Also, the decreased cost will naturally align these providers with their ACOs.

- *How will these incentives influence physician or other eligible professionals' behavior? Please be clear about how you expect changing incentives to be manifested throughout the delivery system*

The expanded access, expanded patient choice and lower costs will be a driving factor in providers selecting outpatient PCI vs. hospital PCI, as the providers will be partnered with or will have ownership in the lab.

- *Has the submitter had prior experience with the use of these incentives? If yes, what have been the effects (both salutary and adverse)? Were there any unintended consequences of the use of these incentives?*

CCC, its patients and managed care plans have benefited from increased access, greater choice and lower costs for the last two years. CCC has experienced the effects of this arrangement, which dramatically reduces costs while maintaining or improving outcomes. No unintended consequences were observed.

- *Will non-financial incentives (e.g., use of behavioral incentives) be used to promote physicians and other eligible professionals' delivery of high-value health care? If yes, please describe them.*

Cardiologist and their patients will enjoy greater satisfaction and high-quality services in the most cost-effective environment allowing greater control over the services by treating physicians. Also, qualified non-hospital cath labs will gain accreditation and recognition for their outcomes and satisfaction scores.

- *How will these incentives influence practitioner behavior? Please be clear about how you expect changing incentives to be manifested throughout the delivery system.*

Improved recognition for their outcomes and affiliation with desirable labs would increase patient referrals.

- *Has the submitter had prior experience with the use of these incentives? If yes, what have been the effects (both salutary and adverse)? Were there any unintended consequences of the use of these incentives?*

CCC has been in business for more than 40 years and involved in managing outpatient cath lab for 17 years. Having control over the quality of care and patient satisfaction in managed and/or owned outpatient cath lab has resulted in very high job satisfaction for CCC's physicians.

5 – Flexibility

Provide the flexibility needed for practitioners to deliver high-quality health care

The goal of this section is to better understand (1) how the proposed payment model could accommodate different types of practice settings and different patient populations, (2) the level of flexibility incorporated into the model to include novel therapies and technologies, and (3) any infrastructure changes that might be necessary for a physician or other eligible professionals to succeed in the proposed model.

Information Items:

- *Can the proposed model be adapted to accommodate the breadth and depth of differences in clinical settings and patient subgroups (e.g., rural physicians and/or patients, physicians in a tertiary/quaternary setting, specific subgroups of patients, etc.)?*

The Bundled PCI Services model can be applied to any clinical setting and patient subgroup where there is a non-hospital cath lab or ASC that can partner with physicians.

- *How can the proposed model be adapted to account for changing technology, including new drug therapies or devices?*

The Bundled PCI Services model may be easily adjusted for changing technologies such as new coronary interventional devices and methods. The adaptation of these technologies would be subject to the approval of Medicare, and bundled pricing can be modified to reflect the cost of the procedure and the cost of new devices as is current practice for inpatient labs.

- *To what extent will practitioners have to adapt to operational burdens and reporting requirements that result from the proposed payment model?*

There should be no additional operational burdens on practitioners under the Bundled PCI Services model. Practitioners will have to meet the same AUC criteria and the same NCDR registry reporting as is now utilized for hospital procedures.

- *How will model participants prepare and build the infrastructure to implement the proposed model?*

As the Initial Model Participant, CCC is in the unique position as it owns a lab that is currently providing PCI services to managed care patients. The lab is the same as was previously used to provide these services to Medicare patients under previous hospital ownership, without any changes in equipment, location, providers or staff. CCC is also one of the most respected cardiology groups in the Southeast. Our physicians are multi-board certified and have decades of experience. Our Cath Lab Director, Bernardo Stein, M.D, is also the director of the Morton Plant Hospital Inpatient Cath Lab. Our physicians routinely participate in clinical trials (often as principal investigator), complete research for affiliated universities, and publish in peer-reviewed journals. The infrastructure is a perfect environment to test this payment model.

Other than operating or partnering with an appropriate non-hospital cath lab, model participants will not have to build infrastructure.

6 – Ability to be Evaluated

Criterion 6 of 10. Ability to be Evaluated: Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

The goal of this section is to describe the extent to which the proposed model or the care changes to be supported by the model can be evaluated and what, if any, evaluations are currently under way that identify evaluable goals for individuals or entities in the model. If there are inherent difficulties in conducting a full evaluation, please identify such difficulties and how they are being addressed.

Information Items:

- *Is the impact of the PFPM on metrics that are included as part of the proposed model able to be evaluated? If so please describe how.*

The PFPM metrics to be evaluated for Bundled PCI Services include the following:

- Appropriate Use Criteria (AUC)
- Outcomes using the NCDR Cath-PCI registry
- Anchor Procedure costs
- 90-Day Episode Risk Sharing
- Patient satisfaction scores

Results of this program will be easily comparable to BPCI Advanced Outpatient PCI

- *What are the evaluable goals at various levels (e.g., for a population, for a provider entity, for individual physicians, etc.)?*

These metrics are all easily quantifiable through existing national criteria as previously described. Each can be evaluated against benchmark databases to compare the Bundled PCI Services Program to that of existing unbundled services provided through hospitals as well as facility to facility for those who participate.

- *Are there any evaluations of the proposed model under development, underway or that have been conducted and that have not been referenced in other sections? If yes, please identify them and state whether findings from those evaluations can be shared.*

CCC has prepared a preliminary evaluation of appropriateness from providing the Anchor Procedure from its Bundled PCI Services proposal for managed care plans as previously described. The metrics for evaluation are also included above.

- *Are there other questions beyond the impact on core metrics which the evaluation should focus on, including through the use of qualitative methods?*

Not at this time.

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.

The goal of this section is to describe the full range of personnel and institutional resources that would need to be deployed to accomplish the proposed model's objectives. Please describe how such deployment might alter traditional relationships in the delivery system, enhance care integration, and improve care coordination for patients.

Information Items:

- *What types of physicians, non-physicians, and other eligible professionals would likely be included in the implementation of this model in order to achieve desired outcomes?*

Because of the nature of the services provided under the Bundled PCI Services model, the only eligible professionals to be included in the implementation of the model would be cardiology physicians, particularly interventional cardiologists and their support staff. As the program grows, ASCs may also be included.

- *How would the model lead to greater integration and care coordination among practitioners and across settings?*

Bundling physician and facility services naturally leads to greater care coordination and alignment of objectives among practitioners and facilities. Ninety-day post procedure risk sharing will provide incentives for Bundled PCI Services providers to manage post procedure costs.

- *To what extent would the proposed model result in changes in workforce requirements compared to more traditional arrangements?*

The Bundled PCI Services program would require non-hospital cath labs and ASCs to enhance their workforces to include training and experience with PCI services. It would require non-hospital cath lab and ASC facilities to upgrade staff and create more private sector employment opportunities with high earning potential.

- *How will the model address coordination with care team members that are not financially accountable (e.g., through program requirements around care processes or voluntary agreements to share in savings/losses)?*

Program participants could share cost savings with high quality, efficient post procedure care providers.

8 – Patient Choice

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

The goal of this section is to describe how patient choice and involvement will be integrated into the proposed PFP. Describe how differences among patient needs will be accommodated and how any current disparities in outcomes might be reduced. For example, please share how the demographics of the patient population and social determinants of care may be addressed.

Information Items:

- *How is patient choice preserved under the model by accommodating individual differences in patient characteristics (including social needs, etc.), conditions, and health-related preferences while furthering population health outcomes?*

Currently, there is no option for patients on Medicare to select a non-hospital cath lab for their PCI procedure, as there is no available payment model. This proposal will offer an additional option for patients who are appropriate for outpatient procedures and allow more patients to participate in programs with APMs.

- *How would the payment model affect disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and geography?*

Expanding appropriate PCI procedures to qualified non-hospital cath labs would expand access to PCI services for all.

- *How would the payment model expand the demographic, clinical, or geographic diversity of participation in alternative payment models beyond existing CMS models (e.g., would the proposed payment model address populations which are not currently addressed in current CMMI models)?*

The proposed model includes interventional cardiologists, who historically have not been active participants in APMs as previously described. Also, this model is not based on an inpatient stay - instead, focusing on a clinical problem defined and addressed in a lower cost outpatient setting.

9 – Patient Safety

Criterion 9 of 10 Patient Safety: How well does the proposal aim to maintain or improve standards of patient safety?

The goal of this section is to describe how patients would be protected from potential disruptions in health care delivery brought about by the changes in payment methodology and provider

incentives. Please describe how disruptions in care transitions and care continuity will be addressed. Safety in this instance should be interpreted to be all-inclusive and not just facility-based.

Information Items:

- *How would the proposed model ensure that patients are not harmed by efforts to achieve savings or to improve specific aspects of quality/outcomes?*

The Bundled PCI Services program will have strict patient selection criteria as previously defined, which requires high risk patients that do not meet the inclusion criteria be treated in appropriate hospital settings.

- *What measures would be used to ensure the provision of necessary care and monitor for any potential stinting of care?*

The model does not have the potential for stinting of care.

- *To what degree will the proposed model ensure the integrity of its intended benefits and what embedded monitoring and potential adjustments are under consideration, should unintended or other incongruent behaviors occur?*

As previously outlined, quality and outcomes for the Bundled PCI Services program would be compared to those for similar patients treated in a hospital setting. Cath labs that do not meet or exceed those criteria may be removed. Patients would continue to follow up with their cardiologist post-operatively, as they would following a hospital-performed PCI.

10– Health Information Technology

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

The goal of this section is to understand the role of information technology in the proposed payment model. In this section please describe how information technology will be utilized to accomplish the model's objectives with an emphasis on any innovations that improve outcomes, improve the consumer experience and enhance the efficiency of the care delivery process. Please also describe goals for better data sharing, reduced information blocking and overall improved interoperability to facilitate the goals of the payment model.

Information Items:

- *How would patients' privacy be protected if new providers or caregivers will have access to personal health information (PHI)?*

As defined by MACRA, we propose that participating outpatient labs must use certified electronic health record technology. Non-hospital cath labs and all providers and caregivers are already subject to the HIPPA privacy requirements.

- *How would the model facilitate or encourage transparency related to cost and quality of care to patients and other stakeholders?*

The Bundled PCI services model is a fixed-price program with a total cost transparency to CMS and the patients. Publishing Appropriate Use Criteria results and outcomes through the NCDR database together with patient satisfaction survey results will give patients information needed to make informed decisions. Publication of 90-day procedure cost sharing results would complete transparency.

- *Will interoperability of electronic health records be needed to guide better decision-making?*

CCC will work towards interfacing NCDR data with its EHR system.

- *Will any information technology innovations be used to support improved outcomes, improve the consumer experience, or enhance the efficiency of the care delivery process?*

Not applicable.

- *How will any health IT requirements included in the model ensure that clinicians have the flexibility to choose from a variety of solutions to meet their needs and leverage existing technology assets where possible?*

The only additional IT requirement will be the ability to input data into the NCDR for outcomes and results tracking. The program will require the reporting of outcomes and patient satisfaction results, accreditation, etc. This information is already available through existing channels.

11 – Supplemental Information

- *If the entity submitting the proposal wishes to serve as a recipient of the proposed payment, please describe the proposed governance structure for the entity.*

See the attached organizational chart.

- *If known, please describe any infrastructure investments that might need to be made by CMS, in addition to changes in the payment model (e.g., different mechanisms for claims processing, data flows, quality reporting, etc.).*

Under the Bundled PCI Services program, providers will be paid a bundled fee for the combined facility and professional services. In addition, Bundled PCI Services providers will share in the total cost risk of related costs through the 90-Day Episode Risk Sharing in a similar manner as BPCI Advanced Outpatient PCI episodes. We propose CCC as the test case for this proposal. Please see the Organizational Chart (Attachment 1) outlining our corporate structure. Other than CMS processing a bundled payment (facility plus professional fees) for the Anchor Procedure which is not currently included in the Medicare Physician Fee Schedule, there should be no other additional infrastructure investment by CMS as the 90-Day Episode Risk Sharing is very similar to the risk sharing in the BPCI Advanced Outpatient PCI Episodes.

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CLEARWATER CARDIOVASCULAR AND INTERVENTIONAL CONSULTANTS, M.D., P.A.
Organizational Chart

