Clearwater
Cardiovascular
Consultants

Paul L. Phillips, M.D.
Richard Sola, M.D.
Jose L. Gallastegui, M.D.
Douglas J. Spriggs, M.D.
Vanessa J. Lucarella, M.D.
Bernardo Stein, M.D.
Jorge P. Navas, M.D.

Aland R. Fernandez, M.D.
H. Andrew Hazlitt, M.D.
Mark J. Hepp, M.D.
Kenneth C. Sabatino, M.D.
Federico E. Lenz, M.D.
Jay K. Amin, M.D.
Jason T. Zelenka, M.D.

Marilyn Y. King, M.D.
Michael O. Barry, M.D.
S. Masood Gilani, M.D.
Andrew P. DeWolfe, M.D.
Donald G. Kikta, Jr., M.D.
A-Hamid Hakki, M.D.
Juan C. Garcia-Morell, M.D.

July 17, 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 Avenue S.W.
Washington, D.C. 20201
PTAC@hhs.gov

RE: **Preliminary Review Team (PRT) Questions for Submitters 7/2/2018**

Dear Preliminary Review Team Members;

Thank you for the consideration you are giving to the proposal submitted by Clearwater Cardiovascular and Interventional Consultants, M.D., P.A. (CCC) to bundle Percutaneous Coronary Interventions (PCI) and migrate appropriate PCIs from higher cost hospital facilities to lower cost non-hospital cardiac catheterization labs.

CCC supports PTAC's efforts in reducing PCI costs while insuring that the services are provided in a safe and effective manner, furnished in accordance with accepted standards of medical practice and in a setting appropriate to the patient's medical needs and conditions.

Like many of the services that have been provided in the past in hospital outpatient departments and have subsequently migrated to lower cost free standing physician office and ambulatory settings, PCI has begun the migration to non-hospital cardiac catheterization labs. As with the prior migrations of services, a significant savings will be realized when PCI services migrate from hospital facilities to non-hospital cardiac catheterization labs.

Approximately 600,000 PCI procedures are performed annually in the United States, one-half (300,000) of which are elective PCI procedures eligible for same day discharge. PCI is associated with costs of $10 billion annually. Of the 300,000 PCI procedures eligible for same day discharge, it is estimated that 90,000 (30%) of the PCI procedures can be migrated from hospital facilities to

non-hospital catherization labs.[1] CCC estimates a costs savings of $1,285 to $3,105 per procedure when these procedures are performed in non-hospital catherization labs and paid under a bundled professional and technical rate. This would result in annual cost savings of $115,000,000 to $280,000,000 per year for the 90,000 procedures when migrated to non-hospital catheterization labs.

Commercial managed care companies and Medicare Advantage Plans are currently leading the migration. We hope traditional Medicare will soon follow. Traditional Medicare is currently steering PCIs to higher cost hospital settings through its reimbursement policy of only paying for PCI in hospital outpatient departments. While unintended, the current reimbursement policy gives hospitals an unfair competitive advantage in providing PCI to Medicare beneficiaries and is inconsistent with the objective of reducing costs while insuring that the services are provided in a safe and effective manner, furnished in accordance with accepted standards of medical practice and furnished in a setting appropriate to the patient's medical needs and conditions.

Below are the questions asked in your 7/2/18 Questions for Submitters immediately followed by CCC's response.

Question 1. On page 2, you propose a "limited scale test case" initially including only Clearwater Cardiovascular Consultants (adding up to two additional non-hospital cath labs in year 2) over a 3-5 year testing period. In response to PTAC comments and recommendations on other proposed models, the Secretary of Health and Human Services has indicated that, "To the extent the limited-scale recommendation for a proposed model test precludes robust evaluation, we would be unlikely to implement such a recommendation."

a) Do you believe that your proposed model, to be implemented on such a small scale would meet this test?

b) How do you envision it being scalable so that the Medicare program would realize cost savings and/or quality improvement?

---

[1] ***Costs Associated With Access Site and Same-Day Discharge Among Medicare Beneficiaries Undergoing Percutaneous Coronary Intervention*** - Amit P. Amin, Mark Patterson, John A. House, Helmut Giersiefen, John A.Spertus, Dmitri V. Baklanov, Adnan K. Chhatriwalla, David M. Safley, David J. Cohen, Sunil V. Rao, Steven P. Marso - JACC: Cardiovascular Interventions Feb 2017, 10 (4) 342-351; DOI:10.1016/j.jcin.2016.11.049

CCC Response

a) Yes. The limited scale test case does not preclude a robust evaluation and would meet the test. The use of a limited scale test case is a proven first step in completing a robust evaluation. A current example of the reason why a limited scale test case is appropriate is the use of the CCC's model by Medicare Advantage Plans in their initiative of realizing scalable cost savings and quality improvement in PCI procedures provided to Medicare beneficiaries. Over the past three (3) years, ten (10) Medicare Advantage Plans have contracted with CCC to provide PCI services in CCC's non-hospital catheterization lab. Five (5) additional Medicare Advantage Plans are in the process of contracting with CCC to provide PCI services to Medicare beneficiaries. Collectively, these Medicare Advantage Plans account for 88% of the Medicare Advantage Plans and cover 90% of the Medicare Advantage beneficiaries in Pinellas County Florida. As of January 1, 2018, Medicare Advantage Plans in Pinellas County had 115,000 Medicare beneficiaries and covered 48% of the total Medicare beneficiaries in the county.

Each of these Medicare Advantage Plans acknowledged that they were using the contract with CCC as their initial step in the development of a scalable model which could potentially roll-out across their other markets. Through this initial step, the Medicare Advantage Plans have been developing and/or refining their utilization/quality care standards, standards of medical practice, facility requirements, bundling & multi procedure payment policies and claims adjudication processes.

b) The CCC model will be scalable when adopted by Medicare and would result in realized cost savings and quality improvements by the Medicare program. There has been significant growth in last few years in the number of non-hospital catheterization labs across the county. This growth has been fueled in large part by Medicare's decision to reimburse non-hospital catheterization labs for the global bundled professional and technical components on peripheral vascular interventional procedures. The number of non-hospital catheterization labs across the county will grow at much higher rate (similar to the growth in Medicare Certified ASCs) as the need to reduce PCI cost increases and as more payers use their payment practices to migrate appropriate PCI procedures from higher cost hospital settings to non-hospital catheterization labs. Non-hospital companies and private investors will finance the rapid growth. Medicare can expedite the realization of the cost savings and quality improvements through the adoption of the CCC model.

Our proposal of the CCC Outpatient Lab as the initial provider in year one would allow CCC, in cooperation with CMS/CMMI, the opportunity to develop comprehensive criteria needed for non-hospital catheterization labs to safely provide Bundled PCI Services. This will help set the guidelines for any non-hospital catheterization labs that provide Bundled PCI Services to meet stringent criteria, safely providing these services with the infrastructure to meet all data reporting requirements. During the first year, we also want to refine Bundled PCI Services patient inclusion/exclusion criteria, again in cooperation with CMS/CMMI.

In year two, after CCC has gained experience providing Bundled PCI Services to Medicare Patients under the proposed model, and after we have refined facility and inclusion/exclusion criteria in cooperation with CMS/CMMI, we proposed "having at least two additional non-hospital catheterization labs" test the application of the criteria and expansion process.

After we successfully expand to three facilities in year two, we would be ready to add more facilities in years 3 – 5 to meet the robust evaluation test.

We anticipate expansion of the proposal to qualified ASCs (Place of Service 24), which will lead to even more robust testing. Currently, many ASCs are multispecialty owned with medical staffs with little or no experience and expertise in PCI. Expanding the proposal to ASCs will require the participating ASCs to add very specialized equipment and retain a highly trained clinical staff with PCI expertise. Participating ASCs would be required to meet the same comprehensive criteria which apply to non-hospital catheterization labs to safely provide Bundled PCI Services. The CCC proposal is an important step in a robust evaluation that would eventually include ASCs.

Expanding the proposal to health system owned non-hospital catheterization labs under Place of Service 11 could also be included in a robust evaluation. Over the past few years, hospitals have been restructuring and moving many outpatient services from Place of Service 22 to Place of Service 11. This has and will continue to be driven by commercial and Medicare Advantage payers electing to contract with competing providers under Place of Service 11 at a lower cost. At the present time, there is no financial reason for health systems to own non-hospital catheterization labs under Place of Service 11. The CCC proposal would provide the reason needed. CCC would welcome qualified non-hospital catheterization labs owned and operated by health systems to participate in Bundled PCI Services.

Like Medicare Advantage Plans, we believe that Medicare should consider the CCC limited scale test case as an initial step in developing and refining their utilization/quality care standards, standards of medical practice, facility requirements, bundling & multi procedure payment policies and claims adjudication processes. Therefore, when fully implemented, the significant costs savings can be realized while insuring that the services are provided in a safe and effective manner in a setting appropriate to the patient's medical needs and conditions.

Question 2. We appreciate CCC's interest in conducting PCI in a less costly setting for selected Medicare patients. However, clarification of the source of cost savings would be helpful.

a) Please help us understand whether moving PCIs for Medicare beneficiaries from an outpatient hospital clinic (with cardiac catheterization capabilities) to a non-hospital cath lab is the main source of savings. In other words, does the proposed model rely primarily on a site of service differential for savings? If there are other efficiencies that result in cost savings, please explain.

b) The proposal states that a bundled payment approach will be used. Based on current findings from the third year evaluation of BPCI,[2] a BPCI model for outpatient PCI may not reduce Medicare payments since post-acute care for PCI (inpatient or outpatient) is limited. Can you please clarify the extent to which you anticipate that BPCI Advanced Outpatient payment would reduce episode payments for PCI in a non-hospital cath lab?

CCC Response

a) No. The site of service differential is only part of the savings under the proposed model.

The additional savings will result from:

i. The delivery of more timely care through increased access to PCI procedures that are currently limited to hospital facilities that are often operated in excess of capacity. More timely care will reduce the cost and reduce the risk of a negative outcome associated with an unnecessary delay;

[2] Source: CMS Bundled Payments for Care Improvement Initiative Models 24: Year 3 Evaluation & Monitoring Annual Report Prepared for CMS by The Lewin Group. October 2017

ii. The elimination of the delay and rescheduling of PCI procedures that frequently occurs in hospital facilities from unscheduled emergent (STEMI) cases. Delays and rescheduling increase costs and increases the risks of a negative outcome;

iii. Reduced complication rates and related costs[3] ;

iv. Performing PCI in a non-hospital catheterization lab eliminates the risk of hospital acquired infections; and

v. When implemented, a reduction in post-acute care (PAC) costs for PCI procedures when provided in CCC's Non-Hospital Catherization lab.

The third year evaluation of BPCI, referred to in your question and the findings that Bundled PCI Services may not reduce Medicare PAC payments, was limited to inpatient PCI cases and BPCI participating acute care hospitals. As a non-hospital independent group, CCC's participation in BPCI is significantly different than the participation of acute care hospitals.

We question the application to our proposal of Lewin's observation in the report that "Relatively few PCI episodes include post-acute care (PAC)[4]." Medicare FFS 90-day Bundled Data obtained from Medicare Limited Data Set for the 12 month period from 10/1/15 to 9/30/16 in connection with CCC's BPCI Advanced application, identified a national average 90-day bundled outpatient PCI costs of $15,900 per case and a Florida average 90-day bundled outpatient PCI costs of $16,249 per case. Of the average 90-day bundled outpatient PCI costs, approximately 30% is post procedure costs.

Below is the detail of the Medicare Limited Data Set information in connection with BPCI Advanced:

---

[3] Costs Associated With Access Site and Same-Day Discharge Among Medicare Beneficiaries Undergoing Percutaneous Coronary Intervention - Amit P. Amin, Mark Patterson, John A. House, Helmut Giersiefen, John A.Spertus, Dmitri V. Baklanov, Adnan K. Chhatriwalla, David M. Safley, David J. Cohen, Sunil V. Rao, Steven P. Marso - JACC: Cardiovascular Interventions Feb 2017, 10 (4) 342-351; DOI:10.1016/j.jcin.2016.11.049

[4] Source: Page 22 CMS Bundled Payments for Care Improvement Initiative Models 24: Year 3 Evaluation & Monitoring Annual Report Prepared for CMS by The Lewin Group. October 2017.

Average 90-Day Bundled Outpatient PCI Cost	National	Florida
Trigger Procedure (Facility & Professional)	$ 11,130	$ 11,374
Post Procedure Costs	$ 4,770	$ 4,875
Average Bundled 90 Day Costs	$ 15,900	$ 16,249
Post Procedure Costs	**National**	**Florida**
Readmissions (Facility & Professional	$ 2,067	$ 2,112
Other Hospital Outpatient	$ 1,511	$ 1,544
SNF, HHHA, IRF, LTCH PAC	$ 477	$ 487
Physician	$ 477	$ 487
ER	$ 159	$ 162
Hospice	$ 80	$ 81
Total Post Procedure Costs	$ 4,770	$ 4,875

We believe that an appropriate BPCI Advanced outpatient payment model can save up to 20% of the post procedure costs, or $975 per episode in Florida, by reducing post procedure ER visits and reducing subsequent hospital readmissions and other PAC through timely and thorough patient follow-up.

Question 3. The PRT would like to better understand your calculation of expected payment for one and two vessel PCI. Table 2 does not indicate a facility fee. How do you anticipate the cost of your facility will be accounted for, if at all, under Medicare payment?

CCC Response

Table 2 on page 6 of our proposal presents the global cost to Medicare for a hospital outpatient PCI by adding the facility fee (APC code) to the physician professional fee (CPT code). The total cost of the anchor procedure for a single vessel hospital outpatient PCI is $11,285 and $17,105 for a multi-vessel PCI. The facility fee in Table 2 for a Single Vessel PCI with Drug Eluting Stent is $10,510 (APC 5193). The facility fee in Table 2 for a Two Vessel PCI with Drug Eluting Stents is $16,019 (APC 5194). The rate listed for each CPT code is the professional fee.

Below is Table 2 from our proposal:

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 (Multi-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 on page 7 compares the total anchor procedure cost of a hospital outpatient PCI ($11,285 single vessel and $17,105 multi-vessel) from Table 2 to CCC's proposed Bundled PCI Services Physician Office (POS 11). The facility fee is included in the bundled amount in Table 3 in the column titled Bundled PCI Services Physician Office (POS 11) and is $10,000 for Single Vessel and $14,000 for Two Vessels PCI. This results in a savings of $1,285 for Single Vessel PCI and $3,105 for Two Vessel PCI. Medicare would account for the facility fee the same as it does for other services in the Medicare Physicians Fee Schedule when done in a physician office under the non-facility payment rate.

We have revised Table 3 in our proposal in response to question number 5 below and the revised Table 3 is presented below:

Table 3 - Anchor Porcedure Weighted Average Cost Savings					
	Anchor Procedure Rate				
Procedure	Weight	Hospital Outpatient (POS 22)	Bundled PCI Services/ Physician Office (POS11)	Difference	Weighted Average Difference
Single Vessel PCI	85%	$ 11,285	$ 10,000	$ 1,285	$ 1,092
Multi Vessel PCI	15%	$ 17,105	$ 14,000	$ 3,105	$ 466
Weighted Average	100%	$ 12,158	$ 10,600		$ 1,558

CCC is proposing a global fee (facility fee plus professional fee) under the Bundled PCI Proposal of $10,000 for a single vessel PCI and $14,000 for a multi-vessel PCI. This pricing would be the global fee for PCI in a non-hospital cath lab under the Bundled PCI Services proposal. This process will aid CMS in establishing the Medicare Physician Fee Schedule price when CMS eventually adds the global fee to the fee schedule.

Question 4. The PRT would like to better understand what happens from a payment perspective if a Medicare patient receiving PCI in a non-hospital cath lab is transferred to a hospital due to an unanticipated event during the surgery.

CCC Response

If a Medicare patient receiving PCI in a non-hospital cath lab is transferred to a hospital due to an unanticipated event during the PCI in the non-hospital cath lab, the cost of the hospital admission would be billed to Medicare and the claims would be adjudicated pursuant to the Medicare regulations. These costs would be included in post procedure/PAC costs for which there would be a risk share under the Bundled PCI Services proposal.

CCC has experienced a very low rate of transfer to the hospital due to unanticipated events in its non-hospital PCI program. Of the 827 PCI procedures performed in the CCC outpatient lab from January 1, 2016 to April 30, 2018, only 3 patients (.36%) have been transferred to the hospital.

Question 5. The proposal indicates that, in the outpatient lab setting, 70 percent of the procedures are Single Vessel PCI and 30 percent are Two Vessel PCI. What is the basis for this estimate? Is this the breakout you would expect for the Medicare population under your proposed model using

the patient selection criteria you mention in the proposal? If you estimate a different split for the Medicare population, please explain.

CCC Response

The preliminary estimate in our proposal indicating a mix of 70% one vessel PCI and 30% two vessels PCI has been updated for the actual PCIs performed in our non-hospital cath lab for period of January 1, 2016 through April 30, 2018. As we have performed a small number of three vessel PCIs in the CCC Outpatient Cath Lab, we have changed the description from two vessel to multi-vessel. Of the 827 PCI cases performed, 705 procedures or 85% were single vessel PCI and 122 procedures or 15% were multi-vessel PCI. See updated Table 3 under Question 3 above.

As noted in 6, below, 43% of the 827 PCIs performed in the CCC Outpatient Cath Lab from January 1, 2016 through April 30, 2018 were for Medicare Advantage Patients. In addition, some of our commercial PCI patients are 65 or older. Our records indicate that 401 or 48.48% of our PCI procedures were performed on patients 65 or older and 426 or 51.52% of our PCI procedures were performed on patients under age 65.

CCC applies the same inclusion/exclusion criteria regardless of age. Based on an older age for the Medicare population as compared to the combined commercial/Medicare Advantage population treated in the CCC Outpatient Lab, we anticipate there would be a slight increase in the percent of multi-vessel PCI in the Medicare population as compared to the combined commercial/Medicare Advantage population.

Question 6. Your proposal states that 825 PCIs have been performed on managed care enrollees between January 1, 2016 and April 30, 2018. The PRT is interested in learning more about managed care plan use of non-hospital cath labs.

a) Could you share the names of the managed care plans and number of PCIs paid for by each plan?

b) Please confirm that none of the 825 managed care plan enrollees are Medicare Advantage enrollees. If some are Medicare Advantage enrollees, how many and at which plans?

CCC Response

a) Our proposal stated "over 825 PCIs". The actual count was 827. CCC actively participates in most managed care plans in the Pinellas County Florida service area. These plans include commercial plans and Medicare Advantage Plans. The major managed care companies with which CCC has provider agreements include Aetna Health; AvMed; Cigna Healthcare; Blue Cross Blue Shield of Florida; Freedom Health; Health Options; Humana Healthcare; Optimum Healthcare; Tricare; and United Healthcare. CCC's contracts with most of these managed care plans include PCI in the CCC Outpatient Cath Lab.

   The confidentiality provisions of our managed care contracts preclude us from disclosing specific aspects of our contracts including volume of procedures.

b) 358 or 43% of the 827 PCI procedures were provided to enrollees of Medicare Advantage Plans. CCC has provider agreements with ten (10) Medicare Advantage Plans to provide PCI in the CCC non-hospital cath lab. CCC has contracts with two (2) Medicare Advantage plans that will begin covering Medicare beneficiaries on January 1, 2019. CCC is in the process of contracting with five (5) additional Medicare Advantage Plans.

   The confidentiality provisions of our managed care contracts preclude us from disclosing specific aspects of our contracts including volume of procedures.

Managed care plans, both Commercial and Medicare Advantage plans, have fully embraced PCI in CCC's Outpatient Cath Lab. Through contracts with CCC, these plans have enabled their members to take advantage of high quality, low cost PCI services with a very low complication rate in the CCC Outpatient Cath Lab. These members have enjoyed high quality services with excellent patient satisfaction and lower out-of-pocket cost than the hospital alternative.

Question 7. Please describe in detail the criteria you will use to ensure that only patients who could safely undergo the procedure would be selected for inclusion in the proposed model.

a) Do you anticipate using the same criteria for non-Medicare patients (generally under age 65) and Medicare enrollees?

b) To what extent will all of the factors that would exclude a patient's participation be known prior to the procedure?

c) Please describe how you triage patients with stable angina to medication therapy as an alternative to PCI.

CCC Response

a) Yes. Since inception of the CCC Outpatient Cath Lab, we have established inclusion/exclusion criteria to insure that only patients who could safely undergo the procedure will be treated in the lab. Applying this criteria has resulted in our low complication rate.

b) Prior to scheduling the procedure, all patients are seen by a CCC cardiologist. Patients who present with the following are excluded:

- 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

Most of these criteria are identified prior to scheduling the procedure. However, we recognize that some anatomic findings are only identified during coronary angiography, thus allowing the operating interventional cardiologists to determine the most appropriate course of treatment.

c) The decision to treat patients with medical therapy as an alternative to PCI is based on several factors including symptomatology (Canadian Cardiovascular Society Angina Class),

response to antianginal therapy, risk assessment and the results of functional studies. We follow the appropriate use criteria treatment guidelines established in the *ACC/AATS/AHA/ASE/ASMC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease*, When coronary angiography reveals a moderate stenosis, we encourage the use of a functional assessment such as IFR.

Question 8. The proposal states that "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." Please clarify what the term "ad-hoc" means in this context.

CCC Response

Ad-hoc PCI refers to the performance of a PCI procedure determined at the time of diagnostic coronary angiography. Ad-hoc PCIs are performed on patients who are symptomatic, have a hemodynamically significant coronary stenosis and an abnormal functional study.

Question 9. Please help the PRT understand the evidence that scrubbing 25 procedures in the previous 12 months (or 5 procedures for someone employed over 5 years in an interventional cath lab) is sufficient training to perform PCI in Medicare patients (who may present, on average, with greater frailty or comorbidities)?

CCC Response

Please allow us to clarify that item number 3 on page 7 of our proposal which is referenced above relates to the nonphysician support staff who work in the lab, such as cath lab techs and RNs. The experience noted above is the minimum experience required by the cath lab support staff during PCI. All of the support staff we have hired to date have significantly more experience than the minimum. All new employees work under direct supervision by an experienced preceptor, cath lab manager and an experienced operating physician until the employee demonstrates independent competence.

With regard to physician operators in the CCC Outpatient Cath Lab, we only allow qualified, high volume, experienced interventional cardiologists employed by CCC who have been granted privileges in the CCC Outpatient Cath Lab to operate in the facility.

Before a new CCC interventional cardiologist is granted privileges in the CCC Outpatient Cath Lab, the individual must obtain interventional cardiology and STEMI privileges at Morton Plant Hospital.

We recognize that experienced high volume operators, working in an accredited facility, will provide the highest quality and lowest complication rate. During the first year of our proposal, we would work closely with CMS/CMMI to develop the requirements for other facilities and operating physicians to participate in Bundled PCI Services.

Question 10. We recognize that the CCC Outpatient Lab is close to a hospital. However:

a) Do you anticipate that location of a non-hospital cath lab of up to 120 minutes travel time away from a hospital is sufficient to ensure quality care and safety for patients who develop complications during a PCI?

b) If this proposed model was scaled for the Medicare program, would you envision it as a safe option in rural areas that may have longer travel time to referral hospital facilities?

c) Can you help the PRT understand the specific measures of the outcomes and complications listed on page 9 that would be tracked? Will the outcomes and complications (pages 8-9) that are not collected by NCDR be available through the electronic health records (EHR)? Do you currently have experience tracking these outcomes (including complications such as falls or infections) through your EHR?

CCC Response

a) No. We believe the travel time to a hospital with coronary revascularization facilities should be no more than thirty (30) minutes for a facility to participate in this proposal at this time.

b) Yes. In the future, we believe a longer travel time may be feasible, especially if it were the only alternative in a rural area. At this time, we do not believe this proposal will be appropriate for rural areas with a longer travel time until the quality and safety standards can be developed.

c) The number and types of all the complications listed on page 9 of the proposal are currently being tracked. Certain outcomes not collected by NCDR are already available through the EHR including NYHA functional class, Canadian angina class and ejection fraction. We are currently tracking complications, including falls and infections, outside of our EHR. We will investigate integrating the tracking of these outcomes and complications through the EHR.

Question 11. We recognize that https://www.ncdr.com/WebNCDR/cathpci/home/reports provides "quarterly risk-adjusted benchmark reports with performance measures and quality metrics to compare an institution's performance with that of peer groups and the national experience." Your proposal indicates that the comparison data for Figures 1-4 are for "other outpatient PCI facilities," which we assume are primarily hospital outpatient clinics.

a) Please explain what "Vol Group" means and what type of patients are in this group.

b) Do the US data apply any other exclusions (e.g., patient age, number of vessels, etc.)

c) In Figure 2, to what extent does the substantially lower adverse event rate for CCC versus US registry data reflect better health of CCC patients (including our assumptions that none of the 825 CCC patients who received PCI is 65 or older, but that the registry includes aged or disabled Medicare beneficiaries)?

CCC Response

a) The Volume (Vol) Group refers to facilities that perform a similar number of PCI procedures annually (currently 201 – 400 annual procedures at the time of our proposal). The data includes all PCIs except STEMIs.

b) The US data does not apply any other exclusions.

c) CCC's adverse event rate includes both patients under and over age 65, as noted in 4, above.

Question 12. The high level of patient satisfaction recorded in your survey may reflect patient preferences for transradial PCI and same-day discharge (SDD) in an outpatient setting, both of which have been increasing over time due to a shift from hospital inpatient to hospital outpatient settings for Medicare beneficiaries receiving PCI. Please help the PRT understand whether you expect that patient satisfaction would be higher for patients receiving PCI in a non-hospital cath lab than in a hospital outpatient clinic with cardiac catheterization capabilities.

CCC Response

As you have seen, CCC has patient satisfaction survey results which document a very high level of patient satisfaction with the CCC Outpatient Cath Lab. We believe that patient satisfaction is largely driven by quality outcomes, highly efficient operations, and outstanding personal care. Non-hospital cath labs potentially benefit by having a higher nurse to patient ratio, greater specificity in the scope of care provided, and greater control over the number and accountability of its caregivers.

Our local hospital uses the same cath lab facilities for both inpatient and outpatient procedures. We understand this approach is common and most hospitals do not necessarily have separate inpatient and outpatient cath lab facilities.

While comparative patient satisfaction surveys do not exist, our physicians report when a patient has had a procedure in both the hospital cath lab and the CCC Outpatient Cath Lab, the patients almost always express a preference for the CCC Outpatient Cath Lab.

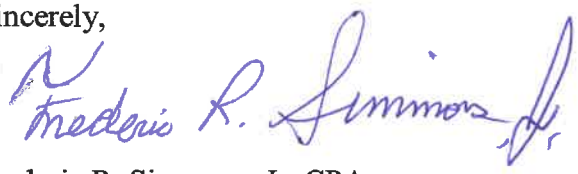
Our local hospital provides very good quality and has been consistently ranked as a Top 100 Heart Hospital. However, hospital cath labs are used for both inpatient and outpatient procedures, and therefore must give preference to emergency cases as well as outpatient cases with complex anatomy who require advanced interventional therapeutics.

As a result, scheduled outpatient procedures in the hospital cath labs often get delayed for several hours. When this happens, a scheduled outpatient who arrives early in the morning must be NPO and may get bumped to the late afternoon before the procedure can start. The patient does not eat for many hours and may become frustrated, while their families become exhausted. The patient does not get discharged until late in the evening or, even worse, the next day.

Contrast that to the CCC Outpatient Cath Lab, which only performs scheduled outpatient procedures. Generally, procedures are performed on schedule and the patient is usually discharged within a few hours of the procedure. The on-time operation of the CCC Outpatient Cath Lab leads to a higher level of satisfaction. In addition, patients treated in the CCC Outpatient Cath Lab are not exposed to potential hospital acquired infections.

We genuinely appreciate the opportunity to respond to the thoughtful questions on our proposal from the Preliminary Review Team. If you have additional questions or need further clarification to our responses, please contact me.

Sincerely,



Frederic R. Simmons, Jr. CPA
Chief Executive Officer
simmonsf@cccheart.com