MARYLAND Health Care Commission

Andrew N. Pollak, MD, Chairman **Ben Steffen**, Executive Director

Application for Certificate of Conformance
Primary and Elective Percutaneous Coronary Intervention

for the
Replacement and Relocation of
University of Maryland Shore Medical Center at Easton

(Form Revised March 2022)

Applicant
Shore Health System, Inc.
January 6, 2023

NOTE: ALL PAGES OF A HOSPITAL'S APPLICATION SHOULD BE NUMBERED CONSECUTIVELY.

Information Regarding Application for a Certificate of Conformance to Provide Primary and Elective PCI Services

The following application form is to be used by hospitals without on-site cardiac surgical backup when applying for a **Certificate of Conformance to Perform Primary Percutaneous Coronary Intervention (PCI) and Elective PCI**. Specific provisions of COMAR 10.24.17 are shown in bold, and listed beneath each is the information that the Commission requires to evaluate each application.

The applicant shall cooperate with the Commission, Commission staff, or any authorized representative(s) in supplying additional information in the course of the application's review.

The form is intended to be completed using Microsoft Word. Applicants are expected to enter narrative text where appropriate, complete the provided tables and forms, and/or submit applicant-prepared documents. The applicant may file the following with the Maryland Health Care Commission at any time: an original application, including the applicant affidavit with ink signature and supporting documents; and six copies of the application, with the applicant affidavit and supporting documents. The applicant must also submit an electronic copy of its application materials. The filing should be directed to:

Eileen Fleck
Chief, Acute Care Policy and Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

If you have any questions regarding the application form, please contact:

Eileen Fleck
Chief, Acute Care Policy and Planning
Maryland Health Care Commission
410-764-3287
eileen.fleck@maryland.gov

MARYLAND

HEALTH

CARE

COMMISSION

_____

MATTER/DOCKET NO.

_____

DATE DOCKETED

Application for Certificate of Conformance to Perform Primary and Elective Percutaneous Coronary Interventions

Applicant Information

Applicant University of Maryland Shore Medical Center at Easton

Street Address 10000 Longwoods Road

City Easton County Talbot State MD Zip Code 21601

Mailing Address (if different) _____

City _____ County _____ State _____ Zip Code _____

Medicare Provider Number(s) _____National Provider Identifier_____

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On April 11, 2016, University of Maryland Shore Medical Center at Easton ("UM SMC at Easton") received a Certificate of Conformance to provide primary and elective percutaneous coronary intervention ("PCI") services at the existing hospital. See **Exhibit 1**. On November 18, 2021, UM SMC at Easton received a Certificate of Ongoing Performance. UM SMC at Easton is now seeking a Certificate of Conformance for primary and elective PCI services in conjunction with its CON application for replacement and relocation of UM SMC at Easton in order to relocate its PCI program to the new hospital. COMAR 10.24.17.04(C)(2). If UM SMC at Easton has responded to a particular standard or criterion in the CON application, the Applicant has referred to those responses in this application in order to avoid duplication.

Review Criteria for a Certificate of Conformance (COMAR 10.24.17.06B)

(1) An applicant hospital shall demonstrate its compliance with the general standards in COMAR 10.24.10.04A.

Q1a. Is the applicant licensed and in good standing? Yes √ No ___
If yes, skip question 1b.

Q1b. Has the hospital's license been suspended, revoked, or subject to disciplinary action in the last five years? Please explain.

Q2a. Is the applicant a Medicare provider in good standing? Yes √ No ___
If no, attach an explanation.

Q2b. In the previous five years, has the applicant been sanctioned, barred, or otherwise excluded from participating in the Medicare program or been placed on a 23- or 90-day termination track? Yes ___ No √

If yes, attach an explanation.

Q3. Is the applicant accredited by the Joint Commission? Yes √ No ___
If no, attach an explanation.

Q4. In the previous three years, has the applicant had its accreditation denied, limited, suspended, withdrawn, or revoked by the Joint Commission or other accreditation organization, or had any other adverse action taken against it by an accreditation organization, including Provisional or Conditional Accreditation, Preliminary Denial of Accreditation, or Denial of Accreditation? Yes ___ No √

If yes, attach an explanation and provide copies of correspondence from the accreditation organization notifying the hospital of each change in its accreditation status and any relevant resulting correspondence.

Q5. In the previous five years, has the applicant been placed on Accreditation Watch by the Joint Commission? Yes ___No √

If yes, attach an explanation and provide copies of correspondence from the accreditation organization notifying the hospital of each change in its accreditation status.

Q6. Please provide a copy of the written policy for the provision of information to the public

concerning charges for its services. At a minimum this policy shall include:

(a) Maintenance of a representative list of services and charges that is readily available to the public in written form at the hospital and on the hospital's internet website.

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

Applicant Response

Please see the CON application response to COMAR 10.24.10.04A - Standard .04A(1) — Information Regarding Charges.

Q7. Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay. Please provide a copy of this policy and details regarding its posting in the hospital and notice to the public, including the methods used to ensure that public notice will reach the relevant population.

Applicant's Response

Please see the CON application response to COMAR 10.24.10.04A - Standard .04A (2)(a) – Charity Care Policy.

Q8. A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Services Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

Applicant's Response

Please see the CON application response to COMAR 10.24.10.04A - Standard .04A (2)(b) – Charity Care Policy.

Q9. A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that is below the statewide average shall document each action it has taken or is taking to improve performance for that Quality Measure.

Applicant's Response

Please see the CON application response to COMAR 10.24.10.04A(3) – Quality of Care.

Need

(2) An applicant shall demonstrate that the proposed program is needed for its service area population through an analysis of current utilization patterns of the population for primary PCI services

Q10. Please provide information on the number of primary PCI cases for the population originating in your hospital's service area and the estimated travel time for this population to reach the nearest existing primary PCI provider. For a hospital that seeks to relocate and which already has primary PCI services and plans to re-establish PCI services at its new location, please provide estimated travel time for the population in its service area assuming the hospital's current PCI program doesn't exist. Please identify the sources and assumptions used to estimate case volume, travel time, and door-to-balloon time.

Applicant's Response

Primary PCI Need

Eileen Fleck, Chief of the Acute Care Policy and Planning division of the MHCC provided UM SMC at Easton with data on PCI cases by Zip Code and hospital for CY 2019, 2020, and 2021. Comparing these data, UM SMC at Easton saw gains in volume for both Primary and Non-Primary PCI.

Table 1
Primary and Non-Primary PCIs
UM SMC at Easton and Statewide
CY 2019, 2020 and 2021

	Primary PCI			Non-Primary PCI		
	2019	2020	2021	2019	2020	2021
Easton	72	62	76	152	167	194
Statewide	2,951	2,860	3,007	9,681	8,018	8,715

Source: MHCC

Need

UM SMC at Easton aggregated the Zip Code data into the counties that are assigned to each Zip Code. The PCI data show that the five county region that Easton serves (Caroline, Dorchester, Kent, Queen Anne's, and Talbot) comprise its Primary PCI service area. The five county service area accounts for 94.7% of UM SMC at Easton's total PCI cases.

Table 2
Primary PCIs at UM SMC at Easton
By County
CY 2021

County	Easton Cases	%	Cum. %
Caroline	19	25.0%	25.0%
Dorchester	13	17.1%	42.1%
Kent	2	2.6%	44.7%
Queen Anne's	14	18.4%	63.2%
Talbot	24	31.6%	94.7%
Subtotal	72	94.7%	
Wicomico	1	1.3%	96.1%
Anne Arundel	2	2.6%	98.7%
Out of State	1	1.3%	100.0%
Subtotal	4	5.3%	
Grand Total	76		

Please note that while the cases from outside UM SMC at Easton's service area contributed 5.3% of the total, the percentage that will be used below in projecting UM SMC at Easton's total cases in future years will be based on the percent that is needed to "mark up" the number of cases from the service area to the total number of cases. That will be 5.6%. (76/72 = 1.056)

Residents of the five county service area generated 106 Primary PCIs in CY 2021. Table 3 below shows the number of PCIs generated by residents of each of the counties and the hospitals where the procedures were performed.

Table 3
Primary PCIs
Residents of the UM SMC at Easton PCI Service Area
By County and Hospital
CY 2021

Row Labels	UM SMC at Easton	Anne Arundel	Baltimore Washington	TidalHealth Peninsula	Prince Georges	University of MD	Delaware Hospitals	Washington DC	Invalid	Grand Total
Caroline	19						2			21
Dorchester	13			4			1		1	19
Kent	2	1					2			5
Queen Anne's	14	11	2			2	2	1		33
Talbot	24	2		1	1					28
Subtotal	72	14	2	5	1	2	7	1	1	106
All Other Counties	4	116	106	133	69	80	469	162	38	2,901
Grand Total	76	130	108	138	70	82	476	163	39	3,007

Although the Primary PCI data provided did not include the age of the patients, UM SMC at Easton is assuming that the affected population is age 45 and older. UM SMC at Easton used the Maryland Department of Planning population projections, which include age cohorts, to calculate the age 45 and older population estimates and projections for 2020, 2025, and 2030. UM SMC at Easton used the Compound Average Growth Rate (CAGR) between 2020 and 2025 to calculate the 2021 population so that it can calculate 2021 use rates by county in order to project need.

Table 4
Population, Age 45 and older
Five Counties in UM SMC at Easton's Primary PCI Service Area
2020 – 2030

	Caroline	Dorchester	Kent	QA	Talbot
2020	15,107	15,827	10,958	26,148	21,542
CAGR, 2020-2025	0.011287	0.010421	0.014262	0.008653	0.005891
2021	15,278	15,992	11,114	26,374	21,669
2025	15,979	16,669	11,762	27,299	22,184
2030	16,948	17,560	12,390	28,647	22,853

Source: Maryland Department of Planning: 2020 Total Population Projections for Non-Hispanic White, Non-Hispanic Black, Non-Hispanic Other and Hispanic by Age and Gender (12/03/2020), planning.maryland.gov/MSDC/Pages/s3_projection.aspx, Accesses 11/8/2022

Using these population estimates and projections plus the total number of Primary PCI cases (to any provider) shown, UM SMC at Easton has calculated the following need projections for Primary PCI in its service area:

Table 5
Population, Age 45 and older PCI Cases CY 2021
Primary PCI Projections to Any Provider
Five Counties in UM SMC at Easton' Primary PCI Service Area
2025 and 2030

	2021 Population Age 45 and older	2021 Cases	2021 Use Rates Per 1,000 Pop.	2025 Population Age 45 and older	2025 Cases	2030 Population Age 45 and older	2030 Cases
Caroline	15,278	21	1.37	15,979	22	16,948	23
Dorchester	15,992	19	1.19	16,669	20	17,560	21
Kent	11,114	5	0.45	11,762	5	12,390	6
Queen Anne's	26,374	33	1.25	27,299	34	28,647	36
Talbot	21,669	28	1.29	22,184	29	22,853	30
Total		106			110		115

Next, UM SMC at Easton calculated the percentage of total cases by county that were performed at UM SMC at Easton in 2021 (market share). These percentages were applied to the projections of total cases calculated above.

Table 6
Calculation of UM SMC at Easton's Market Share
Primary PCI Cases
CY 2021

	Total Cases 2021	Cases at Easton CY 2021	Market Share 2021
Caroline	21	19	90.5%
Dorchester	19	13	68.4%
Kent	5	2	40.0%
Queen Anne's	33	14	42.4%
Talbot	28	24	85.7%
Subtotal	106	72	67.9%
Other MD		3	
Other States		1	
Grand Total		76	

Applying UM SMC at Easton's CY 2021 market share to the total number of cases generated by residents of its service area, UM SMC at Easton projects that there will be 79 primary PCI cases at UM SMC at Easton in 2025 and 82 cases in 2030.

Table 7
Projection of Future Primary PCI Cases
UM SMC at Easton
2025 and 2030

	Easton Market Share 2021	Total Cases 2025	Easton Cases 2025	Total Cases 2030	Easton Cases 2030
Caroline	90.5%	22	20	23	21
Dorchester	68.4%	20	14	21	14
Kent	40.0%	5	2	6	2
Queen Anne's	42.4%	34	14	36	15
Talbot	85.7%	29	25	30	25
Subtotal	67.9%	110	75	115	78
Cases from Other Counties	5.6%		4		4
Total			79		82

Non-Primary PCI Need

UM SMC at Easton aggregated the Zip Code data into the counties that are assigned to each Zip Code. The PCI data show that the five county region that it serves (Caroline, Dorchester, Kent, Queen Anne's, and Talbot) comprise its Non-Primary PCI service area. The five county service area accounts for 94.8% of UM SMC at Easton's total Non-Primary PCI cases.

Table 8
Non-Primary PCIs at UM SMC at Easton
By County
CY 2021

County	Easton Cases	%	Cum. %
Caroline	44	22.7%	22.7%
Dorchester	42	21.6%	44.3%
Kent	11	5.7%	50.0%
Queen Anne's	19	9.8%	59.8%
Talbot	68	35.1%	94.8%
Subtotal	184	94.8%	
Prince George's	1	0.5%	95.4%
Worcester	2	1.0%	96.4%
Other States	7	3.6%	100.0%
Subtotal	10	5.2%	
Grand Total	194		

Please note that while the cases from outside UM SMC at Easton's service area contributed 5.2% of the total, the percentage that will be used below in projecting UM SMC at Easton's total cases in future years will be based on the percent that is needed to "mark up" the number of cases from the service area to the total number of cases. That will be 5.4%. (194/184 = 1.0543)

Residents of the five county service area generated 344 Non-Primary PCIs in CY 2021. Table 9 shows the number of PCIs generated by residents of each of the counties and the hospitals where the procedures were performed.

Table 9
Non-Primary PCIs
Residents of the UM SMC at Easton's PCI Service Area
By County and Hospital
CY 2021

	UM SMC at Easton	Anne Arundel	Baltimore Washington	Johns Hopkins	TidalHealth Peninsula	Prince Georges	Southern MD	St. Joseph	Union Memorial	University of MD	Upper Chesapeake	Washington Adventist	Delaware Hospitals	Washington DC	Invalid	Grand Total
Caroline	44	4			6					11			12	1	1	79
Dorchester	42			1	10		1	1		7	1		1		4	68
Kent	11	3		2	1				1	6			9	1		34
Queen Anne's	19	17	2	1					3	5			9	9		65
Talbot	68	5		1						19		1	0	3		98
Subtotal	184	29	2	5	17	0	1	1	4	48	1	1	31	14	5	344
All Other Counties	10	190	207	402	282	147	191	441	758	370	288	649	1220	899	81	
Grand Total	194	219	209	407	299	147	192	442	762	418	289	650	1251	913	86	8,715

The Non-Primary PCI data provided did not include the age of the patients. UM SMC at Easton is assuming that the affected population is age 45 and older. UM SMC at Easton used the Maryland Department of Planning population projections, which include age cohorts, to calculate the age 45 and older population estimates and projections for 2020, 2025, and 2030. UM SMC at Easton used the Compound Average Growth Rate (CAGR) between 2020 and 2025 to calculate the 2021 population so that it can calculate 2021 use rates by county in order to project need.

Table 10
Population, Age 45 and older
Five Counties in UM SMC at Easton's Non-Primary PCI Service Area
2020-2030

	Caroline	Dorchester	Kent	QA	Talbot
2020	15,107	15,827	10,958	26,148	21,542
CAGR, 2020-2025	0.011287	0.010421	0.014262	0.008653	0.005891
2021	15,278	15,992	11,114	26,374	21,669
2025	15,979	16,669	11,762	27,299	22,184
2030	16,948	17,560	12,390	28,647	22,853

Source: Maryland Department of Planning: 2020 Total Population Projections for Non-Hispanic White, Non-Hispanic Black, Non-Hispanic Other and Hispanic by Age and Gender (12/03/2020), planning.maryland.gov/MSDC/Pages/s3_projection.aspx, Accesses 11/8/2022

Using these population estimates and projections plus the total number of Non-Primary PCI cases (to any provider) shown, UM SMC at Easton has calculated the following need projections for Primary PCI in its service area:

Table 11
Population, Age 45 and older Non-Primary PCI Cases CY 2021
Non-Primary PCI Projections to Any Provider
Five Counties in UM SMC at Easton's Primary PCI Service Area
2025 and 2030

	2021 Population Age 45 and older	2021 Easton Cases	2021 Use Rates Per 1,000 Pop.	2025 Population Age 45 and older	2025 Easton Cases	2030 Population Age 45 and older	2030 Easton Cases
Caroline	15,278	79	5.17	15,979	83	16,948	88
Dorchester	15,992	68	4.25	16,669	71	17,560	75
Kent	11,114	34	3.06	11,762	36	12,390	38
Queen Anne's	26,374	65	2.46	27,299	67	28,647	71
Talbot	21,669	98	4.52	22,184	100	22,853	103
Total		344			357		374

Next, UM SMC at Easton calculated the percentage of total cases by county that were performed at UM SMC at Easton in 2021 (market share). These percentages will be applied to the projections of total cases calculated above.

Table 12
Calculation of UM SMC at Easton's Market Share
Non-Primary PCI Cases
2021

	Total Cases	Cases at Easton	Market Share
	2021	**2021**	**2021**
Caroline	79	44	55.7%
Dorchester	68	42	61.8%
Kent	34	11	32.4%
Queen Anne's	65	19	29.2%
Talbot	98	68	69.4%
Subtotal	344	184	53.5%
Other MD		3	
Other States		7	
Grand Total	344	194	

Applying UM SMC at Easton's CY 2021 market share to the total number of cases generated by residents of its service area, UM SMC at Easton projects that there will be 201 cases at UM SMC at Easton in 2025 and 210 cases in 2030.

Table 13
Projection of Future Non-Primary PCI Cases
UM SMC at Easton
2025 and 2030

	Easton Market Share 2021	Total Cases 2025	Easton Cases 2025	Total Cases 2030	Easton Cases 2030
Caroline	55.7%	83	46	88	49
Dorchester	61.8%	71	44	75	46
Kent	32.4%	36	12	38	12
Queen Anne's	29.2%	67	20	71	21
Talbot	69.4%	100	70	103	72
Subtotal	44.4%	357	191	374	200
% Cases from Other Counties	5.4%		10		11
Total			201		210

UM SMC at Easton projects that it will perform 79 Primary PCIs and 201 Non-Primary PCIs in 2025, thus exceeding 200 total cases, as it did in 2021. The replacement hospital is expected to open July 1, 2028 (FY 2029) and in 2030, UM SMC at Easton projects that it will perform 82 Primary PCIs and 210 Non-Primary PCIs, thus exceeding 200 total cases.

30 Minute Driving Time

In 2015, when UM SMC at Easton first applied for its PCI program, the relevant Maryland State Health Plan section ("State Health Plan for Facilities and Services: Specialized Health Care Services - Cardiac Surgery and Percutaneous Coronary Intervention Services," COMAR 10.24.17, Effective August 18, 2014) then in effect, recognized the need for a Primary PCI program in UM SMC at Easton's five county PCI service area. It quoted a study by the Maryland Institute for Emergency Medical Services Systems (MIEMSS), which analyzed the drive time to acute care Maryland hospitals and some hospitals outside the State based on 2010 information. The map assembled by MIEMSS shows that the two largest geographic regions beyond a 30-minute drive time to a MIEMSS designated cardiac interventional hospital included the Mid-Shore counties of the Eastern Shore (Caroline, Dorchester, Kent, Queen Anne's, and Talbot). (COMAR 10.24.17, page 11).

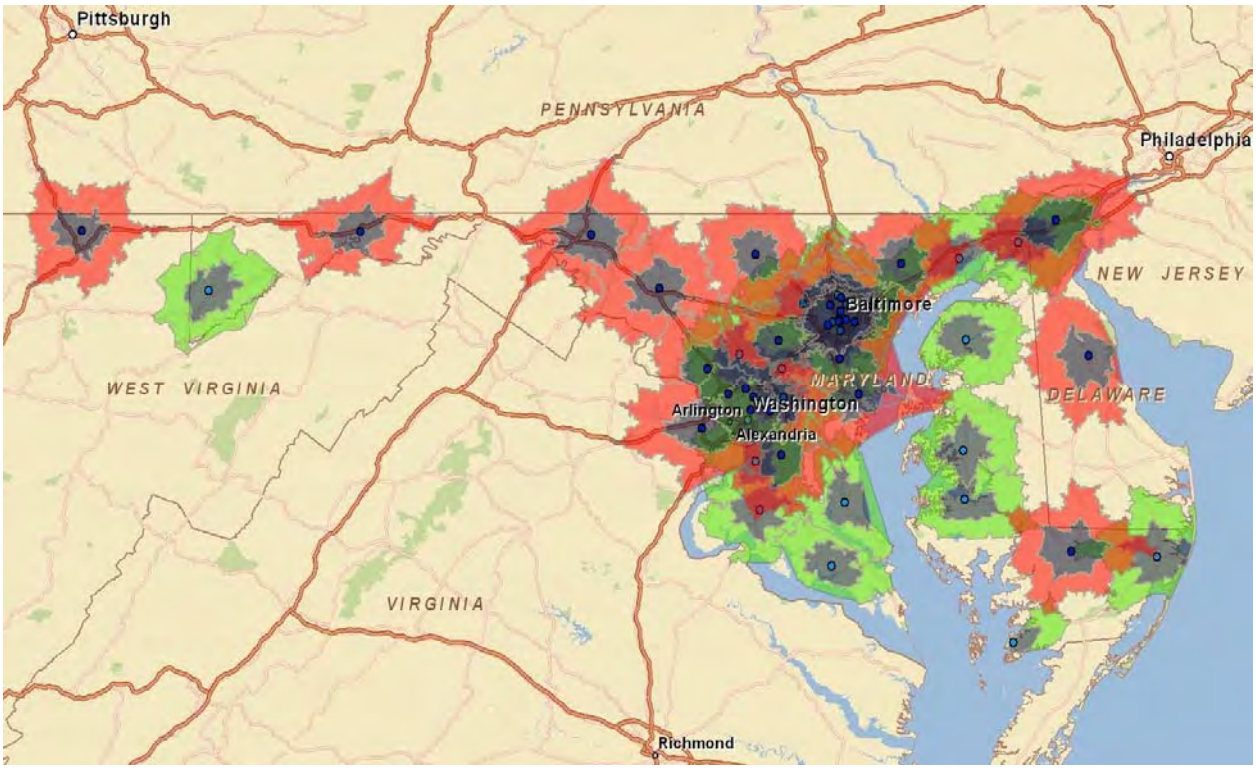
The State Health Plan chapter was updated in January 2019 and includes comparable language:

> The Maryland Institute for Emergency Medical Services Systems (MIEMSS) analyzed the drive time to acute care Maryland hospitals and some hospitals outside the State based on 2018 information. The map assembled by MIEMSS shows that the two largest geographic regions beyond a 30-minute drive time to a MIEMSS designated cardiac interventional hospital are: the three southernmost counties of Southern Maryland (Calvert, Charles, and St. Mary's); and several of

> the Mid-Shore counties of the Eastern Shore (Caroline, Dorchester, Kent, and Queen Anne's). Cardiac Interventional Centers are hospitals that have authorization from the Commission to provide primary PCI and are designated by MIEMSS and approved by its EMS Board to receive STEMI patients being transported by ambulance who meet specific criteria determined by the Maryland Medical Protocols for EMS Providers.

(COMAR 10.24.17, page 11). The MIEMSS map that is cited clearly shows that the Mid-Shore region is one of the few regions in the state that does not have 30-minute access to Primary PCI. (Regions in green do not have adequate access).

Figure 1
Maryland Institute for Emergency Medical Services Systems (MIEMSS) Map of Regions with and without 30 Minute Drive Time to Primary PCI at Acute Care Maryland Hospitals and Some Out of State Hospitals



Source:
http://mhcc.dhmh.maryland.gov/cardiacadvisory/Documents/Statewide_%20STEMI_%20map_MIEMSS_2010.jpg

If the existing PCI program at UM SMC at Easton is not approved for the replacement hospital, the area will revert to not having a PCI program within a thirty-minute drive. Table 14 below shows the driving time between the most populous city in each of the five counties and the programs at which residents of these counties received PCI in 2019. For UM SMC at Easton, the proposed new site was used. Driving time was calculated using Google Maps from the City to the PCI provider. It was generated between 1-2pm on Thursday, May 5, 2022. The table shows that there are no other PCI providers within a 30-minute drive.

Table 14
Driving Time (in Minutes)
Between the Most Populous City in Each County
In UM SMC at Easton's Primary PCI Service Area
And Major PCI Providers
May 5, 2022

	Anne Arundel	Baltimore Wash.	Bayhealth (Sussex, DE)	Christiana (Newark, DE)	Johns Hopkins	Nanticoke (Seaford, DE)	TidalHealth Peninsula	UM SMC at Easton	Univ. of MD
Denton (Caroline)	48	67	40	75	99	34	59	24	79
Cambridge (Dorchester)	68	85	70	98	116	40	38	30	99
Chestertown (Kent)	58	76	68	52	102	79	100	42	85
Centreville (Queen Anne's)	34	53	62	59	87	59	80	21	64
Easton (Talbot)	49	69	63	80	103	46	56	11	80

The above table confirms that if UM SMC at Easton's PCI program is not approved, its service area would return to not being within a 30-minute driving time from a PCI provider.

UM SMC at Easton assumes that the door-to-balloon time is the same at all providers.

Q11. Please provide information and analysis demonstrating that the simultaneous establishment of a primary PCI program and elective PCI program is required to assure the financial viability of the program. Please provide revenue and expense projections for the first four years of operation for both a primary PCI program only and for a program that includes both primary and elective PCI, using the attached Forms A and B and adhering to the instructions provided for those forms. Additionally, please provide an accompanying statement of all assumptions used in development of these revenue and expense projections.

Applicant's Response

As set forth in the response to Question 10, UM SMC at Easton projects that it will have 82 primary PCI cases in 2030. This volume would not be enough cases to enable UM SMC at Easton to retain two interventional cardiologists to maintain the primary PCI program at the replacement hospital. However, adding the projected 210 elective PCI cases to the primary PCI cases will produce a total of 292 PCI cases, which is adequate volume for retaining the cardiologists.

As a member of UM SRH, UM SMC at Easton's rates are set according to the Health Services Cost Review Commission's Global Budgeted Revenue ("GBR") program. With the exception of the downstream stress tests, which will be provided at Chesapeake Cardiology (a cardiology practice owned by UM SRH), all other PCI services will be provided in hospital space. Therefore, HSCRC Reimbursement guidelines apply.

UM SMC at Easton's PCI program is estimated to have positive contribution margin during each of the first four fiscal years that it is in operation at the replacement hospital. In

fiscal year 2032, the PCI program is projected to have a contribution margin of $1,843,030, as shown on Form B.

If UM SMC at Easton were to provide primary PCI only, not only would the whole program not be feasible for the reasons stated above, but UM SMC at Easton would not generate additional Cardiac Catheterization Laboratory volumes or physician follow-up revenue and would generate even less revenue. UM SMC at Easton needs to provide both Primary and Elective PCI for this program to be viable.

A Statement of Assumptions follows Form B**.**

Please refer to the CON application **Exhibit 1**, Table E – Project Budget for a listing of all capital costs for the replacement hospital, in lieu of Form A – Project Budget.

Access

(3) An applicant shall present evidence, including emergency transport data and patient-level data that demonstrate that the proposed program's service area population has insufficient access to emergency PCI services and is receiving suboptimal therapy for STEMI.

Q12. Please provide information that demonstrates that the population to be served by the proposed program has insufficient access to primary PCI services and currently receives suboptimal therapy for STEMI. For a hospital that seeks to relocate and which already has primary PCI services and plans to re-establish PCI services at its new location, please instead address the likely impact on access, if primary PCI services are not established at the new location of the hospital.

Applicant's Response

If UM SMC at Easton's PCI program is not re-established at the replacement hospital, there will be a clear unmet need for a Primary PCI provider in the Mid-Shore region, as demonstrated above in the response to Question 10. This fact is recognized by both MIEMSS and the Commission, as reflected in the State Health Plan. The Mid-Shore region is one of two regions that, without the program at UM SMC at Easton, would not have access to Primary PCI within a 30-minute transport time.

The 2013 STEMI Guideline: Data-driven Recommendations that Reduce Morbidity and Mortality states:

> Primary percutaneous coronary intervention (PCI) remains the recommended method of reperfusion when it can be performed in a timely fashion by experienced operators. EMS transport directly to a PCI-capable hospital for primary PCI is the recommended triage strategy. The concept of "door-to-balloon time" or "door-to-needle time" is replaced with the concept of "first medical contact (FMC)-to-device time," representing both the recognition that the key issue is triaging and treating the patient as soon as possible, not only "counting" when the patient enters an emergency room. The systems goal of FMC-to-device time is 90 minutes or less.

If the proposed program is re-established at the replacement facility, UM SMC at Easton will continue to improve the outcomes of STEMI patients in the Mid-Shore region through its

close proximity to such patients. Without the approval of the program at the replacement hospital, these patients would need to be transferred to farther regions for care. As demonstrated above, UM SMC at Easton's program significantly improves transport time and access to care for residents of the Mid-Shore region. Providing PCI services at the replacement UM SMC at Easton facility would reduce the drive time for patients of the Mid-Shore region to the next closest provider, which as demonstrated in the response to Question 10, would be more than 30 minutes away.

(4) The hospital shall demonstrate that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served.

Q13a. Please provide information on the expected travel time for the population to be served, based on travel from their location of residence to the nearest available provider of primary PCI services and to your hospital. For a hospital that seeks to relocate and which already has primary PCI services and plans to re-establish PCI services at its new location, please provide estimated travel time for the population in its service area based on the proposed new location of the hospital instead of the current location. Please identify the sources and assumptions used for this analysis.

Applicant's Response

Please see the responses to questions 10 and 12.

Q13b. Please provide an explanation as to why an elective PCI program is needed to preserve timely access to emergency PCI services.

Applicant's Response

As discussed in response to Question 10, UM SMC at Easton projects that it will perform 82 Primary PCIs and 210 Non-Primary PCIs in 2030. If UM SMC at Easton did not have an elective PCI program in addition to its primary PCI program, UM SMC at Easton would not generate sufficient volumes for the program to remain financially viable. The lower total volumes that would result from UM SMC at Easton offering primary PCI services only would also result in physician recruiting challenges. The projected 82 Primary PCI cases alone would not be sufficient to retain two full-time interventionalists. By providing both primary and elective PCI services, UM SMC at Easton's interventional cardiologists are consistently able to provide at least 200 PCI cases per year in the aggregate, which allows them to maintain the appropriate skill level required for these specialized procedures.

Moreover, as discussed in response to Question 12, UM SMC at Easton's PCI program is necessary to preserve access to PCI services for patients of the Eastern Shore. Without a PCI program at UM SMC at Easton, patients on the Shore will have no options for treatment within the recommended minimum drive time of 30 minutes, and would be transferred to further options for care.

Because the elective PCI program is needed to ensure financial viability of the PCI program overall and to maintain sufficient PCI case volumes, the elective PCI program is a critical component of UM SMC at Easton's continued ability to offer emergency PCI services. UM SMC at Easton must continue to provide both elective and primary PCI services to ensure patients on the Shore have sufficient access to emergency PCI services.

Volume

(5) An applicant shall document that its proposed primary PCI program will achieve a volume of at least 36 PCI cases by the end of the second year of providing primary PCI services if the hospital is located in a rural area or an annual volume of at least 49 cases if the hospital is located in a non-rural area.

Q14. Please provide information that supports your projection of primary PCI case volume at your hospital by the end of the second full year of operation as a provider of primary PCI.

Applicant's Response

The replacement facility is anticipated to open in July 2028. As demonstrated in the response to Question 10, UM SMC at Easton projects that it will treat approximately 82 Primary PCI cases in 2030.

(6) An applicant shall document that its proposed elective PCI program will achieve a volume of 200 or more total PCI cases by the end of the second year of providing elective PCI services. The Commission may waive the volume requirement of 200 or more total PCI cases by the end of the second year, if the applicant demonstrates that adding an elective PCI program at its projected annual case volume will permit the hospital's PCI service (emergency and elective) to achieve financial viability.

Q15. Are you requesting that the volume requirement of 200 cases be waived?
Yes ___ No √

If yes, skip question 16.

Q16. Please provide information that supports a projected PCI case volume of 200 or more cases by the end of the second full year of operation as a provider of elective PCI. Please provide projections for primary PCI cases and elective PCI cases separately, and include an explanation of the assumptions used to develop the projected primary and elective PCI case volumes.

As demonstrated in the response to Question 10, UM SMC at Easton projects that it will treat approximately 210 Non-Primary PCI cases in 2030.

Institutional Resources

(7) The hospital shall demonstrate that primary PCI services will be available for all appropriate patients with acute myocardial infarction 24 hours per day, seven days per week.

Q17a. Please provide information plans for handling downtime that may occur due to required equipment maintenance or unforeseen circumstances.

Applicant's Response

At the replacement hospital, UM SMC at Easton will perform diagnostic catheterization, cardiac rhythm device implantation (PM, ICD, BiV) in two, dedicated cardiac catheterization

laboratories. As seen on page 7 of the project drawings, attached hereto as **Exhibit 2**, the two cardiac catheterization labs will be located on the second floor across from the electrophysiology lab and adjacent to the Operating Room (OR) suites.

Regular maintenance for radiation emitting imaging equipment is of primary importance in providing safe operations for patients and staff. In that regard, regularly scheduled preventative maintenance will be carried out in a manner to ensure that the laboratories will always remain in service.

In the unlikely event that service is interrupted in both laboratories due to an unforeseen failure, patients scheduled for elective procedures will be rescheduled. "Walk-in" STEMI patients who would possibly arrive during a period where both laboratories are out of service would be transferred to the nearest approved CIC Center in the same manner that UM SMC at Easton currently transfers those patients. For those STEMI patients transferred by EMS, County EMS 911 Centers will be notified of the temporary inability to perform primary angioplasty for STEMI patients arriving by EMS. They will be able to reroute the ambulances and transport STEMI patients to an approved alternative CIC Center by the protocols currently in place.

Q17b. For a hospital with PCI services that seeks to relocate, please provide updated information on the downtime of the CCL since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.

The cardiac cath lab at UM SMC at Easton has experienced three downtime incidents since its last report to MHCC Staff that resulted in the temporary inability to provide primary PCI services. During these downtime incidents, all four of Shore Regional Health's emergency departments (EDs) were notified, as well as the ED/ICU managers, the Administrator on-call, nursing supervisor, ED Medical Director, Chief Medical Officer, the Vice President of Ambulatory Services, Talbot County Region IV EMS and the State Medical Director of MIEMSS. UM SMC at Easton also made courtesy calls to the surrounding EDs and cath labs, including Tidal Health and Anne Arundel Medical Center. Finally, UM SMC at Easton developed a plan to notify EMS of all walk-in STEMIs for immediate transfer to the closest CIC center. Details of the downtime incidents are provided below. This response covers all downtime incidents since last reported, through November 15, 2022.

Date/Time of Incident	Date/Time Resolved	Describe Incident	Specific Considerations
3/17/2021 12:48	3/17/2021 16:39	Code yellow – internal disaster. Water damage and flooding in multiple departments including both cardiac cath labs.	STEMI divert until code yellow cleared and equipment inspected for safe use.
12/23/2021 16:13	12/23/2021 19:39	Lack of staffing. Numerous staff with high risk COVID-19 exposure and required to quarantine per state COVID-19 guidelines and Employee Health directive.	STEMI divert in place. Staffing plan was put into place in order to have staff return to work with monitoring, testing and adequate PPE.
7/15/2022 17:30	7/15/2022 20:00	Lack of staffing. Numerous staff members tested positive for COVID-19 and were required to	STEMI divert was put in place. Staffing plan was put in place to

		quarantine per state COVID-19 guidelines and Employee Health directive	provide coverage and ensure services could resume.

To avoid downtime, UM SMC at Easton schedules preventative maintenance of its two procedure rooms in advance so as to ensure that one of the two procedure rooms are immediately available.

Required preventative maintenance is scheduled and performed by University of Maryland Medical System (UMMS) BioMedical Services and is up to date.

(8) The hospital shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. The hospital shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

Q18a. Please provide a signed statement from the hospital's chief executive officer acknowledging agreement with the above statement.

Applicant's Response

Please see **Exhibit 3**.

Q18b. For a hospital with PCI services that seeks to relocate, please provide updated information on the door-to-balloon times for non-transfer patients by quarter since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.

Applicant's Response

Documentation of Door to Balloon times for transfer and non-transfer cases for each quarter for which data is available since Quarter 4 of 2020 are provided below:

Table 15
Door to Balloon Times for Transfer and Non-Transfer Cases
Q1 2021 through Q1 2022

Quarter	Number of non-transfer primary PCI cases with DTB of 90 minutes or less (STEMI patients)	Total number of non-transfer primary PCI cases	Percent of Cases
2021 Q1	8	8	100%
2021 Q2	5	5	100%
2021 Q3	11	11	100%
2021 Q4	5	5	100%
2022 Q1	9	9	100%

(9) The hospital shall have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to patients with acute myocardial infarction 24 hours per day, seven days per week.

Q19. Please provide information on the proposed staffing pattern, including on-call coverage, and backup coverage that demonstrates the hospital will be able to meet the requirement that cardiac catheterization laboratory and coronary care unit services are available to patients with acute myocardial infarction 24 hours per day, seven days per week.

Applicant's Response

UM SMC at Easton's cardiac catheterization laboratories, along with the ED, telemetry unit, and Intensive Care/Coronary Care Unit (ICU/CCU) are available to patients with acute myocardial infarction 24 hours/day, 7 days/week. The ED, telemetry unit, and ICU/CCU will be staffed 24 hours/day, 7 days/week.

UM SMC at Easton's staffing plans for the cardiac catheterization laboratories at the replacement facility will be the same as for the existing facility. Staff-to-patient ratios determine the staffing level for any given shift. At the existing facility, UM SMC at Easton has two (2) cardiac catheterization laboratories. The current cardiac catheterization laboratory is staffed Monday-Friday, 7 a.m.-5:30 p.m. (See Staffing Pattern in response to Question 20). Staffing consists of a minimum of one interventional cardiologist, one to two registered nurses (RN), and/or one to two cardiovascular technologists assigned to each of two procedure rooms. This will result in teams of a minimum of three staffing personnel with combinations of RNs and technologists. After hours coverage (5:30 p.m.-7 a.m. Monday-Friday and 24 hours per day Saturday and Sunday) are covered by on-call staff. The after hours and weekend call teams will consist of a minimum of one interventional cardiologist supported by a team of three to four

nurses and technologists. Each team will have a minimum of one RN with the rest of the team made up of a combination of RNs and technologists, totaling a minimum of three team members.

UM SMC at Easton
PCI Services
Cardiac Catheterization Laboratory

CCL Room	Days and Hours of Operation							
	Hours	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Room 1	Regular:	7:00am - 5:30pm	7:00am - 5:30pm	7:00am - 5:30pm	7:00am - 5:30pm	7:00am - 5:30pm	N/A	N/A
Room 2	Regular:	8:00am - 5:30pm	8:00am - 5:30pm	8:00am - 5:30pm	8:00am - 5:30pm	8:00am - 5:30pm	N/A	N/A
	On-Call:	5:30pm - 7:00am	5:30pm - 7:00am	5:30pm - 7:00am	5:30pm - 7:00am	5:30pm - 7:00am	24 hours	24 hours

Type of Clinical Staff on Team	Number of Staff	Call Rotation	Response Time
MD	**3**	**1730-0700 M-F; 24 hours Sat-Sun**	**30 minutes**
Nurses	**5**	**1730-0700 M-F; 24 hours Sat-Sun**	**30 minutes**
Technologists	**4**	**1730-0700 M-F; 24 hours Sat-Sun**	**30 minutes**

During regular hours of operation as depicted above, each cardiac catheterization laboratory will consist of a minimum of three staff members available in each of the two laboratories.

Q20. Complete the following table to show the number of physicians, nurses, and technicians who are available and able to provide cardiac catheterization services to acute myocardial infarction patients (as of one week before the due date of the application). Also indicate whether the nursing and technical staff are cross-trained to scrub (S), circulate (C), and monitor (M).

Total Number of CCL Physician, Nursing, and Technical Staff:

	Number/FTEs	Cross-Training (S/C/M)
Physician		
Nurse	(FTE)	
Technician	(FTE)	

Applicant's Response

Considering that only RNs are able to administer medication, each team will consist of a minimum of one RN who will be assigned to circulate and, therefore, capable of administering medications as ordered.

Total Number of CCL Physician, Nursing, and Technical Staff

	Number/FTEs	Cross-Training (S/C/M)
Physician	3.0 FTE	Interventional Cardiologist
Nurse	7.25 FTE	C/M
Technician	3.0 FTE	S/C/M
Coordinator	1.0 FTE	S/C/M

Assignments:
S = Scrub
C = Circulate
M = Monitor

There are a total of eight cardiologists practicing full-time on the Eastern Shore on the staff of UM SMC at Easton. Three FTE interventionalists are on staff for the routine provision of cardiac catheterization services 24 hours per day, seven days per week.

(10) The hospital president or chief executive officer, as applicable, shall provide a written commitment stating the hospital administration will support the program.

Q21. Submit a letter of commitment, signed by the hospital president or chief executive officer, acknowledging that the hospital will provide primary PCI services in accord with the requirements for primary PCI programs established by the Maryland Health Care Commission.

Applicant's Response

Please see **Exhibit 4**.

(11) The hospital shall maintain the dedicated staff necessary for data collection, management, reporting, and coordination with institutional quality improvement efforts.

Q22. Please list each position responsible for these activities for primary PCI services and the number of staff FTEs dedicated to these activities.

Applicant's Response

The Interventional Cardiology PCI Program at the replacement facility will participate in the American College of Cardiology's National Cardiovascular Registry (ACC-NCDR), Get with the Guidelines (GWTG) Registry, Johns Hopkins MACPAQ external review and Cardiac Cath/PCI Registry.

Data entry is completed by existing designated FTE positions within the cardiac catheterization lab and by using the services of a health care clinical data management company, Q-Centrix. The cardiac catheterization Laboratory Manager, Clinical Coordinator, and RNs who work in the cardiac catheterization laboratory also assist with the data collection efforts.

The Regional Director for Cardiovascular Services along with the Medical Director for Cardiac Services and the Director for Interventional Cardiology will oversee the quality data collection process.

(12) The hospital shall complete a PCI development plan that includes appropriate training for the emergency room, catheterization laboratory, coronary care unit, if applicable, post-procedure unit. The plan shall include protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure. In addition, there shall be an on-call coverage back-up plan for primary PCI cases, when an on-call interventionalist covers more than one hospital on a given shift, as well as when two simultaneous STEMI patients present at the hospital.

Q23. Please submit a copy of the applicable policies and procedures. If simultaneous on-call coverage is not permitted, please state this.

Applicant's Response

An on-call coverage back up plan is not required, as UM SMC at Easton's interventionalists will not be covering more than one hospital. Copies of the applicable policies and procedures are attached hereto as **Exhibit 5.**

UM SMC at Easton has established staff training protocols in its ED, cardiac catheterization laboratory (CCL), Intensive Care Unit (ICU), and Telemetry Unit for the care of PCI patients. All new ED staff attend a departmental orientation. During this orientation, the ACS and STEMI processes are reviewed, including EMS notification and arrival and identification based upon presentation in triage and changes in clinical condition. During new nurse residency in the ED, nurses receive education on ACS recognition, 12 lead EKG interpretation, and interventions. ED triage and assessment, as well as processes for STEMI recognition, activation, and management, are reviewed monthly with associated data at the Cardiac Services Steering Committee. Staff receive feedback as necessary based on these monthly reviews. The UM SMC at Easton ED triage nurse must have at least six months of recent emergency nursing experience post-orientation and complete a clinical orientation to the role with a preceptor. Finally, ED staff competencies are reviewed annually, and cardiac assessment is covered as a key component of those competencies.

All staff members in UM SMC at Easton's CCL attend Hospital New Employee Orientation, followed by a CCL departmental orientation. A job description and review is part of each new staff member's orientation to the CCL. UM SMC at Easton also requires an annual skills competency validation for all CCL clinical staff, along with periodic ongoing educational sessions. These ongoing educational trainings may be conducted by interventional cardiologists, vendor experts, or fellow UM SMC at Easton CCL staff. Education may take place in-person, through computer-based education modules, and/or through webinars. UM SMC at Easton requires annual performance evaluations for all employees. The CCL employee performance evaluations include a self-evaluation and two peer evaluations.

Following a determination that a patient needs an inpatient bed, the cardiac catheterization Lab Coordinator works with the inpatient Admission Coordinator to arrange for bed placement based on the patient's outcome. Patients receiving an intervention are placed in the ICU for immediate recovery. Non-interventional catheterization inpatients are placed in the Telemetry unit for immediate recovery. Staff of the UM SMC at Easton ICU and Telemetry Units are required to undergo initial staffing orientation as new employees. All ICU and Telemetry Unit clinical staff have annual competency reviews as well.

(13) The hospital shall identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the cardiac catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

Q24. Please name the anticipated director of interventional cardiology services, or if unknown, please commit to providing this information to Commission staff 90 days prior to first use approval.

Applicant's Response

The Medical Director of interventional cardiology services is Jeffrey Etherton, MD.

(14) The hospital shall design and implement a formal continuing medical education program for staff, particularly the cardiac catheterization laboratory and coronary care unit.

Q25. Please provide a list of the continuing educational programs and activities in which staff in the CCL and the Coronary Care Unit will participate in the first year of operation of the PCI program.

Applicant's Response

UM SMC at Easton's staff participate in continuing education trainings and services throughout the year as needed or required. These educational activities may include independent assigned learning, staff meetings, clinical inquiry meetings, best practice meetings, and PCI performance meetings. UM SMC at Easton requires annual mandatory compliance training for all staff which is assessed, monitored and tracked through a learning management system. The mandatory training modules include, but are not limited to annual safety, moderate sedation, dysrhythmia, fire safety, emergency management and infection control updates. All annual mandatory compliance trainings, educational certificates and rosters received by staff are filed within the department the staff is assigned to work and are included in the staff's annual performance evaluation.

UM SMC at Easton suggests and encourages staff to participate in continuing education. Staff members in the cardiac catheterization lab are assessed in their annual performance evaluation for their efforts to seek and support opportunities for professional growth and development. Unit based and continuing education is provided regularly to staff. For example, in calendar year 2021, UM SMC at Easton provided the following sessions for its cardiac catheterization lab staff:

- Rhythm Correction Devices
- Electrophysiology Studies

- Leadless Pacemaker Devices/ Implantation
- Vascular Access & Complications with Terumo
- Anti-Platelet Therapy
- Peripheral Intervention (pre, intra, post care)
- Peripheral Intervention case study
- Electrophysiology – AVNRT
- Guideline Directed Post Intervention Care
- IVUS/FFR/DFR
- Intra-aortic balloon pump setup and management
- Cardiac Catheterization Case Reviews

Unit based and continuing education sessions offered thus far in calendar year 2022 include:

- Cardiac Intervention Review
- Cardiac Catheterization Case Reviews
- Anti-Platelet Therapy
- FFR
- Implant Devices / Rhythm Correction updates
- IVUS
- Intra-aortic balloon pump
- Emergency Management; Code Cart and Defibrillator

(15) A hospital performing primary PCI without on-site cardiac surgery shall have a formal written agreement with a tertiary institution that provides for the unconditional transfer of the hospital's patients for any required additional care, including emergent or elective cardiac surgery or PCI.

Q26. Does the hospital have a current signed and dated agreement with a tertiary care center that provides for the unconditional transfer of primary PCI patients from the applicant hospital to the tertiary institution and that covers the transfer of each non-primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI? Yes √ No ___

If yes, please provide a copy. If no, provide either a new agreement or a signed and dated amendment to an existing agreement.

Applicant's Response

Please see **Exhibit 6**.

(16) A hospital that performs primary PCI without on-site cardiac surgery shall maintain its agreement with a licensed specialty care ambulance service that, when clinically necessary, guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by the hospital.

Q27. Does the hospital's signed and dated formal written agreement with a currently licensed advanced cardiac support emergency medical services provider guarantee the arrival of an air or ground ambulance at the applicant hospital within 30 minutes of a request from that hospital for the transport of a primary PCI patient to a tertiary care

center? Yes √ No ___

If yes, please provide a copy. If no, provide either a new agreement or a signed and dated amendment to an existing agreement with a currently licensed advanced cardiac support emergency medical services provider that provides such a guarantee.

Applicant's Response

Please see **Exhibit 7** for Shore Health System's contract with Butler Medical Transport, LLC ("Butler"). Section 3.A requires Butler to arrive within 30 minutes for all "Time-Critical Transports" and Section 3.H requires Butler to arrive within 30 minute for all patients meeting STEMI criteria.

Quality

(17) A hospital shall develop a formal process for interventional case review that includes regularly scheduled meetings (at least every other month) with required attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

Q28a. Please submit a signed letter of commitment from the hospital chief executive officer, acknowledging that the hospital will meet this standard, if the applicant hospital obtains Commission approval to establish a primary PCI program.

Applicant's Response

Please see **Exhibit 8**.

Q28b. For a hospital with PCI services that seeks to relocate please provide updated information on the dates and attendees at interventional case review meetings since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.

Applicant's Response

Please see **Exhibit 9** for the dates and attendees at interventional case review meetings since last reported to MHCC Staff as part of UM SMC at Easton's latest Certificate of Ongoing Performance application that was filed on August 26, 2020. This Exhibit provides dates and attendees at meetings of the Cardiac Services Steering Committee, during which interventional case reviews are conducted, through September 2022.

(18) A hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

Q29a. Please submit a signed letter of commitment from the hospital chief executive officer, acknowledging that the hospital will meet this standard, if the applicant hospital obtains Commission approval to establish a primary PCI program.

Applicant's Response

Please see **Exhibit 10**.

Q29b. For a hospital relocation project, in which the hospital already has PCI services, please provide updated information on the dates and attendees at multiple care area group meetings since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.

Applicant's Response

Many years ago, long before UM SRH submitted an application for a Certificate of Conformance for performing PCI services at UM SMC at Easton, the Department of Cardiovascular Services established a multi-disciplinary group: the Cardiac Services Steering Committee.

This group originally was focused on evaluating the patient experience and clinical outcomes of patients who entrusted their cardiac care to UM SRH facilities. Initially those meetings were held every other month.

However, since approval to provide primary elective PCI by MHCC in October 2015, the meetings were changed to monthly meetings.

Please see **Exhibit 9** for a list of attendees of meetings of the Cardiac Services Steering Committee since last reported through February 2021 to MHCC as part of its recent Certificate of Ongoing Performance. This Exhibit provides the dates and attendees of all meetings through September 2022.

(19) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period as provided in Regulation .08 that includes at least three cases per physician or all cases if the interventionalist performed fewer than three cases.

Q30a. Please submit a signed letter of commitment from the hospital chief executive officer, acknowledging that, if the applicant hospital obtains Commission approval to establish a primary PCI program, the hospital will meet this standard.

Applicant's Response

Please see **Exhibit 11**.

Q30b. For a hospital relocation project, in which the hospital already has PCI services, please provide updated information on the results from external reviews completed since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.

Applicant's Response

UM SMC at Easton has contracted with Maryland Academic Consortium for Percutaneous Coronary Intervention Appropriateness of Quality (MACPAQ) to perform periodic external case reviews as required by MHCC.

A copy of each Executive Summary report issued by MACPAQ since last reported to MHCC through June 2020 as part of its recent Certificate of Ongoing Performance is provided in **Exhibit 12**. Reports are available through June 2021, the most recent report UM SMC at Easton received from MACPAQ.

(20) The hospital shall evaluate the performance of each interventionalist through an internal or external review as described in COMAR 10.24.17.07C (4)(d).

Q31a. Please submit a signed letter of commitment from the hospital chief executive officer, acknowledging that, if the applicant hospital obtains Commission approval to establish a primary and elective PCI program, the hospital will meet this standard.

Applicant's Response

Please see **Exhibit 13**.

Q31b. For a hospital relocation project, in which the hospital already has PCI services, please provide updated information that demonstrates the hospital has continued to comply with this standard the since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process.

Applicant's Response

Please see the response to Question 30b.

Physician Resources

(20) Physicians who perform primary PCI services at a hospital that provides primary PCI without on-site cardiac surgery shall achieve an average annual case volume of 50 over a 24-month period. A hospital without on-site cardiac surgery shall track physicians' volume on a rolling eight quarter basis and report the results to the Commission on a quarterly basis.

Q32a. Please submit a signed letter from the hospital chief executive officer, acknowledging that, if the applicant hospital obtains Commission approval to establish a primary PCI program, it will submit documentation that demonstrates compliance with this standard 90 days prior to first use. The applicant shall submit to Commission staff a roster of all physicians who will be performing primary PCI with documentation showing that each currently meets the case volume requirement, using Form C.

Applicant's Response

Please see **Exhibit 14**. Please see copies of Form C below for each physician who will be performing PCI services at the existing facility.[1] UM SMC at Easton assumes that these same interventionalists will perform primary PCI at the replacement facility. Because the

[1] The volumes shown in Form C for each physician may include some diagnostic procedures that did not result in a PCI. This is because the data is pulled based on a CPT code of "heart cath with no indication of PCI or not." Accordingly, the aggregate volume of all procedures in Form C for each Easton physician may be slightly higher than the aggregate primary and elective actual PCI volumes shown in response to question 10.

replacement facility is not expected to open until July 1, 2028, there may be changes to UM SMC at Easton's physician staffing prior to its opening. UM SMC at Easton will re-submit updated Form C 90 days prior to first use at the replacement facility.

Q32b. For a hospital relocation project, in which the hospital already has PCI services, please provide updated information that demonstrates the hospital has continued to comply with this standard since last reported to MHCC staff as part of the Certificate of Ongoing Performance application process. Staff notes that for the period of CY 2020 and CY 2021, this standard was waived due to the COVID-19 pandemic.

Applicant's Response

Please see the Applicant's response to Question 32a. Each Form C submitted provides the interventionalists' volumes since they were last reported with UM SMC at Easton's Certificate of Ongoing Performance.

Patient Selection

(21) An applicant shall commit to providing primary PCI services only for suitable patients. Suitable patients are:

Patients described as appropriate for primary PCI in Expert Guidelines[2]

Patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) reasonably concludes may be harmed if transferred to a tertiary institution, either because the patient is too unstable or because the temporal delay will result in worse outcomes.

Patients for whom primary PCI services were not initially available who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of cases.

Patient who experienced a return of spontaneous circulation following cardiac arrest and present at a hospital without on-site cardiac surgery for treatment, when the treating physician(s) reasonably concludes that transfer to a tertiary institution may be harmful for the patient.

(22) The hospital shall commit to providing elective PCI services only for suitable patients. Suitable patients are:

Patients described as appropriate for elective PCI in Expert Guidelines.

For elective PCI programs without cardiac surgery on-site, patients at high procedural risk are not suitable for elective PCI, as described in Expert Guidelines.

[2] Expert Guidelines are the Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHS) for Management of Patients with Acute Myocardial Infarction or in the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention.

Q33. Please provide a signed statement from the hospital's chief executive officer and medical director of cardiac interventional services attesting to the hospital's commitment to meeting the standards for patient selection.

Applicant's Response

Please see **Exhibit 15**.

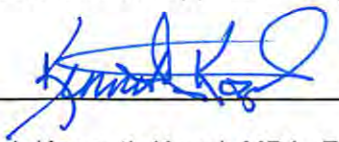
Section E – Applicant Affidavit

I solemnly affirm under penalties of perjury that the contents of this application, including all attachments, are true and correct to the best of my knowledge, information, and belief. I understand that if any of the facts, statements, or representations made in this application change, the hospital is required to notify the Commission in writing.

If the Commission issues a Certificate of Conformance to permit the hospital to perform PCI procedures, the hospital agrees to timely collect and report complete and accurate data as specified by the Commission. I further affirm that this application for a Certificate of Conformance to perform primary and elective percutaneous coronary interventions has been duly authorized by the governing body of the applicant hospital, and that the hospital will comply with the terms and conditions of the Certificate of Conformance and with other applicable State requirements.

If the Commission issues a Certificate of Conformance to permit the hospital to perform PCI procedures, the hospital agrees that it will voluntarily relinquish its authority to provide PCI services upon receipt of notice from the Executive Director of the Commission if the hospital fails to meet the applicable standards for a Certificate of Conformance, Certificate of Ongoing Performance, or performance standards included in a plan of correction when the hospital has been given an opportunity to correct deficiencies through a plan of correction.

I have been designated by the Board of Directors of the applicant hospital to complete this affidavit on its behalf.

Signature of Hospital-Designated Official 

Printed Name of Hospital-Designated Official: Kenneth Kozel, MBA, FACHE

Title: President & CEO

Date: January 6, 2023

Form A: PROJECT BUDGET

INSTRUCTION: This form is to be completed if capital expenditures will be necessary for the applicant hospital to provide primary PCI services. All estimates for 1.a.-d., 2.a.-h., and 3 are for current costs as of the date of application submission and should include the costs for all intended construction and renovations to be undertaken. DO NOT CHANGE THIS FORM OR ITS LINE ITEMS. IF ADDITIONAL DETAIL OR CLARIFICATION IS NEEDED, ATTACH ADDITIONAL SHEETS.

The Applicant notes that a CON Application for the replacement hospital has been filed concurrently with this Certificate of Conformance Application. The Applicant has completed Table E – Project Budget in that CON Application. For all capital expenditures associated with the replacement hospital, please see the CON Application Table E in lieu of this Form A.

A. Use of Funds

1. Capital Costs:

a.	New Construction	$ _____
(1)	Building	_____
(2)	Fixed Equipment (not included in construction)	_____
(3)	Land Purchase	_____
(4)	Site Preparation	_____
(5)	Architect/Engineering Fees	_____
(6)	Permits, (Building, Utilities, Etc)	_____
SUBTOTAL		$ _____
b.	Renovations	
(1)	Building	$ _____
(2)	Fixed Equipment (not included in construction)	_____
(3)	Architect/Engineering Fees	_____
(4)	Permits, (Building, Utilities, Etc.)	_____
SUBTOTAL		$ _____
c.	Other Capital Costs	
(1)	Major Movable Equipment	_____
(2)	Minor Movable Equipment	_____
(3)	Contingencies	_____
(4)	Other (Specify)	_____
TOTAL CURRENT CAPITAL COSTS (a - c)		$ _____
d.	Non Current Capital Cost	
(1)	Interest (Gross)	$ _____
(2)	Inflation (state all assumptions, Including time period and rate)	$ _____

TOTAL PROPOSED CAPITAL COSTS $ _____
(a - d)

2. Financing Cost and Other Cash Requirements:

a.	Loan Placement Fees	$ _____
b.	Bond Discount	_____
c.	Legal Fees (CON Related)	_____
d.	Legal Fees (Other)	_____
e.	Printing	_____
f.	Consultant Fees	
	CON Application Assistance	_____
	Other (Specify)	_____
g.	Liquidation of Existing Debt	_____
h.	Debt Service Reserve Fund	_____
i.	Principal Amortization Reserve Fund	_____
j.	Other (Specify)	_____

TOTAL (a - j) $ _____

3. Working Capital Startup Costs $ _____

TOTAL USES OF FUNDS (1 - 3) $ _____

B. Sources of Funds for Project:

1.	Cash	_____
2.	Pledges: Gross _____, less allowance for uncollectables _____ = Net	_____
3.	Gifts, bequests	_____
4.	Interest income (gross)	_____
5.	Authorized Bonds	_____
6.	Mortgage	_____
7.	Working capital loans	_____
8.	Grants or Appropriation	
	(a) Federal	_____
	(b) State	_____
	(c) Local	_____
9.	Other (Specify)	_____

TOTAL SOURCES OF FUNDS (1-9) $ _____

Lease Costs:

a. Land	$_____	x _____	= $_____
b. Building	$_____	x _____	= $_____
c. Major Movable Equipment	$_____	x _____	= $_____
d. Minor Movable Equipment	$_____	x _____	= $_____
e. Other (Specify)	$_____	x _____	= $_____

Form B: REVENUES AND EXPENSES – Percutaneous Coronary Intervention Services

INSTRUCTIONS: Specify whether data are for calendar year or fiscal year. All projected revenue and expense figures should be presented in current dollars. Specify sources of non-operating income. This table must be accompanied by a statement of all assumptions used in projecting all revenues and expenses. Please assure that the revenue and expenses figures in this table are consistent with the historic and project utilization of PCI services at the applicant hospital and the information on staffing of this service provided elsewhere in this application.

Revenues and Expenses – PCI Services	Projected Years (ending with third full year in which the applicant projects provision of primary PCI services			
CY or FY (Circle)	2029	2030	2031	2032
1. Revenue				
a. Inpatient Services	$1,684,885	$1,700,049	$1,715,348	$1,730,781
b. Outpatient Services	$3,623,376	$3,655,986	$3,688,885	$3,722,075
c. Gross Patient Services				
2. Adjustments to Revenue				
d. Allowance for Bad Debt	$36,998	$37,331	$37,667	$38,006
e. Contractual Allowance	$938,663	$947,111	$955,634	$964,232
f. Charity Care	$10,951	$11,050	$11,149	$11,250
g. Net Patient Services Revenue	$4,321,649	$4,360,543	$4,399,783	$4,439,368
h. Other Operating Revenues (Specify)				
i. Net Operating Revenue	$4,321,649	$4,360,543	$4,399,783	$4,439,368
3. Expenses				
a. Salaries, Wages, and Professional Fees, (including fringe benefits)	$718,926	$731,352	$743,993	$756,852
b. Contractual Services				
c. Interest on Current Debt				
d. Interest on Project Debt				
e. Current Depreciation				
f. Project Depreciation				
g. Current Amortization				

Revenues and Expenses – PCI Services	Projected Years (ending with third full year in which the applicant projects provision of primary PCI services			
CY or FY (Circle)	2029	2030	2031	2032
h. Project Amortization				
i. Supplies	$1,589,651	$1,658,736	$1,730,824	$1,806,043
j. Other Expenses (Purchased Services)	$31,093	$31,857	$32,641	$33,444
k. Total Operating Expenses[(1)]	$2,339,670	$2,421,945	$2,507,457	$2,596,338
4. Income				
a. Income from Operation[(2)]	$1,981,979	$1,938,598	$1,892,327	$1,843,030
b. Non-Operating Income				
c. Subtotal				
d. Income Taxes				
e. Net Income (Loss)	$1,981,979	$1,938,598	$1,892,327	$1,843,030
h. Project Amortization				
i. Supplies				
j. Other Expenses (Specify)				
5. **Patient Mix:** **A. Percent of Total Revenue**				
1) Medicare	55.7%	55.7%	55.7%	55.7%
2) Medicaid	18.5%	18.5%	18.5%	18.5%
3) Blue Cross	8.4%	8.4%	8.4%	8.4%
4) Commercial Insurance	6.7%	6.7%	6.7%	6.7%
5) Self-Pay	0.2%	0.2%	0.2%	0.2%
6) Other[(3)]	10.5%	10.5%	10.5%	10.5%
7) TOTAL	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Note (1): Total Operating Expenses includes direct departmental expense only and does not include expenses related to depreciation, interest, or allocated overhead.

Note (2): Income from Operation reflects Contribution Margin only.

Note (3): Other includes Title V, Other Government Programs, Workmen's Compensation, Charity, Donor, HMO, and Unknown.

ASSUMPTIONS:

Project Description:

Analysis looks at moving UM SMC at Easton's Percutaneous Coronary Intervention (PCI) program, to the replacement hospital when it opens in fiscal year 2029. This projection was developed using the same assumptions from the hospital financial plan, applied to actual revenue expenses generated by the existing PCI program.

Total Equipment and Construction Cost:

These costs are included in the main project budget submitted with the CON application. There will be two cardiac catheterization labs at the replacement hospital.

Volume

Volumes were assumed to be as projected in the PCI Application and are explained therein. Inpatient/Outpatient mix is consistent with fiscal year 2022 actual experience.

Payor Mix

Based on patients seen at UM SMC at Easton in fiscal year 2022:
Medicare: 55.7%
Medicaid: 18.5%
Blue Cross: 8.4%
Commercial: 6.7%
Self-Pay: 0.2%
Other [(1)]: 10.5%

Note (1): Other includes Title V, Other Government Programs, Workmen's Compensation, Charity, Donor, HMO, and Unknown

Reimbursement %

Revenue is projected based on fiscal year 2023 budget and grows by 0.9% annually, with volumes, through the projection period. To be conservative, the Applicant does not assume any revenue inflation in the projection.

Deductions as a percent of gross revenue through the projection period are consistent with the assumptions used for the Replacement Facility deductions assumptions. Bad debts are assumed to be 3.75% of charges, charity care is assumed to be 1.11% of charges, and contractual allowances are assumed to be 13.73% of charges.

Expenses

Expenses are based on fiscal year 2023 budget. Expense assumptions are consistent with the assumptions used for the Replacement Facility financial projection through fiscal year 2032.

Salaries
FTEs are projected based on fiscal year 2023 budget of 5.4 FTEs, which grow with volumes at a variability factor of 25%. Projected FTEs for fiscal years 2029 through 2032 are 5.5.

Consistent with the Replacement Facility financial projection, salary inflation is assumed to be 1.5% annually and volume variability is assumed to be 25%.

Fringe benefits are assumed to be 23% throughout the projection, consistent with the Replacement Facility financial projection.

Supplies
Consistent with the Replacement Facility financial projection supply inflation is assumed to be 3.6% annually and volume variability is assumed to be 80%.

Other (Purchased Services)
Consistent with the Replacement Facility financial projection purchased services inflation is assumed to be 2.0% annually and volume variability is assumed to be 50%.

Contribution Margin

Analysis is incremental only. This is not a reflection of the program's profitability but rather the net financial impact to the system.

Pro forma contribution margin includes only direct departmental expenses. Direct allocated and indirect overhead expense associated with Administration / Corporate functions are not allocated / reflected.

Form C. Please use this form to identify for each physician and quarter the volume of primary and non-primary PCI cases performed by the physician.

Interventionalist: Sardi, G.

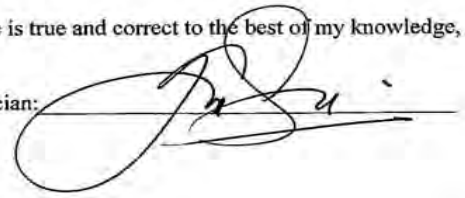
Quarter Ending	PCI Cases at Applicant Hospital			PCI Cases at Other Hospitals			Total PCI Cases- All Hospitals
	pPCI	npPCI	Total	pPCI	npPCI	Total	
March 2021	15	36	51				
June 2021	26	48	74				
September 2021	12	40	52				
December 2021	20	35	55				
March 2022	14	50	64				
June 2022	16	47	63				
September 2022	12	32	42				

Source of Data: QCentrix and EPIC

Affidavit

I solemnly affirm under penalties of perjury that the information contained in the above table is true and correct to the best of my knowledge, information, and belief.

Date: 12/01/22.

Signature of Physician: 

Form C. Please use this form to identify for each physician and quarter the volume of primary and non-primary PCI cases performed by the physician.

Interventionalist: Etherton, J. _____

Quarter Ending	PCI Cases at Applicant Hospital			PCI Cases at Other Hospitals			Total PCI Cases- All Hospitals
	pPCI	npPCI	Total	pPCI	npPCI	Total	
March 2021	18	58	76				
June 2021	24	67	91				
September 2021	20	65	85				
December 2021	23	60	83				
March 2022	12	85	97				
June 2022	22	55	77				
September 2022	13	71	84				

Source of Data: QCentrix and EPIC

Affidavit

I solemnly affirm under penalties of perjury that the information contained in the above table is true and correct to the best of my knowledge, information, and belief.

Date: Nov. 23, 2022

Signature of Physician: _____

Form C. Please use this form to identify for each physician and quarter the volume of primary and non-primary PCI cases performed by the physician.

Interventionalist: Pena, I.

Quarter Ending	PCI Cases at Applicant Hospital			PCI Cases at Other Hospitals			Total PCI Cases- All Hospitals
	pPCI	npPCI	Total	pPCI	npPCI	Total	
March 2021	19	38	57				
June 2021	27	52	79				
September 2021	36	52	88				
December 2021	29	43	72				
March 2022	22	46	68				
June 2022	21	61	82				
September 2022	28	60	88				

Source of Data: QCentrix and EPIC

Affidavit

I solemnly affirm under penalties of perjury that the information contained in the above table is true and correct to the best of my knowledge, information, and belief.

Date: 11/25/22

Signature of Physician: _____

INDEX OF EXHIBITS

INDEX OF TABLES

INDEX OF FIGURES

Figure	Description

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

January 6, 2023
Date

Ken Kozel, MBA FACHE
President and Chief Executive Officer
University of Maryland Shore
Regional Health

#813835

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

January 6, 2023
Date

DocuSigned by:
JoAnne Hahey
DFC8B488258E42A...

JoAnne Hahey, CPA
Senior Vice President and Chief Financial Officer
University of Maryland Shore Regional Health

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

January 6, 2023
Date

William Huffner, MD, MBA, FACEP, FACHE, CMO and Senior Vice President of Medical Affairs
University of Maryland Shore Regional Health

#813847

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

January 6, 2023
Date

DocuSigned by:
Jeffrey Etherton
535C85D958B24E2...

Jeffrey Howard Etherton, MD
Medical Director, Interventional Cardiology
University of Maryland Shore Regional Health

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

January 6, 2023
Date

DocuSigned by:
Hilary Cassel
000C6A23DZ13495...

Hilary Cassel, MBA, BSN, RN
Regional Heart & Vascular Center Director
University of Maryland Shore Regional Health

EXHIBIT 1

MARYLAND HEALTH CARE COMMISSION

Certificate of Conformance

TO: Kenneth D. Kozel
President and Chief Executive Officer
University of Maryland Shore Medical Center at Easton
219 S. Washington Street
Easton, Maryland 21601

April 11, 2016
(Date)

RE: Emergency and Elective Percutaneous Coronary Intervention Services

CC-15-20-0001
(Docket No.)

SERVICE DESCRIPTION

This Certificate of Conformance authorizes the University of Maryland Shore Medical Center at Easton (UMSMC-E or Hospital) to establish both emergency (primary) and elective (non-primary) percutaneous coronary intervention (PCI) services. Emergency PCI includes PCI capable of relieving coronary vessel narrowing associated with ST-segment elevation myocardial infarction (STEMI) or STEMI equivalent, as defined by the Maryland Health Care Commission (MHCC) in COMAR 10.24.17. Elective PCI is PCI provided to a patient who is not suffering from STEMI or STEMI equivalent, but whose condition is appropriately treated with PCI as provided in COMAR 10.24.17.

The Hospital estimates that the capital expenditure related to the establishment of emergency and elective PCI services will be $2,568,600, primarily for fixed equipment and building expenses.

ORDER

MHCC reviewed Staff's Report and Recommendation and, based on that analysis and the record in the review, ordered, on March 17, 2016, that a Certificate of Conformance with required conditions be issued authorizing the establishment of elective and primary PCI services at UMSMC-E if, on or before April 11, 2016, UMSMC-E provided documentation satisfactory to Commission staff that:

1. The Hospital has protocols for both routine and infrequent emergency situations, such as recurrent ischemia or infarction, failed angioplasty requiring emergency CABG surgery, and primary angioplasty system failure; and

2. The Hospital has executed an agreement that provides for 30-minute response time regardless of the circumstances.

The Hospital met the required conditions by providing satisfactory documentation on April 11, 2016. Specifically, UMSMC-E submitted: (1) its protocol for addressing conditions such as

recurrent ischemia or infarction and failed angioplasty requiring emergency coronary artery bypass graft surgery; and (2) a copy of an amended agreement with Best Care Ambulance, effective April 6, 2016, that provides for a 30-minute response time regardless of circumstances.

CONDITIONS

This Certificate of Conformance is issued with the following conditions:

1. At least 90 days prior to first use approval, UMSMC-E shall provide the names of its medical director and interventionalists on staff and documentation that each interventionalist on staff has achieved an average annual case volume of 50 or more PCI cases over the two-year period;

2. UMSMC-E shall agree to comply with the requirements for a Certificate of Ongoing Performance outlined at COMAR 10.24.17.07C and D;

3. UMSMC-E shall agree to voluntarily relinquish its authority to provide elective PCI or both emergency and elective PCI and close its program in a timely manner upon notice by the Executive Director of MHCC if it: (i) has failed to comply with standards for a Certificate of Ongoing Performance or a Certificate of Conformance; (ii) has been given an opportunity to address the deficiencies identified by the Commission through an approved plan of correction; and (iii) has failed to adequately correct the deficiencies.

4. UMSMC-E shall apply for a Certificate of Ongoing Performance on or before June 30, 2020.

ACKNOWLEDGEMENT OF RECEIPT OF CERTIFICATE OF CONFORMANCE

Acknowledgement of your receipt of this Certificate of Conformance, stating acceptance of its terms and conditions, is required within thirty (30) days.

MARYLAND HEALTH CARE COMMISSION

Ben Steffen
Executive Director

cc: Manjula Paul, Health Officer, Talbot County
Donna Kinzer, Executive Director, HSCRC
Kevin Seaman, M.D., F.A.C.E.P., Executive Director, MIEMMS

EXHIBIT 2

UNIVERSITY of MARYLAND MEDICAL SYSTEM

HKS

SHORE HEALTH EASTON REPLACEMENT HOSPITAL

EASTON, MD

OWNER

UNIVERSITY OF MARYLAND HEALTH SYSTEM
250 W. PRATT STREET
SUITE 2400
BALTIMORE, MD 21201

SHORE HEALTH SYSTEM
219 S. WASHINGTON STREET
EASTON, MD 21601
BALTIMORE, MD 21201

ARCHITECT

HKS INC.
2100 E. CARY ST.
SUITE 100
RICHMOND, VA 23223

INTERIORS

HKS INC.
2100 E. CARY ST.
SUITE 100
RICHMOND, VA 23223

CIVIL

DAFT MCCUNE WALKER INC.
BERLIN OFFICE, THE PAVILIONS
11200 RACETRACK ROAD, SUITE 202
BERLINE, MD 21811

MEP

HIGHLAND ASSOCIATES
102 HIGHLAND AVENUE
CLARKS SUMMIT, PA 18411

STRUCTURAL

O'DONNELL & NACCARATO
111 SOUTH INDEPENDENCE MALL EAST
SUITE 950
PHILADELPHIA, PA 19106-2545

LANDSCAPE

MAHAN RYKIEL ASSOCIATES
THE STUEFF SILVER BUILDING
800 WYMAN PARK DRIVE, SUITE 100
BALTIMORE, MD 21211

INFORMATION TECHNOLOGY

SMITH SECKMAN REID, INC.
2995 SIDCO DRIVE
NASHVILLE, TN 37204

FOOD SERVICE

L2M FOOD SERVICE DESIGN GROUP
811 CROMWELL PARK DRIVE, SUITE 113
GLEN BURNIE, MD 21061

MEDICAL EQUIPMENT

MITCHELL PLANNING ASSOCIATES
2794 OAKBROOK DRIVE
WESTON, FL 33332

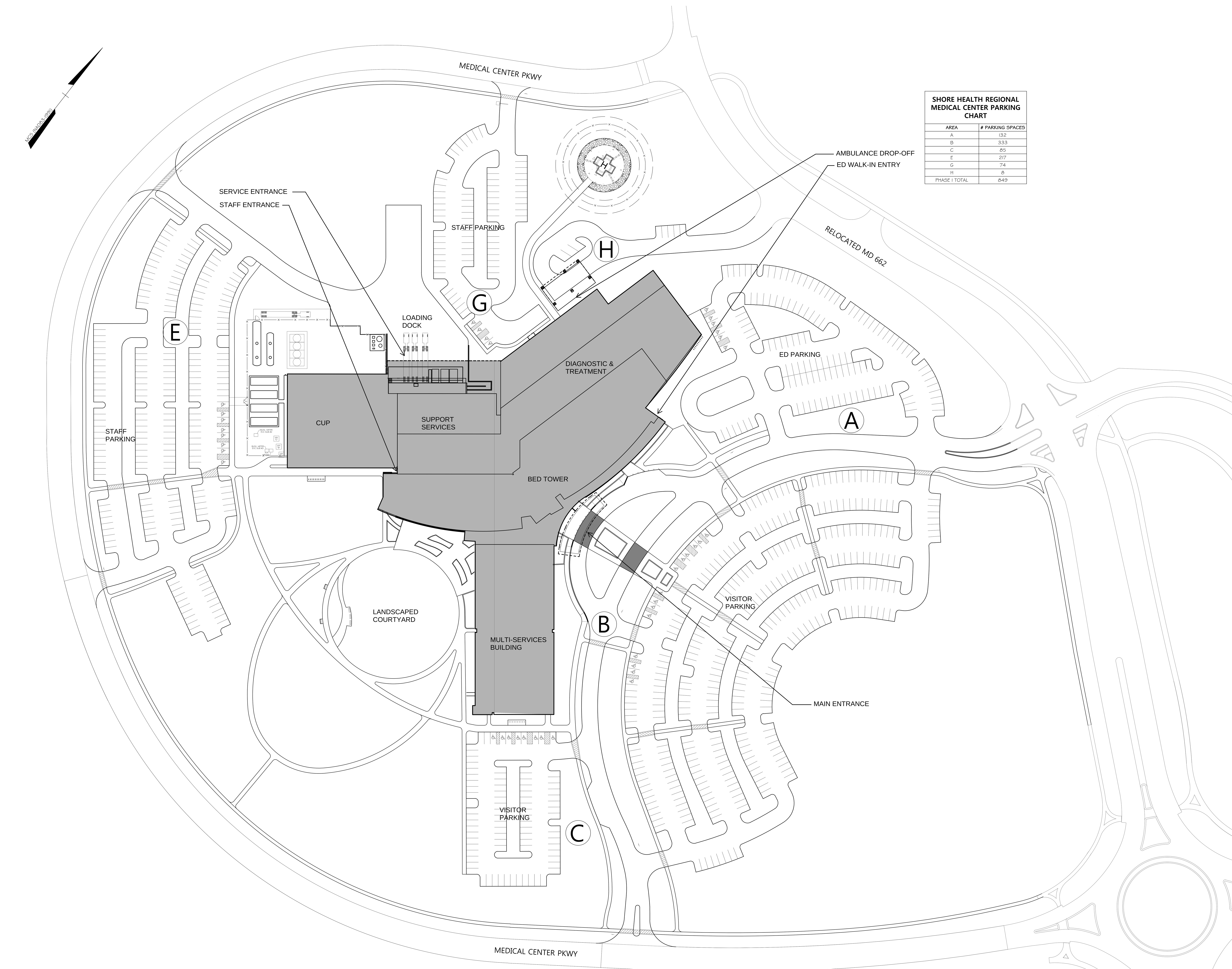
OWNER'S CONSULTANTS

FM GLOBAL
2100 RESTON PARKWAY, SUITE 600
RESTON, VA 20191

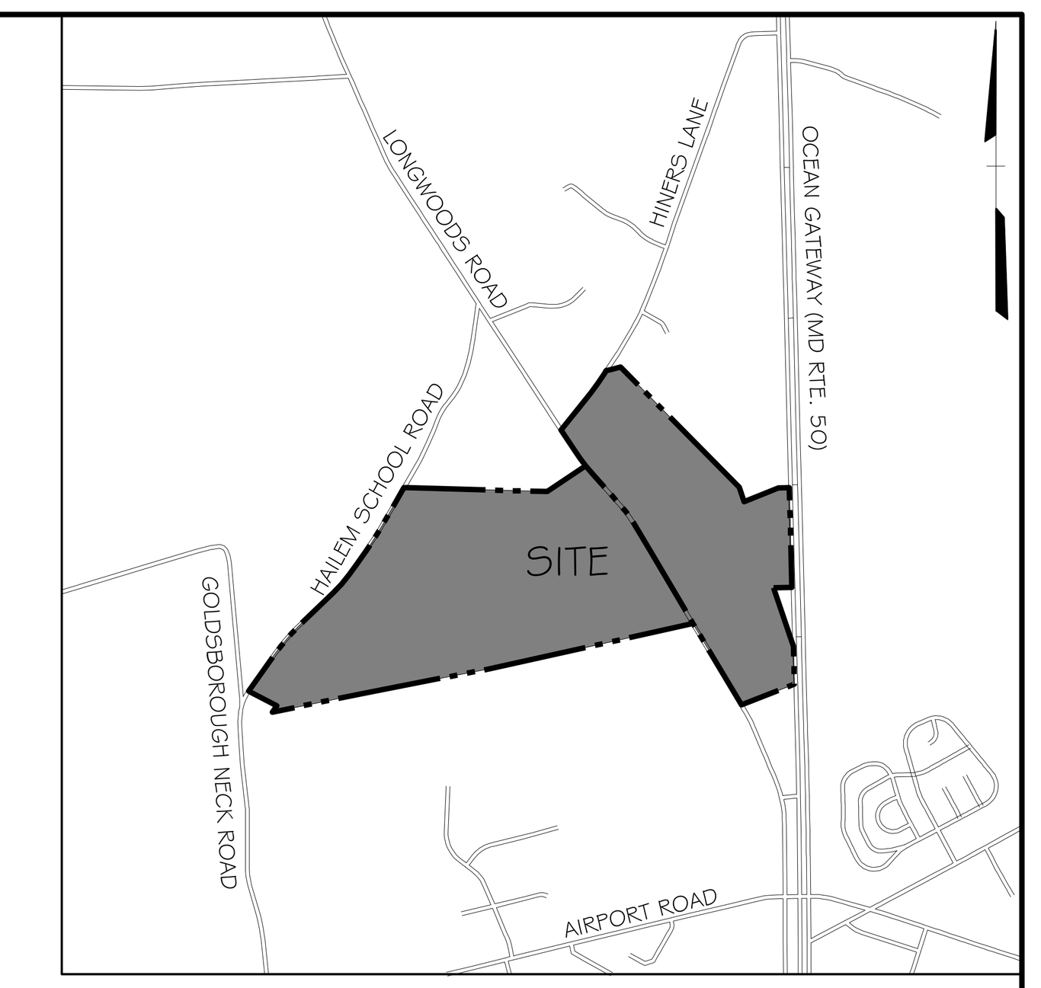
CON SUBMISSION

JANUARY 6, 2023 [UPDATED]

HKS # - 19782.000



SHORE HEALTH REGIONAL MEDICAL CENTER PARKING CHART	
AREA	# PARKING SPACES
A	132
B	333
C	85
E	217
G	74
H	8
PHASE I TOTAL	849



VICINITY MAP

Scale: 1"=2000'

PLAN

SCALE: 1" = 60'

HKS

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HKS, Inc.
2100 E. Cary Street, Suite 100
Richmond, VA 23223

1250 Eye Street NW, Suite 600
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STRUCTURAL
O'Donnell & Naccarato
111 South Independence Mall East
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Philadelphia, PA 19106-2524

LANDSCAPE
Mahan Rykiel Associates
The Stueff Silver Building
800 Wyman Park Drive, Suite 100
Baltimore, MD 21211

INFORMATION TECHNOLOGY
Smith Seckman Reid, Inc.
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Nashville, TN 37204

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811 Cromwell Park Drive, Suite 113
Glen Burnie, MD 21061

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Mitchell Planning Associates
2794 Oakbrook Drive
Weston, FL 33332

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University of Maryland Health System
250 W. Pratt Street
Suite 2400
Baltimore, MD 21201

Shore Health System
219 S. Washington Street
Easton, MD 21601

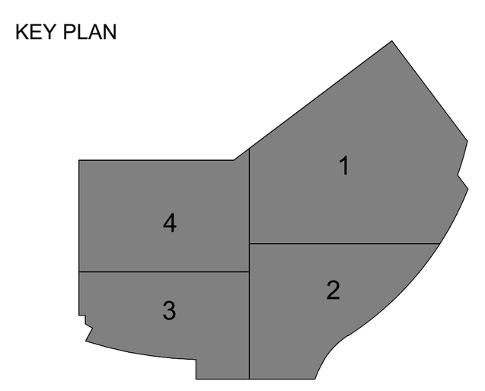
OWNER'S CONSULTANT
FM Global
2100 Reston Parkway, Suite 600
Reston, VA 20191

INTERIM REVIEW ONLY

These documents are incomplete, and are released for interim review only and are not intended for regulatory approval, permit, or construction purposes.

Civil Engineer: Kristy M Bishoff
PE Reg. No.: 28823
Date: 10/25/2022

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION

NO.	DESCRIPTION	DATE

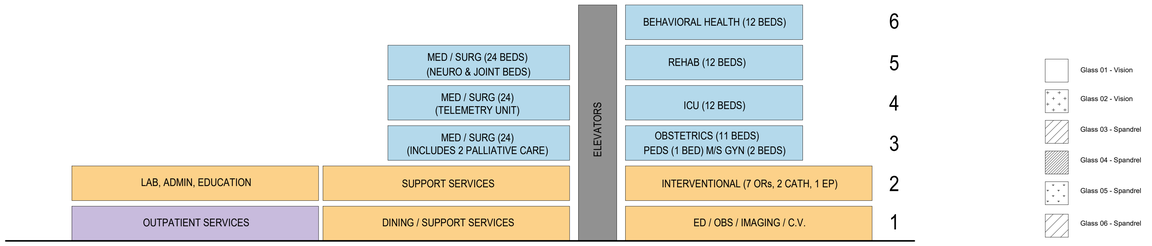
HKS PROJECT NUMBER
19782.010

DATE
JANUARY 6, 2023

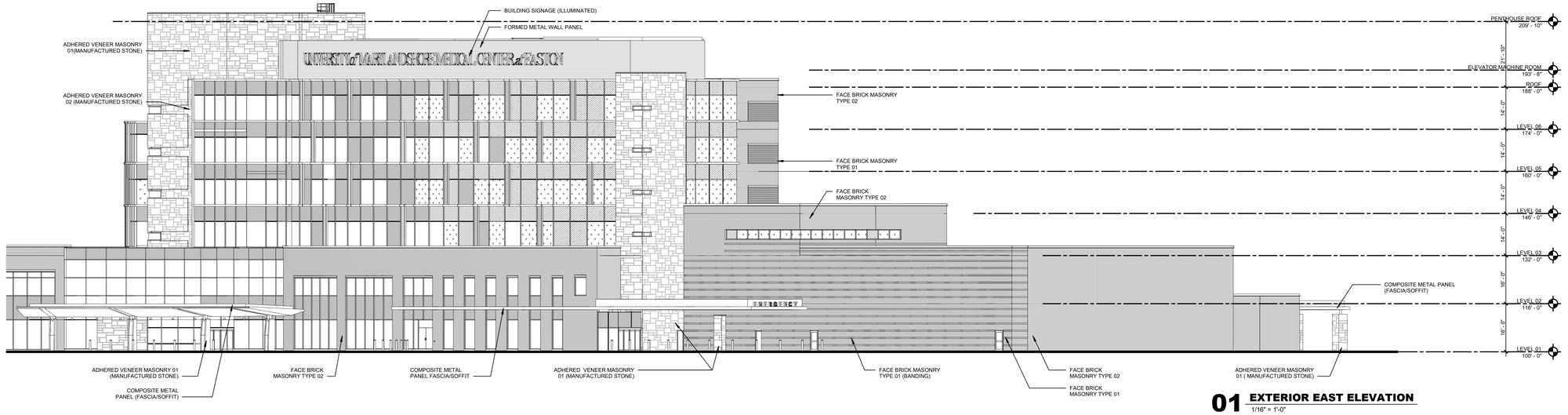
ISSUE
CON SUBMISSION

SHEET TITLE
PHASE 1 DEVELOPMENT SITE PLAN

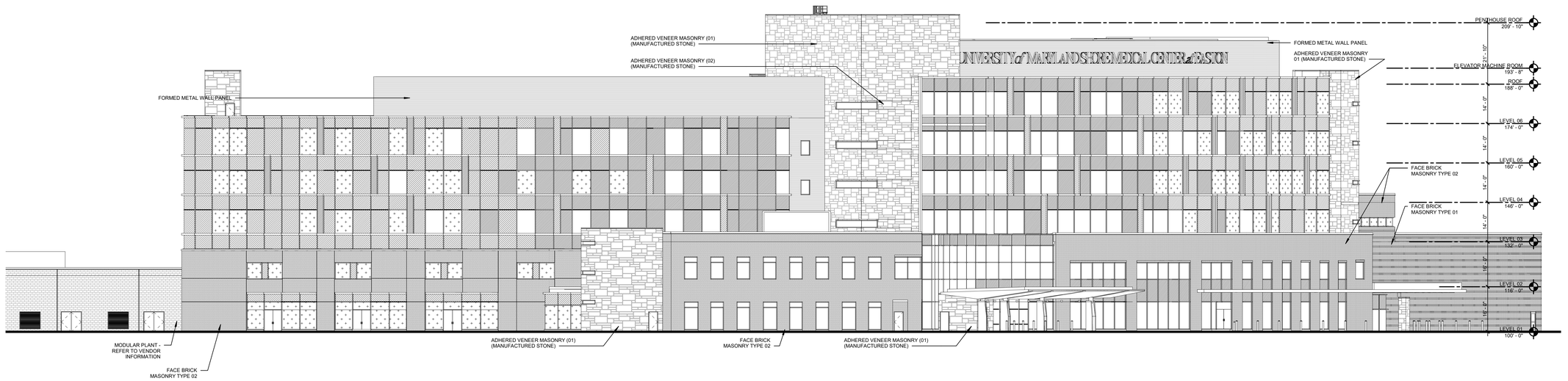
SHEET NO.
CON 07



03 STACKING DIAGRAM
3/4" = 1'-0"



01 EXTERIOR EAST ELEVATION
1/16" = 1'-0"



02 EXTERIOR SOUTH ELEVATION
1/16" = 1'-0"

PLOT DATE:
11/28/2022 4:11:21 PM

HKS

ARCHITECT
HKS, Inc.
2100 E. Cary Street, Suite 100
Richmond, VA 23223

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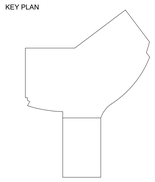
Architect: Shannon B. Kraus
Arch. Reg. No.: 16103
Date: 10/25/2022

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION

NO.	DESCRIPTION	DATE

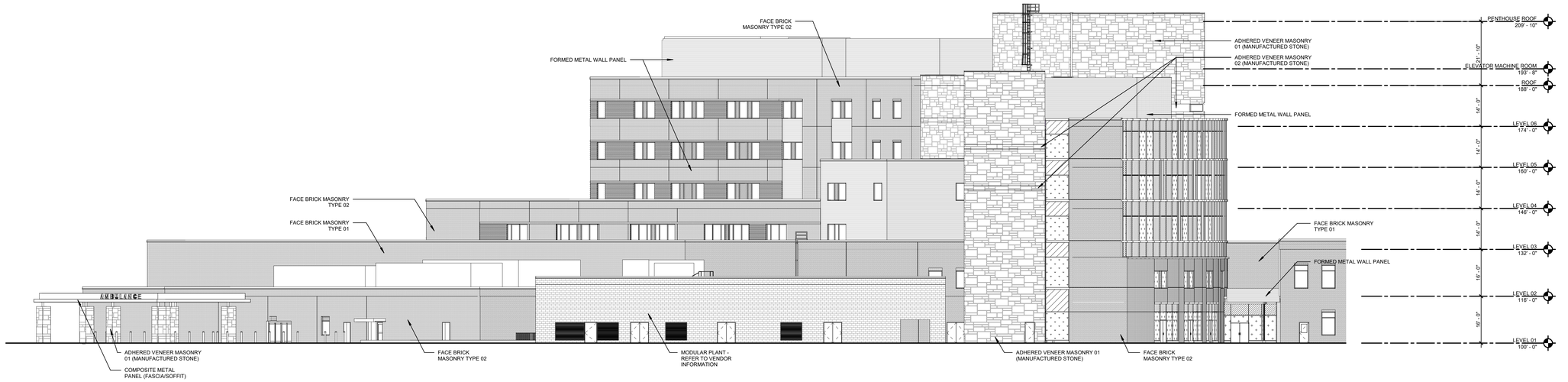
HKS PROJECT NUMBER
19782.010

DATE
JANUARY 6, 2023

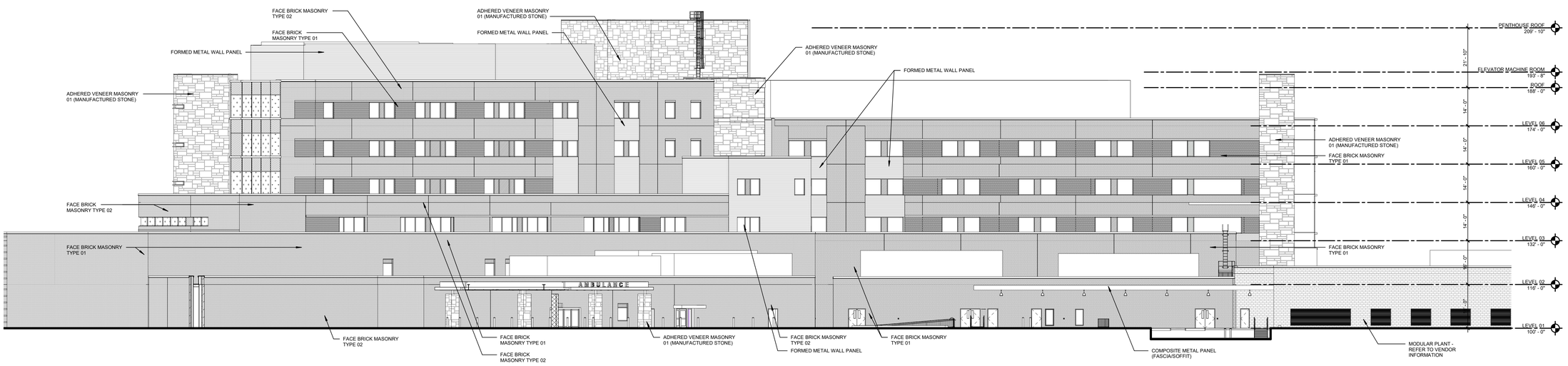
ISSUE
CON SUBMISSION

SHEET TITLE
EXTERIOR ELEVATIONS

SHEET NO.
A5.010



01 **EXTERIOR WEST ELEVATION**
1/16" = 1'-0"



02 **EXTERIOR NORTH ELEVATION**
1/16" = 1'-0"

PLOT DATE:
11/28/2022 4:11:26 PM

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INTERIM REVIEW ONLY

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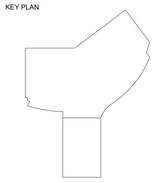
Architect: Shannon B. Kraus
Arch. Reg. No.: 16103
Date: 10/25/2022

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION

NO.	DESCRIPTION	DATE

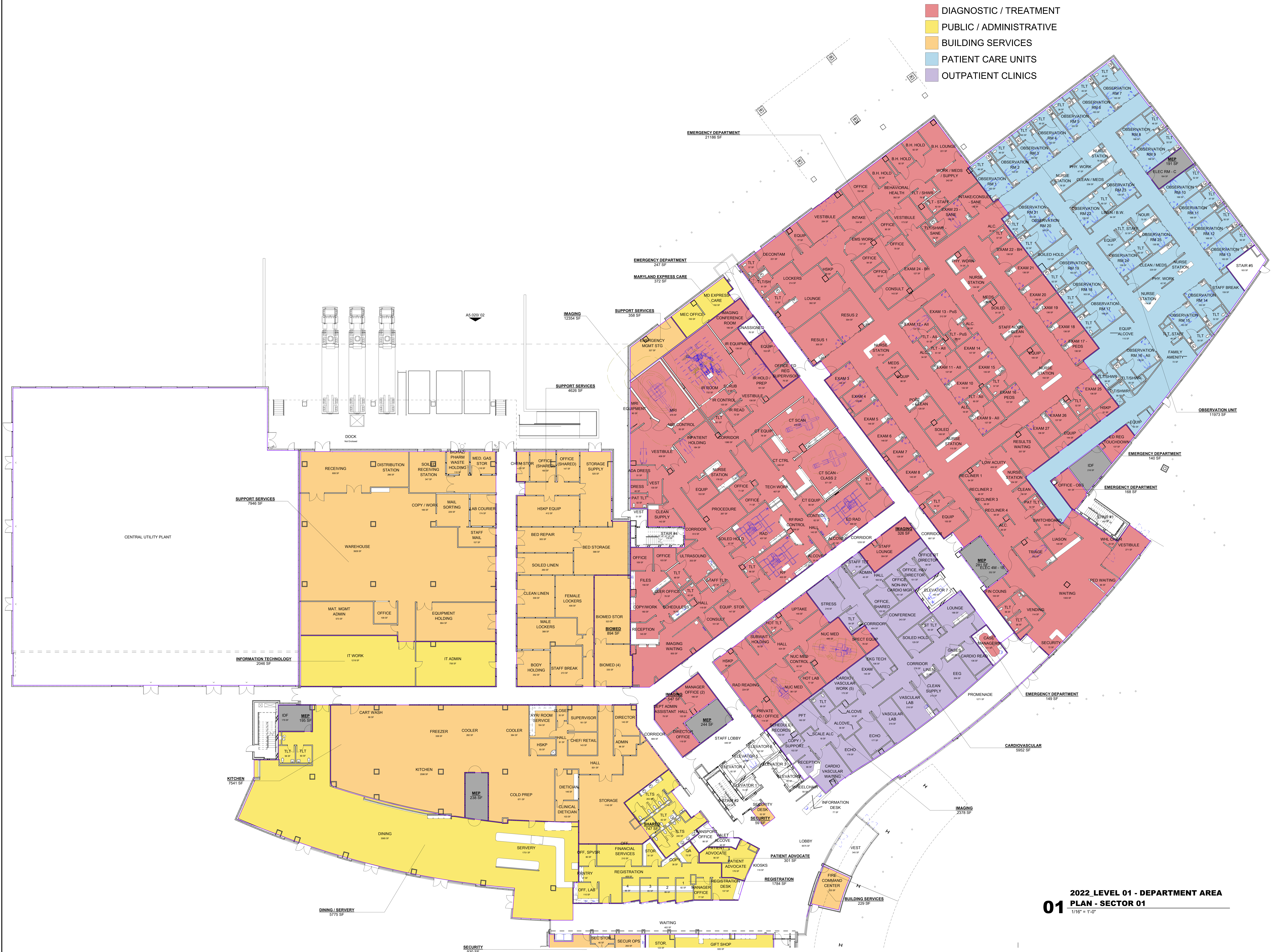
HKS PROJECT NUMBER
19782.010

DATE
JANUARY 6, 2023

ISSUE
CON SUBMISSION

SHEET TITLE
EXTERIOR ELEVATIONS

SHEET NO.
A5.020



01 **2022_LEVEL 01 - DEPARTMENT AREA PLAN - SECTOR 01**
1/16" = 1'-0"

PLOT DATE: 11/28/2022 4:12:08 PM

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Arch. Reg. No.: 16103
Date: 10/25/2022

KEY PLAN

PLAN NORTH TRUE NORTH

REVISION
NO. DESCRIPTION DATE

HKS PROJECT NUMBER
19782.010

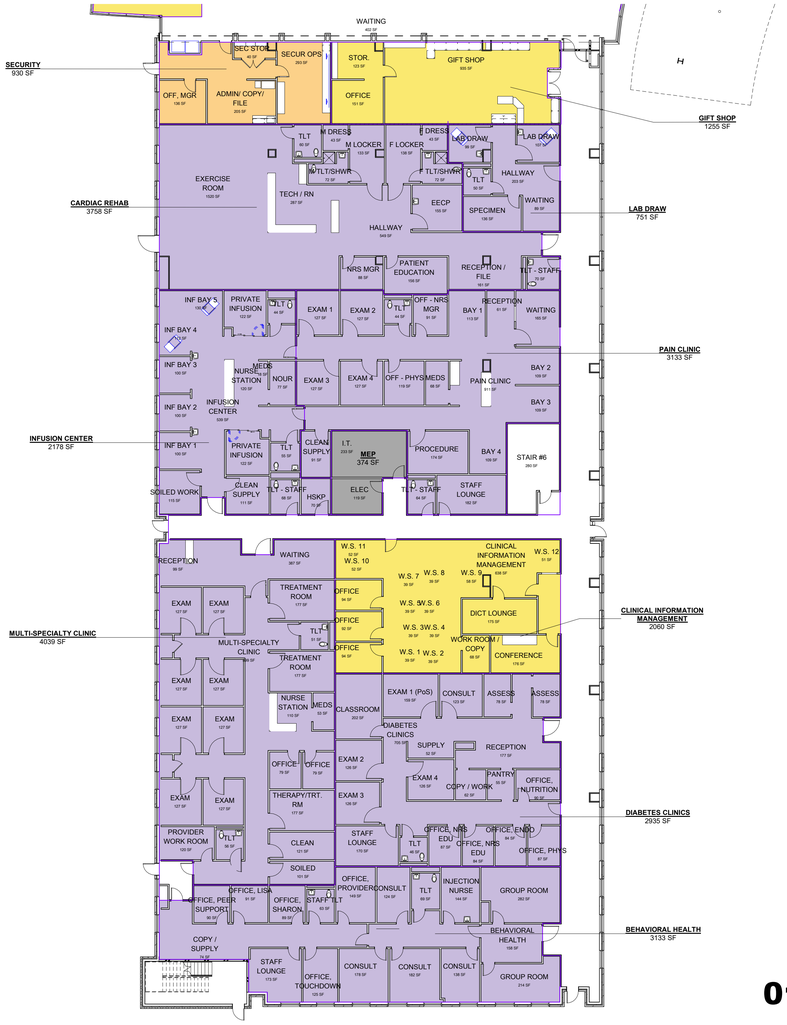
DATE
JANUARY 6, 2023

ISSUE
CON SUBMISSION

SHEET TITLE
LEVEL 01 - DEPARTMENTAL AREA PLAN SECTOR 01

CON 08

DIAGNOSTIC / TREATMENT
PUBLIC / ADMINISTRATIVE
BUILDING SERVICES
PATIENT CARE UNITS
OUTPATIENT CLINICS



01 **2022_LEVEL 01 - DEPARTMENT AREA PLAN - SECTOR 02**
1/16" = 1'-0"

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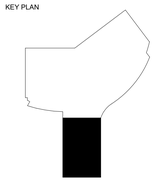
Architect: Shannon B. Kraus
Arch. Reg. No.: 16103
Date: 10/25/2022

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION
NO. DESCRIPTION DATE

HKS PROJECT NUMBER
19782.010

DATE
JANUARY 6, 2023

ISSUE
CON SUBMISSION

SHEET TITLE
LEVEL 01 - DEPARTMENTAL AREA PLAN SECTOR 02

CON 08A

PLOT DATE:
11/28/2022 4:12:12 PM

DIAGNOSTIC / TREATMENT
PUBLIC / ADMINISTRATIVE
BUILDING SERVICES
PATIENT CARE UNITS
OUTPATIENT CLINICS

INTERVENTIONAL
30968 SF

CENTRAL STERILE
7300 SF

PHARMACY
4843 SF

SHARED
478 SF

SUPPORT SERVICES
914 SF

ADMIN
1361 SF

EDUCATION
1784 SF

CHAPEL
597 SF

SHARED
1038 SF

PREP & RECOVERY
16128 SF

01 2022_LEVEL 02 - DEPARTMENT AREA PLAN - SECTOR 01
1/16" = 1'-0"

PLOT DATE:
1/26/2023 4:12:51 PM

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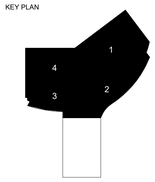
Architect: Shannon B. Kraus
Arch. Reg. No.: 16103
Date: 10/25/2022

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION
NO. DESCRIPTION DATE

HKS PROJECT NUMBER
19782.010

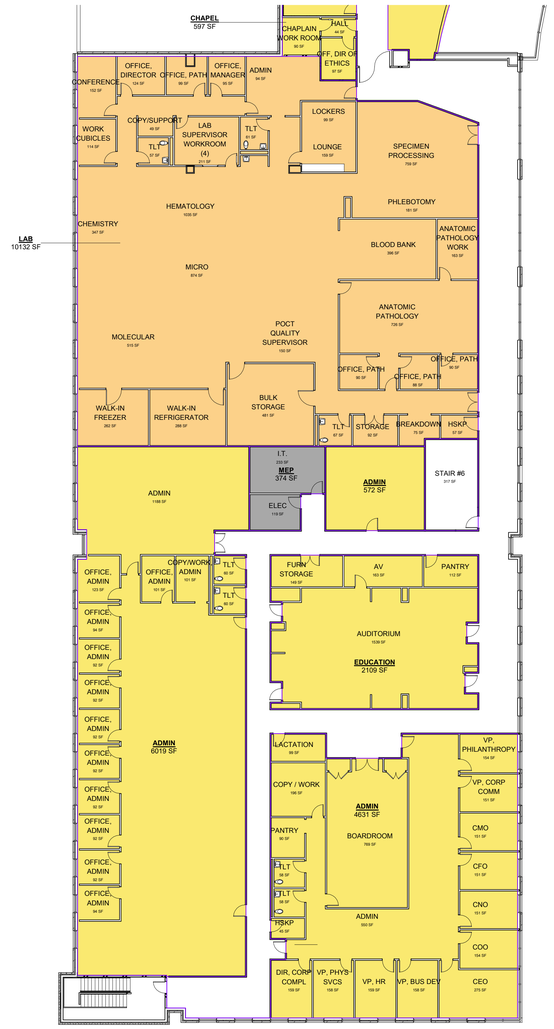
DATE
JANUARY 6, 2023

ISSUE
CON SUBMISSION

SHEET TITLE
LEVEL 02 - DEPARTMENTAL AREA PLAN SECTOR 01

CON 09

DIAGNOSTIC / TREATMENT
PUBLIC / ADMINISTRATIVE
BUILDING SERVICES
PATIENT CARE UNITS
OUTPATIENT CLINICS



01 **2022_LEVEL 02 - DEPARTMENT AREA PLAN - SECTOR 02**
1/16" = 1'-0"

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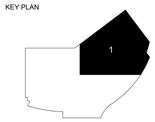
Architect: Leslie Hanson
Arch. Reg. No.: 16795
Date: 01/23/2013

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION

NO.	DESCRIPTION	DATE

HKS PROJECT NUMBER
19782.010
DATE
JANUARY 6, 2023
ISSUE
CON SUBMISSION

SHEET TITLE
LEVEL 02 - DEPARTMENTAL AREA PLAN SECTOR 02
CON 09A

PLOT DATE:
1/26/2023 4:12:54 PM

DIAGNOSTIC / TREATMENT
PUBLIC / ADMINISTRATIVE
BUILDING SERVICES
PATIENT CARE UNITS
OUTPATIENT CLINICS

01 **2022_LEVEL 03 - DEPARTMENT AREA PLAN**
1/16" = 1'-0"

PLOT DATE:
1/26/2022 4:13:16 PM

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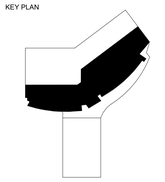
Architect: Shannon B. Kraus
Arch. Reg. No.: 16103
Date: 10/25/2022

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION

NO.	DESCRIPTION	DATE
A	Perinatal Unit reduces to 11 Beds with adjacent 5 Bed Med/Surg Unit	Jan. 13, 2017

HKS PROJECT NUMBER
19782.010

DATE
JANUARY 6, 2023

ISSUE
CON SUBMISSION

SHEET TITLE
LEVEL 03 - DEPARTMENTAL AREA PLAN

SHEET NO.
CON 10

DIAGNOSTIC / TREATMENT
PUBLIC / ADMINISTRATIVE
BUILDING SERVICES
PATIENT CARE UNITS
OUTPATIENT CLINICS

01 2022_LEVEL 04 - DEPARTMENT AREA PLAN
1/16" = 1'-0"

PLOT DATE:
1/28/2022 4:13:30 PM

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Architect: Shannon B. Kraus
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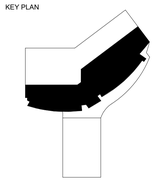
Date: 10/25/2022

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION
NO. DESCRIPTION DATE

HKS PROJECT NUMBER
19782.010

DATE
JANUARY 6, 2023

ISSUE
CON SUBMISSION

SHEET TITLE
LEVEL 04 - DEPARTMENTAL AREA PLAN

SHEET NO.
CON 11

DIAGNOSTIC / TREATMENT
PUBLIC / ADMINISTRATIVE
BUILDING SERVICES
PATIENT CARE UNITS
OUTPATIENT CLINICS

01 2022_LEVEL 05 - DEPARTMENT AREA PLAN
1/16" = 1'-0"

PLOT DATE:
11/28/2022 4:13:43 PM

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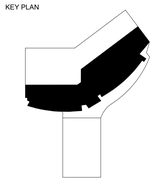
Architect: Shannon B. Kraus
Arch. Reg. No.: 16103
Date: 10/25/2022

KEY PLAN



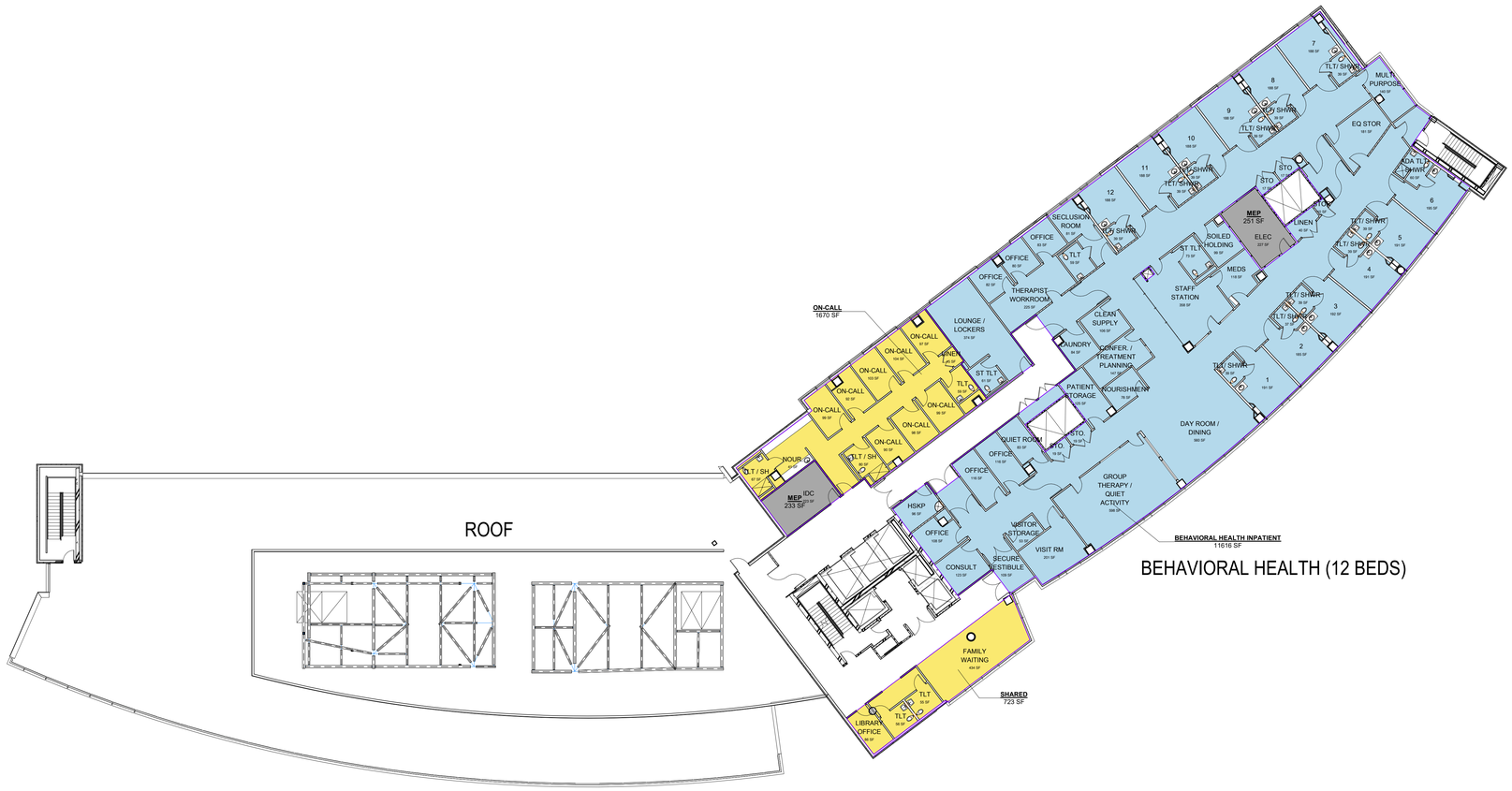
PLAN NORTH TRUE NORTH

REVISION
NO. DESCRIPTION DATE

HKS PROJECT NUMBER
19782.010
DATE
JANUARY 6, 2023
ISSUE
CON SUBMISSION

SHEET TITLE
LEVEL 05 - DEPARTMENTAL AREA PLAN
SHEET NO.
CON 012

DIAGNOSTIC / TREATMENT
PUBLIC / ADMINISTRATIVE
BUILDING SERVICES
PATIENT CARE UNITS
OUTPATIENT CLINICS



01 **2022_LEVEL 06 - DEPARTMENT AREA PLAN**
1/16" = 1'-0"

PLOT DATE:
1/26/2023 4:13:52 PM

HKS

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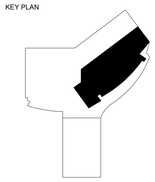
Architect: Shannon B. Kraus
Arch. Reg. No.: 16103
Date: 10/25/2022

KEY PLAN



PLAN NORTH TRUE NORTH

REVISION
NO. DESCRIPTION DATE

HKS PROJECT NUMBER
19782.010

DATE
JANUARY 6, 2023

ISSUE
CON SUBMISSION

SHEET TITLE
LEVEL 06 - DEPARTMENTAL AREA PLAN

SHEET NO.
CON 013

EXHIBIT 3

UNIVERSITY of MARYLAND
SHORE REGIONAL HEALTH

January 6, 2023

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21225

Dear Mr. Steffen,

As part of our modified CON application seeking replacement of University of Maryland Shore Medical Center at Easton ("UMSMC-E"), we are seeking a Certificate of Conformance to move our primary and elective PCI program to the replacement hospital. I am submitting this letter of commitment that if University of Maryland Shore Regional Health ("UM SRH") obtains Commission approval to establish a primary PCI Program at the replacement hospital, UMSMC-E shall commit to providing primary PCI services as soon as possible and not to exceed 90 minutes from patient arrival at the hospital, excluding transfer cases, for at least 75 percent of appropriate patients. UMSMC-E shall also track the door-to-balloon times for transfer cases and evaluate areas for improvement.

Sincerely,

Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

EXHIBIT 4

UNIVERSITY of MARYLAND
SHORE REGIONAL HEALTH

January 6, 2023

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21225

Dear Mr. Steffen,

As part of our modified CON application seeking replacement of University of Maryland Shore Medical Center at Easton ("UMSMC-E"), we are seeking a Certificate of Conformance to move our primary and elective PCI program to the replacement hospital. I am submitting this letter of commitment to provide the staffing and facility support necessary at the replacement hospital to provide primary PCI services in accordance with the requirements for primary PCI programs established by the Maryland Health Care Commission.

The Primary PCI program is part of our System's vision and overall strategic plan. We are 100% committed to the program to provide critical care Cardiovascular services to our community.

Sincerely,

Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

EXHIBIT 5

Cross Reference: SRH Administrative Policy TX-103

1.0 Purpose

1.1 To facilitate and ensure the care of patients with acute ST elevation myocardial infarction (STEMI) comply with evidence based medicine and guidelines established by American College of Cardiology (ACC) and the American Heart Association (AHA). The goal is to facilitate rapid recognition and treatment of patients with STEMI such that time from medical contact to balloon time for percutaneous coronary intervention (PCI) is kept within a standard of 90 minutes or less.

2.0 Policy

2.1 There will be a dedicated staffed cardiac catheterization laboratory (Cath Lab) 24 hours per day seven days per week that will enable PCI to be performed to STEMI population.

2.2 All emergent cases take priority over scheduled cases.

3.0 Cardiac Cath Lab Operations Providing 24 hours/day of Coverage

3.1 Normal staffed hours of operation are defined as Monday-Friday 7:00 a.m. – 3:30 p.m.

3.2 After hours of operation staffing is assured by two rotating Call Teams assigned to provide coverage for all hours not covered under normal hours of operation.

3.2.1 Cath Lab Call Team members are required to respond to the Cath Lab within thirty (30) minutes of notification (See PCI-12).

4.0 Patient Presenting to ED

4.1 When a patient presents to the ED ("walk-in") and is determined to meet STEMI criteria (See 7.0), the following will occur:

4.2 ED physician will confirm STEMI criteria and

4.2.1 Contact the Interventional Cardiologist (STEMI Cardiologist) on call and convey clinical assessment along with any diagnostic results available to include:

4.2.1.1 Allergy to Aspirin

4.2.1.2 Allergy to iodinated contrast agents

4.2.1.3 Patient on Metformin, or has a history of renal failure

4.3 Upon confirmation of STEMI, ED physician will initiate "STEMI Alert" by calling or instructing ED staff to call the Switchboard to activate "STEMI Alert." (See 8.0)

5.0 Pre Hospital Patient – Suspected STEMI

5.1 If patient is pre-hospital and is suspected of STEMI by EMS providers, EMS providers will immediately contact the ED according to MIEMSS EMS Protocol. EMS provider will transmit 12 Lead ECG via LifeNet for confirmation by ED physician.

5.2 ED physician will confirm STEMI criteria and

5.2.1 Contact the Interventional Cardiologist (STEMI Cardiologist) on call and convey clinical assessment along with any diagnostic results available to include:

5.2.1.1 Allergy to Aspirin
5.2.1.2 Allergy to iodinated contrast agents
5.2.1.3 Patient on Metformin, or has a history of renal failure

5.3 Upon confirmation of STEMI, ED physician will initiate "STEMI Alert" by calling or instructing ED staff to call the Switchboard to activate "STEMI Alert." (See 8.0)

6.0 If patient is an inpatient, see also SRH Administrative Policy TX-103

6.1 If patient suspected of acute coronary syndrome, chest pain, or symptoms of cardiac condition, the Nurse(s) assigned to the patient will initiate "Medical Emergency Team" (MET) process (See SRH TX-103).

6.2 If following MET assessment 12 Lead ECG is not diagnostic of STEMI, patient will be placed on continuous Telemetry monitoring.

7.0 STEMI Inclusion Criteria

7.1 ST elevation of > 1mm in 2 contiguous leads.
7.2 New Left Bundle Branch Block (LBBB).
7.3 Patient is over the age of 18.
7.4 If the patient is on Metformin, there is no history of renal failure (creatinine < 1.7).

8.0 STEMI Alert Process

8.1 Once confirmation of STEMI has been determined based on patient presentations described above, the STEMI Alert process will be activated by the Hospitalist (inpatient STEMI), ED physician or the ED staff as directed by the ED physician.

8.2 The Switchboard operator will be instructed to activate the STEMI Alert process.

8.3 For all hours 24/7 the Switchboard Operator will overhead page "STEMI Alert"

8.3.1 If STEMI Alert is associated with an EMS transport ETA, the ETA will be paged along with STEMI Alert page.

8.3.2 This will serve to notify the Nursing Supervisors and Respiratory Care Practitioner and dictate immediacy of response to ED.

8.3.3 Switchboard Operator will activate the VOLO paging system to alert the Cardiac Cath Lab on call team to respond during hours or normal operation as well as after hours of normal operation (On Call hours).

8.3.3.1 The VOLO paging system consists of a predetermined "scenario" that includes a text message along with a verbal message of "STEMI Alert."

8.3.3.2 The STEMI On Call Team responds as having received the message by way of VOLO response.

8.3.3.3 After hours STEMI Call Team is required to respond to CCL in 30 minutes.

8.3.4 ED physician or Hospitalist (inpatient STEMI) will call the Interventional Cardiologist on call (designated as "STEMI Cardiologist").

8.3.4.1 Interventional Cardiologist will contact the ED physician or Hospitalist (inpatient STEMI) for details of STEMI Alert.

8.3.5 The Switchboard will be provided with a call schedule for Interventional Cardiologist (STEMI Cardiologist) and CCL staff On Call Team.

8.4 Cardiac Cath Lab STEMI Response

8.4.1 During normal working hours (M-F 7A-3:30P) the CCL Team will immediately prepare one of the two procedure rooms available to accept the STEMI patient from the ED.

8.4.1.1 If procedures are already under way in both Cath Labs, the Interventional Cardiologist will determine which of the two procedures can be aborted.

8.4.1.2 If necessary, the patient who can be safely removed from a procedure under way will be placed in the holding area of the CCL.

8.4.1.3 A CCL room will be immediately prepared to receive ED STEMI patient.

8.4.2 After normal hours of operation (M-F 7A-3:30P) a CCL STEMI On Call Team is available.

8.4.2.1 The VOLO Alert (as described 8.3.3.1) will be used to summon the On Call Team who are required to respond to the CCL within 30 minutes.

8.4.2.2 Upon arrival of the On Call Team, the first member to arrive will contact the ED and let them know that when CCL is preparing to accept STEMI patient.

8.4.2.3 CCL Call Team will follow the predetermined sequence of room preparation (See PCI-13).

8.4.2.4 Once CCL Team including Interventional Cardiologist are ready to accept STEMI patient, a team member will notify the ED and report to the ED to assist with transfer along with Interventional Cardiologist, if not already in the ED.

	Policy
Effective	05/17
Revised	01/18
Revised	
Policy Owner	Gary Jones, Regional Director, Cardiovascular Services

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	EMERGENCY SERVICES	POLICY NO:	
		REVISED:	09/20
	DESIGNATED TRIAGE AREA QUALIFICATIONS	PAGE #:	1 of 1
		SUPERSEDES	08/17

PURPOSE: To ensure that Emergency Services (ES) Registered Nurses (RN) triaging in the designated triage area have the necessary knowledge and skills before acting independently.

SCOPE: RN

POLICY:

1.0 The RN assigned to the designated triage area will have a minimum of one year of recent emergency nursing experience.

1.1 This time period does not include the orientation period.

1.2 The RN assigned to the designated triage area must have prior experience with the Emergency Severity Index (ESI) 5 Level Triage tool.

1.2.1 If the RN does not have this experience, ESI triage education and successful completion of a clinical orientation with a preceptor must occur prior to being assigned designated triage area duties.

2.0 The designated area triage nurse must have successfully completed Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS) or Emergency Nursing Pediatric Course (ENPC), and neonatal resuscitation as described in Department Specific Certification Requirements policy.

3.0 Ultimately, the decision regarding competency of a triage nurse belongs to ES leadership.

Policy	
Effective	07/11
Revised/ Reviewed	09/20; 08/17; 07/14; 03/12
Policy Owner	Emergency Department Coordinating Council
Approved by:	
• **EDCC**	8/17/17
•	Kathy Elliott, Director Acute Care and Emergency Services- Chestertown: 8/17/17
•	Diane Walbridge , Director Acute Care and Emergency Services- Easton, Dorchester, Queenstown: 8/31/17
SPIRIT Form	ED Coordinating Council 04/15/15

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	EMERGENCY SERVICES Guideline	POLICY NO:	NA
		REVIEWED:	03/21
	TRIAGE OF EMERGENCY SERVICE (ES) PATIENTS	PAGE #:	1 of 2
		SUPERSEDES	03/18

PURPOSE: Triage provides immediate assessment, intervention, and priority assignment of all persons seeking emergency care and is performed in an orderly manner, facilitating the flow of patients through the Emergency Services (ES) care area.

SCOPE: RN

POLICY:

1.0 The registered nurse will evaluate and categorize each patient upon arrival to the Emergency Department utilizing the Emergency Severity Index (ESI) 5 Level Triage

1.1 The initial evaluation shall include triage fields in Epic but not limited to:

1.1.1 Patient's name

1.1.2 Age

1.1.3 Date and time of initial triage evaluation

1.1.4 Mode of transportation on arrival (i.e., walk-in, wheelchair, car, ambulance)

1.1.5 Home medication history, herbal supplements

1.1.6 Use of tobacco/alternatives, alcohol, and other substances (legal or illegal)

1.1.7 Allergies, include allergies to latex

1.1.8 Chief complaint in the patient's own words

1.1.9 Medical history

1.1.10 Tetanus status, if applicable.

1.1.11 Immunization status

1.1.12 Last menstrual period for all women of child-bearing age or as applicable

1.1.13 Weight in kg and height

1.1.14 Vital signs

1.1.15 Nursing observations

1.1.16 Glasgow coma scale, LAMS Score if applicable

1.1.17 Infectious disease screening

2.0 All patient information is documented in the patient's medical record.

3.0 All patients will be directly placed in a bed if bed is available.

3.1 Pediatric and vulnerable adults with known or suspected abuse and/or neglect will be placed in a room that is able to be visualized from the nurses' station. If indicated, a room change will be performed to meet the identified need.

Policy	
Effective	07/92
Revised/ Reviewed	03/21; 03/18; 06/15; 07/14; 06/12; 06/11; 05/08; 11/06; 05/05; 05/03; 09/00; 09/97
Approved by:	
• **EDCC**	3/4/21
SPIRIT Form	ED Coordinating Council 04/15/15
Policy Owner	Emergency Department Coordinating Council

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	ADMINISTRATIVE PROCEDURE	POLICY NO:	PC-32 (TX-103)
		REVISED:	01/22
	IDENTIFICATION OF PATIENTS HAVING A STEMI	PAGE #:	1 of 6
		SUPERSEDES	06/18

PURPOSE

To ensure that all patients with a ST segment elevation myocardial infarction (STEMI) are identified and receive early evidence-based care, thereby reducing morbidity/mortality due to STEMI.

DEFINITION

STEMI: A **ST** **E**levation **M**yocardial **I**nfarction is a clinical syndrome defined by characteristic symptoms of myocardial ischemia in association with persistent electrocardiographic (ECG) ST elevation and subsequent release of biomarkers of myocardial necrosis. ECG evidence of a STEMI include new ST – segment elevation at the J-point in at least 2 contagious leads $\geq$ 2mm in men, $\geq$ 1.5mm in women in lead V2 to V3, or $\geq$ 1mm in other contagious chest lead or limb leads. Other conditions which are treated as a STEMI are a new or presumed new Left Bundle Branch Block an isolated posterior MI. A STEMI is a medical emergency requiring prompt intervention thru PCI (percutaneous coronary intervention) or thrombolytics to salvage the myocardium.

Percutaneous Coronary Intervention (PCI): A minimally invasive procedure used for the purpose of restoring blood flow thru narrowed or blocked coronary arteries.

POLICY

1.0 EMERGENCY SERVICES EARLY RECOGNITION OF STEMI

Early recognition of a STEMI is essential to facilitate goal-directed care for patients.

1.1 Patients 30 years of age or older with the following stated complaints presenting to Emergency Services (ES) will have an ECG obtained within ten (10) minutes of arrival to determine the presence of a STEMI.

1.1.1 Pressure or tightness of heaviness in the chest

1.1.2 Pain in the chest

1.1.3 Pain in the back (not related to injury or chronic pain)

1.1.4 Pain in the jaw

1.1.5 Pain in the neck

1.1.6 Pain in the left shoulder or upper extremity

1.1.7 Shortness of breath or dyspnea on exertion

1.1.8 Sweating

1.1.9 Weakness

1.1.10 Nausea or indigestion

1.1.11 Vomiting

1.1.12 Several external fatigue

1.1.13 Chest "misery"

1.2 Patients 29 years of age or less who present with the following stated complaint will have an ECG obtained within ten (10) minutes of arrival to determine the presence of a STEMI

1.2.1 Chest pain

1.2.2 Presence of Cardiac History

1.3 The completed ECG will be given to the ES Physician for STEMI diagnoses.

2.0 ACTIVATION OF A STEMI ALERT

For patients whose ECG is indicative of a STEMI, the ES LIP will transmit a photograph of the ECG via TigerConnect to the interventional cardiologist who is listed as on-call for that service in the TigerSchedule, along with brief patient details. If the interventional cardiologist does not respond within 10 minutes, the ES LIP will activate the STEMI alert. The STEMI Alert and location will be announced overhead two (2) times.

2.1 For Easton dial 1111

2.2 For Cambridge dial #1111

2.3 For Queenstown dial 309

2.4 For Chestertown dial 1111

3.0 THE STEMI ALERT RESPONDERS TEAM WILL CONSIST OF:

3.1 ES Registered Nurse

3.2 ES LIP

3.3 Nursing Technician

3.4 Clinical Laboratory (where applicable)

3.5 Respiratory Therapy (where applicable)

3.6 Nursing Manager/Administrative Supervisor, when available

3.7 Cath Lab Staff, when available

4.0 TEAM RESPONSIBILITIES

4.1 The ES Nurse will complete patient assessment and vital signs. Establish patient monitoring and IV access.

4.2 The ES LIP will perform patient assessment and order appropriate plan of care based on the STEMI order set.

4.3 Nursing Technician will assist with patient care as delegated by the Registered Nurse.

4.4 The Clinical Laboratory will assist with the collection of the blood samples if present.

4.5 The Respiratory Therapist will assist with oxygenation and airway management as ordered by the Emergency Services LIP if present.

4.6 The Bed Planner/Administrative Supervisor will coordinate Intensive Care Unit bed availability if required.

4.7 The Cath Lab staff will help in the transport of the patient to the cath lab when available.

5.0 TREATMENT PRIORITIES OF THE TEAM INCLUDE:

5.1 Oxygenation and airway management

5.2 Hemodynamic stability

5.3 Rapid Percutaneous Coronary Angioplasty.

5.4 Expeditious transport to closest accepting CIC facility

6.0 COORDINATION OF PATIENT CARE

6.1 The Emergency Services LIP is responsible for the coordination of the patient's care with the STEMI Dr. to achieve optimal patient outcome.

7.0 CARE OF THE PATIENT PRESENTING AT SHORE EMERGENCY CENTER AT QUEENSTOWN, SMC AT CAMBRIDGE OR CHESTERTOWN WITH A STEMI:

7.1 These patients will be transferred to the closest approved CIC center.

8.0 INPATIENT STEMI ALERT FOR SMC at EASTON

8.1 Pt reports symptoms of myocardial infarction. RN to assess patient and take vital signs. Call a MET.

8.2 Apply cardiac monitor and O2 to maintain O_2 saturation greater than or equal to 94%. Treat the patient's symptoms.

8.3 Hospitalist to order ECG STAT/ Hospitalist to read ECG STAT. If STEMI is identified the Hospitalist will call the STEMI interventional cardiologist

8.4 STEMI ALERT Activated as outlined in 2.0

8.5 STEMI Physician order set is initiated.

8.6 Defibrillator pads are placed.

Patient is prepared to go to Cath Lab. Patient will be transported to the ICU unless the Cath Lab is readily available to care for the patient.

8.7 Send the ECG with the patient to the Cath Lab.

8.8 Cath Lab will call Administrative Supervisor or Admission Coordinator when they are ready to receive the patient.

8.9 The hospital operator will contact the Cath Lab on-call team (VOLO).

8.10 The STEMI interventional cardiologist will determine PCI inclusion criteria; explain the risks and benefits of the procedure to the patient/family and obtain informed consent prior to the procedure.

9.0 INPATIENT STEMI ALERT FOR SMC AT CHESTERTOWN

9.1 Pt reports symptoms of myocardial infarction. RN to assess patient and take vital signs. Call a MET.

9.2 Apply cardiac monitor and O2 to maintain O_2 saturation greater than or equal to 94%. Treat the patient's symptoms.

9.3 Hospitalist to order ECG STAT/ Hospitalist to read ECG STAT. If STEMI is identified the Hospitalist will call the STEMI interventional cardiologist.

9.4 STEMI ALERT Activated as outlined in 2.0

9.5 STEMI Physician order set is initiated.

9.6 Defibrillator pads are placed on the patient in right and left mid axillary line

9.7 RN to call LIFE LINE at ext 5433 to notify Easton ED of incoming STEMI with estimated time of arrival (ETA).

9.7.1 Easton ED will follow steps as outlined in 2.0 to initiate STEMI alert for Easton.

9.8 Inpatient staff to contact appropriate transportation to coordinate transport to the CIC center.

SRH Administrative Policy TX	
Effective	08/17
Revised	12/17
Revised	06/18
Approved	Critical Care Committee
SRH Administrative Policy PC	
Revised	12/21
Approved	Cardiac Steering Committee
Policy Owner	Jessica Fluharty, MSN, RN, Regional Director of Emergency Services

REFERENCE:

1. *Bates, E. Causes of Delay and Associated Mortality in Patients Transferred with STEMI. http://www.hcplive.com/journals/cardiology-review-online/2012/february2012/causes-of-causes-of-delay-and-associated-mortality-in-patients-transferred-with-stemi-#sthash.QKLX1zTw.dpuf; 2012.*
2. O'Gara, P et al. 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infraction: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* (2012) 1-88.
3. Gibson, M. et al. Primary percutaneous coronary intervention in acute ST Elevation myocardial infarction: Peri-procedural management *htts//www.uptodate.com. 2016*
4. *2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and 2013 ACCF/AHA Guideline for the Management of ST Elevation Myocardial infarction; 2015*

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	ADMINISTRATIVE POLICY & PROCEDURE	POLICY NO:	LD-90
		REVIEWED:	10/20
	EMERGENCY MEDICAL SERVICES (EMS) ALERT	PAGE #:	1 of 6
		SUPERSEDES	02/18

PURPOSE

The Emergency Medical Services (EMS) Alert Policy is to be initiated to provide criteria to guide decisions to initiate ambulance diversion and utilizes guidelines developed by the Maryland Institute for Emergency Medical Services Systems Region IV in defining alert status.

DEFINITIONS

1. **Red Alert:** Red alert is not an Emergency Department (ED) alert. It is a facility alert to EMS that the facility has no staffed inpatient cardiac monitored beds available. The hospital will receive unstable Priority I cardiac monitored patients from within its catchment area for initial stabilization and patients requiring specialized care (e.g. OB, stroke, STEMI, etc). Subsequent transfer to another facility for admission to a cardiac monitored bed may be necessary following stabilization. EMS will consider transport to other facilities based on Maryland EMS Protocol for stable Priority II and Priority III cardiac monitored patients and may bypass if based on conditions of other facilities within the 911 area, the other facility can accommodate the cardiac monitored patient. **Non-cardiac** monitored Priority II and Priority III patients will be accepted. Patients requiring potential admission may need transfer to another facility for admission. If adjacent facilities are on Red Alert, EMS transports to the most appropriate facility

2. **Yellow Alert:** The Emergency Department temporarily requests that it receive no patients in need of urgent medical care based on Maryland EMS Protocols. The hospital will receive unstable patients (Priority I) and patients requiring specialized care (e.g. OB, stroke, STEMI, etc) from within its catchment area for initial stabilization. Subsequent transfer to another facility for admission to a bed may be necessary. This alert should be utilized for unplanned or unexpected incidents and may not exceed two (2) hours for each event for a total of six (6) hours for any 24-hour period beginning at midnight. If adjacent facilities are on Yellow Alert, EMS transports to the most appropriate facility.

3. **Mini-Disaster:** Must be approved by the State EMS Medical Director via SYSCOM: The hospital or Emergency Department reports that their facility has, in effect, suspended operations and can receive absolutely no patients due to a situation such as a power outage, gas leak, bomb threat, etc. Unless the situation is isolated to the Emergency Department, all other means of patient

admissions must be halted prior to Mini-Disaster alert being implemented. Critical Care overloads are not considered justification for a Mini-Disaster Alert.

4. **Blue Alert:** This overrides all alerts, except the Mini-Disaster Alert, resulting in all patients from within that jurisdiction to be transported to the closest facility appropriate for the patient's medical needs. The EMS System is temporarily taxed to its limits in cases of weather or significant circumstances that contributed to high demand for EMS service (e.g. snow, flooding, transportation etc).

5. **Priority I Patient**: Critically ill or injured person requiring immediate attention; unstable patients with potentially life-threatening injury or illness.

6. **Priority II Patient**: Less serious condition, requiring emergency medical attention but not immediately endangering the patient's life.

7. **Priority III Patient**: Non-emergent condition, requiring medical attention but not on an emergency basis.

POLICY

1.0 INITIATION OF RED ALERT

1.1 The Bed Coordinator/Administrative Supervisor in collaboration with Inpatient Nurse Manager, Charge Nurse/ Designee determine that the conditions within the Inpatient Departments warrant a discussion related to the inpatient bed capacity for staffed monitored beds, and the need to go on Red Alert.

1.2 The Nursing Director of the facility/Bed Coordinator/Administrative Supervisor will make a recommendation regarding implementation of Red Alert based on:

1.2.1 Review of information related to bed capacity and staffing.

1.2.2 Review of strategies attempted to remedy issues with bed capacity and staffing.

1.3 If The Nursing Director of the facility/Administrative Supervisor believes it is in the best interest of the facility to implement Red Alert, the Nursing Director of the facility/Administrative Supervisor will make a recommendation to the Administrator on Call (AOC) who will make the final decision.

1.3.1 The Bed Coordinator/Administrative Supervisor will notify Emergency Medical Resources Center (EMRC), 911 centers, and local hospitals as per Attachment A.

1.3.1.1 There is no time limit on Red Alert. The length of time on Red Alert is based on availability of staffed inpatient monitored beds.

1.3.1.2 Efforts should be made to clear monitored beds as quickly as possible (e.g. downgrades for Telemetry/ ICU) or to call in extra staff to minimize the alert situation.

1.3.2 The Bed Coordinator/Administrative Supervisor verifies Alert Status on CHATS at www.MIEMSS.org.

2.0 INITIATION of YELLOW ALERT

2.1 Criteria to consider before making the decision to implement Yellow Alert:

2.1.1 Is the request related to a major safety concern due to level of care patients in the ED are requiring? (i.e. Codes, sepsis, STEMI, etc).

2.1.2 Emergency Department census

2.1.3 The number of patients waiting in the ED to be seen along with average wait time to be seen.

2.1.4 Number of ED holds awaiting inpatient bed or transfer

2.1.5 Calling in the Surge LIP and/ or additional nursing staff.

2.1.6 Discharges pending within 30 minutes on inpatient units.

2.1.7 Discharges pending from EDs.

2.1.8 Status in the other SRH EDs and adjacent facilities.

2.2 The Emergency Department Nurse Manager, Charge Nurse/ Designee in collaboration with the Emergency Department physician recognize that the conditions in the Emergency Department warrant a discussion about the need to go on Yellow Alert.

2.2.1 If the Emergency Department Nurse Manager, Charge Nurse/ Designee and the Emergency Department Physician do not agree, the Emergency Services site Medical Director will be contacted.

2.3 The Emergency Department Nurse Manager, Charge Nurse/ Designee notifies the Nursing Director of the facility/ Administrative Supervisor to discuss the situation in the ED that is recognized to warrant Yellow Alert.

2.3.1 If the Emergency Department Nurse Manager, Charge Nurse/ Designee, Nursing Director of the facility/Administrative Supervisor and the Emergency Services site Medical Director do not agree the Chain of Command will be followed and the Regional Medical Director will be contacted.

2.4 The Nursing Director of the facility/Administrative Supervisor will determine the need to go on Yellow Alert based on information collected from Emergency Department Nurse Manager, Charge Nurse/ Designee as determined in 2.1 above.

2.5 If the Nursing Director of the facility/Administrative Supervisor determines that conditions warrant Yellow Alert, the Nursing Director of the facility/Administrative Supervisor will make a recommendation to the AOC. The AOC will make the final decision.

2.5.1 If there is no response within 15 minutes from the Administrator on Call, the decision will be independently made to initiate Yellow Alert.

2.5.2 There is a time limit to Yellow Alert. Yellow Alert may not exceed two (2) hours for each event for a total of six (6) hours for any 24-hour period beginning at midnight.

2.6 The Nursing Director of the facility/Administrative Supervisor will notify the Emergency Department Nurse Manager, Charge Nurse/ Designee of approval to proceed with Yellow Alert.

2.7 The Emergency Department Nurse Manager, Charge Nurse/ Designee will:

2.7.1 Notify EMRC, 911 centers, and local hospitals as per Attachment A.

2.7.2 Verify Alert Status on CHATS at www.MIEMSS.org.

2.7.3 Assure the Emergency Department maintains EMS Alert Contributions/Functions as per Attachment B.

2.8 Other Hospital Departments are to maintain EMS Alert Contributions/Functions as per Attachment B.

3.0 DISCONTINUATION OF EMS ALERT

3.1 The Emergency Department Nurse Manager, Charge Nurse/ Designee

3.1.1 Notifies the Nursing Director of the facility/Administrative Supervisor as soon as conditions in the Emergency Department allow for discontinuation of Alert status (Red or Yellow).

3.1.2 Notifies EMRC, local 911 centers and local hospitals per Attachment A that the Alert has been discontinued.

3.2 The Nursing Director of the facility /Administrative Supervisor notifies the Administrator on Call that the Emergency Department is off of Red or Yellow Alert.

Effective	05/01
Approved	Senior Leadership
Revised	09/04
Revised	07/06
Reviewed	08/08
Revised	10/11 *(Editorial Changes)*
Revised	08/12 *(Editorial Change)*

Reviewed	10/16
Revised	09/17
Revised	02/18
Revised	10/20
Policy Owner	Melanie Donaway, Director of Organizational Excellence

UNIVERSITY of MARYLAND SHORE MEDICAL CENTER AT EASTON	CARDIAC CATHETERIZATION LAB	POLICY NO:	PCI-11
		REVISED:	03/20
	STEMI ALERT PROCESS	PAGE #:	1 of 2
		SUPERSEDES	02/19

Cross Reference: SRH TX-103 Identification of Patients Having a STEMI
PCI-12 Cardiac Cath Lab On-Call Process
PCI-14 How to Address When More Than One STEMI is Identified at the Same Time

PURPOSE

1.0 To assure that the Cardiac Cath Lab UMSMC-Easton is able to provide timely access to STEMI Primary Angioplasty 24 hours/day, 365 days/year.

POLICY

2.0 STEMI Inclusion Criteria
- **2.1** ST elevation of > 1mm in 2 contiguous leads.
- **2.2** New Left Bundle Branch Block (LBBB).
- **2.3** Patient is over the age of 18.
- **2.4** If the patient is on Metformin, there is no history of renal failure (creatinine < 1.7).

3.0 STEMI Alert Process
- **3.1** Once confirmation of STEMI has been determined, the STEMI Alert process will be activated by the ED physician or the ED staff as directed by the ED physician.
- **3.2** The Switchboard operator will be instructed to activate the STEMI Alert process. (See also PCI-12)
- **3.3** For all hours 24/7 the Switchboard Operator will overhead page "STEMI Alert"
  - **3.3.1** If STEMI Alert is associated with an EMS transport ETA, the ETA will be paged along with STEMI Alert page.
  - **3.3.2** This will serve to notify the Nursing Supervisors and Respiratory Care Practitioner and dictate immediacy of response to ED.
  - **3.3.3** Switchboard Operator will then activate the VOLO paging system to alert the Cardiac Cath Lab on call team to respond during hours or normal operation as well as after hours of normal operation (On Call hours).
    - **3.3.3.1** The VOLO paging system consists of a predetermined "scenario" that includes a text message along with a verbal message of "STEMI Alert."
    - **3.3.3.2** The STEMI On Call Team responds as having received the message by way of VOLO response.
    - **3.3.3.3** After hours STEMI Call Team is required to respond to CCL in 30 minutes.
  - **3.3.4** Switchboard will call the Interventional Cardiologist on call (designated as "STEMI Cardiologist").
    - **3.3.4.1** If not already accomplished as defined in PCI-12, Interventional Cardiologist will contact the ED physician for details of STEMI Alert.
  - **3.3.5** The Switchboard will be provided with a call schedule for Interventional Cardiologist (STEMI Cardiologist) and CCL staff On Call Team.

4.0 Cardiac Cath Lab STEMI Response (See also PCI-12)

4.1.1 During normal working hours (M-F 7A-5:30P) the CCL Team will immediately prepare one of the two procedure rooms available to accept the STEMI patient from the ED.

4.1.1.1 If procedures are already under way in both Cath Labs, the Interventional Cardiologist will determine which of the two procedures can be aborted.

4.1.1.2 If necessary, the patient who can be safely removed from a procedure under way will be placed in the holding area of the CCL.

4.1.1.3 A CCL room will be immediately prepared to receive ED STEMI patient.

4.1.1.4 See PCI-14 How to Address When More Than One STEMI is Identified at the Same Time.

4.1.2 After normal hours of operation (M-F 7A-5:30P) a CCL STEMI On Call Team is available.

4.1.2.1 The VOLO Alert (as described 8.3.3.1) will be used to summon the On Call Team who are required to respond to the CCL within 30 minutes.

4.1.2.2 Upon arrival of the On Call Team, the first member to arrive will contact the ED and let them know that when CCL is preparing to accept STEMI patient.

4.1.2.3 CCL Call Team will follow the predetermined sequence of room preparation (See PCI-13).

4.1.2.4 Once CCL Team including Interventional Cardiologist are ready to accept STEMI patient, a team member will notify the ED and report to the ED to assist with transfer along with Interventional Cardiologist, if not already in the ED.

Policy	
Effective	05/17
Revised	01/18
Revised	05/18
Revised	02/19
Revised	03/20
Policy Owner	Gary Jones, Director, Heart and Vascular

UNIVERSITY of MARYLAND SHORE MEDICAL CENTER AT EASTON	CARDIAC CATHETERIZATION LAB	POLICY NO:	PCI-12
		REVISED:	03/20
	CARDIAC CATHETERIZATION (STEMI) LABORATORIES ON-CALL PROCESS	PAGE #:	1 of 2
		SUPERSEDES	05/18

Cross Reference: Transfer of STEMI Patient from ED
SRH Administrative Policy TX-103
PCI-11 STEMI Alert Process

PURPOSE

1.0 To provide guidelines to the EDs and inpatient areas that require emergent intervention during off hours between 5:00pm and 7:00am, Monday through Friday and 7:00am on Saturday through 7:00am Monday.

PROCEDURE

2.0 Cardiac Catheterization (STEMI)

2.1 When a patient presents to the ED (Walk-in, Transfer, or EMS) or is an inpatient and is determined to meet STEMI criteria, the following will occur:

2.1.1 The ED charge nurse will activate the STEMI on-call page by calling Switchboard with instructions to overhead page "STEMI Alert" and to activate the Cardiac Cath Lab STEMI On-Call Team based on call rotation calendar provided by Cardiac Cath Lab. The Nursing Supervisor will be alerted to STEMI Alert by overhead page. Nursing Supervisor will confirm availability of a staffed ICU bed based upon the process that has been developed in conjunction with Nursing Services.

2.1.2 The ED physician will contact the on-call Interventional Cardiologist and discuss the case. The on-call Interventional Cardiologist schedule and phone numbers can be found on the SRH Intranet. The ED will scan the STEMI EKG to the Interventional Cardiologist upon request.

2.1.3 The on-call team members will respond and are expected to arrive at the hospital within thirty (30) minutes of page. The team STEMI on-call lead cardiovascular specialist will contact the Switchboard to confirm receipt of call. The same individual will contact any team member(s) that has not responded in an attempt to complete the four man team.

2.1.3.1 ED to document time Interventional Cardiologist notified and returned call.

2.1.4 The first team member on site will call ED (5557) for patient information and request that the ED begin preparing the patient for transfer to the Cath Lab. As soon as a third member arrives to the Cath Lab: (See Start Up Procedure PCI-13)

2.1.4.1 When it is determined that the Cath Lab is ready to receive the patient, a Cath Lab Team member will contact the ED and advise.

2.1.4.2 A Cath Lab Team member will go to the ED to assist with transfer to the Cath Lab.

2.1.5 Upon transfer to the Cath Lab, the ED nurse will give bedside report to the STEMI team. The ED nurse will deliver to the Cath Lab nurse a signed, timed and dated STEMI EKG and the patient chart.

2.1.6 The Interventional Cardiologist on-call schedule will be maintained monthly and the schedule will be posted on all units including the ED and the Switchboard. The schedule is posted on the SRH Intranet on-call schedules.

2.1.6.1 Click on physician name and the hours and contact number are listed. If this physician is involved in another procedure, he will inform ED physician in accordance with Second STEMI Policy and Procedure (See PCI-14).

Policy	
Effective	05/17
Revised	01/18
Revised	05/18
Reviewed	02/19
Revised	03/20
Policy Owner	Gary Jones, Director, Heart and Vascular

UNIVERSITY of MARYLAND SHORE MEDICAL CENTER AT EASTON	CARDIAC CATHETERIZATION LAB	POLICY NO:	PCI-13
		REVISED:	02/22
	START UP PROCEDURE FOR CATH LAB STEMI "CALL IN"	PAGE #:	1 of 1
		SUPERSEDES	05/17

POLICY:

1.0 After hours (7A-5:30P M-F) coverage for emergency Cardiac Cath is assured by rotating Call Teams of a minimum of three staff members to provide coverage for all hours not covered under normal hours of operation. Cath Lab Call Team members are required to respond to the Cath Lab within thirty (30) minutes of notification. See also: Primary Coronary Intervention (STEMI) Policy # (PCI-10).

PROCEDURE:

2.0 Open door to the Cath Lab and lock door open

2.1 Notify Emergency Department (and Nursing Supervisor if after hours) that first call team member has arrived

3.0 Open door to the Cath Lab #2 and lock door open

4.0 Turn power on to Philips X-ray

5.0 Turn power on to Mac Lab

6.0 Turn power on to defibrillator and validate quality check

7.0 Unlock and open supply cabinets

8.0 Obtain patient information from Emergency Department to enter into monitoring and x-ray system

8.1 Cath Lab RN to obtain handoff from ED RN to get report

9.0 Inform Emergency Department that we will call for patient once all Cath Lab staff arrives

10.0 Bring PCI supply carts close to room

11.0 Call for patient once all staff arrive

11.1 A minimum of one Cardiac Cath staff report to the Emergency Department to get patient handoff report and assist with transport to Cath Lab.

12.0 Notify Syscom/Maryland Express Care Transfer Center at x1232 that we are performing a Primary PCI

Policy	
Effective	05/17
Reviewed	05/18
Revised	02/22
Revised	
Policy Owner	Dyshekia Strawberry, Manager, Cardiac Cath Lab

UNIVERSITY of MARYLAND SHORE MEDICAL CENTER AT EASTON	CARDIAC CATHETERIZATION LAB	POLICY NO:	PCI-14
		REVISED:	02/22
	HOW TO ADDRESS WHEN MORE THAN ONE STEMI IS IDENTIFIED AT THE SAME TIME	PAGE #:	1 of 1
		SUPERSEDES	01/18

1.0 PURPOSE

1.1 To provide guidelines to the ED and Cardiac Catheterization Laboratory (CCL) team members when caring for multiple STEMI patients in the CCL.

2.0 PROCEDURE

2.1 When multiple STEMI patients are identified and potentially will arrive in the ED near or at the same time:

2.1.1 The ED physician will contact the Interventional Cardiologist (STEMI Cardiologist) who is on call or available as assigned to the CCL and provide details of case(s).

2.1.2 The STEMI Alert process will be activated. See Policy (PCI-11).

2.1.3 The after-hours On-Call Team will respond and are expected to arrive at the hospital within thirty (30) minutes of page.

2.1.4 The Nursing Supervisor on duty will be informed to provide adequate support for when the patients are ready to be transferred to the ICU following their procedure.

2.2 Determining Patient Priority – See the attached Algorithm

2.2.1 The Interventional Cardiologist performs a STEMI procedure on the most critical patient after discussing both cases with the ED physician(s).

2.2.2 The Interventional Cardiologist will assess the potential time required to begin the second arriving STEMI patient.

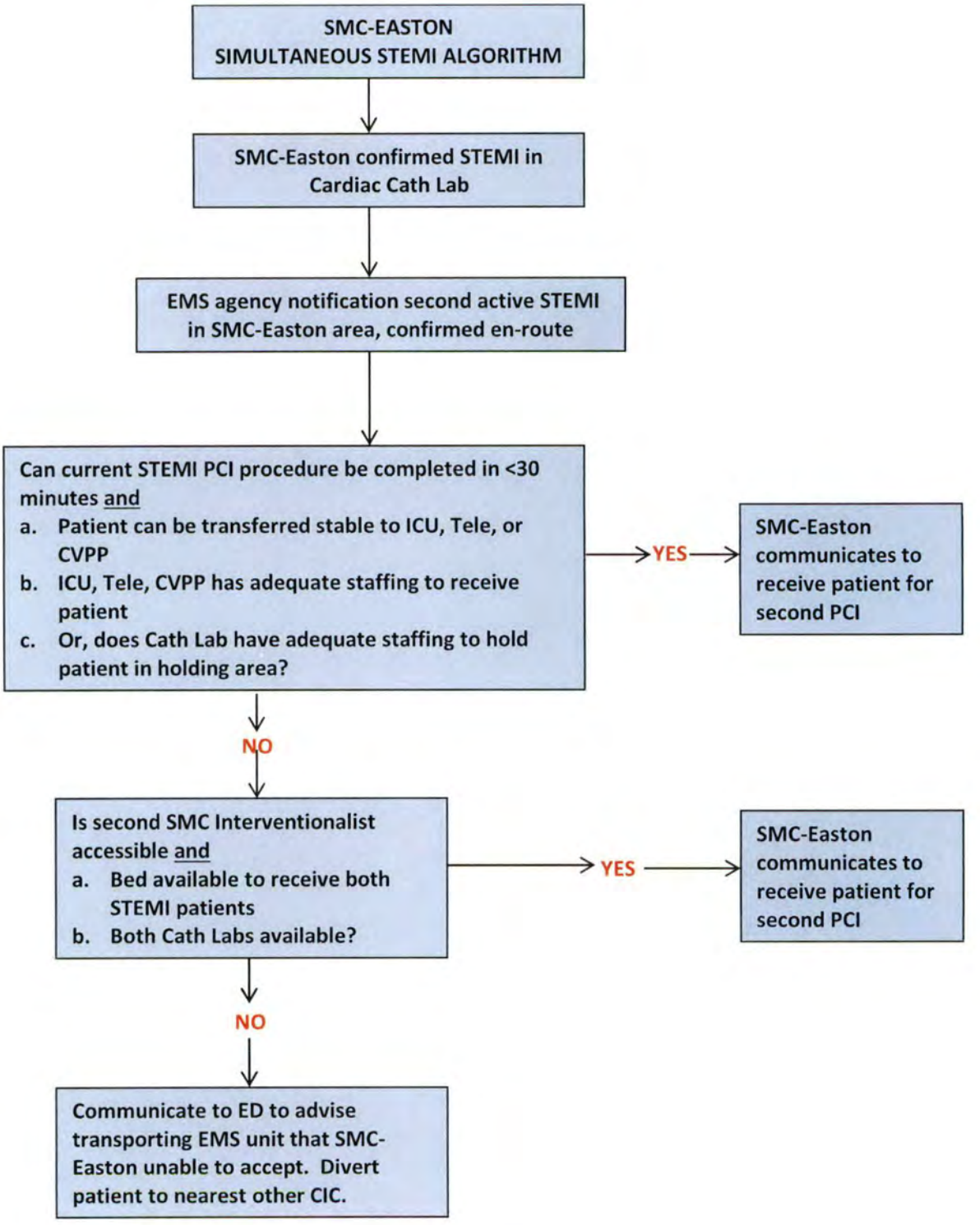
2.2.2.1 If the delay in starting the second STEMI patient is greater than the transport time to the nearest MIEMSS designated CIC Center, the ED will be instructed to transfer the second STEMI patient or direct the responding EMS unit to direct the patient to the nearest MIEMSS designated CIC Center.

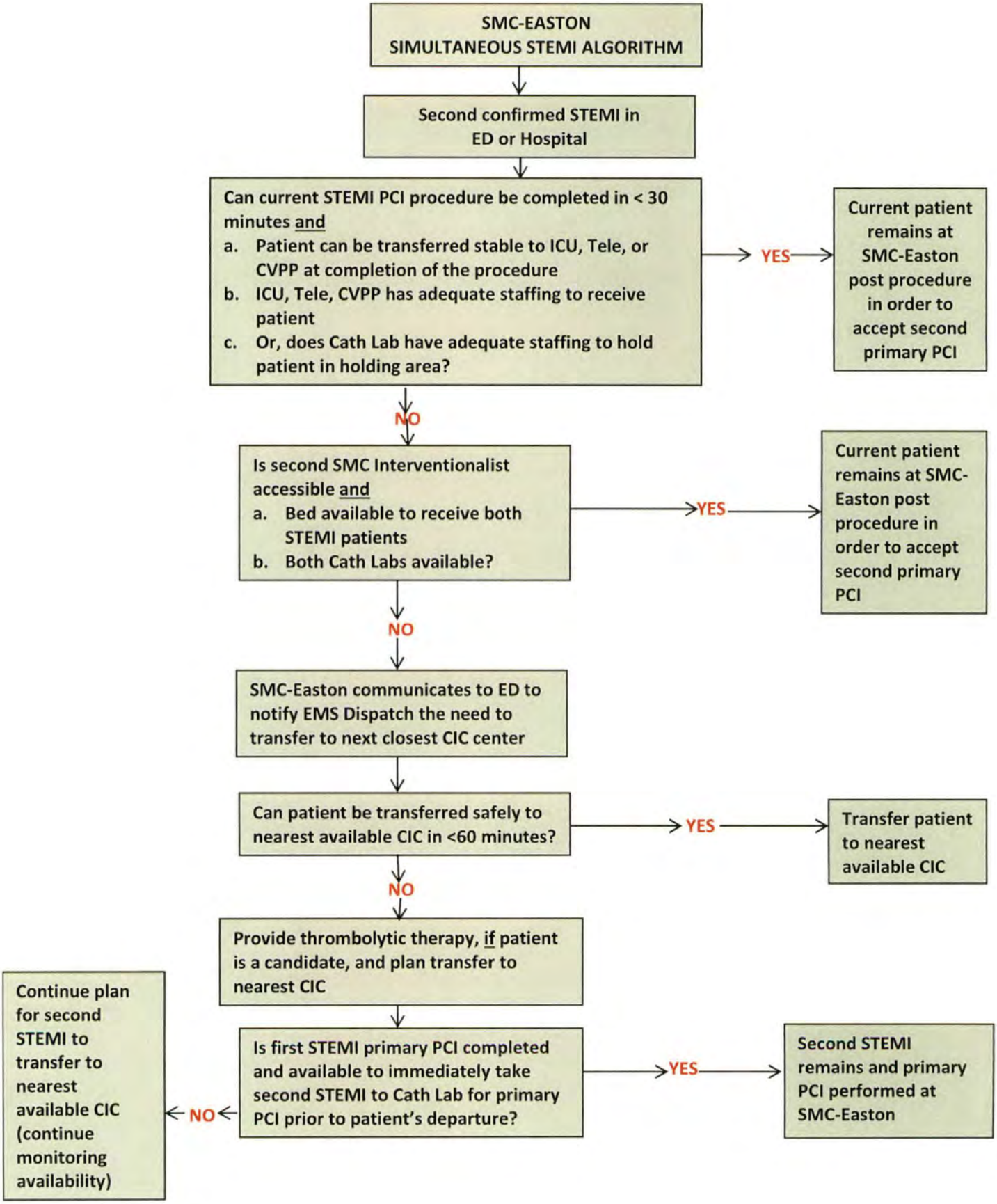
2.2.3 The remaining patient(s) will be monitored in the ED by the ED staff.

2.2.4 The Interventional Cardiologist performs a STEMI procedure on the second most critical patient, etc.

2.2.5 As soon as the team completes their case, they are designated as the primary on-call team until all cases are completed and the original primary on-call team resumes responsibility.

Policy	
Effective	05/17
Revised	01/18
Revised	02/22
Policy Owner	Dyshekia Strawberry, Manager, Cardiac Cath Lab


SMC-EASTON
SIMULTANEOUS STEMI ALGORITHM
SMC-Easton confirmed STEMI in Cardiac Cath Lab
EMS agency notification second active STEMI in SMC-Easton area, confirmed en-route
Can current STEMI PCI procedure be completed in <30 minutes and
a. Patient can be transferred stable to ICU, Tele, or CVPP
b. ICU, Tele, CVPP has adequate staffing to receive patient
c. Or, does Cath Lab have adequate staffing to hold patient in holding area?
YES
SMC-Easton communicates to receive patient for second PCI
NO
Is second SMC Interventionalist accessible and
a. Bed available to receive both STEMI patients
b. Both Cath Labs available?
YES
SMC-Easton communicates to receive patient for second PCI
NO
Communicate to ED to advise transporting EMS unit that SMC-Easton unable to accept. Divert patient to nearest other CIC.


SMC-EASTON
SIMULTANEOUS STEMI ALGORITHM
Second confirmed STEMI in ED or Hospital
Can current STEMI PCI procedure be completed in < 30 minutes and
a. Patient can be transferred stable to ICU, Tele, or CVPP at completion of the procedure
b. ICU, Tele, CVPP has adequate staffing to receive patient
c. Or, does Cath Lab have adequate staffing to hold patient in holding area?
YES
Current patient remains at SMC-Easton post procedure in order to accept second primary PCI
NO
Is second SMC Interventionalist accessible and
a. Bed available to receive both STEMI patients
b. Both Cath Labs available?
YES
Current patient remains at SMC-Easton post procedure in order to accept second primary PCI
NO
SMC-Easton communicates to ED to notify EMS Dispatch the need to transfer to next closest CIC center
Can patient be transferred safely to nearest available CIC in <60 minutes?
YES
Transfer patient to nearest available CIC
NO
Provide thrombolytic therapy, if patient is a candidate, and plan transfer to nearest CIC
Is first STEMI primary PCI completed and available to immediately take second STEMI to Cath Lab for primary PCI prior to patient's departure?
YES
Second STEMI remains and primary PCI performed at SMC-Easton
NO
Continue plan for second STEMI to transfer to nearest available CIC (continue monitoring availability)

UNIVERSITY of MARYLAND SHORE MEDICAL CENTER AT EASTON	CARDIAC CATHETERIZATION LAB	POLICY NO:	PCI-16
		REVISED:	05/17
	TRANSFER POLICY FOR THE INTERFACILITY TRANSPORT OF PRIMARY ANGIOPLASTY PATIENTS	PAGE #:	1 of 2
		SUPERSEDES	

PURPOSE

1.0 The waiver for primary angioplasty in hospitals without open heart surgery requires that University of Maryland Medical Center at Easton (UMSMC-E) have a process in place that will ensure that an ALS equipped ambulance will arrive within thirty (30) minutes of a request for patient transfer to a tertiary facility prepared to perform open heart surgery.

2.0 This Transfer Policy exists to provide a clear notification, request and transfer process that will ensure timely and efficient response should a patient undergoing primary angioplasty require transfer to the University of Maryland Medical Center (UMMC). In addition, this will provide a mechanism that will improve access to and utilization of appropriate resources.

3.0 This Transfer Policy will also include those patients whose experience recurrent ischemia, failed PCI requiring additional intervention to include CABG.

POLICY

4.0 NOTIFICATION

4.1 The purpose of notification is to provide preparation time for the mobilization of important resources should a request be made.

4.2 Notification is to be made at the point the patient has been identified for PTCA. A member of UMSMC-E cardiac catheterization team will notify the Maryland Express Care Transfer Center at the University of Maryland Medical Center by dialing 410-328-1234. This contact should be made as soon as possible after getting the patient on the cardiac cath table and it is known that the patient will be receiving primary angioplasty.

4.2.1 Identify the facility as UMSMC-E and notify the Transfer Center that there is a patient about to undergo primary angioplasty.

4.2.2 Provide the Transfer Center with logistical information, patient demographics and brief clinical information that they may request.

4.2.3 If the decision is made to transport the patient, as soon as possible, fax a copy of the patient's "face sheet" with demographic data to the Transfer Center at 410-328-1235.

5.0 POINT OF CONTACT

5.1 The Maryland Express Care Transfer Center (TC) at UMMC will be the sole source of contact throughout the process. All inquiries related to patient transport should go through the TC. This allows for the most timely and efficient utilization of resources and avoids conflicting communication.

5.2 Air transport is the preferred and most expeditious form of transportation in this time sensitive pPCI area. If a helicopter is not available or able to travel to respond to UMSMC-E, the Transfer Center will contact the UMSMC-E contractual vendor for appropriate ground transportation.

6.0 NO TRANSPORT NECESSARY

6.1 Once transport is deemed not necessary, a member of the UMSMC-E cath lab team will notify the Transfer Center.

7.0 REQUEST FOR TRANSPORT

7.1 If patient transport becomes necessary, a member of the UMSMC-E cath lab team will place a request to the Transfer Center with the following information:

7.1.1 Will the patient require an intra-aortic balloon pump?

7.1.2 Patient status report

7.2 A copy of the patient's medical record will accompany the patient

7.3 The TC will dispatch the Express Care Team to include an RN and balloon pump if requested. Maryland Express Care guarantees arrival of the air ambulance within thirty (30) minutes of a request by UMSMC-E for patient transport. Such response time includes the period from receipt of a call by UMSMC-E to arrival of the air ambulance at UMSMC-E.

7.3.1 If Maryland Express Care air ambulance is not available or able to fly, the Transfer Center will notify either another air ambulance vendor or the UMSMC-E contractual ground transportation vendor, as appropriate.

7.3.2 If all vendor resources are exhausted with no Critical Care team availability, the TC will dispatch a UMMC cardiac fellow/attending and an ALS team to respond within thirty (30) minutes.

7.3.3 If all vendor resources are exhausted with no Critical Care team availability and no UMMC Cardiac fellow/attending availability, the TC will proceed with contacting the UMSMC-E contractual ground transportation vendor.

7.3.4 If the UMSMC-E ground transportation vendor cannot provide a Critical Care team, the TC will contact the UMSMC-E cath lab staff to inform them of the lack of Critical Care transport availability, and appropriate UMSMC-E staff will accompany the patient during transport with the dispatched ALS team. The UMSMC-E staff member will be returned to UMSMC-E immediately following the transport.

7.4 If the balloon pump is not available in a timely manner, Maryland Express Care can utilize the UMSMC-E balloon pump and will return it to UMSMC-E expediently after delivering the patient to the University of Maryland Medical Center.

Policy	
Effective	05/17
Revised	
Revised	
Policy	
Reviewed	05/18
Policy Owner	Gary Jones, Regional Director

UNIVERSITY of MARYLAND SHORE MEDICAL CENTER AT EASTON	CARDIAC CATHETERIZATION LAB	POLICY NO:	CCL-27
		REVISED:	12/2021
	EMERGENCY TRANSFER FROM THE CARDIAC CATH LAB	PAGE #:	1 of 1
		SUPERSEDES	11/2017

POLICY: The following guidelines will be instituted, should the need arise, based upon a deterioration in patient condition requiring immediate transfer to another facility.

To ensure a quick and decisive method for transfer of a critical patient to another facility.

CROSS REFERENCE: SRH Hospital Transfer Policy CC-11
PCI-16 Transfer Policy for the Interfacility Transfer of Primary Angioplasty Patients

1.0 The cardiologist will be present in order to initiate the stabilization process.

2.0 Immediate efforts will be undertaken to provide support and medical stabilization while transport is being arranged to include: Pharmacologic intervention, pacemaker insertion, intubation/ventilation, and intra-aortic balloon pumping.

3.0 The cardiologist will determine the referral center.

4.0 The cardiologist will arrange for an emergency admission to the referral center.

5.0 Once confirmation of emergency medical transfer is received from the referral center the cath team, RN or technologist, will contact transport services to arrange for aeromedical transfer by the medical flight.

5.1 In the event aeromedical transfer is not possible, arrangements will be made for emergency ground transfer.

6.0 Transfer of medical responsibility for the patient occurs when:

6.1 The Transfer Team arrives at UM SRH at Easton and accepts transfer of patient to their equipment and personnel support.

6.2 When ground transport arrives at the referral center and the referral center accepts responsibility for the patient.

Policy	
Effective	05/15/2003
Revised	07/2006
Revised	05/2008
Reviewed	4/12/2013
Revised	11/2017
Revised	12/2021
Policy Owner	Dyshekia Strawberry, MSN, BS, RN-BC, Manager, Cardiac Cath Lab

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	ADMINISTRATIVE POLICY & PROCEDURE	POLICY NO:	PC-07 (CC-07)
		REVISED:	03/22
	GROUND AND AIR TRANSPORT: BLS, ALS & CRITICAL CARE	PAGE #:	1 of 4
		SUPERSEDES	08/21

PURPOSE:

To provide a comprehensive system of inter-hospital transport services for Shore Regional Health and the entire Eastern Shore.

POLICY:

1.0 GENERAL INFORMATION

1.1 Contract Vendor/Maryland Express Care is the inter-hospital transfer service for Shore Regional Health (SRH).

1.2 The Maryland Access Center is coordinated by University of Maryland Medical Center or the contract vendor via designated number.

1.3 The inter-hospital critical care ground component of this service is based at SRH at Easton.

1.4 A contracted vendor is utilized for transports for BLS level of care transports or for ALS or SCT (Specialty Care Transport – Paramedic staffed) level of care when the dedicated team is not available.

1.5 All transports will be carried out in compliance with current EMTALA and COMAR regulations.

1.6 For emergent ED transfers inclusive of but not limited to Trauma, STEMI or laboring (active laboring) patients, ED staff may call 911 for transport by Department of Emergency Services if a licensed commercial service is not available in a timely manner.

1.7 Reference Birthing Center Transport Policy: Transport- Newborn & Transport- Maternal

2.0 REQUEST FOR TRANSPORT

2.1 All requests to transport patients from SRH, within SRH, and other hospitals via ground or air (rotor or fixed-wing) will be made by contacting the contract vendor or University of Maryland Access Center at 1-800-373-4111 or directly from SHS at Extension 1234. Level of care required is based on patient care need and condition which is determined by the SRH

medical staff. Notify communication center if specialized equipment is required, i.e. bariatric unit

2.1.1 Consult selection – select 1

2.1.2 For ground transport, specifying level of care (BLS, ALS SCT with nurse) – select 2

2.1.2.1 Request lights and siren for urgent transports

2.1.2.2 Request routine for non-urgent

2.1.2.3 Auto-launch for air/ground – select 3

2.1.2.4 Maryland Neonatal Team – select 4

2.2 Transport will be arranged in the most efficient and timely manner focusing attention on the patient's medical condition and level of care needed for safe transport.

2.3 In the event the patient is being transferred to University of Maryland Medical Center, the Access Center will facilitate physician-to-physician communication and confirm bed availability.

3.0 BASIC LIFE SUPPORT (BLS) TRANSPORTS

3.1 BLS transports require only basic life support assessment and/or interventions.

4.0 ADVANCED LIFE SUPPORT (ALS) TRANSPORTS

4.1 ALS transports may require advanced life support assessments and/or interventions.

5.0 SPECIALTY CARE TRANSPORTS (SCT)

5.1 Specialty Care transports require advanced critical care assessments and interventions. These transports are carried out according to established medical guidelines.

5.2 All transfers will follow the MIEMSS protocols and MEC (Maryland Express Care) clinical guidelines for transportation. Alteration from the protocols/guidelines requires collaboration between the sending Practitioner and the consulting MEC medical director.

6.0 In an emergent situation when SRH RN staff must accompany the patient due to unavailable SCT staffed units, the transporting RN must be competent to care for the patient and meet the MD Board of Nursing standards as defined in COMAR 10.27.09.04.

6.1 Contact the Administrative supervisor for additional resources /personnel if needed

6.2 SRH Nurses who come in to complete the transport will be paid a bonus in the following manner for performing a transport.

Bonus for transport coverage	
Shift	**Bonus**
Day	$125.00
Evening	$150.00
Night	$200.00
Holiday/Weekend Day	$150.00
Holiday/Weekend Evening	$175.00
Holiday/Weekend Night	$225.00

7.0 REPORTING OF FOLLOW-UP INFORMATION ON TRANSPORTED PATIENTS TO SENDING PHYSICIANS AND NURSING UNITS

7.1 Sending physicians or nurses may contact Maryland ExpressCare nurses if further follow-up is needed.

SRH Administrative Policy CC	
Effective	03/98
Revised	12/99
Revised	10/02
Revised	03/04
Submitted	Program Coordinator Maryland Express Care
Revised	10/07
Submitted	Program Coordinator, Maryland Express Care
Revised	08/09 (Minor Revisions)
Submitted	Christopher Mitchell, Director Emergency and Outpatient Services
	Terri Ross, Director, Case Management
Revised	11/11
Submitted	Christopher Mitchell, Director Emergency and Outpatient Services
	Colin Fluharty, Program Coordinator, Maryland Express Care
Revised	10/13 (Minor Editorial Revisions)
Submitted	Karen Van Trieste, RN
SRH Administrative Policy- PC	
Revised	08/21
Revised	03/22
Policy Owner	Jessica Fluharty, Director Emergency Services

UNIVERSITY OF MARYLAND
SHORE REGIONAL HEALTH
CARDIAC CATHETERIZATION LABORATORY

ANNUAL SKILLS COMPETENCIES

Employee Name	Emp#	Unit	Validator's Initials / Signature

COMPETENCY - Employee is able to demonstrate correctly the following components of care by validation code: **1 = Direct Observation 2 = Observation of Simulation** **3 = Written Exam 4 = Verbal Recounting** **5 = Chart Audit 6 = Self-Learning Module**	**Validation Code(s)**	**Met**	**Not Met**	**Date**	**Initials**
MONITORING (Demonstrate)					
Powering the hemodynamic computer monitor					
Registering a new patient/ creating a new patient file					
How to initiate the NIBP cuff, timer					
How to input pertinent patient data (case #, staff, allergies, labs, equipment, IV fluids, pt Identification, consent, meds, etc).					
Demonstrate how to zero and calibrate transducer					
Demonstrate how to record rhythm and pressure Waveforms (changing scale and sweep speed).					
Initiating Thermodilution Cardiac Output on the hemodynamic monitor					
Inputing blood sats for Fick cardiac output					
Calculating valve areas, resistances, and shunts					
Demonstrating how to initiate Training Mode					
Demonstrate documentation of dual transducers					
Demonstrating how to initiate Full Disclosure Mode					

COMPETENCY - Employee is able to demonstrate correctly the following components of care by validation code: 1 = Direct Observation 2 = Observation of Simulation 3 = Written Exam 4 = Verbal Recounting 5 = Chart Audit 6 = Self-Learning Module	Validation Code(s)	Met	Not Met	Date	Initials
Demonstrating how to create a pseudo-pullback Using LV and AO waveforms					
Demonstrate how to print reports, write/copy patient cath angiography CD					
Demonstrate recording, troubleshooting & set-up of FFR/IVUS/IFR					
CIRCULATOR (Demonstrate)					
Proper positioning of patient on table to ensure Comfort, privacy and X-ray panning capability					
Proper placement of lead wires, NIBP cuff, manual and Doppler peripheral pulse checks, pulse oximetry probe placement					
Proper leveling and flushing of transducer					
Proper connection of manifold connecting lines to fluids, contrast and transducer hook-up					
Proper connection of Acist connecting lines to fluids, contrast and transducer hook-up					
Proper procedure to switch between Manifold and Acist injection systems					
Assessment of IV site and function to include proper function, location site, restarting IV if necessary					
Demonstrate collecting and ordering blood samples for labs and oxygen saturation analysis.					
Proper Thermodilution Cardiac output injections					
Able to discuss dosage, route of delivery and side effects of meds used in the lab					
Able to locate appropriate supplies requested and proper sterile hand-off of supplies to scrub					
Understanding of x-ray exposure reduction methods					
SCRUB (Demonstrate)					
Proper sterile setup of procedural table and supplies					
Proper hand scrub, sterile gowning and gloving					
Sterile prep and drape of patient					

COMPETENCY - Employee is able to demonstrate correctly the following components of care by validation code: **1 = Direct Observation 2 = Observation of Simulation** **3 = Written Exam 4 = Verbal Recounting** **5 = Chart Audit 6 = Self-Learning Module**	**Validation Code(s)**	**Met**	**Not Met**	**Date**	**Initials**
Demonstrate Acist set-up and troubleshooting					
Demonstrate manifold set-up and troubleshooting					
Demonstrate Barbeau-Allen's test					
Demonstrate set-up of radial caths					
Demonstrate set-up of peripheral vascular intervention cases					
Handling of guide wires including pre-loading of catheters, catheter - wire exchanging					
Proper technique of withdrawing arterial and venous blood samples for oxygen saturation analysis					
Proper technique for leaving sheaths in-place for monitoring and/or transferring patient to another facility					
HEMOSTATIS (Demonstrate)					
Proper monitoring of patient vial signs and continuation of patient documentation					
Peripheral pulse check prior to, during, and post Sheath removal					
Discuss sheath removal with patient prior to removal To ensure cooperation and understanding					
Proper hand position using manual pressure to Ensure hemostatic control of bleeding					
Proper placement of Femstop clamp					
Demonstrate TR band use					
Demonstrate assistance with deployment of hemostatic collagen plug devices					
Discuss documentation of hematoma, and physician notification					
Discuss patient post cath instructions					
CONTRAST POWER INJECTOR (Demonstrate)					
How to insert syringe and fill with contrast					
How to attach the injector tubing and how to clear					

the air bubbles from the injector					
How to input the volume, flow rate, and linear rise for power injection					
COMPETENCY - Employee is able to demonstrate correctly the following components of care by validation code: **1 = Direct Observation 2 = Observation of Simulation** **3 = Written Exam 4 = Verbal Recounting** **5 = Chart Audit 6 = Self-Learning Module**	**Validation Code(s)**	**Met**	**Not Met**	**Date**	**Initials**
Demonstrate proper use of ACIST contrast injection system					
IMAGING (Demonstrate)					
Powering up of Imaging Equipment					
Discuss the function of each switch/button on the table control panel and the control room panel					
Moving the C-Arm in all positions requested					
Disengaging the X-Ray pedals to prevent accidental exposure to staff					
IMAGING (Demonstrate) (Continuation)					
Discuss radiation safety as related to the distance of the image intensifier tube to exam table					
Discuss radiation safety of patient and staff in relation to distance of the x-ray tube and shielding					
INTRA-AORTIC BALLOON PUMP (Demonstrate)					
Proper technique and procedure for balloon pump Preparation					
Describe technique for balloon insertion					
Describe proper position of balloon					
Describe proper timing of IABP inflation & deflation					
Describe proper documentation of IABP					
Demonstrate working knowledge of pump console including printout of waveforms, reading augmentation of pressures and alarms					
Identification of main trigger and activation options					
Demonstrate setup of arterial pressure lines, transducer, flushing and zeroing of lines					
Describe connection of IABP catheter and setup of IABP console for balloon pump augmentation					

Troubleshooting and resolving alarms/problems					

COMPETENCY - Employee is able to demonstrate correctly the following components of care by validation code: 1 = Direct Observation 2 = Observation of Simulation 3 = Written Exam 4 = Verbal Recounting 5 = Chart Audit 6 = Self-Learning Module	Validation Code(s)	Met	Not Met	Date	Initials
TEMPORARY PACEMAKER INSERTION (Demonstrate/Explain)					
How to check and change battery in generator box					
How to connect catheter extension cable to generator box and temporary pacing catheter					
Identifying the different temporary pacing catheter for femoral insertion and subclavian/internal jugular vein insertion					
How to perform threshold check using temporary pacemaker generator box					
DEFIBRILLATOR (Demonstrate/Explain)					
Proper testing and documentation of AM defibrillator check					
Different methods of emergency defibrillation using Defibrillator pads					
Identify steps required for defibrillation					
Identify steps required for synchronized cardioversion					
Identify steps required for transcutaneous pacing					
Explain proper positioning of defibrillator pads for specific procedures					
PROCEDURAL KNOWLEDGE (Explain)					
Left Heart Catheterization					
Right Heart Catheterization					
Right and Left Heart Catheterization					
Pericardial Centesis					
Reveal Linq Loop Recorder Insertion					
Permanent Pacemaker Implantation					
Automatic Internal Cardiac Defibrillator (AICD) Implantation					
Bi-Ventricular Pacemaker Implantation					

COMPETENCY - Employee is able to demonstrate correctly the following components of care by validation code: **1 = Direct Observation 2 = Observation of Simulation** **3 = Written Exam 4 = Verbal Recounting** **5 = Chart Audit 6 = Self-Learning Module**	**Validation Code(s)**	**Met**	**Not Met**	**Date**	**Initials**
Transesophageal Echocardiogram					
External Cardioversion					
Dobutamine Stress Echocardiogram					
INTERVENTIONAL CARDIOLOGY					
Percutaneous Coronary Intervention (PCI)					
Primary Angioplasty/Stent procedures					
STEMI Protocols, Policy and Procedure					
Elective Angioplasty/Stent procedures					
Protocols Policy and Procedure					
Post Procedure Patient Care					
Complications Review					
ELECTROPHYSIOLOGY					
Mapping procedures					
Ablation procedures					

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	CRITICAL CARE DEPARTMENT	POLICY NO:	
		REVIEWED:	08/17
	ADMISSION AND DISCHARGE TO THE INTENSIVE CARE UNIT (ICU)	PAGE #:	1 of 5
		SUPERSEDES	08/13

PURPOSE: To ensure appropriate utilization of Intensive Care Unit (ICU) resources.

SCOPE: ICU RN

POLICY:

1.0 Patients, 16 years or older, with life-threatening or potentially life-threatening illness, requiring extensive medical or nursing care, advanced technological and/or pharmacological treatment modalities, will be considered appropriate candidates for ICU admission. A prioritization model defines those that will benefit most from the ICU (Category 1) to those that will not benefit at all (Category 4).

1.1 **Category 1** – Unstable. Requires intensive treatment and monitoring that cannot be provided outside of the ICU. Examples: ventilator support, continuous vasoactive drug infusions, etc.

1.2 **Category 2** – High risk for sudden deterioration. Requires intensive monitoring and may potentially need immediate intervention. Example: Patient with chronic comorbid conditions who develops acute severe medical or surgical illness and patients with severe sepsis.

1.3 **Category 3** – Reduced likelihood for recovery due to underlying illness. May receive intensive treatment to relieve acute illness but limits on therapeutic efforts may be set, such as no intubation or cardiopulmonary resuscitation.

1.4 **Category 4** – Little or no anticipated benefit from ICU care. Required care and monitoring can safely be administered in a non-ICU setting or patients with terminal and irreversible illness facing imminent death. Admission of this type of patient is generally not considered appropriate for ICU admission, but may be considered on an individual basis.

2.0 It is the responsibility of the attending physician (or designee) to request ICU admission when indicated.

2.1 Eligible patients and patients with severe sepsis may be admitted to the ICU at any time during the day or night.

2.2 Newly admitted or transferred patients must be seen by the attending physician (or designee) at the time of the decision to admit or transfer, or within one hour after admission to the ICU.

2.3 A physician's note summarizing the patient's condition, must be completed on any patient admitted or transferred to the ICU.

2.4 The attending physician (or designee) will be responsible for ensuring that the family is notified of the patient's transfer to the ICU.

2.5 At the time of transfer into the ICU and at the time of discharge from the ICU, all previous physicians' orders will be automatically canceled.

2.5.1 Transfer orders will be transcribed by the receiving nursing unit.

2.5.2 "Stat" and "Now" orders are to be initiated prior to transfer.

2.5.3 **At Shore Regional Health at Dorchester, new orders are not required when the patient is changed from ICU status to Telemetry status.**

2.5.4 The ICU Admission / Transfer orders are mandatory and can be used in conjunction with a Diagnosis-specific order set (i.e., heart failure, chest pain, Neurosurgery, etc.)

2.5.5 When new orders are required, Medication Reconciliation is performed by the transferring unit.

3.0 Only physicians who have been granted admitting/attending ICU privileges may be responsible for patients in the ICU.

3.1 Current information on each member of the medical staff who is privileged to admit/attend in the ICU and to perform specific procedures will be maintained on the Shore Regional Health (SRH) Intranet.

3.2 Attending physician designees must also have ICU privileges.

3.3 Any provider privileged by the SRH Medical Staff may consult in any area of the organization, including ICU.

4.0 Patients may be admitted to the ICU through the Emergency Department, Surgical Services, another inpatient nursing unit, from other hospitals and from the SRH Cardiac Catheterization Laboratory.

4.1 All admissions to the ICU from Surgery will be confirmed by the surgeon prior to the start of surgery.

4.2 A RN must accompany the patient to the ICU, provide a detailed report to the ICU RN and have a completed set of ICU admission orders.

5.0 ICU patients are to be visited by their attending physician (or designee) at least once daily, and documentation of the findings and plan of care is to be made by the physician in the Progress Note section of the medical record.

6.0 Consultations should be liberally utilized when the nature of the patient's problem extends beyond the physician's scope of expertise.

6.1 If a member of the health care team believes that appropriate consultation is not being utilized, the ICU Committee Chairperson will be approached to investigate / discuss with the attending physician.

7.0 Intravenous access will be maintained until the time of discharge from the ICU.

8.0 Pediatric patients, under the age of 16, are not routinely admitted to the ICU, but may be admitted to the ICU for stabilization of condition in preparation for transfer to another facility.

8.1 ICU nurses and Pediatric nurses will collaborate in order to provide clinically effective, age-appropriate care to pediatric patients in the ICU awaiting transfer.

9.0 Patients will be continuously evaluated as to appropriateness of continued ICU stay.

9.1 Patients will be considered appropriate for discharge from the ICU when their conditions are no longer life-threatening, they no longer require advanced technological and/or pharmacological treatment modalities, and/or they will no longer benefit from intensive medical / nursing care.

9.2 It is the responsibility of the attending physician (or designee) to promptly transfer patients to lower levels of care when appropriate.

9.3 It is the responsibility of the ICU RN to notify the attending physician (or designee) of changes in condition which may change a patient's eligibility for ICU.

10.0 Patients admitted for a procedure, treatment, or monitoring available only in the ICU will be eligible for discharge upon its completion.

11.0 Patients may not be discharged from the ICU with arterial, pulmonary artery, intracranial monitoring or temporary pacing catheters in place.

12.0 Patients who experience further deterioration of a condition with no apparent hope of recovery and/or who are not to be resuscitated will be appropriate candidates for discharge from the ICU.

13.0 In the event that the ICU is fully occupied and a critically ill patient needs to be admitted, the following guidelines will be followed:

13.1 Attending physician or designee (with input from consulting physicians as required) will evaluate ICU patient at least daily to determine whether patient continues to meet criteria for ICU status.

13.2 Patients requiring admission to ICU will be carefully evaluated by attending physician and any necessary consulting physicians to determine that patient to be admitted meets criteria for ICU admission, and that the needs of the patient to be admitted exceed those of the patient being considered for transfer out of the ICU.

13.3 The ICU staff will obtain physician orders to transfer the most appropriate patient out of the ICU.

13.4 Category 4 patients are considered the most eligible for transfer out of ICU, Category 1 patients are considered the least eligible for transfer out.

13.5 If it is not appropriate to transfer any patient out of the ICU, or if a bed utilization conflict occurs, the Chairperson of the ICU Committee (or designee) will be notified.

13.5.1 The Chairperson of the ICU Committee (or designee) has the authority to transfer out of the ICU any patient whose condition does not require medical / nursing intensive care intervention.

13.5.2 Decisions affecting patient care will be communicated to attending physician by ICU Committee Chairperson.

14.0 No patient will be a direct admission to the ICU.

14.1 The patient will be sent to the Emergency Room for evaluation and the ER/ Admitting physician will make the determination of the receiving unit.

Policy	
Effective	12/92
Revised/ Revised	08/17; 08/13; 04/09; 06/07; 07/06; 03/05; 03/04; 08/03; 11/97,2/16
Policy Owner:	Critical Care Team
Approved by:	
• **Critical Care Committee**	
SPIRIT Form	Critical Care Committee 8/2017

REFERENCE:

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	CRITICAL CARE DEPARTMENT	POLICY NO:	
		REVIEWED:	08/17
UM SMC at Dorchester UM SMC at Easton UM SEC at Queenstown	ADMISSION AND DISCHARGE TO THE TELEMETRY UNIT	PAGE #:	1 of 5
		SUPERSEDES	04/13

PURPOSE: To ensure appropriate utilization of Telemetry Unit resources.

SCOPE: Telemetry RNs

POLICY:

1.0 The use of the Telemetry Unit will be under the administrative supervision of the Cardiac Steering Committee through the Medical Director, Cardiology Services or his/her designee.

2.0 Criteria for admission may include, but not limited to:

2.1. Chest Pain- R/O MI

2.2. Acute MI-Diagnosed

2.3. Implanted Defibrillator Lead

2.4. Implanted Pacemaker Lead

2.5. Uncomplicated Ablation

2.6. Syncope of Unknown Origin

2.7. Syncope with Arrhythmia

2.8. Major Surgery

2.9. Complex Major Surgery

2.10. CHF Acute/Subacute

2.11. CVA/Stroke

2.12. Lifevest Patient

2.13. Complex Cardiac Disorder

2.14. IV Antiarrhythmic

2.15. PO/IV Antiarrhythmic Load

2.16. Proarrhythmic Medications-PHA

2.17. IV Inotrope/Chronotrope

3.0 Any Licensed Independent Practitioner (LIP) on the active medical staff may order telemetry for his or her patient.

4.0 It is the responsibility of the attending LIP (or designee) to request telemetry admission when indicated.

4.1. Eligible patients may be admitted to the Telemetry Unit at any time during the day or night.

4.2. The attending LIP (or designee) will be responsible for ensuring that the family is notified of the patient's transfer to the Telemetry Unit.

5.0 Patients may be admitted to the Telemetry Unit through the Emergency Department (ED), Surgical Services, another inpatient nursing unit, from other hospitals, from the SHS Cardiac Catheterization Laboratory, and from physicians' offices.

5.1. Direct admission to the Telemetry Unit is dependent on bed availability.

6.0 Cardiac monitoring will be performed on all patients with orders for telemetry according to the Administrative Policy: Telemetry Monitoring Protocol and the Critical Care Policy: Cardiac Rhythm Monitoring Policy.

7.0 The attending LIP is required to observe the telemetry records daily.

8.0 Intravenous access will be maintained until the time of discharge from the Telemetry Unit.

9.0 Patients will be continuously evaluated as to the appropriateness of continued Telemetry Unit stay.

9.1. The ongoing need for telemetry monitoring will be assessed every twenty four hours by using the Administrative Policy: Telemetry Monitoring Protocol.

9.2. Patients will be considered appropriate for discharge from the Telemetry Unit when their condition no longer requires cardiac rhythm monitoring or pharmacological treatment modalities requiring cardiac rhythm monitoring, and/or they will no longer benefit from medical / nursing care specific to the Telemetry Unit.

9.3. When a patient no longer meets the criteria to continue telemetry monitoring, the Telemetry Unit nursing staff has the authority to transfer the patient to an appropriate Multi-Specialty Care Unit bed.

10.0 Patient needs not considered appropriate for admission to the Telemetry Unit include, but may not be limited to:

10.1. Mechanical ventilation.

10.2. Arterial catheter / pressure monitoring.

10.3. Pulmonary artery catheter / pressure monitoring.

10.4. Active temporary pacing.

10.5. Administration of IV Nitroglycerin.

10.6. Administration of Nitroprusside.

10.7. Administration of Norepinephrine.

10.8. Administration of Phenylephrine.

10.9. Administration of Fibrinolytics (except for declotting of lines).

10.10. Titration of vasoactive IV infusions.

10.11. Severe Sepsis or Septic Shock.

10.12. Significant ventricular dysrhythmias unresponsive to antiarrhythmic regimens initiated in ED or on the Telemetry Unit.

10.13. Patients requiring intensive nursing care that cannot be managed on the Telemetry Unit.

11.0 In the event that the Telemetry Unit is fully occupied, or all telemetry transmitters are in use, and a patient is awaiting admission to the unit, the following guidelines will be followed:

11.1. Patients to be admitted to the Telemetry Unit will be carefully evaluated by the attending LIP, and any necessary consulting physicians, in order to determine that criteria for Telemetry Unit admission are met and that the needs of the patient to be admitted exceed those of the patient being considered for discontinuance of telemetry monitoring / discharge from the Telemetry Unit.

11.2. Telemetry Unit nursing personnel will contact the attending physician or designee to obtain orders to discontinue telemetry / transfer off of Telemetry Unit of the most appropriate patient, utilizing the following guidelines:

11.2.1. Patients without dysrhythmia and plan in place for discharge within 24 hours.

11.2.2. Cardiac / coronary disease ruled out.

11.3. If it is not appropriate to discontinue telemetry of any patient, or if a bed utilization conflict occurs, the Medical Director of Cardiology Services (or designee) will be notified.

11.3.1. The Medical Director of Cardiology Services (or designee) has the authority to order discontinuation of telemetry monitoring on any patient whose condition does not meet the criteria for Telemetry Unit admission.

11.3.2. Decisions affecting patient care will be communicated to attending LIP by the Medical Director of Cardiology Services.

Policy	
Effective	01/81
Revised/ Reviewed	08/17; 04/13; 12/11; 04/09; 06/07; 07/06; 03/05; 04/04; 10/03
Policy Owner	Critical Care Committee
Approved by:	Critical Care Leadership Team
• **Critical Care Committee**	
SPIRIT Form	Critical Care Committee 8/2017

REFERENCE:

1. Guidelines on Admission and Discharge for Adult Intermediate Care Units. Society of Critical Care Medicine, 1998.
2. American Heart Association Practice guideline to use of Telemetry monitoring. 2004
3. Telemetry monitoring: Are Admission Criteria Based on Evidence. America Journal of Critical Care. July,2015.

UNIVERSITY of MARYLAND SHORE MEDICAL CENTER AT EASTON	CARDIAC CATHETERIZATION LAB	POLICY NO:	PCI-16
		REVISED:	05/17
	TRANSFER POLICY FOR THE INTERFACILITY TRANSPORT OF PRIMARY ANGIOPLASTY PATIENTS	PAGE #:	1 of 2
		SUPERSEDES	

PURPOSE

1.0 The waiver for primary angioplasty in hospitals without open heart surgery requires that University of Maryland Medical Center at Easton (UMSMC-E) have a process in place that will ensure that an ALS equipped ambulance will arrive within thirty (30) minutes of a request for patient transfer to a tertiary facility prepared to perform open heart surgery.

2.0 This Transfer Policy exists to provide a clear notification, request and transfer process that will ensure timely and efficient response should a patient undergoing primary angioplasty require transfer to the University of Maryland Medical Center (UMMC). In addition, this will provide a mechanism that will improve access to and utilization of appropriate resources.

3.0 This Transfer Policy will also include those patients whose experience recurrent ischemia, failed PCI requiring additional intervention to include CABG.

POLICY

4.0 NOTIFICATION

4.1 The purpose of notification is to provide preparation time for the mobilization of important resources should a request be made.

4.2 Notification is to be made at the point the patient has been identified for PTCA. A member of UMSMC-E cardiac catheterization team will notify the Maryland Express Care Transfer Center at the University of Maryland Medical Center by dialing 410-328-1234. This contact should be made as soon as possible after getting the patient on the cardiac cath table and it is known that the patient will be receiving primary angioplasty.

4.2.1 Identify the facility as UMSMC-E and notify the Transfer Center that there is a patient about to undergo primary angioplasty.

4.2.2 Provide the Transfer Center with logistical information, patient demographics and brief clinical information that they may request.

4.2.3 If the decision is made to transport the patient, as soon as possible, fax a copy of the patient's "face sheet" with demographic data to the Transfer Center at 410-328-1235.

5.0 POINT OF CONTACT

5.1 The Maryland Express Care Transfer Center (TC) at UMMC will be the sole source of contact throughout the process. All inquiries related to patient transport should go through the TC. This allows for the most timely and efficient utilization of resources and avoids conflicting communication.

5.2 Air transport is the preferred and most expeditious form of transportation in this time sensitive pPCI area. If a helicopter is not available or able to travel to respond to UMSMC-E, the Transfer Center will contact the UMSMC-E contractual vendor for appropriate ground transportation.

6.0 NO TRANSPORT NECESSARY

6.1 Once transport is deemed not necessary, a member of the UMSMC-E cath lab team will notify the Transfer Center.

7.0 REQUEST FOR TRANSPORT

7.1 If patient transport becomes necessary, a member of the UMSMC-E cath lab team will place a request to the Transfer Center with the following information:

7.1.1 Will the patient require an intra-aortic balloon pump?

7.1.2 Patient status report

7.2 A copy of the patient's medical record will accompany the patient

7.3 The TC will dispatch the Express Care Team to include an RN and balloon pump if requested. Maryland Express Care guarantees arrival of the air ambulance within thirty (30) minutes of a request by UMSMC-E for patient transport. Such response time includes the period from receipt of a call by UMSMC-E to arrival of the air ambulance at UMSMC-E.

7.3.1 If Maryland Express Care air ambulance is not available or able to fly, the Transfer Center will notify either another air ambulance vendor or the UMSMC-E contractual ground transportation vendor, as appropriate.

7.3.2 If all vendor resources are exhausted with no Critical Care team availability, the TC will dispatch a UMMC cardiac fellow/attending and an ALS team to respond within thirty (30) minutes.

7.3.3 If all vendor resources are exhausted with no Critical Care team availability and no UMMC Cardiac fellow/attending availability, the TC will proceed with contacting the UMSMC-E contractual ground transportation vendor.

7.3.4 If the UMSMC-E ground transportation vendor cannot provide a Critical Care team, the TC will contact the UMSMC-E cath lab staff to inform them of the lack of Critical Care transport availability, and appropriate UMSMC-E staff will accompany the patient during transport with the dispatched ALS team. The UMSMC-E staff member will be returned to UMSMC-E immediately following the transport.

7.4 If the balloon pump is not available in a timely manner, Maryland Express Care can utilize the UMSMC-E balloon pump and will return it to UMSMC-E expediently after delivering the patient to the University of Maryland Medical Center.

Policy	
Effective	05/17
Revised	
Revised	
Policy	
Reviewed	05/18
Policy Owner	Gary Jones, Regional Director

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	CRITICAL CARE DEPARTMENT	POLICY NO:	
		REVIEWED:	08/17
	HIGH CENSUS: ICU	PAGE #:	1 of 3
		SUPERSEDES	08/13

PURPOSE: To provide guidelines for the management of multiple high acuity ICU patients during periods of high census.

SCOPE: ICU RN

POLICY:

1.0 In the event that the ICU is fully occupied and a critically ill patient needs to be admitted, the following guidelines will be followed:

1.1 All ICU patients will be evaluated at least daily by attending physician or designee (with input from consulting physicians as required) to determine the patient continues to meet criteria for ICU status.

1.2 Patients requiring admission to ICU will be carefully evaluated by the attending physician and any necessary consulting physicians to determine that patient to be admitted meets criteria for ICU admission, and that the needs of the patient to be admitted exceed those of the patient being considered for transfer out of the ICU.

1.3 The ICU staff will obtain physician orders to transfer the most appropriate patient out of the ICU (see Critical Care Policy: Admission and Discharge to the Intensive Care Unit).

1.4 If a bed utilization conflict occurs, the Chairperson of the Critical Care Committee (or designee) will be notified.

1.5 The chairperson of the Critical Care Committee (or designee) has the authority to transfer out of the ICU any patient whose condition does not require medical/nursing/surgical/intensive care intervention.

2.0 If it is not appropriate to transfer any patient out of the ICU and an in-house patient requires transfer to ICU, the care of the patient will be according to the following guidelines:

2.1 The patient may be transferred to a Telemetry Critical Care bed once appropriate staff is available.

2.2 The patient and or family will be given the option to transfer to one of the other SRH hospitals with ICU beds or transfer out of SRH to another facility.

2.3 The patient may be transferred to the Post-Anesthesia Care Unit once appropriate staff is available. The PACU at Chestertown is not used for High ICU Census overflow. This only occurs at UMMS Dorchester and Easton.

2.3.1 This is only to occur if a Telemetry Critical Care bed is not available.

2.3.2 PACU On-call staff will not be utilized unless approved by the department director.

2.3.3 The situation will be evaluated by the Directors of Nursing or designee (s) the evening of the opening of the PACU to determine the impact on surgery the following day.

2.4 The patient may be transferred to another appropriate facility at the discretion of the attending physician.

2.5 Ongoing evaluation of ICU population will continue in order to procure an ICU bed at the earliest possible time.

Effective	03/05
Revised	08/17; 08/13; 04/09; 06/07; 07/06
Policy Owner	Critical Care Team
Approved by:	Critical Care Committee 8/17
• **Critical Care Committee**	
SPIRIT Form	Critical Care Committee 8/2017

REFERENCE:

1. Guidelines for ICU Admission, Discharge, and Triage. Society of Critical Care Medicine. 1998.
2. A Joint Position Statement on ICU Overflow Patients. American Society of PeriAnesthesia Nurses, American Association of Critical-Care Nurses, American Society of Anesthesiologists: Anesthesia Care Team

Committee, and Committee on Critical Care Medicine and Trauma Medicine. June, 2000.

UNIVERSITY of MARYLAND SHORE REGIONAL HEALTH	ADMINISTRATIVE POLICY & PROCEDURE	POLICY NO:	EC-71
		REVISED:	04/16
	ICU BED SURGE (MASS DISASTER)	PAGE #:	1 of 2
		SUPERSEDES	2/13

PURPOSE:

To prepare the Intensive Care Units (ICUs) at Shore Regional Health (SRH) for surge of 300% in preparation for mass disaster.

BACKGROUND:

Mass numbers of critically ill victims will stress the ability of SRH to maintain usual ICU services.

1.0 TREATMENT SPACE

When the traditional ICU beds are full to capacity, additional critically ill patients will receive care in non-ICU hospital rooms that are concentrated in specific units/areas. Additional ICU beds should be prioritized in the following order:

1.1 Chestertown (300% = 24)

1.1.1 IMC (24 beds)

1.1.2 PACU (5 beds)

1.1.3 Same Day Surgery (8 beds)

1.2 Dorchester (300% = 24)

1.2.1 Telemetry (8 beds)

1.2.2 PACU (7 bays)

1.2.3 OR Rooms 1 and 4 (2 bays)

1.2.4 Holding area (3 bays)

1.3 Easton (300% = 30)

1.3.1 Telemetry (up to 28 monitored beds)

If necessary to gain additional beds, Telemetry patients that are stable are to be evaluated for discharge or transferred to Neuro.

1.3.2 Neuro (8 monitored beds)

1.3.3 PACU (***8*** monitored beds)

1.3.4 Same Day Surgery (***9*** beds).

2.0 STAFFING

In the event there are not a sufficient number of critical care nurses to appropriately manage patients then non-critical care nurses should be assigned to an ICU RN to assist in routine patient care as a nurse extender. One critical care nurse will work collaboratively with up to 3 non-critical care nurses.

Effective	12/09
Approved	ICU Committee: October 2009
Revised	02/13
Revised	04/16
Approved	Critical Care Committee: 04/20/16
Policy Owner	Ruth Ann Jones, Interim Sr. Vice President/CNO

REFERENCES:

Devereaux, A. V.; Dichter, J. R.: Christian, N. N., et al (2008). Definitive care for the critically ill during a disaster; A framework for allocation of scarce resources in mass critical care. Chest, 133, 51S-66S.

Robinson, L., Hick, J. L. , Hanfling, D. G. , et al, (2008). Definitive care for the critically ill during a disaster: A framework for optimizing critical care surge capacity. Chest, 133, 18S-31S.

EXHIBIT 6

UNIVERSITY OF MARYLAND SHORE REGIONAL HEALTH
TRANSFER POLICY
FOR THE INTERFACILITY TRANSPORT OF
PRIMARY ANGIOPLASTY PATIENTS

Effective Date: 10/13/2015

Sponsoring Department: Cardiac Catheterization Laboratory

PURPOSE:

The waiver for primary angioplasty in hospitals without open heart surgery requires that University of Maryland Medical Center at Easton (UMSMC-E) have a process in place that will ensure that an ALS equipped ambulance will arrive within 30 minutes of a request for patient transfer to a tertiary facility prepared to perform open heart surgery.

This Transfer Policy exists to provide a clear notification, request and transfer process that will ensure timely and efficient response should a patient undergoing primary angioplasty require transfer to the University of Maryland Medical Center (UMMC). In addition, this will provide a mechanism that will improve access to and utilization of appropriate resources.

POLICY:

A. NOTIFICATION:

1. The purpose of notification is to provide preparation time for the mobilization of important resources should a request be made..

2. Notification is to be made at the point the patient has been identified for PTCA. A member of the UMSMC-E cardiac catheterization team will notify the Maryland Express Care Transfer Center at the University of Maryland Medical Center by dialing (410) 328-1234. This contact should be made as soon as possible after getting the patient on the cardiac cath table and it is known that the patient will be receiving primary angioplasty.

    a. Identify the facility as UMSMC-E and notify the Transfer Center that there is a patient about to undergo primary angioplasty.
    b. Provide the Transfer Center with logistical information, patient demographics and brief clinical information that they may request.
    c. If the decision is made to transport the patient, as soon as possible, fax a copy of the patient's "face sheet" with demographic data to the Transfer Center at (410)328-1235.

B. POINT OF CONTACT:

The Maryland Express Care Transfer Center (TC) at UMMC will be the sole source of contact throughout the process. All inquiries related to patient transport should go through the TC. This allows for the most timely and efficient utilization of resources and avoids conflicting communication.

Air transport is the preferred and most expeditious form of transportation in this time sensitive pPCI area. If a helicopter is not available or able to travel to respond to UMSMC-E, the Transfer Center will contact the UMSMC-E contractual vendor for appropriate ground transportation.

C. NO TRANSPORT NECESSARY:

Once transport is deemed not necessary, a member of the UMSMC-E cath lab team will notify the Transfer Center

D. REQUEST FOR TRANSPORT:

If patient transport becomes necessary, a member of the UMSMC-E cath lab team will place a request to the Transfer Center with the following information:

1. Will the patient require an intra-aortic balloon pump?
2. Patient status report

A copy of the patient's medical record will accompany the patient

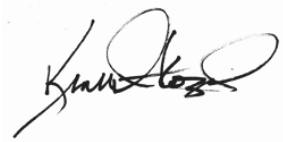
3. The TC will dispatch the ExpressCare Team to include an RN and balloon pump if requested. Maryland ExpressCare guarantees arrival of the air ambulance within thirty (30) minutes of a request by UMSMC-E for patient transport. Such response time includes the period from receipt of a call by UMSMC-E to arrival of the air ambulance at UMSMC-E.

    a. If Maryland ExpressCare air ambulance is not available or able to fly, the Transfer Center will notify either another air ambulance vendor or the UMSMC-E contractual ground transportation vendor, as appropriate.
    b. If all vendor resources are exhausted with no Critical Care team availability, the TC will dispatch a UMMC cardiac fellow/attending and an ALS team to respond within 30 minutes.
    c. If all vendor resources are exhausted with no Critical Care team availability and no UMMC Cardiac fellow/attending availability, the TC will proceed with contacting the UMSMC-E contractual ground transportation vendor.
    d. If the UMSMC-E ground transportation vendor can not provide a Critical Care team, the TC will contact the UMSMC-E cath lab staff to inform them of the lack of Critical Care transport availability, and appropriate UMSMC-E staff will accompany the patient during t ransport with the dispatched ALS team.. The UMSMC-E staff member will be returned to UMSMC-E immediately following the transport.

4. If the balloon pump is not available in a timely manner, Maryland ExpressCare can utilize the UMSMC-E balloon pump and will return it to UMSMC-E expediently after delivering the patient to the University of Maryland Medical Center.

This Transfer Policy will be in effect for patients undergoing primary angioplasty following the granting of the waiver to perform primary angioplasty without open heart surgery back-up, and involves agreement between UMSMC-E and Maryland ExpressCare.

Approved:
Chief Operating Officer



Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

Dana Farrakhan, Senior Vice President
University of Maryland Medical Center

EXHIBIT 7

Schedule B: Description of Services and Pricing

RECITALS

WHEREAS, BUTLER MEDICAL TRANSPORT, LLC (Butler Medical) is a commercial ambulance service initiating calls in Maryland and is and must be licensed by the Maryland Institute for Emergency Medical Services System (MIEMSS) under education Section 13-515, Annotated Code of Maryland, and COMAR 30.09. BUTLER MEDICAL is a provider of Specialty Care Transport, Advanced life Support, and Basic Life Support ambulance services operating under the MIEMSS commercial license number 105; and

WHEREAS, BUTLER MEDICAL offers a full range of ground transportation services, including, but not limited to, transportation to the UNIVERSITY of MARYLAND MEDICAL SYSTEM (Hospital), from the Hospital to another facility for admission, and/or treatment, diagnostic study, or consultation, return to the HOSPITAL, and discharge from the HOSPITAL; and

WHEREAS, the HOSPITAL and BUTLER MEDICAL desire to enter into an agreement whereby BUTLER MEDICAL will provide ambulance services on a scheduled and non-scheduled basis to the HOSPITAL.

Part 1. SOW for Butler Medical's Interfacility Transport Services for Shore Regional Health

Section 1. Interfacility Transport Services

A. Overview of Services. BUTLER MEDICAL will provide the following services:, *Advanced Life Support (ALS) Transport, Advanced Life Support 2 (ALS 2) Transport, Basic Life Support BLS) Transport,* and *Wheelchair Transport.*

1. *Advanced Life Support Transport.* ALS Transports include any transport that requires skills in the Maryland Protocols that are above the level of a BLS provider but are within the scope of practice of an ALS provider, not including optional protocols. BUTLER MEDICAL does participate in the optional protocols for SCT level calls,that allow EMT-Ps to administer IV Heparin, IV Integrilin, and to use and manage chronic ventilator-dependent patients. Examples of ALS transports include: ECG monitor, Lidocaine drip management, managing a patient with an External Jugular or IO infusion line.

2. *Advanced Life Support 2 Transport.* ALS 2 Transports are transports requiring response to critically ill patients which requires at least one skill which may include intubation, pacing, and/or defibrillation. There also must be the administration of at least three medications.

3. *Basic Life Support Transport.* BLS Transport includes patient assessment, airway monitoring, suction, oxygen therapy, splinting and fracture management, bleeding management, bandaging, cardiopulmonary resuscitation, automated external defibrillation ("AED"), emergency childbirth, and any patient who is non-ambulatory, which does not require a higher level of care than BLS pursuant to the Maryland Medical Protocols for EMS Providers.

4. *Wheelchair Transport*. Wheelchair Transport is transport of a patient that: (a) can transfer themselves from a chair into a wheelchair with minimal or no assistance, (b) does not require monitoring or one-on-one supervision during the transport, (c) is not on oxygen other than that provided by and monitored by the patient, and (d) must sit safely on their own without any assistance.

B. Hours of Service. Continuous coverage is provided twenty-four (24) hours a day, seven (7) days a week for, ALS, ALS 2 and BLS Transports. Wheelchair service will be provided to the HOSPITAL at their request between the hours of 0800-2000 (8:00 a.m. to 8:00 p.m.), seven (7) days a week.

C. Staff. All vehicles are staffed with at least a Maryland State Certified Emergency Medical Technician Basic (EMT-B), Emergency Medical technician Intermediate (EMT-1) or Emergency Medical Technician Paramedics (EMT-P). All drivers will have a minimum of an EVO certification, licensed in accordance with the Code of Maryland Regulations (COMAR) Title 30 subtitle 09: Commercial Ambulance Services. BUTLER MEDICAL will maintain appropriately trained staff (both clinical and customer service skills) and provide evidence of their existing training program in each area when requested.

D. MIEMSS. BUTLER MEDICAL participates in MIEMSS Optional Supplemental Program, Specialty Care Paramedic (COMAR 30.03.03.06). All medical transports are governed by the Maryland Medical Protocols for EMS Providers, and BUTLER MEDICAL agrees to comply with such regulations.

E. Holidays. Holidays shall be defined as Christmas Day, New Year's Day, Thanksgiving Day and Independence Day. During said holidays, wheelchair service will not be provided and Time Critical Transports may take up to sixty (60) minutes, and Non Time Critical Transports may take up to one hundred and twenty (120) minutes.

F. Dispatch Services. BUTLER MEDICAL shall provide a single direct line phone number (with the appropriate roll-over services) to its dispatch center, and the HOSPITAL (including its employees, contractors, and related staff) shall have a designated phone number for requesting all transport services under this Agreement.

Section 3. Response Times, Time-Critical Transports, and Non Time-Critical Transports

A. Time-Critical Transports (Non-Scheduled). Time-Critical Transports, will be defined as, and limited to the transfer of an acute care inter-facility patient requiring a minimum of an ALS level of care and a lights & sirens transport, which will be defined as an ambulance transport, where all emergency warning devices are activated during transport. Said transports must be requested by a physician, who will be required to provide his or her name as the ordering physician who requests a Time-Critical transport. For "Time-Critical Transports", Butler Medical will arrive at HOSPITAL within thirty (30) minutes of receiving the call. If for any reason, the time frame for arrival is or will be greater than thirty (30) minutes, HOSPITAL, in its sole discretion, may request Butler Medical to call other transport companies to provide patient transport or HOSPITAL may call another transport company to provide the patient transport.

B. Non Time-Critical Transports (Non-Scheduled). Non Time-Critical Transports (Non-Scheduled), will be defined as, and limited to the immediate transfer of a patient who is in a critical bed, i.e., Emergency Department, and or is being transferred to another hospital from units including but not limited to Cardiac Cath lab, ICU/CCU, and or Labor & Delivery. For "Non Time-Critical Transports", BUTLER MEDICAL will arrive at HOSPITAL within sixty (60) minutes providing all necessary items required for transport, subject to the provisions of Section II, Section E for Holidays, and Section VIII - Inclement Weather. If, for any reason, the time frame for arrival is greater than sixty (60) minutes,

HOSPITAL in its sole discretion, may request BUTLER MEDICAL to call other transport companies to provide patient transport or HOSPITAL may call another transport company to provide the patient transport.

C. Non Time-Critical Transports (Pre-Scheduled) Non Time-Critical Transports (Pre-Scheduled), will be defined as patients being discharged from inpatient hospital units, and or patients being transferred to another hospital where the time must be scheduled to accommodate receiving facility. The patients will be scheduled for an agreed upon time no less than one hundred twenty (120) minutes form the time the call is placed, and BUTLER MEDICAL agrees to arrive at the scheduled time +/- 5 minutes, minutes providing all necessary items required for transport, subject to the provisions of Section II, Section E for Holidays, and Section VIII - Inclement Weather.

D. Special Request Patients. For "Special Request Patients", BUTLER MEDICAL will arrive at HOSPITAL within two hundred and forty (240) minutes providing all necessary items required for transport. "Special Request Patients", by definition cannot be either "Non Time-Critical Transports", or "Time-Critical Transports", they are defined as patients whose transport is greater than seventy miles one direction but less than one hundred and fifty miles one way, and or, require a special stretcher including but not limited to a bariatric stretcher and or Large Body Surface Area Stretcher. Patients whose requested transfer is greater than one hundred and fifty miles one way require twenty four hours' notice, to provide for a crew that can safely transport the patient.

E. UM – Shore Medical Center at Chestertown. Recognizing the unique geographical challenges of the physical location of the afore mentioned facility, and its limited volume, the Metrics outlined in A-D of Section 3, will have an additional thirty (30) minute response time above and beyond what is already allotted by applicable category.

F. Seasonality/Bay Bridge. The seasonal traffic patterns, and corresponding response challenges those pose on consistent timeliness, are an impedance during the summer months. This can and is coupled by closures on route 50, or any of its corresponding bridges, including but not limited to the Bay Bridge, year-round. In recognition of this between Memorial Day and Labor Day it is recognized traffic will not allow for the response times outlined in A-D of this section, while the goal for response times will remain as noted above, for compliance reporting metrics, and additional thirty (30) minutes shall be added during the dates outlined. Additionally, should there be a documented closure on route 50 or one of its bridges including but not limited to the Bay Bridge, responses delayed during this closure will be discounted for metric reporting purposes only. Accurate ETA's will still be given to UMMS and its affiliates, as well as updates regarding the closures.

G. Stroke. For patients identified as patients meeting the MIEMSS defined stroke center criteria needing transfer from one HOSPITAL campus to another HOSPITAL. BUTLER MEDICAL will arrive at the HOSPITAL within thirty (30) minutes of receiving the call. HOSPITAL agree to put BUTLER MEDICAL on standby for any impending transfers of this nature as soon as they are aware there is a "possibility" of transfer of a patient meeting this criteria.

H. STEMI. For patients identified as patients meeting the MIEMSS defined STEMI criteria needing transfer to another HOSPITAL. BUTLER MEDICAL will arrive at the HOSPITAL within thirty (30) minutes of receiving the call. HOSPITAL agree to put BUTLER MEDICAL on standby for any impending transfers of this nature as soon as they are aware there is a "possibility" of transfer of a patient meeting this criteria.

I. Response Time Reporting. BUTLER MEDICAL acknowledges and agrees that the timely transport of patients is extremely important to HOSPITAL and it is a material part of this Agreement. Accordingly, BUTLER MEDICAL will keep accurate records of its response times, and provide HOSPITAL with a

monthly report (in a format mutually agreeable by the parties) of response times ("Response Time Reports"). If BUTLER MEDICAL fails to maintain a 90% "on time" reliability factor (i.e., it must meet the response times set forth in this Agreement 90% of the time), then Butler Medical will report weekly to HOSPITAL on changes or improvements it is implementing to rectify the situation and obtain the 90% reliability factor. Butler Medical will provide HOSPITAL with weekly Response Time Reports until it has obtain and maintained a 90% reliability factor for three (3) consecutive weeks, and then it will resume its monthly Response Time Reports. If BUTLER MEDICAL fails to meet the 90% reliability factor for a total of twelve (12) weeks in any 12 month rolling period or fails to meet the 90% reliability factor for eight (8) consecutive weeks, then such will be deemed a material default of this Agreement. It is acknowledge and agreed that the response times and reliability factor contemplated herein will be measured and determined, collaboratively, based on all transports in the three categories of service as provided in subsections A, B, and D above, including any specifically scheduled transports.

Section 4. Responsibilities of Hospital

The HOSPITAL must provide BUTLER MEDICAL at the time of the transport request with the demographic sheet to include two (2) patient identifiers: the patient's (1) date of birth, and (2) social security number.

All requests for ground transportation for all patients leaving the HOSPITAL shall be made through BUTLER MEDICAL'S communications center.

If the HOSPITAL utilizes another company to transport a patient without first requesting BUTLER MEDICAL, and BUTLER MEDICAL was otherwise ready, able and willing to handle such transport, then the HOSPITAL shall be billed for such transport at seventy-five percent (75%) of the Rate specified on Exhibit A. Before charging the HOSPITAL under the terms of this paragraph, BUTLER MEDICAL shall first provide the HOSPITAL with written notice that it has used another company to transport a patient without first requesting BUTLER MEDICAL to provide the service, and thereafter the HOSPITAL shall have ten (10) days to resolve the matter. If the HOSPITAL continues to use another company for transport without first requesting BUTLER MEDICAL to handle the transport after such ten (10) day period, then the HOSPITAL shall be billed as provided herein for such services. It is agreed, however, that the HOSPITAL shall in no event be billed for using another company for transport, as provided herein, if BUTLER MEDICAL was not otherwise ready, able and willing to handle such transport or the HOSPITAL was unable to contact BUTLER MEDICAL because its phone lines were not working

Section 5. Responsibilities of Butler Medical

It is acknowledged and agreed that this Agreement is to provide the HOSPITAL with a single "one-stop shop" for all of the HOSPITAL's (including its patients) ground transportation needs, including without limitation in a single call center to handle all of the HOSPITAL's transportation requests. Accordingly, BUTLER MEDICAL agrees to create (to the extent it does not currently exist) and maintain throughout the Term of this Agreement an appropriate dispatch/communications center with the appropriate capacity to timely receive, manage, administer, and otherwise handle all of the HOSPITAL's requests for patient transports and to maintain the required trained staff and fleet of vehicles to service the HOSPITAL's patient transports. The HOSPITAL's requests for patient transports shall be made to BUTLER MEDICAL'S dispatch/communications center in accordance with Section II. F. above. It is acknowledged and agreed, however, that from time to time during the Term of this Agreement and because of spikes or peaks in the demand for patient transports, BUTLER MEDICAL may not be able to timely fulfill a patient transport request from the HOSPITAL. In such case, BUTLER MEDICAL will promptly notify the HOSPITAL and Butler shall be responsible for obtaining a secondary source of transport for the HOSPITAL. The HOSPITAL will make the final decision regarding alternative transportation; provided,

however, that the HOSPITAL shall be required to accept any qualified licensed provider of transport services arranged by BUTLER MEDICAL (whose charges and rates are within industry standard). BUTLER MEDICAL shall not be held financially responsible for transports completed by another vendor if the HOSPITAL elects to use another resource.

The HOSPITAL will work collaboratively with BUTLER MEDICAL to request transports as soon as the HOSPITAL identifies the need to transfer to another healthcare organization. This will help facilitate BUTLER MEDICAL to provide a better experience for the HOSPITAL and for the patient.

Section 6. Wheelchair Service

BUTLER MEDICAL reserves the right to substitute ambulance service for any wheelchair request, with the understanding that the responsible Party will be billed at the wheelchair rate.

Section 7. Inclement Weather

In the event of inclement weather, defined as significant stormy and turbulent weather, it is recognized that BUTLER MEDICAL may institute their Code Blue weather policy in various degrees depending on weather severity. This is done in order to ensure that patient and crew safety comes first and foremost. Code Blue is a staged implementation in the following order:

(1) Suspension of all wheelchair van transports.
(2) Implementation of a Priority 9 Response Profile
(3) Suspension of all residence transports.

BUTLER MEDICAL shall not take the following steps except when State and/or county authorities have declared a state of emergency

(4) Suspension of all non-interfacility emergency transports
(5) Suspension of all service.

BUTLER MEDICAL agrees to promptly notify the designated person at HOSPITAL (which HOSPITAL from time to time identifies via written notice to Butler Medical) upon the implementation and cessation of the Code Blue weather policy. It is mutually understood that during this time the safety of the crew and patient, is of the highest priority, even above the timeliness of service.

Section 8. Compensation, Billing and Collections

A. Insured Patients Discharged from the Hospital.

1. *Medicare*. BUTLER MEDICAL agrees to accept Medicare coverage and not to balance bill patients other than for deductibles or co-pays as applicable by federal and state law. The HOSPITAL agrees to provide Certification of Medical Necessity ("CMN") form(s) and authorization(s) (prior to transport or as completed by case management) as necessary to allow for appropriate billing.

2. *Medical Assistance Patients*. Transportation arrangements for Medical Assistance Patients are made through the appropriate County Health Department. The HOSPITAL shall arrange a transport with BUTLER MEDICAL for patients who have Medical Assistance, and BUTLER MEDICAL shall provide the transport. In no event will the status as a Medical Assistance Patient have any impact on the timing of and quality of delivery of services by BUTLER MEDICAL or the HOSPITAL to the patient.

3. *Other Insured Patients*. For patients with valid insurance coverage, BUTLER MEDICAL assumes all risk of billing and collection. BUTLER MEDICAL will bill the patient and their insurance directly at the rates in Exhibit A under Retail Cost. Certain insurance carriers require the discharging/referring hospital to obtain authorization for services. In such cases, if it is known at the time of transport, the HOSPITAL will obtain the authorization number. BUTLER MEDICAL will accept all risk of collection for medically necessary services to insured patients; however, in the event that services are not medically necessary or are an uncovered benefit then BUTLER MEDICAL shall bill the patient for the transport, following the procedure described in Section X, Section B.2.c. Billing and collection records will be maintained by BUTLER MEDICAL for a minimum of seven (7) years as required by law, and the HOSPITAL may review these records upon reasonable notice during normal business hours.

B. Uninsured Patients or Insured Patients Without Transport Benefits Discharged from the Hospital.

1. *Uninsured Patients with Pre-Authorization to Bill the Hospital*. BUTLER MEDICAL will only directly bill the HOSPITAL for the patient's transportation when pre-authorized by the designated person at the HOSPITAL (who will be identified by the HOSPITAL from time to time by written notice to BUTLER MEDICAL). BUTLER MEDICAL will bill the HOSPITAL for pre-authorized transports at the HOSPITAL Rate listed in Exhibit A. For purposes of this subsection, if there is any dispute regarding whether or not the HOSPITAL provided a pre-authorization to transport a patient, BUTLER MEDICAL shall have the burden of showing that such transportation was pre-authorized by the HOSPITAL. The Parties shall cooperate with each other to develop a standard operating procedure for such pre-authorization.

2. *Uninsured Patients Other Than Those with Pre-Authorization to Bill the Hospital and/or Insured Patients without Transport Benefits.*

a. Fees. BUTLER MEDICAL will bill uninsured patients who were not pre-authorized for payment, consistent with Section X, Section B.1., above, in accordance with the standard patient charge listed in Exhibit A under Retail Cost. In addition, if a patient has insurance but the services are not medically necessary or are an uncovered benefit, BUTLER MEDICAL will bill the patient in accordance with the standard BUTLER MEDICAL fee schedule in Exhibit A under Retail Cost.

b. Fee Notification and Payment. The HOSPITAL staff will notify the patient of the fee for transport. BUTLER MEDICAL shall not require payment at the time of service on any transports.

c. When BUTLER MEDICAL bills these patients described in subsection (2) (a), the billing process must include at least two (2) statements or letters sent to the patient's address, and two (2) phone calls to the patient or their financial guarantor. Of the two (2) required collection attempts, the final statement will include a demand for payment in the form of a collection letter and will indicate that in the absence of payment the patient's unpaid account will be reported to a credit agency. If these efforts have failed to either result in a payment, or least a good faith effort of a payment by the patient, by either setting up a payment plan and or providing new or corrected insurance information, HOSPITAL shall be considered the payer of last resort if the patient fails to pay. In such cases, HOSPITAL will be invoiced in accordance with Exhibit A of this contract.

C. Inpatient Roundtrip Transportation. When a transport is requested for any inpatient transported to another health service facility and returned to the HOSPITAL within the same day, BUTLER

MEDICAL will bill the HOSPITAL at the HOSPITAL Rate in Exhibit A. BUTLER MEDICAL may not bill patients for inpatient roundtrip transports.

D. Invoice Statements. Within the first five (5) days of the first (1st) day and the fifteenth (15th) day of each month, BUTLER MEDICAL will mail an invoice for services and uncollected accounts. These statements must include a patient-by-patient listing showing base rate, mileage, and any add-on charges for all patients for the preceding month. Each invoice must also include for each transport: (1) a run number, (2) some unique and consecutive invoice number, and (3) the date of service. BUTLER MEDICAL must apply checks received from the HOSPITAL to the patients' accounts identified on the check. The HOSPITAL is not required to pay invoices that do not meet the requirements of this Section D and/or are not submitted within the timeframe specified by this Section D. All undisputed invoices are to be paid by the HOSPITAL within thirty (30) days from the receipt of the invoice, or they shall be considered delinquent. In the case of insurance denials, BUTLER will provide basic denial reasons on the initial invoice, as well as provide any further insurance denial documentation or follow up as requested by HOSPITAL.

E. Facility Rates. Facility Rates listed in Exhibit A of this agreement are based on the standard Medicare Fee schedule for ambulance transports and are no less than or equal to 80% of the published fee schedule for Ambulance Transport, published annually by The Centers for Medicare and Medicaid Services, on or around January 1st. Prices shall never decrease, and will increase in accordance with the fee schedule changes that are published annually to ensure they are never less than 80% of the published fee schedule for Ambulance Transport.

Section 9. Patient Preference

All patients needing transport to any hospital will be transported to the nearest appropriate hospital. In the event that BUTLER MEDICAL is requested to transport a patient to a hospital that is not the nearest appropriate, it is recognized that some insurance companies may not cover the cost of said transport. The cost of said transport shall be the responsibility of the patient, and payment will be required at time of service, unless approved for payment by the HOSPITAL.

Section 10. Medicare

BUTLER MEDICAL is a provider for Medicare Part B. Assignment will be taken for any medically appropriate transfers. The patient must be transferred to a Medicare approved destination, meet Medicare's medical necessity criteria, and have a valid CMN form.

Section 11. Quality Assurance

BUTLER MEDICAL is dedicated to the quality of services it provides, and shall perform its services under the Agreement consistent with industry standards, in compliance with all federal, state and local laws, regulations and ordinances, and through the use of reasonable care. BUTLER MEDICAL represents and warrants that it has obtained, and will maintain throughout the Term of this Agreement, all required permits, licenses, and related governmental approvals to perform the services under this Agreement, including without limitation, any and all permits, licenses, and related governmental approvals required to operate the vehicles used to perform the services hereunder. All patient care records are reviewed by an EMS supervisor for accuracy and completeness. Any major event or incident that occurs will be reviewed at the next regularly scheduled Quality Assurance Board Meeting. All questions or concerns communicated to the management of BUTLER MEDICAL will be addressed and responded to immediately. BUTLER MEDICAL will be responsible for the licensure and credentialing/competency of its own staff. BUTLER MEDICAL shall immediately notify the HOSPITAL in the event of an injury or death of a patient of the HOSPITAL while in the care of BUTLER MEDICAL and/or it there is any accident

(vehicle or otherwise) involving BUTLER MEDICAL while it is transporting or otherwise caring for a Hospital patient. Butler shall cooperate with the HOSPITAL in completing any follow-up investigation of the matter.

Section 12. Medical Education/Medical Direction

In accordance with the Code of Maryland Regulations (COMAR) Title 30.09, BUTLER MEDICAL is required to have an arrangement whereby the medical staff of BUTLER MEDICAL may receive continuing medical education and practical experience. BUTLER MEDICAL is contracted with a professional teaching agency to provide and maintain certification and licensure. Currently, Dr. Michael DiNappoli provides medical direction for BUTLER MEDICAL, and Dr. Michael DiNappoli provides SCT medical direction. BUTLER MEDICAL agrees to retain these doctors (or other individuals with similar credentials) at all times during the Term of this Agreement.

Section 13. Fuel Costs

BUTLER MEDICAL reserves the right to increase mileage charges with thirty (30) days advance written notice to the HOSPITAL, if there has been a greater than fifteen percent (15%) increase in the cost of fuel as of the date of this Agreement, in accordance with the following: BUTLER MEDICAL'S right to increase mileage charges shall be based on the American Automobile Association's ("AAA") determination for the average cost of gasoline (or diesel) for Frederick and Washington Counties, Maryland, pursuant to its online "fuel price finder" calculator (or other similar publication if AAA no longer publishes its "fuel price finder" portal). The increase in mileage charges applied shall be the actual increase in the price of a gallon of gasoline (or diesel) as set forth above divided by the average miles per gallon obtained from the vehicles used to provide the services under this Agreement (which may be reasonably estimated by BUTLER MEDICAL). If BUTLER MEDICAL desires to increase the mileage charges herein, it shall notify the HOSPITAL and the Parties shall mutually agree on such increase; provided, however, the HOSPITAL agrees that it shall not unreasonably withhold its consent to such increase provided that BUTLER MEDICAL has reasonably shown that the fuel prices have increased by more than fifteen percent (15%), in accordance with the terms set forth herein. If there is an increase in mileage charges as provided herein, then BUTLER MEDICAL shall be required to decrease the mileage charges as fuel prices decline (based on the same procedure noted above); provided, however, that the mileage charges shall never be less than the original amount specified on Exhibit A.

Section 14. Patients Considered to be Patients of the Hospital

Patients being transferred from the HOSPITAL are considered to be inpatients of the HOSPITAL until delivered to and received by a responsible Party at the designated destination facility. Patients who are admitted to or have been discharged from the HOSPITAL and are not being transferred to another facility are not considered inpatients of the HOSPITAL.

Section 15. Key Performance Indicators

1. Interfacility Transport (IFT) Key Performance Metrics (KPI's) are to include a monthly report with the following data elements for scheduled calls
    a. Date and time request for transport was initiated
    b. Date and time trip was scheduled
    c. Actual Arrival Date and Time
    d. Transport Level of Service (SCT, ALS, BLS, Wheelchair)
    e. Name of the Company that performed if not BUTLER
    f. Originating Hospital

g. Destination Hospital

2. Interfacility Transport (IFT) Key Performance Metrics (KPI's) are to include a monthly report with the following data elements for non-scheduled calls
    a. Date and time request for transport was initiated
    b. Actual Arrival Date and Time
    c. Total Response Time in Minutes
    d. Transport Level of Service (SCT, ALS, BLS, Wheelchair)
    e. Name of the Company that performed if not BUTLER
    f. Originating Hospital
    g. Destination Hospital
3. BUTLER will provide a separate report of all transports with the primary payor

Signatures: Part 1. SOW for Butler Medical's Interfacility Transport Services for Shore Regional Health

IN WITNESS WHEREOF, the parties below agree to this Schedule B: Part 1 as of the Effective Date.

(Provider)
Provider's Name: **Butler Medical Transport, LLC**

By: _____

Name: William Rosenberg

Title: CEO

Date: 1/28/2022

UMMS Affiliates:
Shore Health System, Inc. (f/k/a The Memorial Hospital at Easton) d/b/a University of Maryland Shore Medical Center at Easton

By: _____

Name: Kenneth Kozel

Title: CEO

Date: 1/26/2022

Shore Health System, Inc. (f/k/a The Memorial Hospital at Easton) d/b/a University of Maryland Shore Medical Center at Dorchester

By: _____

Name: Kenneth Kozz

Title: CEO

Date: 1/26/2022

Shore Health System, Inc. (f/k/a The Memorial Hospital at Easton) d/b/a University of Maryland Shore Medical Center at Chestertown

By: _____

Name: Kenneth Kozz

Title: CEO

Date: 1/26/2022

University of Maryland Access Center (UMAC)
UMMS Corporate Shared Services

By: _____

Name: Todd J. Crocco

Title: Vice President

Date: 1/27/2022

Part 2. SOW for UMMS Maryland ExpressCare (MEC) Critical Care Transport (Shore Regional Health)

The following requirements are specific to the Maryland ExpressCare critical care transports performed by Butler.

Preamble: Overview of Maryland ExpressCare Service

1. The current 052 license for "Maryland ExpressCare" (MEC) is issued to UMMC/UMMS and shall remain under their control.

2. MEC has historically provided the necessary medical direction, oversight, and equipment and shall continue to do so under this Agreement. MEC Shore operates under the current 052 license which specifies "UMMC/UMMS" as the holder.

3. To provide the level of specialty/critical care transport expected of Maryland ExpressCare, it is necessary to for MEC to employ experienced critical care RNs equipped with items not typically available to commercial vendors and shall continue to do so.

4. Butler has been providing SCT services (as ExpressCare) for several years under the 052 license. They have also been billing for SCT transports for trips conducted with the designated vehicle and shall continue to do so under this Agreement.

5. UMMS/UMMC has historically not billed for MEC transports. In the previous Contract, Butler has been responsible for the task of billing the transport to third party payers and shall continue to do so under this Agreement, and provide credit for all collections received from billing, less any applicable fees within the contract.

Section 1. TRAINING / EDUCATION

- Critical care paramedic (CCP) hiring requirements:
    - **Preferred** qualifications for CCPs include: A Critical Care Emergency Medical Transport Program (CCEMTP) course or equivalent, FP-C or CCP-C certification, previous critical care transport experience, 3-5 years of experience in a high volume/high acuity ALS system*
    - **Required** qualifications: Current certification as a Nationally Registered Paramedic (NRP) or state licensure with the ability to attain reciprocity
      (The Parties may need to modify the aforementioned requirements based upon paramedic availability. Modifications will be in writing and signed by both Parties.)

- New hires (hired after contract execution) will be required to complete the Maryland ExpressCare critical care transport orientation program and achieve approval from MEC leadership and Medical Directors. The program is tailored to the individual paramedic needs / experience but can incorporate clinical rotations, cadaver labs, and up to 9 weeks of didactic training.

- Employees current employed or semi-regularly working at Maryland ExpressCare currently as of the execution of this agreement, will be required to complete a sequence of abridged competencies to re-certify there approval to work at MEC as approved by their Medical Directors by ~~December 31st of 2021~~ February 28, 2022

- Critical care paramedic candidates from Butler Medical Transport will be compensated for the time and travel associated with required courses. Required courses are detailed in the Maryland ExpressCare educational plan previously circulated.

- UMMS recognizes the need to approve between 7-8 FTE candidates and compensate for required training to maximize the possibility of a CCP candidates availability to fill in for regular FTE CCP in case of vacation or last minute vacancy as a result of illness/injury/bereavement or similar situation.

Section 2. STAFFING

- Maryland ExpressCare will partner with Butler Medical Transport to maintain at least one (1) fully staffed critical care transport unit and crew on a 24 hour, 7 day per week basis. Butler will

provide at least 1 Critical Care Paramedic (CCP) and 1 Emergency Vehicle Operator (EVO), the EVO for MEC shall be certified at no less than the EMT level. This provision eliminates the need for the "After Hours Transport Program."

Section 3. DISPATCH/COMMUNICATIONS

- Maintaining situational awareness about transport unit location and availability is of extreme importance.
- Butler Medical Transport will share their computer aided dispatch software with Maryland Access Center (MAC) personnel. This will allow the ability to have real-time data regarding the location of Shore Health transport resources.
- Butler Medical Transport will maintain and execute primary dispatching functions

Section 4. QUALITY ASSURANCE AND IMPROVEMENT

- Butler Medical Transport will provide MEC nursing and provider leadership with access to Trauma Soft. Trauma Soft is Butler's electronic prehospital medical record.
- Butler Medical Transport will designate a paramedic, EMT-I, and or RN to serve as a Quality Assurance/Quality Improvement Officer (QIO). The QIO will coordinate chart review and comply with MIEMSS reporting requirements.

Section 5. ACCREDITATION CONSIDERATIONS

The Maryland ExpressCare Critical Care Transport program is actively working towards CAMTS (Commission on the Accreditation of Medical Transport Systems) accreditation (https://www.camts.org/wp-content/uploads/2017/05/CAMTS-11th-Standards-DIGITAL-FREE.pdf) Therefore, paramedics supplied by Butler will be held to specific minimum requirements such as:

- Critical care experience and competencies (ACLS, NRP, STABLE, PALS)
- Certification as a flight paramedic (FP-C) or critical care paramedic (CCP-C) within 2 years of hire
- Maintenance of annual competencies and attendance at required skills sessions

Section 6. Key Performance Indicators (KPI) for Butler's transports for Maryland ExpressCare:

Monthly Performance Measurements:

1. Performance must be measured and shared directly with UMMS every month, by the 5th business day of the next month. A standardized dashboard shall be developed which includes the capability to show exceptions by the "unit" in the hospital.

2. A quarterly financial reconciliation of charges and outstanding payments shall be presented directly with UMMS in an electronic, standardized format. Billing estimates shall be completed for reconciliation within 60 days.

3. Butler shall conduct patient Experience / Satisfaction Measurement /Surveys to be shared monthly with UMMS.

4. In the event a third party vendor is used to supplement service; performance metrics for this service shall be tracked by Butler and reported quarterly and upon request by UMMS

EXHIBIT A

Statement of Work:
Pricing for Interfacility Transports Billed to UMMS as Payer of Last Resort

Charge	Hospital Rate
SCT-RN Base Rate	$638.60
SCT Base Rate	$638.60
ALS Emergency Base Rate	"$373.34
ALS Non-Emergency Base Rate	"$235.79
BLS Emergency Base Rate	"$314.38
BLS Non-Emergency Base Rate	"$196.49
Wheelchair Base Rate	"$75.00
Wait Time – SCT-RN	"$50.00
Wait Time – SCT	"$50.00
Wait Time – ALS	"$40.00
Wait Time – BLS	"$30.00
Wait Time – W/C	"$20.00
Mileage – SCT-RN/Ambulance	"$7.70
Mileage – SCT/Ambulance	"$7.70
Mileage – ALS/Ambulance	"$7.70
Mileage – BLS/Ambulance	"$7.70
Mileage – Wheelchair	"$3.00

- Wait Time is based on fifteen (15) minute increments, with the first half (1/2) hour being free (applicable only to re-bundled transportation)
- All rates are based on one-way transportation

EXHIBIT B

Statement of Work:
Pricing for Butler's Maryland ExpressCare Critical Care Transport Services

Service	24 Hour Transport Fee
Emergency Medical Technician ("EMT-B")	$28.26 per hour
Emergency Medical Technician – Paramedic ("EMT-P")	$39.77 per hour
Dedicated Vehicle Fixed Expenses	$6295.17 per month The rate includes the vehicle lease, insurance, certification and license fees
Mileage Fee	$0.71 per mile The rate includes all vehicle-.related expenses not indicated in the dedicated vehicle fixed expenses, above

Service	24 Hour Transport Fee
Management Fee	Ten percent (10%) of the cash receipts collected by Contractor for the transports performed as part of the dedicated Express Care service

Signatures: Part 2. SOW for UMMS Maryland ExpressCare (MEC) Critical Care Transport (Shore Regional Health)

IN WITNESS WHEREOF, the parties below agree to this Schedule B: Part 2 as of the Effective Date.

(Provider)
Provider's Name: **Butler Medical Transport, LLC**

By: _____

Name: William Rosenberg

Title: CEO

Date: 1/28/2022

UMMS Affiliates:

Shore Health System, Inc. (f/k/a The Memorial Hospital at Easton) d/b/a University of Maryland Shore Medical Center at Easton

By: _____

Name: Kenneth Kozel

Title: CEO

Date: 1/26/2022

Shore Health System, Inc. (f/k/a The Memorial Hospital at Easton) d/b/a University of Maryland Shore Medical Center at Dorchester

By: _____

Name: Kenneth Kozel

Title: CEO

Date: 1/26/2022

Shore Health System, Inc. (f/k/a The Memorial Hospital at Easton) d/b/a University of Maryland Shore Medical Center at Chestertown

By: _____

Name: Kenneth Kozel

Title: CEO

Date: 1/26/2022

University of Maryland Access Center (UMAC)
UMMS Corporate Shared Services

By: _____

Name: Todd J. Crocco

Title: Vice President

Date: 1/27/2022

EXHIBIT 8

UNIVERSITY of MARYLAND
SHORE REGIONAL HEALTH

January 6, 2023

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21225

Dear Mr. Steffen,

As part of our modified CON application seeking replacement of University of Maryland Shore Medical Center at Easton ("UMSMC-E"), we are seeking a Certificate of Conformance to move our primary and elective PCI program to the replacement hospital. I am submitting this letter of commitment that if University of Maryland Shore Regional Health (UM SRH) obtains Commission approval to establish a primary PCI Program at the replacement hospital, formal, regularly scheduled meetings for the purpose of interventional case review will be established at the replacement hospital. The meetings will be mandatory for interventionists and other physicians, nurses, and technicians who care for primary PCI patients.

Sincerely,

Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

EXHIBIT 9

CARDIAC SERVICES STEERING COMMITTEE
MEETING DATES/ATTENDEES
AUGUST 26, 2020 – SEPTEMBER 21, 2022

Wednesday, August 26, 2020 7:30 AM
Presiding: Steve Eisemann
Present: Dr. Jeff Etherton, Tina Blalock, Dr. Gabriel Sardi, Colin Fluharty, Jess Fluharty, Dr. Walt Atha, Renee Edsall, Mary Alice VanHoy, Alicia Pritchard, Pam Addy, Ross Jones

Wednesday, September 16, 2020 7:30 AM
Presiding: Gary Jones
Present: Steve Eisemann, Dr. Jeff Etherton, Dr. Tim Shanahan, Dr. Jane Wang, Mary Alice VanHoy, Colin Fluharty, Leslie Vohs, Jess Fluharty, Alicia Fuchs, Chris Matulay

Wednesday, October 28, 2020 7:30 AM
Presiding: Steve Eisemann
Present: Gary Jones, Dr. Jeff Etherton, Dr. Tim Shanahan, Dr. Ben Remo, Dr. Ivan Pena, Dr. Gabriel Sardi, Dyshekia Strawberry, Tina Blalock, Colin Fluharty, Mary Alice VanHoy, Leslie Vohs, Jess Fluharty, Renee Edsall

Wednesday, November 18, 2020 7:30 AM
Presiding: Steve Eisemann
Present: Gary Jones, Dr. Jeff Etherton, Dr. Ben Remo, Dr. Ivan Pena, Dr. Gabriel Sardi, Dyshekia Strawberry, Tina Blalock, Colin Fluharty, Mary Alice VanHoy, Leslie Vohs, Jess Fluharty, Alicia Fuchs, Jessica Alvarez, Dr. Brendon Paltoo
Excused: Dr. Tim Shanahan, Dr. Walt Atha

No Meeting held December 23, 2020 due to Christmas Holiday

Wednesday, January 20, 2021 7:30 AM
Presiding: Steve Eisemann
Present: Dyshekia Strawberry, Dr. Ivan Pena, Tina Blalock, Gary Jones, Pam Addy, Colin Fluharty, Dr. Gabriel Sardi, Jeff Fluharty, Luanne Satchell, Leslie Vohs, Dr. Jeff Etherton, Ross Jones, Dr. Ben Remo, Josh Cherrix

Wednesday, February 24, 2021 7:30 AM
Presiding: Steve Eisemann
Present: Josh Cherrix, Dr. Tim Shanahan, Dr. Jeff Etherton, Dr. Ben Remo, Dr. Walt Atha, Pam Addy, Dyshekia Strawberry, Jess Fluharty, Luanne Satchell, Leslie Vohs, Jess Alvarez, Tina Blalock

Wednesday, March 17, 2021 7:30 AM
Presiding: Josh Cherrix
Present: Dr. Ben Remo, Dr. Tim Shanahan, Dr. Ivan Pena, Dr. Brendon Paltoo, Dyshekia Strawberry, Jessie Alvarez, Jess Fluharty, Tina Blalock, Steve Eisemann, Mary Alice VanHoy

Wednesday, April 28, 2021 7:30 AM
Presiding: Josh Cherrix
Present: Dyshekia Strawberry, Dr. Ivan Pena, Jess Fluharty, Jess Alvarez, Luanne Satchell, Ross Jones, Dr. Jeff Etherton, Dr. Gabriel Sardi, Mary Alice VanHoy, Dr. Walt Atha, Leslie Vohs

Wednesday, May 19, 2021 7:30 AM
Presiding: Josh Cherrix
Present: Dyshekia Strawberry, Dr. Tim Shanahan, Dr. Gabriel Sardi, Dr. Walt Atha, Jess Fluharty, Ross Jones, Leslie Vohs, Tina Blalock

Wednesday, June 23, 2021 7:30 AM
Presiding: Josh Cherrix
Present: Dr. Jeff Etherton, Dr. Walt Atha, Pam Addy, Dyshekia Strawberry, Ross Jones, Leslie Vohs, Tina Blalock, Courtney Galbraith, Mary Alice VanHoy, Luanne Satchell

Wednesday, July 21, 2021 7:30 AM
Meeting Cancelled

Wednesday, August 25, 2021 7:30 AM
Presiding: Josh Cherrix
Present: Dr. Jeff Etherton, Dr. Walt Atha, Dr. Gabriel Sardi, Dr. Tim Shanahan, Debbie Timms, Dyshekia Strawberry, Ross Jones, Jess Fluharty, Tina Blalock, Mary Alice VanHoy, Luanne Satchell

Wednesday, September 15, 2021 7:30 AM
Presiding: Josh Cherrix
Present: Dr. Jeff Etherton, Dr. Walt Atha, Dr. John Botsis, Dr. Ivan Pena, Jess Alvarez, Dyshekia Strawberry, Mary Alice VanHoy, Luanne Satchell

Wednesday, October 27, 2021 7:30 AM
Presiding: Josh Cherrix
Present: Dr. Tim Shanahan, Dr. Gabriel Sardi, Dr. Jeff Etherton, Dr. John Botsis, Ross Jones, Dyshekia Strawberry, Tina Blalock

Wednesday, November 17, 2021 7:30 a.m.
Consent Meeting via Email
Participants: Lead: Dyshekia Strawberry; Pam Addy, Jessica Alvarez, Dr. Walt Atha, Tina Blalock, Dr. John Botsis, Dr. Brendon Paltoo, Dr. Jeff Etherton, Jessica Fluharty, Ross Jones, Chris Matulay, Dr. Ivan Pena, Dr. Ben Remo, Dr. Tim Shanahan, Deborah Timms, Mary Alice VanHoy, Nicole Noga

Wednesday, December 22, 2021 7:30 a.m.
Meeting Cancelled due to Christmas Holiday and Technical Difficulties

Wednesday, January 19, 2022 7:30 AM
Presiding: Dr. Tim Shanahan
Present: Dr. Tim Shanahan, Dr. Gabriel Sardi, Dr. Ivan Pena, Dr. Walt Atha, Dyshekia Strawberry, Nicole Noga, Mary Alice VanHoy, Jess Fluharty, Tina Blalock

Wednesday, January 19, 2022 7:30 AM
Presiding: Dyshekia Strawberry
Present: Dr. Jeff Etherton, Dr. Tim Shanahan, Dr. Steven Obrzut, Nicole Noga, Jess Fluharty, Tina Blalock, Ross Jones, Luanne Satchell, Kathy Elliott

Wednesday, March 16, 2022 7:30 AM
Presiding: Dyshekia Strawberry
Present: Dr. Jeff Etherton, Dr. Tim Shanahan, Dr. Steven Obrzut, Dr. Ivan Pena, Chris Matulay, Tina Blalock, Luanne Satchell, Mary Alice VanHoy
Excused: Nicole Noga, Jess Fluharty

Wednesday, April 27, 2022 7:30 AM
Presiding: Dyshekia Strawberry
Present: Dr. Tim Shanahan, Dr. Steven Obrzut, Dr. Gabriel Sardi, Nicole Noga, Chris Matulay, Ross Jones, Tina Blalock, Luanne Satchell, Mary Alice VanHoy

Wednesday, May 18, 2022 7:30 AM
Presiding: Dyshekia Strawberry
Present: Hilary Cassel, Dr. Tim Shanahan, Dr. Ivan Pena, Dr. Jeff Etherton, Nicole Noga, Ross Jones, Tina Blalock, Luanne Satchell, Mary Alice VanHoy, Jess Fluharty

Wednesday, May 18, 2022 7:30 AM
Presiding: Dyshekia Strawberry
Present: Hilary Cassel, Dr. Tim Shanahan, Dr. Ivan Pena, Dr. Jeff Etherton, Nicole Noga, Ross Jones, Tina Blalock, Luanne Satchell, Mary Alice VanHoy, Jess Fluharty

Wednesday, June 22, 2022 7:30 AM
Presiding: Hilary Cassel
Present: Dyshekia Strawberry, Dr. Ivan Pena, Dr. Gabriel Sardi, Dr. Steven Obrzut, Nicole Noga, Ross Jones, Tina Blalock, Luanne Satchell, Mary Alice VanHoy, Jess Fluharty, Chris Matulay

Wednesday, July 20, 2022 7:30 AM
Presiding: Hilary Cassel
Present: Dyshekia Strawberry, Dr. Timothy Shanahan, Dr. Jeff Etherton, Ross Jones, Tina Blalock, Chris Matulay

Wednesday, August 24, 2022 7:30 AM
Presiding: Hilary Cassel
Present: Dr. Timothy Shanahan, Dr. Gabriel Sardi, Dr. Ivan Pena, Dyshekia Strawberry, Ross Jones, Tina Blalock, Mary Alice VanHoy, Chris Matulay

Wednesday, September 21, 2022 7:30 AM
Presiding: Hilary Cassel
Present: Dr. Jeff Etherton, Dr. Ivan Pena, Dr. Gabriel Sardi, Dr. Eric Maniago, Jessica Caraker, Mary Alice VanHoy, Dyshekia Strawberry, Tina Blalock

EXHIBIT 10

UNIVERSITY of MARYLAND
SHORE REGIONAL HEALTH

January 6, 2023

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21225

Dear Mr. Steffen,

As part of our modified CON application seeking replacement of University of Maryland Shore Medical Center at Easton ("UMSMC-E"), we are seeking a Certificate of Conformance to move our primary and elective PCI program to the replacement hospital. I am submitting this letter of commitment that if University of Maryland Shore Regional Health (UM SRH) obtains Commission approval to establish a primary PCI program at the replacement hospital, the hospital will create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and will meet monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

Sincerely,

Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

EXHIBIT 11

UNIVERSITY of MARYLAND
SHORE REGIONAL HEALTH

January 6, 2023

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21225

Dear Mr. Steffen,

As part of our modified CON application seeking replacement of University of Maryland Shore Medical Center at Easton ("UMSMC-E"), we are seeking a Certificate of Conformance to move our primary and elective PCI program to the replacement hospital. I am submitting this letter of commitment that the replacement hospital will conduct external reviews at least semi-annually, as determined by the Commission, of at least five percent of randomly selected PCI cases performed in the applicable time period as provided in the Commission's regulations, which will include at least three cases per physician or all cases if the internationalist performed fewer than three cases.

Sincerely,

Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

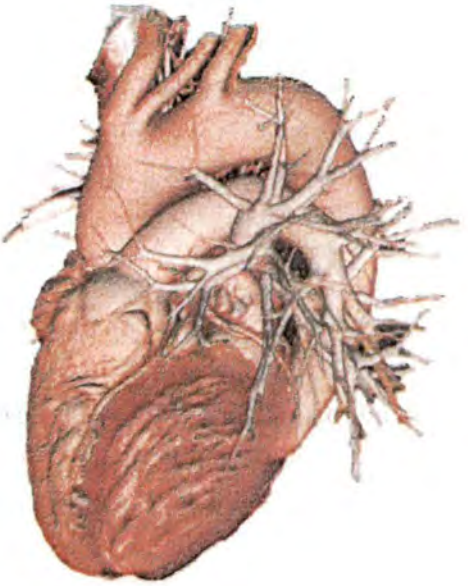
EXHIBIT 12

Shore Medical Center

A Report From:

MACPAQ

The MARYLAND ACADEMIC CONSORTIUM FOR PERCUTANEOUS CORONARY INTERVENTION APPROPRIATENESS AND QUALITY



Percutaneous Coronary Intervention Quality Case Review
Time Period: January to June, 2020

I. Introduction:

This report summarizes the results of an external peer-review by the Maryland Academic Consortium for Percutaneous coronary Intervention Appropriateness and Quality (MACPAQ), for review of percutaneous coronary intervention as requested by **Shore Medical Center at Easton** meeting the Maryland COMAR 10.17.24. MACPAQ is a MHCC-approved Peer review system. **This report encompasses cases performed from January to June, 2020.**

All invasive angiograms, percutaneous coronary intervention and relevant clinical data were evaluated and assessed by an experienced board certified interventional cardiologist at the respective academic institutions, not affiliated with Shore Medical Center.

II. Methodology:

Percutaneous coronary interventional procedures (PCI) were selected for review in a random fashion in accordance with COMAR regulations. Briefly, a list of all PCI's (excluding primary PCI procedures for acute myocardial infarctions) were forwarded to MACPAQ for random case selection. Five percent of these cases that were performed at Shore Medical Center were randomly selected by MACPAQ (as per COMAR 10.17.24) for external review that included at least 6 cases per interventional physician (for the year) or all cases if the interventional cardiologist performed fewer than 6 cases per year. Shore Medical Center then provided the information on the randomly selected cases to MACPAQ.

The de-identified (i.e. "blinded") blinded clinical data and invasive angiograms were processed (to ensure de-identification of patient, hospital, and physician information) and managed at the MACPAQ Core Center. The cases were assigned to at least one MACPAQ Reviewer (interventional cardiologist) not affiliated with Shore Medical Center or its health system. The invasive coronary angiograms (ICA) and clinical data were then transmitted to the blinded reviewers.

Appropriateness was evaluated by THREE separate criteria:

1) **Angiographic criteria = "Angiographic Appropriateness"**
   -defined by the Reviewer's assessment as to whether the lesion was severe enough to warrant intervention based on the cine angiogram alone (i.e. lesion greater than or equal to 70% diameter stenosis by visual assessment);

2) **Clinical standard of care = "Clinical Appropriateness"**
   - defined by the Reviewers' clinical judgment, based on the combined clinical scenario and angiogram;

3) **ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT Appropriate Use Criteria for Coronary Revascularization = "AUC Appropriateness"**
   - defined by the ACC/SCAI/AHA Appropriate Use Criteria (2016/2017)

Several additional variables reported by the reviewer include: thoroughness and accuracy of the report and clinical documentation.

Procedures that were assessed to be *'Rarely Appropriate'* by a Reviewer were then assessed by a second Reviewer. If the two Reviewers' assessments were not concordant, then the case was additionally reviewed by a third Reviewer and adjudicated by agreement of 2 or more of the group. Other significant findings may have also triggered additional review. Reviewers may have also requested an additional Reviewer for specific cases. The consensus data was included in this report. When applicable, multiple Reviewer comments were included also in the report. It was determined by the group that through this mechanism, diligent review of both the invasive angiogram and clinical data a comprehensive review was accomplished.

III. Results

A. Baseline Information

A list of **74 cases** were forwarded to MACPAQ for random selection, from **3 separate Operators.** A total of 10 patient cases (12%) were reviewed, meeting the COMAR required minimum 5% of the coronary interventions for External Review for this 6 month period.

Shore Medical Center Operator (MACPAQ Assigned Number)	Number of PCI Cases Reviewed
112	3
113	3
133	3
Total	**9**

After completion of initial MACPAQ Core Center processing and review, 9 cases were assessed by at least one of seven MACPAQ independent interventional cardiologists. Physician Peer Reviewers assessed the angiograms and relevant clinical case material in a blinded fashion.

Of 9 patients cases reviewed, there were a total of 11 separate lesions or vessels intervened upon, including 7 case with 1 PCI lesions/vessels and two cases with 2 lesions.

1. Case Mix

Summary of selected pre-procedural characteristics are listed below.

a. Clinical Presentation

Results - Baseline Information - Case Mix - Clinical Presentation

	%	n
Stable Angina	13%	1
ACS	89%	8
Unstable Angina	38%	3
NSTEMI	50%	4
STEMI	13%	1

B. PCI Success

Of lesion PCI's submitted for review, 91% of interventions were assessed to be 'Successful' by COMAR definitions. To summarize the criteria:

a) For stent procedures, "Success" was defined as <10% residual stenosis AND TIMI 3 flow. "Partially Successful" was defined as 10 to less than 50% residual stenosis and TIMI 3 flow. "Unsuccessful" was defined as >10% residual stenosis within a stent having less than TIMI 3 flow; >50% stenosis; or less than TIMI 2 flow.
b) For plain balloon angioplasty (POBA), "Success" was defined as <50% residual stenosis with TIMI 3 flow. "Unsuccessful POBA" was defined as >50% residual stenosis OR less than TIMI 2 flow.

Summary of Procedural Outcomes per Lesion

	n	%
Successful stent	10	91%
Partially successful stent	1	9%
Successful POBA	0	0%
Unsuccessful Stent	0	0%
Unsuccessful POBA	0	0%

C. Complications

There were 2 cases with complications (22%) observed in the cases reviewed. Additional case details are in Appendix B.

Case	Complication	Documented in Cath Report	Treated
FDV271	Distal wire perforation Distal embolization/No Reflow Stent edge dissection	Yes	Yes.
BHW673	Hypotension, bradycardia, and chest discomfort post procedure requiring repeat catheterization showing patency of the previous mentioned stents.	Not applicable	Yes

TABLE 1

PCI LESION SEVERITY (Reviewers') and Post-procedure Results

Patient ID	Coronary Segment	Reviewer Visual Estimate %	Post-PCI Residual Stenosis	Post PCI TIMI Grade Flow	Procedure Successful?
AHR493	2 = Mid RCA	50-70*	< 10%	3	Successful Stent
ALM800	12 = Proximal left anterior descending	80	< 10%	3	Successful Stent
AQA750	18 = Proximal Left circumflex artery	80-90	< 10%	3	Successful Stent
AQE780	14 = Distal left anterior descending	99	10-50%	3	Partially Successful Stent
ASG828	13 = Mid I left anterior descending	80	< 10%	3	Successful Stent
AUL127	2 = Mid RCA	90	< 10%	3	Successful Stent
BHW673	2 = Mid RCA	100	< 10%	3	Successful Stent
EXA313	3 = Distal RCA	90	< 10%	3	Successful Stent
FDV271	2 = Mid RCA	90	< 10%	3	Successful Stent
Second Lesions					
ASG828	14 = Distal Left anterior descending artery	80	< 10%	3	Successful Stent
EXA313	6 = 1 st Right posterior lateral branch	90	< 10%	3	Successful Stent

**** dFFR was performed for stenosis severity, and met criteria for "obstructive"***

D. Other Important Assessments

Below are the results of other important assessments that the Peer Reviewers made as part of the case review. These include required questions as stated in the most current COMAR 10.27.17 (11/2015).

1. Agreement with Catheterization Report Stenosis Severity 91% (10 of 11 lesions)

This assessment compares the Operators' documented stenosis severity (**by angiography alone**) of PCI lesion/s with the Peer Reviewer assessment. See **Appendix A** for individual case assessment in cases of disagreement.

Patient ID	*Segment #*	*Reviewer Visual Estimate of % Stenosis Severity*	*Operator Cath Report of % Stenosis Severity*	*Agree with the Catheterization Report Stenosis*
AHR493*	2 = Mid RCA	50-70	80	Yes

Dfr was performed and was 0.81 which is indicative of obstruction

2. Agreement with procedural outcome documented 91% (10 of 11 lesions)

This compares the Operators' documented outcome with the Peer Reviewer assessment.

AQE780 Unable to assess success due to limited imaging.

3. Agreement with Operator Diagnosis of ACS versus non-ACS 89% (8 of 9 cases)

Of cases that were performed for Acute Coronary Syndrome (ACS) indications, the Reviewers agreed with the diagnosis of an ACS in all but one case.

4. Agreement with Operator Diagnosis of ACS type (if applicable) 88% (7 of 8 ACS cases)

ACS Type	Number of cases	Agreement (%)
Non-Q wave MI	4	100%
ST-Elevation MI	1	100%
Unstable Angina	3	67%

5. Agreement with Catheterization Report Stenosis Severity of Non-intervened lesions/vessels

This assessment compares the Operators' documented stenosis severity (**by angiography alone**) of PCI lesion/s with the Peer Reviewer assessment. "Not applicable" may be in cases that complete diagnostic images were not available or no lesions were present.

Assessment	N	Percent
Agree	9	100%
Disagree	0	0
Not Applicable	0	0

6. Alternative Therapy to PCI could be considered (Reviewer Opinion):

Not Applicable	78%	(7 of 9)
Applicable	22%	(2 of 9)
Consideration of alternative WAS documented	11%	(1 of 2)
Consideration of alternative NOT documented	11%	(1 of 2)

Reviewers assessed the patient record to determine whether treatment other than PCI, such as cardiac surgery or medical therapy, was documented to have been considered in cases where it would have been appropriate to consider alternative treatment, based on current Guidelines (i.e. coronary artery bypass surgery or medical therapy) or clinical standards. This question was **not applicable (based on the Reviewer's opinion) in 7 of 9 cases** sent for review. In other words, the Reviewers felt that PCI was the most appropriate revascularization strategy in these cases, and that alternatives (CABG or medical therapy) were not reasonable to consider. In the remaining cases, the Reviewers assessed the documentation in the patient record to determine whether treatment other than PCI, such as cardiac surgery or medical therapy, was considered in cases where it would have been appropriate to consider alternative treatment. **This question applied in 2 cases , of which 50% had** documentation describing the consideration of bypass surgery or medical therapy as a treatment alternative prior to PCI.

E. Procedure Appropriateness Results:

The summary of the appropriateness ratings is listed below and the appropriateness ratings were assessed per lesion/vessel. For example, if a patient had 2 vessels intervened upon, there were 2 separate assessments. The summary of the appropriateness ratings (per lesion/vessel) are listed below.

See **TABLE II and Table III** for individual Operator Results.

Summary of Appropriateness Ratings (per lesion).

1) **Angiographic Appropriateness (lesion severity and suitability for PCI) -Per lesion**
Based on the percentage of stenosis, given accepted guidelines that stenosis of 70 percent or greater is appropriate for treatment, stenosis between 50 to 69 percent may be appropriate for treatment, and stenosis less than 50 percent is rarely appropriate for treatment

%	n	
91%	10	interventions were judged to be appropriate+
9%	1	intervention were judged to be of uncertain/ may be appropriate
0%	0	interventions were judged to rarely appropriate

2) **Clinical Appropriateness (based on standard clinical practice)**
*See individual case descriptions and assessments in **Appendix B** for cases determined to be "uncertain/may be appropriate" and "rarely appropriate)*

%	n	
73%	8	interventions were judged to be appropriate
27%	3	intervention were judged to be uncertain/ may be appropriate
0%	0	intervention were judged to be rarely appropriate

3. **ACC/AHA Appropriate Use Criteria for PCI (AUC Criteria)**
*See individual case descriptions and assessments in **Appendix B** for cases determined to be "uncertain/may be appropriate" and "rarely appropriate)*

%	n	
91%	10	interventions were judged to be appropriate
9%	1	intervention were judged to be uncertain/ may be appropriate
0%	0	intervention were judged to be rarely appropriate
0%	0	intervention not addressed in current AUC guidelines

TABLE II

Appropriateness Ratings by Individual Operator

Below is a summary of the individual Operator Appropriateness performance.

Patient cases: 9 Total lesions: 11

			ANGIOGRAPHIC APPROPRIATENESS			CLINICAL APPROPRIATENESS			ACC/AHA APPROPRIATENESS (AUC- Guideline)			
Physician Number	Total Patient Cases	Total Lesions Reviewed	Appropriate	May be Appropriate	Rarely Appropriate*	Appropriate	May be Appropriate	Rarely Appropriate*	Appropriate	May be Appropriate	Rarely Appropriate*	Not addressed in current AUC guidelines
112	3	4	4	0	0	2	2	0	4	0	0	0
113	3	4	4	0	0	4	0	0	4	0	0	0
133	3	3	2	1	0	2	1	0	2	1	0	0
Total		**11**	**10**	**1**	**0**	**8**	**3**	**0**	**10**	**1**	**0**	**0**
Percent		**100%**	**91%**	**9%**	**0%**	**73%**	**27%**	**0%**	**91%**	**9%**	**0%**	**0%**

* The term "inappropriate" has now been replaced by "rarely appropriate" to acknowledge individual circumstances where the procedure could be considered reasonable. Assessments were made on the case data available to the Reviewers.

TABLE III

Appropriateness Ratings by Individual Operator: Percent of Cases

Below is a summary of the individual Operator Appropriateness performance

			ANGIOGRAPHIC APPROPRIATENESS			CLINICAL APPROPRIATENESS			ACC/AHA APPROPRIATENESS (AUC- Guideline)			
Physician Number	Total Patient Cases Reviewed	Total Lesions Reviewed	Appropriate	May be Appropriate	Rarely Appropriate*	Appropriate	May be Appropriate	Rarely Appropriate*	Appropriate	May be Appropriate	Rarely Appropriate*	Not addressed in current AUC guidelines
112	3	4	100%	0%	0%	50%	50%	0%	100%	0%	0%	0%
113	3	4	100%	0%	0%	100%	0%	0%	100%	0%	0%	0%
133	3	3	67%	33%	0%	67%	33%	0%	67%	33%	0%	0%
Total		**11**	**10**	**1**	**0**	**8**	**3**	**0**	**10**	**1**	**0**	**0**
Percent		**100%**	**91%**	**9%**	**0%**	**73%**	**27%**	**0%**	**91%**	**9%**	**0%**	**0%**

* *The original AUC term "inappropriate" had been used in the 2009 and 2011 PCI AHA/ACC Clinical AUC Guidelines. AUC terminology evolved. The term "inappropriate" has now been replaced by* ***"rarely appropriate"*** *to acknowledge individual circumstances where the procedure could be considered reasonable. Assessments were made on the case data available to the Reviewers.*

EXECUTIVE SUMMARY COMMENTS /RECOMMENDATIONS

The Reviewers felt that the overall procedural performance of the physicians reviewed and the hospital was satisfactory There were 9 patient cases reviewed which included a total of 11 separate lesions / PCI's. Of the 9 patient-cases, 91% were successful. There were 2 cases with complications (22%). The review found that 100% of the cases were classified as "appropriate" or "may be appropriate" for all lesions treated.

On a per-lesion basis (n=11), the assessment of lesion severity (i.e. percent of blockage) of the PCI lesions was accurate, with 91% of the readings by the Operators in agreement with the Reviewers' (Appendix A). In regards to lesion assessment of non-PCI vessels, the Reviewers agreed with the Operator in 100% of cases.

Based on Angiographic criteria, 91% were considered to be "appropriate", and 9% (n=1) was assessed as "may be appropriate". In that one case, the Operator also performed funtional lesion assessment (with DFR) and showed the lesion to be obstructive/flow limiting. Note that DFR is superior to angiography alone for assessing lesion severity. There were no PCI lesions considered "rarely appropriate".

Based on clinical criteria, 73% (8 of 11 lesions) of lesions were considered to be "appropriate", and the remainder 27% were assessed to be "may be appropriate". There were no PCI lesions considered "rarely appropriate

Based on Guideline / Appropriate Use Criteria (AUC), 91% of lesions were considered "appropriate", one case "may be appropriate". There were no PCI lesions considered "rarely appropriate

Documentation and diagnosis of the presence of an 'Acute Coronary Syndrome" was 89% (8 of 9 cases) based on the provided documentation. Documentation of procedural outcomes were 91% accurate. Documentation of treatment alternatives to PCI, such as CABG or medical therapy, was not assessed to be required 2 of 9 cases. In the cases where the reviewer thought it would be reasonable to consider alternative therapy, there was documentation that such a consideration was made in one of the two cases (50%).

The Reviewers assessed the the Operators to be technically good. There werer 2 cases with complications (see report). Technical recommendations are contained in the report.

Appendix A

Stenosis Severity of PCI lesions as assessed by the Reviewers and Correlation with Documented Catheterization Report.

Patient ID	***Segment #***	***Reviewer Visual Estimate %***	***Operator Cath Report Stenosis Severity %***	***Agree with the Catheterization Report Stenosis (Yes or No)***	***Agree with the Catheterization report stenosis of the vessels not intervened upon?***
AHR493	2 = Mid RCA	50-70*	80	No	Yes
ALM800	12 = Proximal LAD	80	80	Yes	Yes
AQA750	18 = Proximal Left circumflex	80-90	90	Yes	Yes
AQE780	14 = Distal left anterior descending	99	99	Yes	Yes
ASG828	13 = Mid left anterior descending	80	75/80	Yes	Yes
AUL127	2 = Mid RCA	90	85	Yes	Yes
BHW673	2 = Mid RCA	100	100	Yes	Yes
EXA313	3 = Distal RCA	90	90	Yes	Yes
FDV271	2 = Mid RCA	90	Severe	Yes	Yes
Second Lesions					
ASG828	14 = Distal LAD	80	75/80	Yes	Yes
EXA313	6 = 1 st Right posterior lateral	90	90	Yes	Yes

**** DFR or FFR performed and was obstructive.***

Invasive Lesion Measurements

Patient ID	*Operator*	*Segment*	*Reviewer Visual Estimate %*	*IVUS or FFR*	*Result*
AHR493	133	50-70	80	Yes - FFR	Dfr was performed and was 0.81 which is indicative of obstruction
ASG828	112	80	75/80	Yes - FFR	DFR 0.79

Appendix B

Selected Individual Cases and Images

Identifier: ASG828

Clinical history: An 80 year man with history of hyperlipidemia, hypertension, gastrointestinal bleed who presented with shortness of breath and an episode of atypical chest pain. A stress test was performed with the patient reaching 5.9 METS without symptoms and a small area of ischemia in the right coronary artery and circumflex territory.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
13 = Mid I left anterior descending	80	75/80	Yes
14 = Distal Left anterior descending artery	80	75/80	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
13 = Mid I left anterior descending	Appropriate	Maybe appropriate	Appropriate
14 = Distal Left anterior descending artery	Appropriate	Maybe appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)

Complications: None None

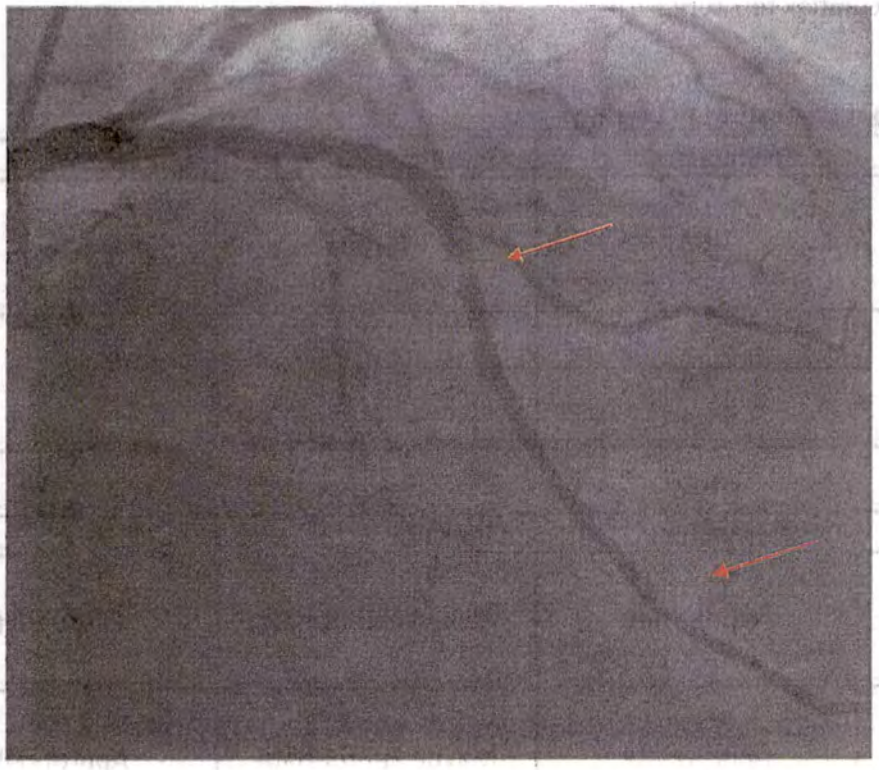
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	No= disagree
Type of ACS:	Unstable Angina
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:

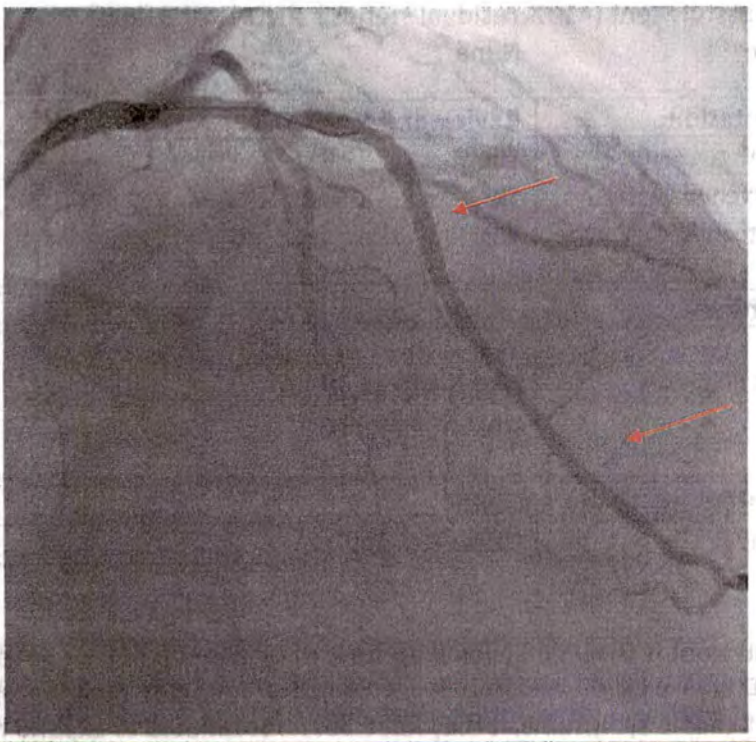
80 WM w hx recent GIB. Anginal equivalent is DOE/SOB (single episode of CP noted). ETT was abnormal but in Circ/RCA distribution not in LAD where lesion was found. Doing DFR of LAD was very appropriate. Given age, recent GI bleed and absent classic symptoms, it may have been reasonable to expand med

medical therapy with long acting nitrates and Ranexa before referring for cath but once referred operator did the right thing and I believe helped this man.

Pre PCI:



Post PCI:



Identifier: AQE780

Clinical history: A 70 year old woman with a history of diabetes, hypertension, morbid obesity and hyperlipidemia admitted through the emergency room with chest pain. The chest pain resolved with SL nitroglycerin during transport with resolution of symptoms. EKG demonstrated subtle ST elevation the anterior leads with the initial troponin was 0.07. The serial cardiac markers continued to rise.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
14 = Distal left anterior descending	99	99	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
14 = Distal left anterior descending	Appropriate	Appropriate	Appropriate

PCI result: Partially Successful Stent (10 to <50% residual stenosis AND TIMI 3
Complications: None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	No - Disagree
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Non-Q-Wave myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

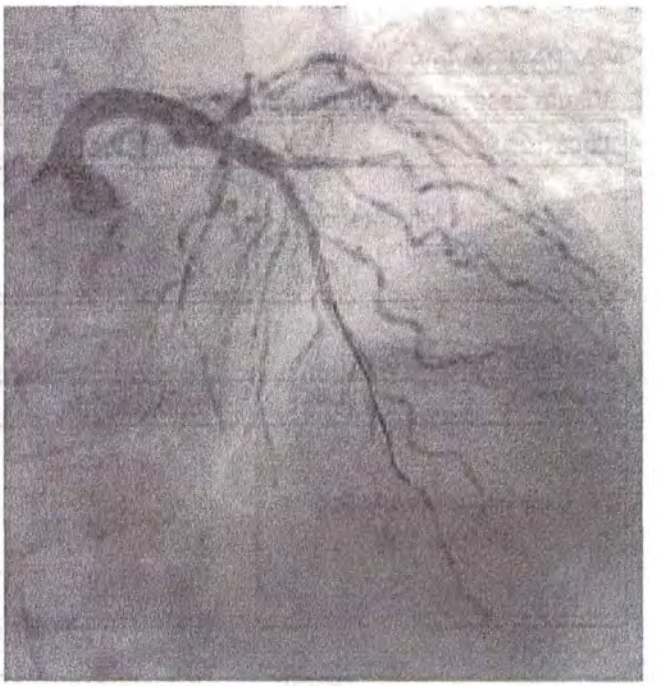
Reviewers Comments:

The patient is a 70 year old woman with history of HTN, hyperlipidemia, and Diabetes Mellitus who was admitted through the ED with chest pain. Initial troponin 0.07 and the ECG showed septal MI age undetermined initially felt to be STEMI but was then said not meet criteria. She was treated for ACS; her troponin continued to trend upward to 8. she was then taken to `urgent cath` the next morning. This showed diffuse calcified triple vessel disease with a reasonable assumption that the distal LAD

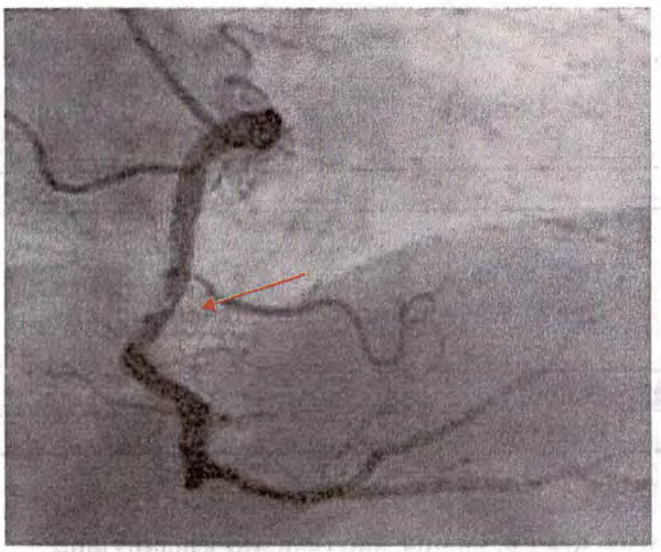
99% lesion was culprit. PCI was performed successfully however the final angiograms were obtained with the guidewire still across the lesion. That being said the distal LAD is diffusely diseased and would be at high risk of rethrombosis or restenosis. Clearly surgery for the distal LAD could not be recommended. The RCA and circumflex marginal also have significant lesions that might be addressed if clinically appropriate in the future.

Pre PCI:

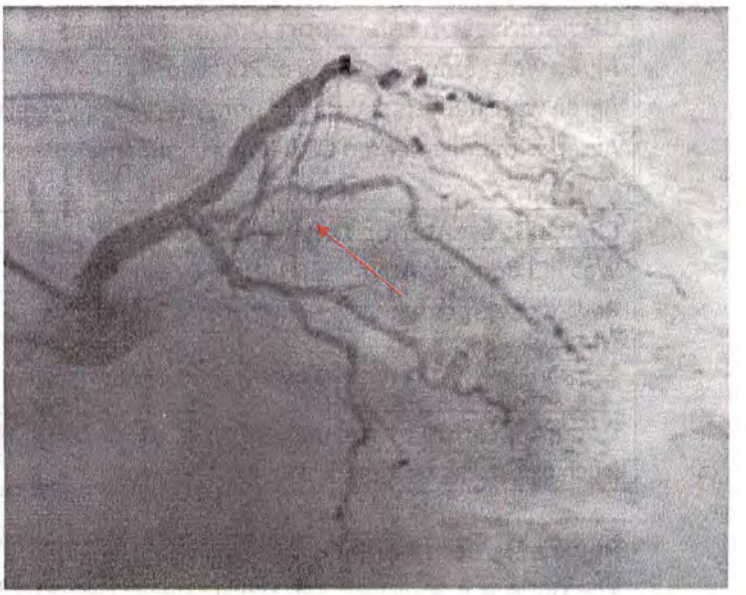
Post PCI



Right coronary artey:



Circunflex artrey:



Identifier: **BHW673**

Clinical history:
A 59 year old man with history of tobacco, diabetes, hypertension and morbid obesity admitted with unstable angina.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
2 = Mid RCA	100	100	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
2 = Mid RCA	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)

Complications: Post procedure hypotension, bradycardia, and chest discomfort requiring repeat catheterization showing patency of the previous stents.

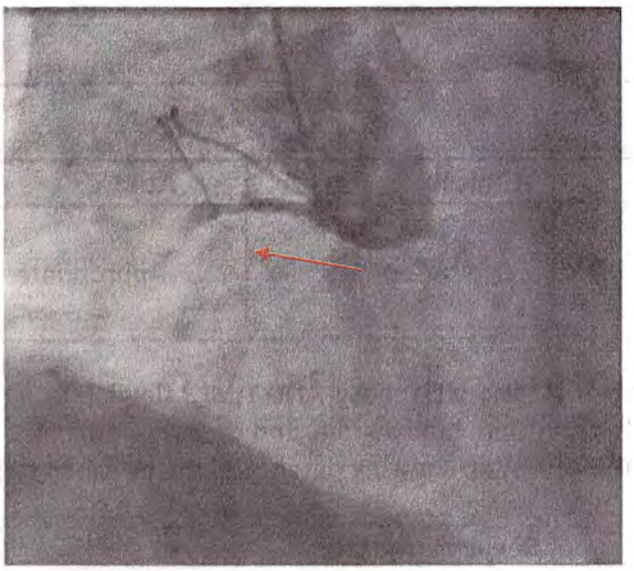
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Non-Q-Wave myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:
The patient presented a few weeks prior with what was thought to be symptoms of peptic ulcer disease. Stress test was reportedly negative. He continued to have pain and fortunately the cardiologist did not believe the falsely negative stress test and the patient then was sent for coronary angiography showing a subtotal occlusion of the RCA. The patient developed hypotension, bradycardia, and chest discomfort post procedure requiring repeat catheterization showing patency of the previous mentioned stents.

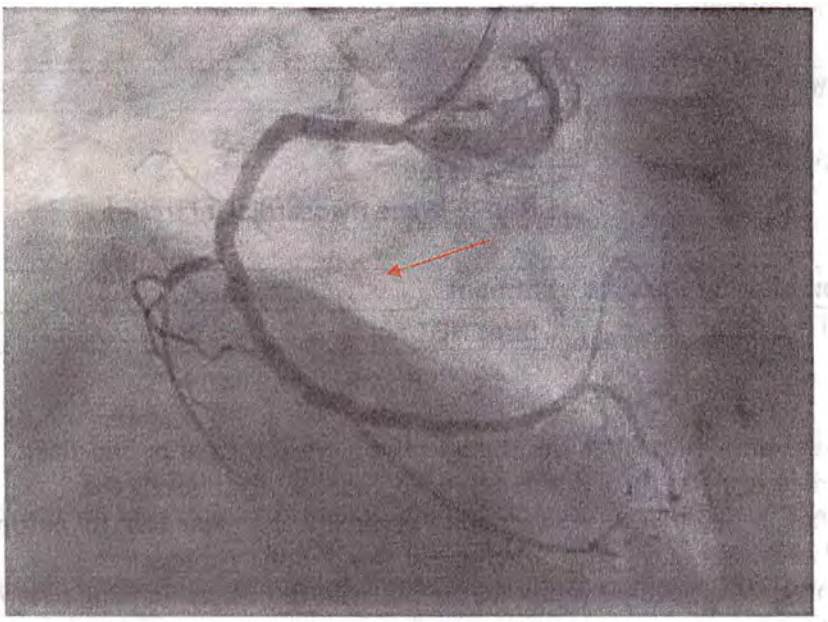
Technical comment:

2 comments: the total occlusion was likely sub-acute but could have been more chronic since it appears difficult to get through. The operator should have confirmed intraluminal placement of the wire with distal injection through a small balloon or microcatheter before dilating. Second, the patient reportedly had an episode of hypotension and bradycardia post procedure and underwent repeat catheterization which was appropriate. However, an echocardiogram to exclude effusion and also hemoglobin given history of ulcer should have been done, indeed it might have but documentation supplied for the review was limited.

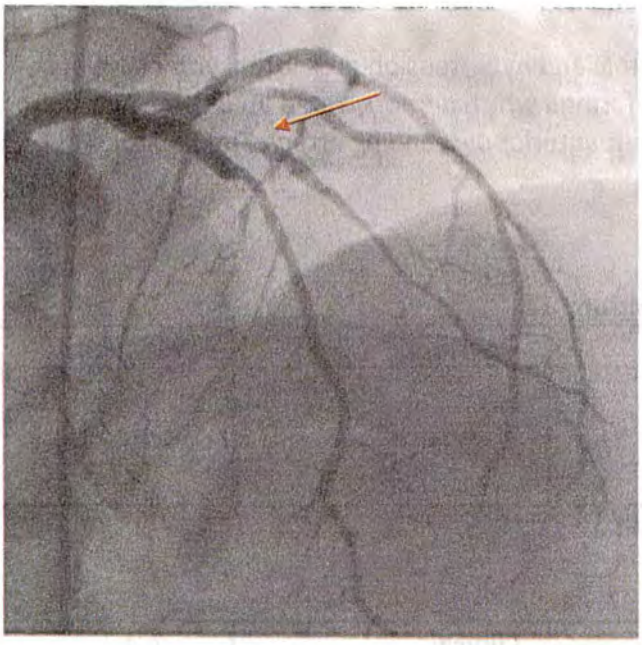
Pre PCI:



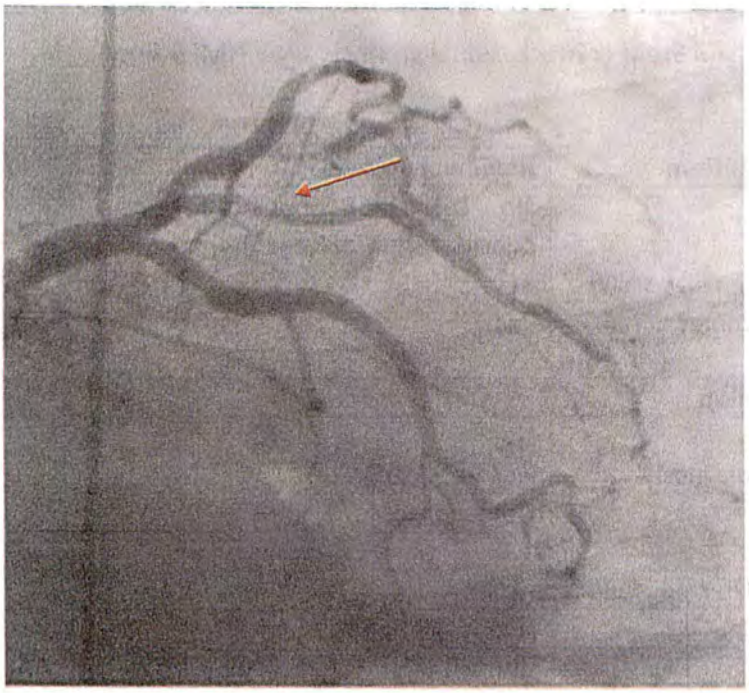
Post PCI:



Diagonal branch:



Marginal:



Identifier: AHR493

Clinical history:
A 62 year old woman with history of hyperlipidemia and hypertension presented with chest discomfort and dyspnea. A calcium scan was performed which demonstrated an elevated calcium score primarily in the right coronary artery and left anterior descending artery. The patient was on Norvasc and lipid lowering agents

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
2 = Mid RCA	50-70*	80	**No**

* dFR was 0.81 meeting criteria for "obstructive lesion"

PCI Appropriateness

Location	Angiographic	Clinical	AUC
2 = Mid RCA	Maybe appropriate	Maybe appropriate	Maybe appropriate

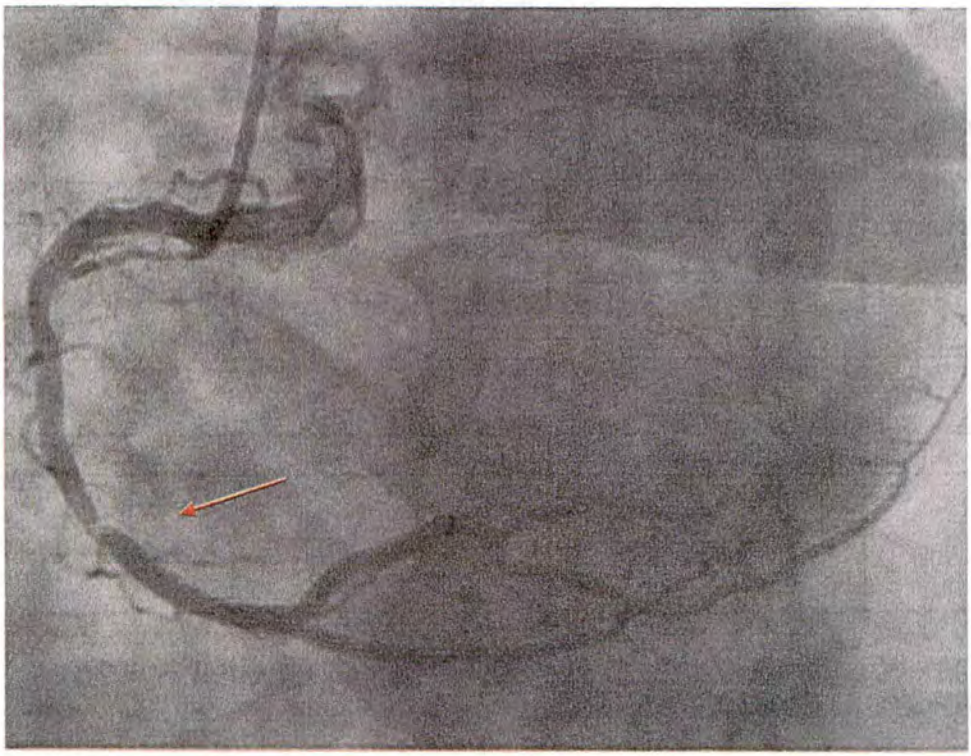
PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	**No = DISAGREE** (does not take into consideration dFR results)
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	No
Reviewer agrees with the operator's ACS diagnosis	Not Applicable
Type of ACS:	Not Applicable
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

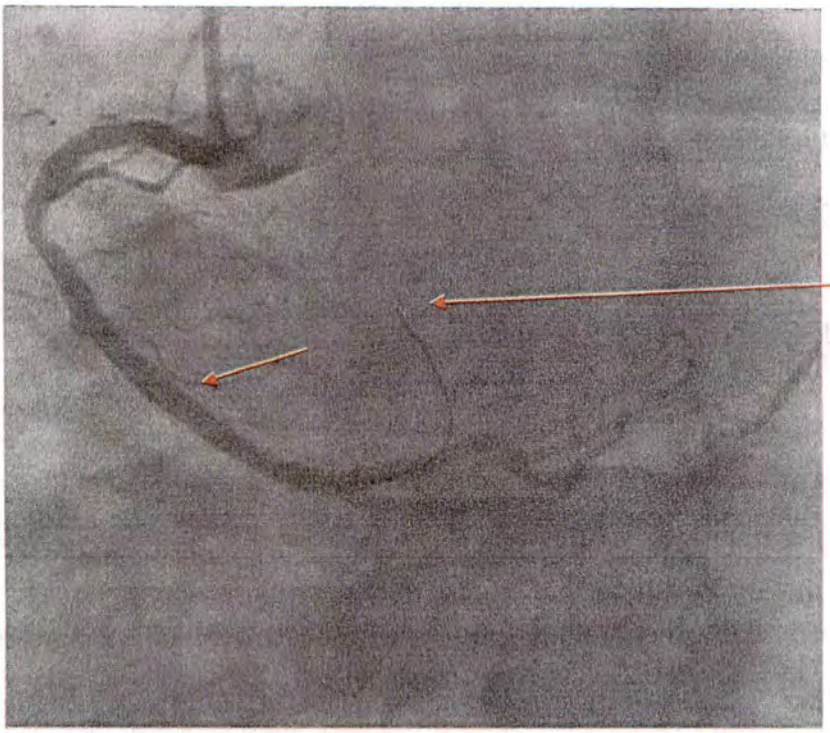
Reviewers Comments:
The patient is a 62 year old woman with stable angina with risk factors of HTN, hyperlipidemia, and diabetes. She presents to cardiologist with exertional chest pain and dyspnea. Known to have high calcium in LAD and RCA. She presents for elective angiography and possible intervention. The angiogram showed a mid RCA lesion that was imaged in 3 projections with one suggestive of a significant lesion. There is branch overlap however and I would call the narrowing no greater than 50-

60% however the physicians performed a dFR which was O.81 (this meaning a significant obstruction). PCI was performed with a residual lesion of <10%..

Pre PCI:



Post PCI:



Technical comment:

Poor wire position risks distal wire perforation

Identifier: AUL127

Clinical history:
A 70 year old woman with history of diabetes, hypertension, hyperlipidemia and asthma initially presented with an anterior ST elevation. The index cardiac catheterization showed LAD lesion which was stented. The patient was noted to have significant right coronary artery disease for which he patient presented for staged intervention.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
2 = Mid RCA	90	85	Yes

PCI Appropriateness

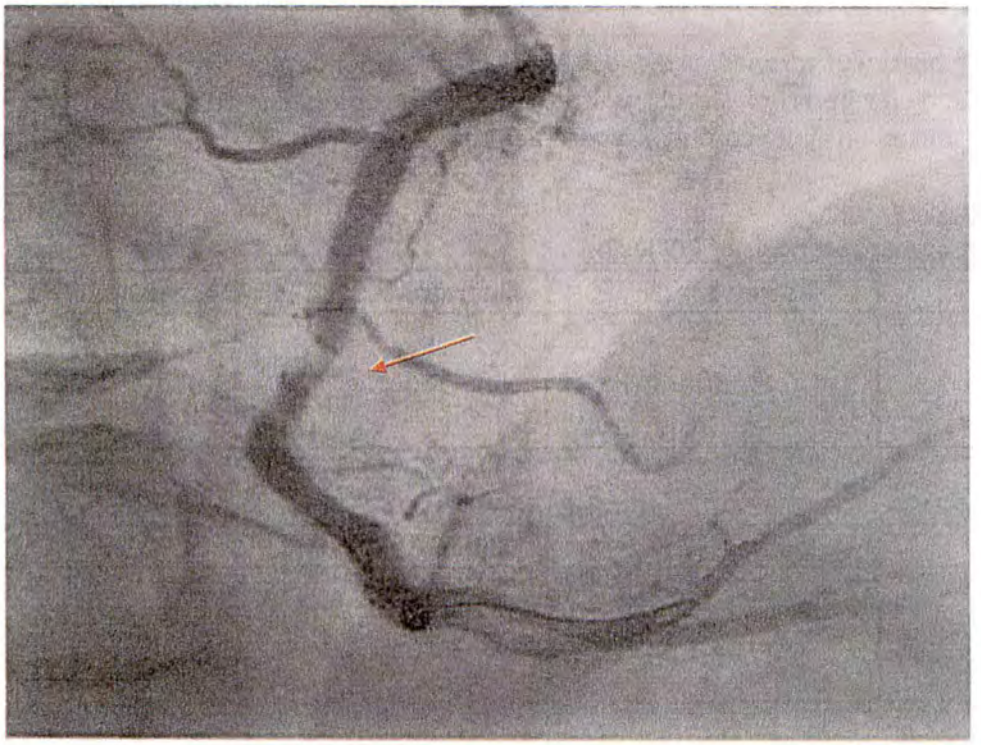
Location	Angiographic	Clinical	AUC
2 = Mid RCA	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

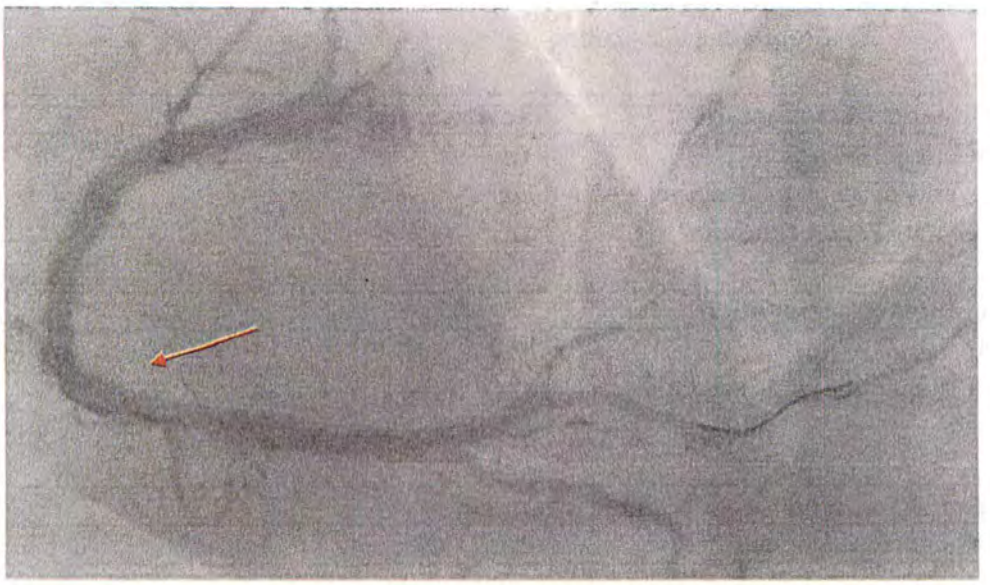
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	ST-Elevation Myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	No

Reviewers Comments:
70 y.o. woman had primary PCI after acute anterior ST Elevation. The MI treated with PCI of the LAD with drug eluting stent. She has known severe mid RCA 85% stenosis and presented with exertional angina. She is now referred for revascularization. This was a staged approach for complete revascularization is appropriate. Rotational atherectomy should have been performed given the extensive concentric calcification; a reasonable result was obtained but there is mild residual stenosis.

Pre PCI:



Post PCI:



Identifier: FDV271

Clinical history:
A 68 year old man with history of coronary artery disease (including prior deployment of four stents), hypertension and elevated cholesterol admitted through the emergency room with chest pain. The patient was started on acute coronary syndrome protocol.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
2 = Mid RCA	90	Severe	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
2 = Mid RCA	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Distal wire perforation

Complications: Distal embolization/No Reflow
Stent edge dissection

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Unstable Angina
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:
68 y.o. male who presented with history of coronary artery disease with 4 stents placed in 2006 at a hospital in New Jersey, history of dyslipidemia, hypertension tobacco use. He presented with of sudden onset of precordial chest discomfort after walk in his driveway, consistent with unstable angina. Coronary angiography demonstrated disease in RCA, described as " thrombosis of the mid right coronary artery" which was treated but complicated by small distal wire perforation, stent edge dissection and angiographic "no reflow" (see below).

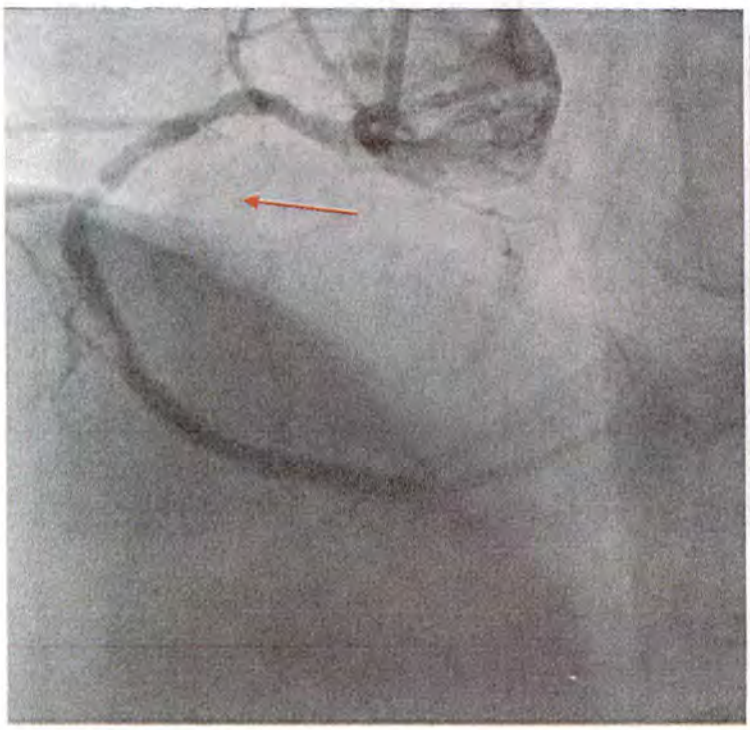
Technical comment:

There were several technical issues, though this was a challenging case due to lack of guide support. First, after the first stent was deployed the guideliner and wire were removed and there was embolization, likely of air or clot, from the guideliner. The Operator describes this as "no reflow" which is technically correct, but it was likely due to air. The operator then changed to femoral approach (for support – which was wise) and additional stents were placed for residual disease (and edge dissection) proximal to the other stent. Given the initial challenges with the prior guide, if one is changing to a femoral approach for guide support, a more aggressive guide may also have been considered for added support (i.e. AL or AR).

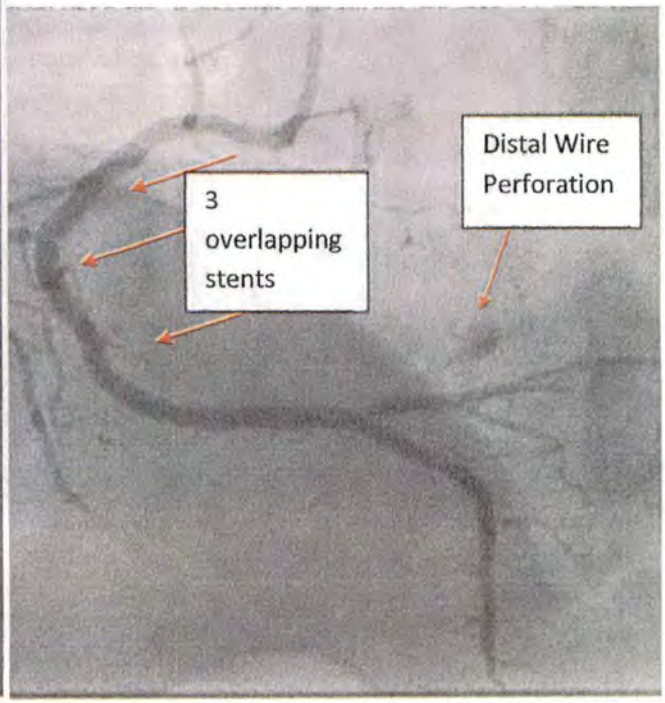
The patient had a clear distal wire perforation which was initially watched and subsequently brought back to the lab for re-look a few hours later. Echocardiography was reported as negative. The small wire perforation resulted from wire placement distally in a small vessel.. It is unclear as to why original stent was so short and why 3 stents were used and not one longer stent. This potentially could have been due to difficult delivery.

In regards to the wire perforation, from the report, it took multiple wires to cross into the distal vessel, and ultimately a PT Graphix was able to cross. This specific wire may be useful for crossing, but offers little support for the intervention and is prone to track into small vessels and cause wire perforations – as the Operator noted very well in the cath report. Exchanging the wire with a microcatheter (if possible) for a more supportive wire (BMW, BHW or Wiggle) earlier may have offered more support while reducing the risk of perforation. I suspect the Operator would have considered this if they were able to do it. It may not have been possible at the time.

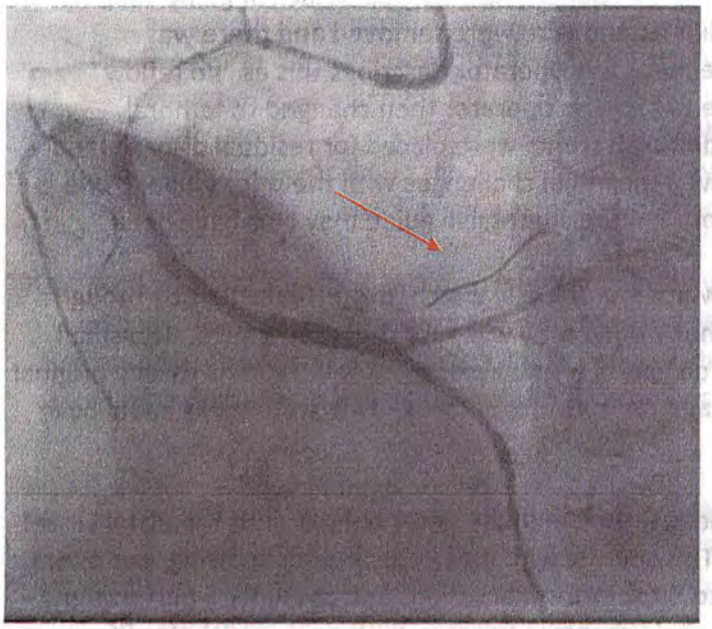
Pre PCI:



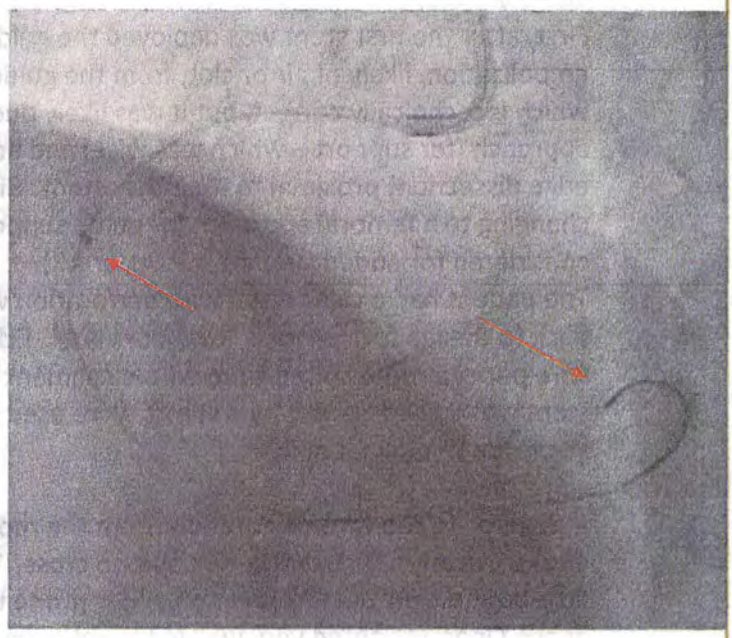
Post PCI



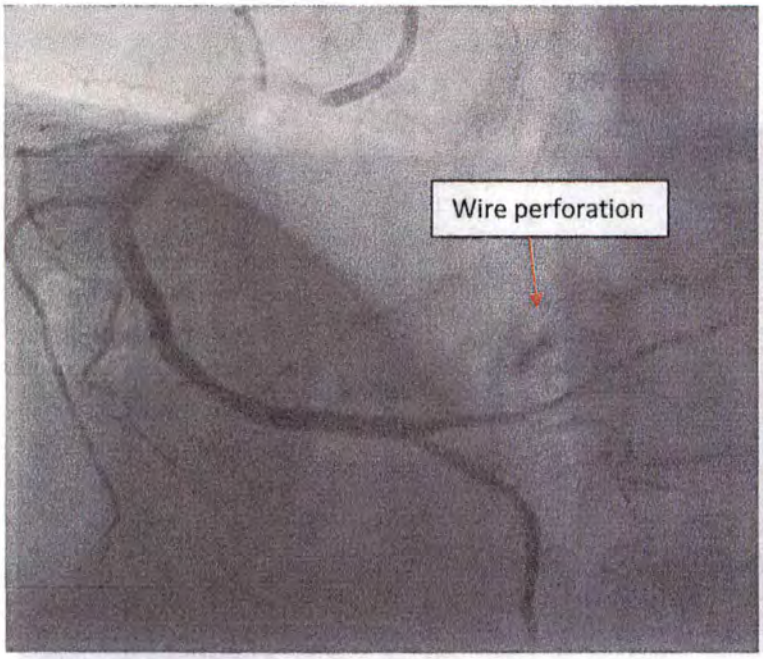
Intra-procedural wire positions

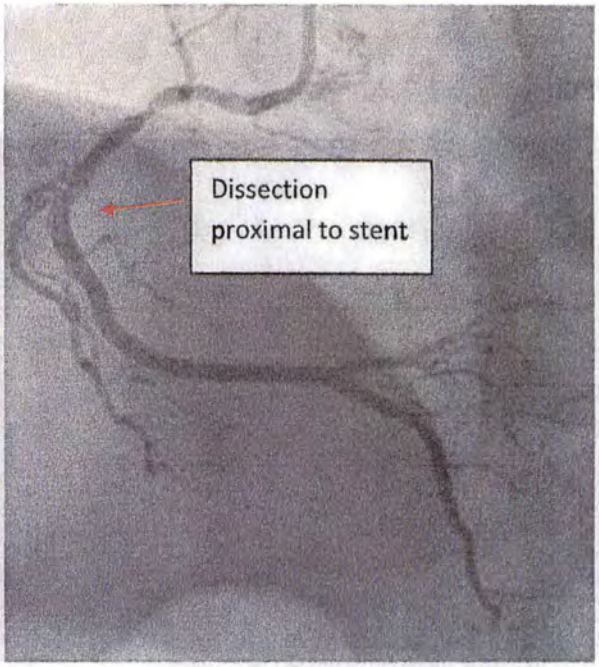


Guideliner and distal wire



Distal wire perforation, dissection proximal to stented segment after wire removal . No image with guideliner pulled back and wire still in place.





Identifier: **EXA313**

Clinical history:
A 75 year old man with a history of coronary artery disease with prior stenting, peripheral vascular disease chronic obstructive pulmonary disease, hypertension and elevated cholesterol was referred for cardiac catheterizations for chest pain and dyspnea.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
3 = Distal RCA	90	90	Yes
6 = 1 st Right posterior lateral branch	90	90	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
3 = Distal RCA	Appropriate	Appropriate	Appropriate
6 = 1 st Right posterior lateral branch	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None None
Additional Notes: Yes
Acute mental status changes were likely the result of medications. Concern appropriately raised for acute CNS event with appropriate work up ordered. Ultimately resolved without sequelae or need for intervention.

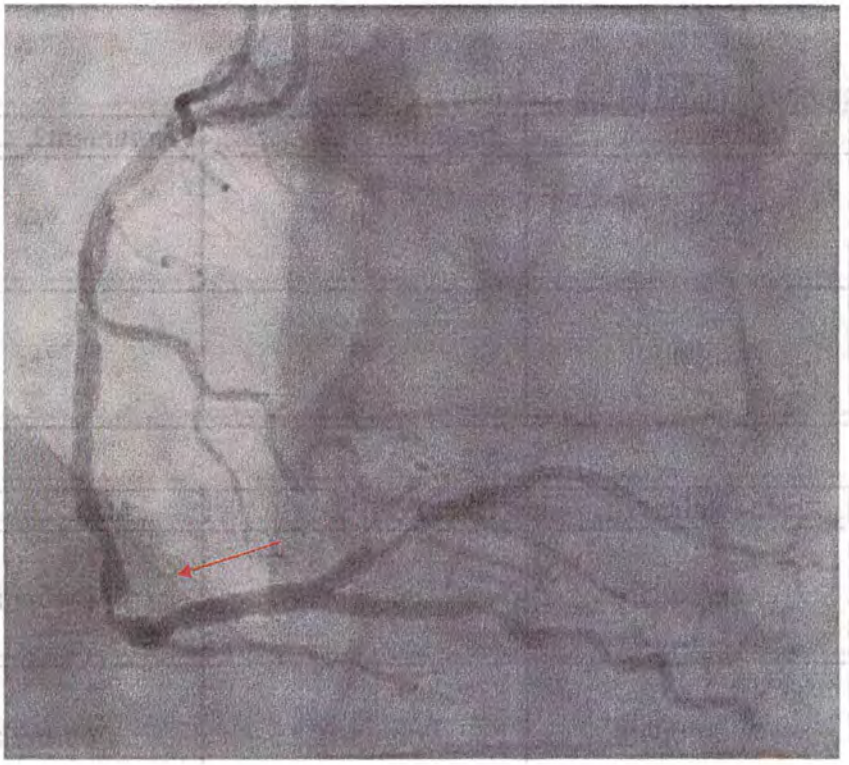
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Unstable Angina
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:

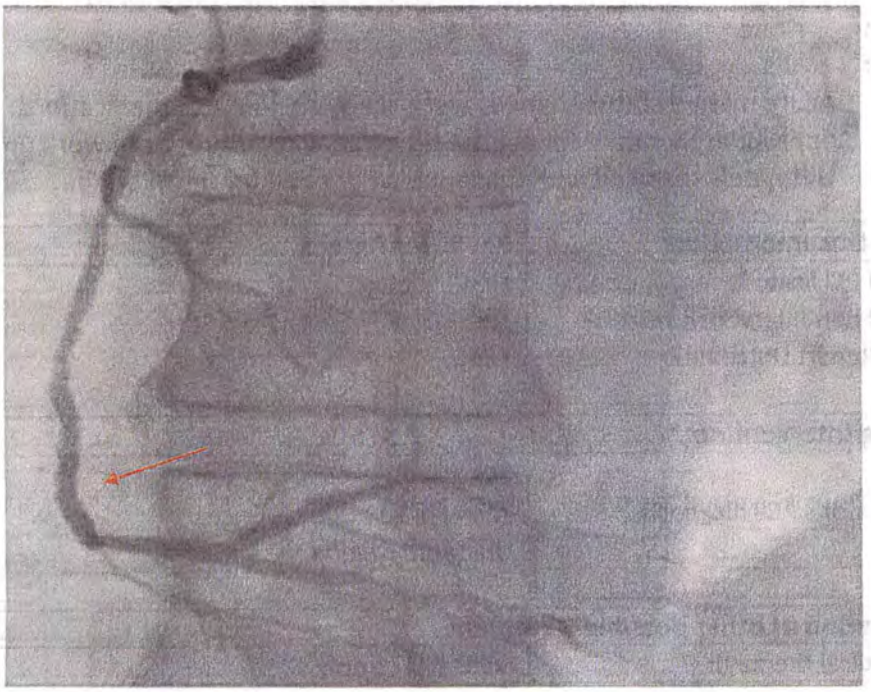
Appropriate PCI for clinical unstable angina presentation with syncope.

Techcnical comment: There appears to be an area of narrowing distal to the stent. This may be due to spasm, or incomoplete coverage of the lesion, which did appear to extend around the bend.

Pre PCI:



Post PCI:



Identifier: AQA750

Clinical history:
A 53 year old woman with past medical history notable for coronary artery disease, chronic congestive heart disease. In the emergency room EKG demonstrated ST depression in the inferior lateral leads. The patient was started on acute coronary syndrome protocol and then taken to the catheterization laboratory

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
18 = Proximal Left circumflex artery	80-90	90	Yes

PCI Appropriateness

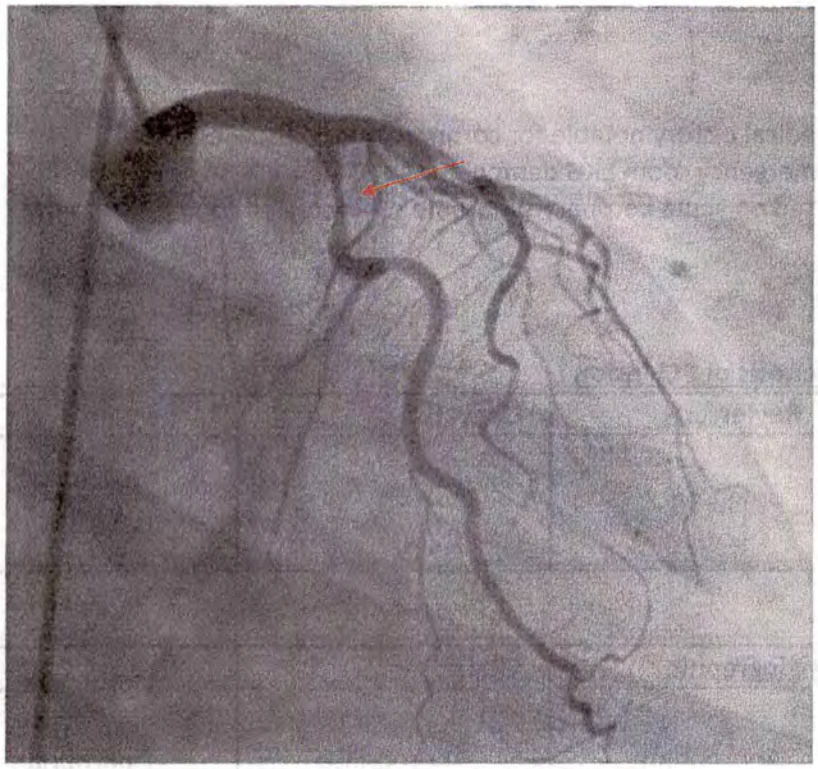
Location	Angiographic	Clinical	AUC
18 = Proximal Left circumflex artery	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

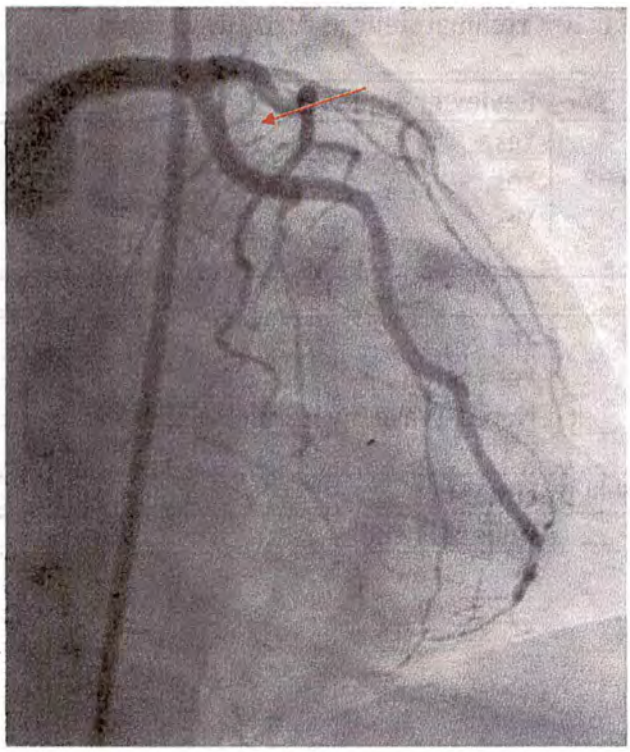
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Non-Q-Wave myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:
Beautiful procedure. Excellent result.

Pre PCI:



Post PCI:



Identifier: **ALM800**

Clinical history:
A 47 year old man with a history notable for Lyme disease who was admitted through the emergency room after cardiac arrest. Reported loss of conscious after biking, CPR was initiated by bystanders. EMS arrived rhythm noted to ventricular fibrillation requiring cardioversion back to normal sinus.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
12 = Proximal left anterior descending	80	80	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
12 = Proximal left anterior descending	Appropriate	Appropriate	Appropriate

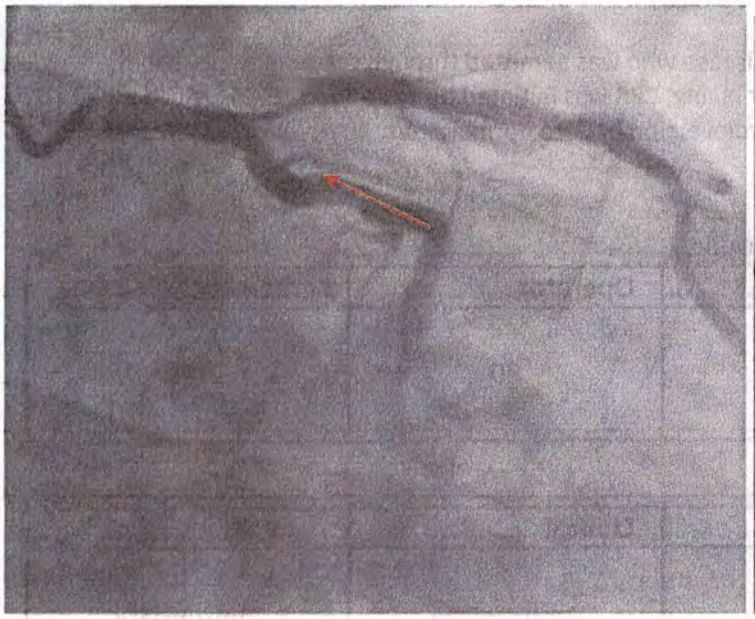
PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Non-Q-Wave myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Yes

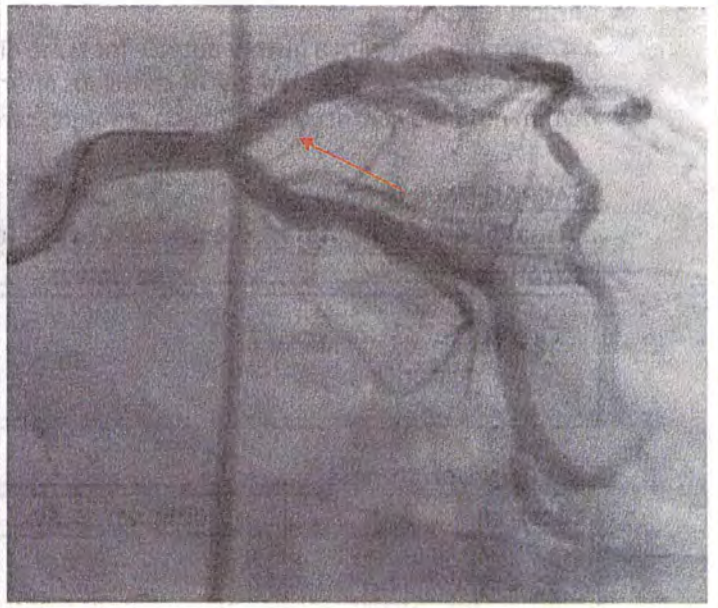
Reviewers Comments:
VF presentation always clouds these types of cases but no question this prox LAD widow maker could easily have been the problem even without preceding hx of UA (VF arrest occurred while pt was on bike. He is an avid rider with no prior symptoms noted)

Technical comment:
LAD stent even at 3.5 is likely undersized, but the enemy of good enough sometimes is better. IVUS can help clarify, though, if it is indeed good enough (i.e. opposed). Appropriate use of safety wire in Circ noted. Wire position in LAD was in small branch and increases risk of complications (perforation/dissection) and unable to see distal LCX wire in images provided, to make sure similar issue does not occur. Would encourage Operator to frequently monitor wire position throughout case to avoid issues. Solid final result.

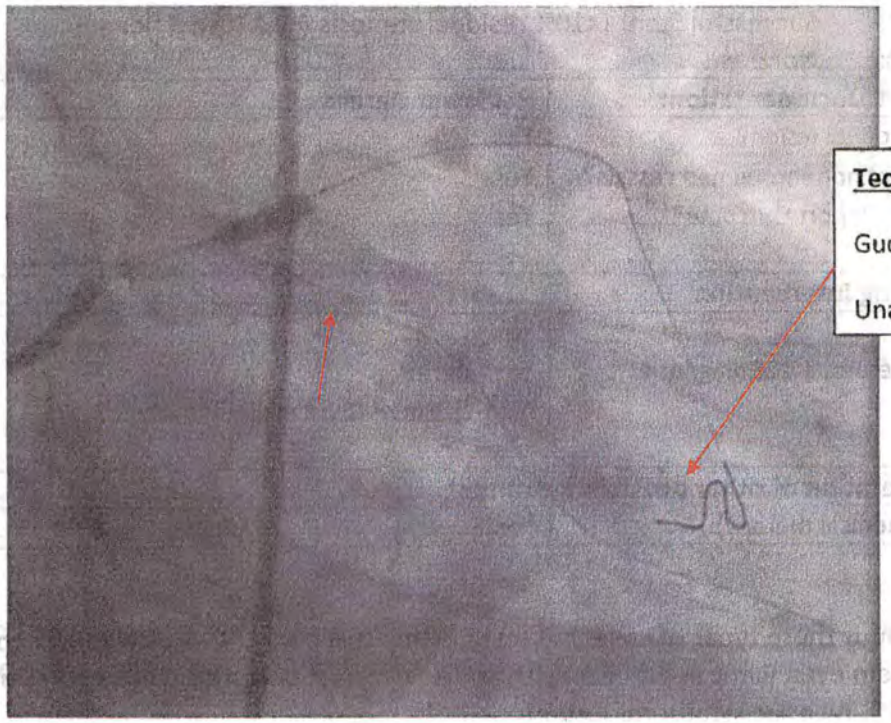
Pre PCI:



Post PCI



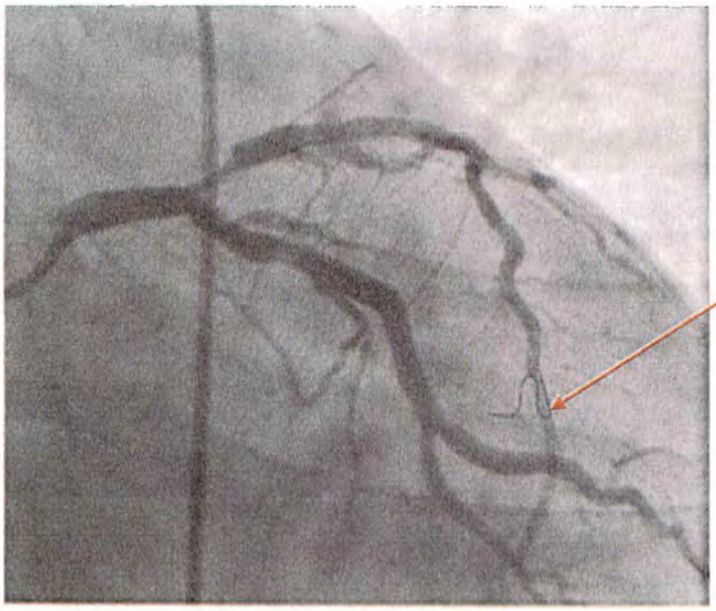
Safety wire in LCX given proximal LAD disease.



Technical Comment

Gudiewire in small branch in Lad

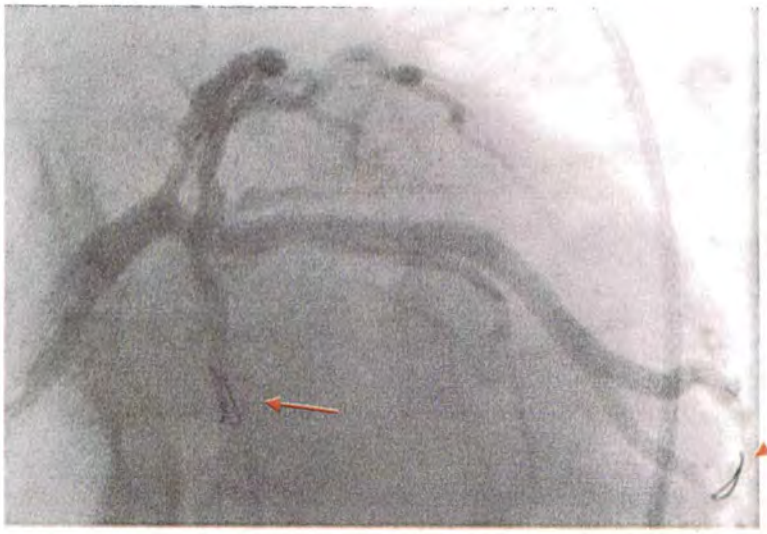
Unable to see distal tip of LCX safety wire.



Technical Comment

Gudiewire in small branch in Lad

Unable to see distal tip of LCX safety wire.



Technical Comment

Both wires in small branches and wire doubled back

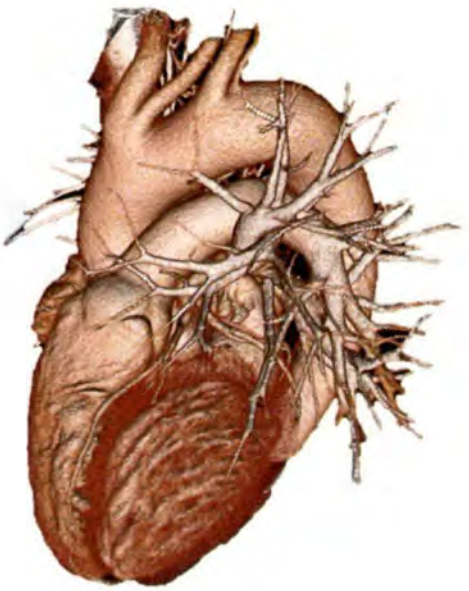
Increasing the risk of dissection or wire perforation.

Shore Medical Center

A Report From:

MACPAQ

*The **M**ARYLAND **A**CADEMIC **C**ONSORTIUM FOR **P**ERCUTANEOUS CORONARY INTERVENTION **A**PPROPRIATENESS AND **Q**UALITY*



Percutaneous Coronary Intervention Quality Case Review
Time Period: January to June, 2021

I. Introduction:

This report summarizes the results of an external peer-review by the Maryland Academic Consortium for Percutaneous coronary Intervention Appropriateness and Quality (MACPAQ), for review of percutaneous coronary intervention as requested by **Shore Medical Center at Easton** meeting the Maryland COMAR 10.17.24. MACPAQ is a MHCC-approved Peer review system. **This report encompasses cases performed from January to June, 2021.**

All invasive angiograms, percutaneous coronary intervention and relevant clinical data were evaluated and assessed by an experienced board certified interventional cardiologist at the respective academic institutions, not affiliated with Shore Medical Center.

II. Methodology:

Percutaneous coronary interventional procedures (PCI) were selected for review in a random fashion in accordance with COMAR regulations. Briefly, a list of all PCI's (excluding primary PCI procedures for acute ST elevation myocardial infarctions) were forwarded to MACPAQ for random case selection. Five percent of these cases that were performed at Shore Medical Center were randomly selected by MACPAQ (as per COMAR 10.17.24) for external review that included at least 6 cases per interventional physician (for the year) or all cases if the interventional cardiologist performed fewer than 6 cases per year. Shore Medical Center then provided the information on the randomly selected cases to MACPAQ.

The de-identified (i.e. "blinded") blinded clinical data and invasive angiograms were processed (to ensure de-identification of patient, hospital, and physician information) and managed at the MACPAQ Core Center. The cases were assigned to at least one MACPAQ Reviewer (interventional cardiologist) not affiliated with Shore Medical Center or its health system. The invasive coronary angiograms (ICA) and clinical data were then transmitted to the blinded reviewers.

Appropriateness was evaluated by THREE separate criteria:

1) **Angiographic criteria = "Angiographic Appropriateness"**
   -defined by the Reviewer's assessment as to whether the lesion was severe enough to warrant intervention based on the cine angiogram alone (i.e. lesion greater than or equal to 70% diameter stenosis by visual assessment);

2) **Clinical standard of care = "Clinical Appropriateness"**
   - defined by the Reviewers' clinical judgment, based on the combined clinical scenario and angiogram;

3) **ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT Appropriate Use Criteria for Coronary Revascularization = "AUC Appropriateness"**
   - defined by the ACC/SCAI/AHA Appropriate Use Criteria (2016/2017)

Several additional variables reported by the reviewer include: thoroughness and accuracy of the report and clinical documentation.

Procedures that were assessed to be *'Rarely Appropriate'* by a Reviewer were then assessed by a second Reviewer. If the two Reviewers' assessments were not concordant, then the case was additionally reviewed by a third Reviewer and adjudicated by agreement of 2 or more of the group. Other significant findings may have also triggered additional review. Reviewers may have also requested an additional Reviewer for specific cases. The consensus data was included in this report. When applicable, multiple Reviewer comments were included also in the report. It was determined by the group that through this mechanism, diligent review of both the invasive angiogram and clinical data a comprehensive review was accomplished.

III. Results

A. Baseline Information

A list of **89 cases** were forwarded to MACPAQ for random selection, from **3 separate Operators.** A total of 11 patient cases (12%) were reviewed, meeting the COMAR required minimum 5% of the coronary interventions for External Review for this 6 month period.

Shore Medical Center Operator (MACPAQ Assigned Number)	Number of PCI Cases Reviewed
112	5
113	3
133	3
Total	**11**

After completion of initial MACPAQ Core Center processing and review, 11 cases were assessed by at least one of seven MACPAQ independent interventional cardiologists. Physician Peer Reviewers assessed the angiograms and relevant clinical case material in a blinded fashion.

Of 11 patients cases reviewed, there were a total of 15 separate lesions or vessels intervened upon, including 2 case with 2 PCI lesions/vessels and one case with 3 lesions.

1. Case Mix

Summary of selected pre-procedural characteristics are listed below.

a. Clinical Presentation

Results - Baseline Information - Case Mix - Clinical Presentation

	%	n
Stable Angina	18%	2
ACS	82%	9
Unstable Angina	33%	3
NSTEMI	44%	4
STEMI	22%	2

B. PCI Success

Of lesion PCI's submitted for review, 87% of interventions were assessed to be 'Successful' by COMAR definitions. To summarize the criteria:

a) For stent procedures, "Success" was defined as <10% residual stenosis AND TIMI 3 flow. "Partially Successful" was defined as 10 to less than 50% residual stenosis and TIMI 3 flow. "Unsuccessful" was defined as >10% residual stenosis within a stent having less than TIMI 3 flow; >50% stenosis; or less than TIMI 2 flow.
b) For plain balloon angioplasty (POBA), "Success" was defined as <50% residual stenosis with TIMI 3 flow. "Unsuccessful POBA" was defined as >50% residual stenosis OR less than TIMI 2 flow.

Summary of Procedural Outcomes per Lesion

	n	%
Successful stent	13	87%
Partially successful stent	1	7%
Successful POBA	0	0%
Unsuccessful Stent	0	0%
Unsuccessful POBA	1	7%

C. Complications

There were no cases with complications (0%) observed in the cases reviewed

TABLE 1

PCI LESION SEVERITY (Reviewers') and Post-procedure Results

Patient ID	Coronary Segment	Reviewer Visual Estimate %	Post-PCI Residual Stenosis	Post PCI TIMI Grade Flow	Procedure Successful?
ADT722	3 = Distal RCA	90	< 10%	3	Successful Stent
AME139	14 = Distal left anterior descending	80-90	< 10%	3	Successful Stent
APF293	21 = 2 nd Obtuse marginal	70*	< 10%	3	Successful Stent
AQC719	15 = 1 st Diagonal branch	80	< 10%	3	Successful Stent
DRT795	3 = Distal RCA	100	< 10%	3	Successful Stent
EME553	11 = Left main	90	< 10%	3	Successful Stent
ESQ447	2 = Mid RCA	90	< 10%	3	Successful Stent
FGC072	12 = Proximal left anterior descending	90	10-50%	3	Partially Successful Stent
FYG874	13 = Mid left anterior descending	75	< 10%	3	Successful Stent
NQT448	13 = Mid left anterior descending	90	< 10%	3	Successful Stent
ZTN007	21 = 2 nd Obtuse marginal	90	< 10%	3	Successful Stent
Second Lesions					
ADT722	13 = Mid Left anterior descending artery	90	< 10%	3	Successful Stent
AME139	20 = 1 st Obtuse marginal	80	>50%	3	**Unsuccessful POBA**
FGC072	13 = Mid Left anterior descending artery	50*	< 10%	3	Successful Stent
Third Lesions					
FGC072	20 = 1st Obtuse marginal	80-90	10-50%	3	Successful Stent

**** DFR/IFR was performed for stenosis severity and met obstructive criteria***

D. Other Important Assessments

Below are the results of other important assessments that the Peer Reviewers made as part of the case review. These include required questions as stated in the most current COMAR 10.27.17 (11/2015).

1. **Agreement with Catheterization Report Stenosis Severity** **100% (15 of 15 lesions)**
   This assessment compares the Operators' documented stenosis severity (**by angiography alone**) of PCI lesion/s with the Peer Reviewer assessment.

2. **Agreement with procedural outcome documented** **93% (14 of 15 lesions)**

   This compares the Operators' documented outcome with the Peer Reviewer assessment.

3. **Agreement with Operator Diagnosis of ACS versus non-ACS** **100% (11 of 11 cases)**

Of cases that were performed for Acute Coronary Syndrome (ACS) indications, the Reviewers agreed with the diagnosis of an ACS in all cases.

4. **Agreement with Operator Diagnosis of ACS type (if applicable) 100% (9 of 9 ACS cases)**

ACS Type	Number of cases	Agreement (%)
Non-Q wave MI	4	100%
ST-Elevation MI	2	100%
Unstable Angina	3	100%

5. **Agreement with Catheterization Report Stenosis Severity of Non-intervened lesions/vessels**

   This assessment compares the Operators' documented stenosis severity (**by angiography alone**) of PCI lesion/s with the Peer Reviewer assessment. "Not applicable" may be in cases that complete diagnostic images were not available or no lesions were present.

Assessment	N	Percent
Agree	11	100%
Disagree	0	0
Not Applicable	0	0

6. Alternative Therapy to PCI could be considered (Reviewer Opinion):

Not Applicable	91%	(9 of 11)
Applicable	9%	(2 of 11)
Consideration of alternative WAS documented	0%	(0 of 11)
Consideration of alternative NOT documented	9%	(2 of 11)

Reviewers assessed the patient record to determine whether treatment other than PCI, such as cardiac surgery or medical therapy, was documented to have been considered in cases where it would have been appropriate to consider alternative treatment, based on current Guidelines (i.e. coronary artery bypass surgery or medical therapy) or clinical standards. This question was **not applicable (based on the Reviewer's opinion) in 9 of 11 cases** sent for review. In other words, the Reviewers felt that PCI was the most appropriate revascularization strategy in these cases, and that alternatives (CABG or medical therapy) were not reasonable to consider. In the remaining cases, the Reviewers assessed the documentation in the patient record to determine whether treatment other than PCI, such as cardiac surgery or medical therapy, was considered in cases where it would have been appropriate to consider alternative treatment. **This question applied in 2 cases , of which neither had** documentation describing the consideration of bypass surgery or medical therapy as a treatment alternative prior to PCI. In one of the cases, consideration of medical therapy or CABG was suggested by 2 different reviewers., with PCI being also reasonable.

E. Procedure Appropriateness Results:

The summary of the appropriateness ratings is listed below and the appropriateness ratings were assessed per lesion/vessel. For example, if a patient had 2 vessels intervened upon, there were 2 separate assessments. The summary of the appropriateness ratings (per lesion/vessel) are listed below.

See **TABLE II and Table III** for individual Operator Results.

Summary of Appropriateness Ratings (per lesion).

1) **Angiographic Appropriateness (lesion severity and suitability for PCI) -Per lesion**
Based on the percentage of stenosis, given accepted guidelines that stenosis of 70 percent or greater is appropriate for treatment, stenosis between 50 to 69 percent may be appropriate for treatment, and stenosis less than 50 percent is rarely appropriate for treatment

%	n	
93%	14	interventions were judged to be appropriate+
7%	1	intervention were judged to be of uncertain/ may be appropriate
0%	0	interventions were judged to rarely appropriate

2) **Clinical Appropriateness (based on standard clinical practice)**
*See individual case descriptions and assessments in **Appendix B** for cases determined to be "uncertain/may be appropriate" and "rarely appropriate)*

%	n	
80%	12	interventions were judged to be appropriate
20%	3	intervention were judged to be uncertain/ may be appropriate
0%	0	intervention were judged to be rarely appropriate

3. **ACC/AHA Appropriate Use Criteria for PCI (AUC Criteria)**
*See individual case descriptions and assessments in **Appendix B** for cases determined to be "uncertain/may be appropriate" and "rarely appropriate)*

%	n	
87%	13	interventions were judged to be appropriate
13%	2	Interventions were judged to be uncertain/ may be appropriate
0%	0	intervention was judged to be rarely appropriate
0%	0	intervention not addressed in current AUC guidelines

TABLE II

Appropriateness Ratings by Individual Operator

Below is a summary of the individual Operator Appropriateness performance.

Patient cases: 11 Total lesions: 15

			ANGIOGRAPHIC APPROPRIATENESS			CLINICAL APPROPRIATENESS			ACC/AHA APPROPRIATENESS (AUC- Guideline)			
Physician Number	Total Patient Cases Reviewed	Total Lesions Reviewed	Appropriate	May be Appropriate	Rarely Appropriate	Appropriate	May be Appropriate	Rarely Appropriate*	Appropriate	May be Appropriate	Rarely Appropriate*	Not addressed in current AUC guidelines
112	5	6	6	0	0	6	0	0	6	0	0	0
113	3	5	4	1	0	3	2	0	3	2	0	0
133	3	4	4	0	0	3	1	0	4	0	0	0
Total		**15**	**14**	**1**	**0**	**12**	**3**	**0**	**13**	**2**	**0**	**0**
Percent		**100%**	**93%**	**7%**	**0%**	**80%**	**20%**	**0%**	**87%**	**13%**	**0%**	**0%**

* *The original AUC term "inappropriate" had been used in the 2009 and 2011 PCI AHA/ACC Clinical AUC Guidelines. AUC terminology evolved. The term "inappropriate" has now been replaced by* ***"rarely appropriate"*** *to acknowledge individual circumstances where the procedure could be considered reasonable. Assessments were made on the case data available to the Reviewers.*

TABLE III

Appropriateness Ratings by Individual Operator: Percent of Cases

Below is a summary of the individual Operator Appropriateness performance

			ANGIOGRAPHIC APPROPRIATENESS			CLINICAL APPROPRIATENESS			ACC/AHA APPROPRIATENESS (AUC- Guideline)			
Physician Number	Total Patient Cases Reviewed	Total Lesions Reviewed	Appropriate	May be Appropriate	Rarely Appropriate	Appropriate	May be Appropriate	Rarely Appropriate*	Appropriate	May be Appropriate	Rarely Appropriate*	Not addressed in current AUC guidelines
112	3	4	100%	0%	0%	100%	0%	0%	100%	0%	0%	0%
113	3	4	80%	20%	0%	60%	40%	0%	60%	40%	0%	0%
133	3	4	100%	0%	0%	75%	25%	0%	100%	0%	0%	0%
Total		**15**	**14**	**1**	**0**	**12**	**3**	**0**	**13**	**2**	**0**	**0**
Percent		**100%**	**93%**	**7%**	**0%**	**80%**	**20%**	**0%**	**87%**	**13%**	**0%**	**0%**

* *The original AUC term "inappropriate" had been used in the 2009 and 2011 PCI AHA/ACC Clinical AUC Guidelines. AUC terminology evolved. The term "inappropriate" has now been replaced by* ***"rarely appropriate"*** *to acknowledge individual circumstances where the procedure could be considered reasonable. Assessments were made on the case data available to the Reviewers.*

EXECUTIVE SUMMARY COMMENTS /RECOMMENDATIONS

The Reviewers felt that the overall procedural performance of the physicians reviewed and the hospital was very good There were 11 patient cases reviewed which included a total of 15 separate lesions / PCI's. Of the 15 lesions treated, 87% were successful. There were no complications observed in the cases reviewed.

On a per-lesion basis (n=15), the assessment of lesion severity (i.e. percent of blockage) of the PCI lesions was accurate, with 100% of the readings by the Operators in agreement with the Reviewers' (Appendix A). In regards to lesion assessment of non-PCI vessels, the Reviewers agreed with the Operator in 100% of cases.

Based on Angiographic criteria, 93% were considered to be "appropriate", and 7% (n=1) was assessed as "may be appropriate".

Based on clinical criteria, 80% (12 of 15 lesions) of lesions were considered to be "appropriate, and 20% (n=3) were "may be appropriate". There were no PCI lesions considered "rarely appropriate

Based on Guideline / Appropriate Use Criteria (AUC), 87% of lesions were considered "appropriate", 13% (n=2) "may be appropriate". There were no PCI lesions considered "rarely appropriate

Documentation and diagnosis of the presence of an 'Acute Coronary Syndrome" was 100% (9 of 9 cases) based on the provided documentation. Documentation of procedural outcomes were 93% accurate. Documentation of treatment alternatives to PCI, such as CABG or medical therapy, was not assessed to be required 9 of 11 cases. In the cases where the reviewer thought it would be reasonable to consider alternative therapy such as medical therapy or CABG (n=2), there was documentation that such a consideration was not made in either case (0%). Invasive lesion assessment with DFR was used in 2 cases.

Of note, there were 2 cases that were primary PCI interventions for ST elevateion myocardial infarctions (ST elvation on ECG and occluded coronary artery, with primary PCI). These cases were reviewed, but per COMAR regulations, generally should be replaced by non-primary PCI cases for purposes of appropriateness review.

The Reviewers assessed the the Operators to be technically very good. There werer no cases with complications .

Appendix A

Stenosis Severity of PCI lesions as assessed by the Reviewers and Correlation with Documented Catheterization Report.

Patient ID	***Segment #***	***Reviewer Visual Estimate %***	***Operator Cath Report Stenosis Severity %***	***Agree with the Catheterization Report Stenosis (Yes or No)***	***Agree with the Catheterization report stenosis of the vessels not intervened upon?***
ADT722	3 = Distal RCA	90	90	Yes	Yes
AME139	14 = Distal left anterior descending	80-90	85	Yes	Yes
APF293	21 = 2 nd Obtuse marginal	70*	70	Yes	Yes
AQC719	15 = 1 st Diagonal branch	80	80	Yes	Yes
DRT795	3 = Distal RCA	100	100	Yes	Yes
EME553	11 = Left main	90	90	Yes	Yes
ESQ447	2 = Mid RCA	90	90	Yes	Yes
FGC072	12 = Proximal left anterior descending	90	85	Yes	Yes
FYG874	13 = Mid left anterior descending	75	75	Yes	Yes
NQT448	13 = Mid left anterior descending	90	90	Yes	Yes
ZTN007	21 = 2 nd Obtuse marginal	90	90	Yes	Yes
Second Lesions					
ADT722	13 = Mid Left anterior descending artery	90	90	Yes	Yes
AME139	20 = 1 st Obtuse marginal	80	80	Yes	Yes
FGC072	13 = Mid Left anterior descending artery	50*	50-60	Yes	Yes
Third Lesions					
FGC072	20 = 1st Obtuse marginal	80-90	85	Yes	Yes

**** DFR/IFR was performed for stenosis severity and met obstructive criteria***

Invasive Lesion Measurements

Patient ID	*Operator*	*Operator Visual Estimate %*	*Reviewer Visual Estimate %*	*IVUS or FFR*	*Result*
APF293	133	70	70	Yes - FFR	DFR = 0.85
FGC072	113	50-60	50	Yes - FFR	DFR = 0.76 of mid lesion post proximal LAD stent. More proximal disease may have contributed to result

Appendix B

Selected Individual Cases and Images

Identifier: AME139

Clinical history:
An 80-year-old woman with history of diabetes, history of hepatitis, coronary artery disease including prior stenting approximately 10 years ago, hypertension and elevated cholesterol who presented with progressive exertional dyspnea. A cardiac myocardial perfusion showed mild ischemia with an ejection fraction of 45%.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
14 = Distal left anterior descending	80-90	85	Yes
20 = 1 st Obtuse marginal	80	80	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
14 = Distal left anterior descending	Appropriate	Appropriate	Appropriate
20 = 1 st Obtuse marginal	Appropriate	Appropriate	Appropriate

PCI result:	Successful Stent (<10% residual stenosis AND TIMI 3 flow) Unsuccessful POBA (OM)	
Complications:	None	None

Catheterization Lab Report Documentation:	**Reviewer Agrees**
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	No
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	No
Reviewer agrees with the operator's ACS diagnosis	Not Applicable
Type of ACS:	Not Applicable
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	No

Reviewers Comments:

Reviewer 1: 80 year old female with known CAD and previous LAD stents x 3 over 10 years ago. She had mild ischemic cardiomyopathy now with progressive exertional dyspnea suggestive of angina. She is referred for left heart cath and also renal angiogram due to resistant hypertension (on 5-6 meds). She had a prior unremarkable nuclear test, but results and date of that test are not available. Her symptoms could have been exacerbated or completely due to her resistant hypertension. On angiography, the most severe lesion was the LAD, though the LCX was also tight but technically more difficult and higher risk given the ostial nature of the OM1 lesion and dominant LCX. The Operator attained a very nice result in the LAD. The OM was very tortuous and calcified, and not an easy lesion. I may have chosen to try to treat this medically at this time. Due to her symptoms and her reduction in ejection fraction, this would make the procedure AUC appropriate (i.e. higher risk stress even though no stress was done).

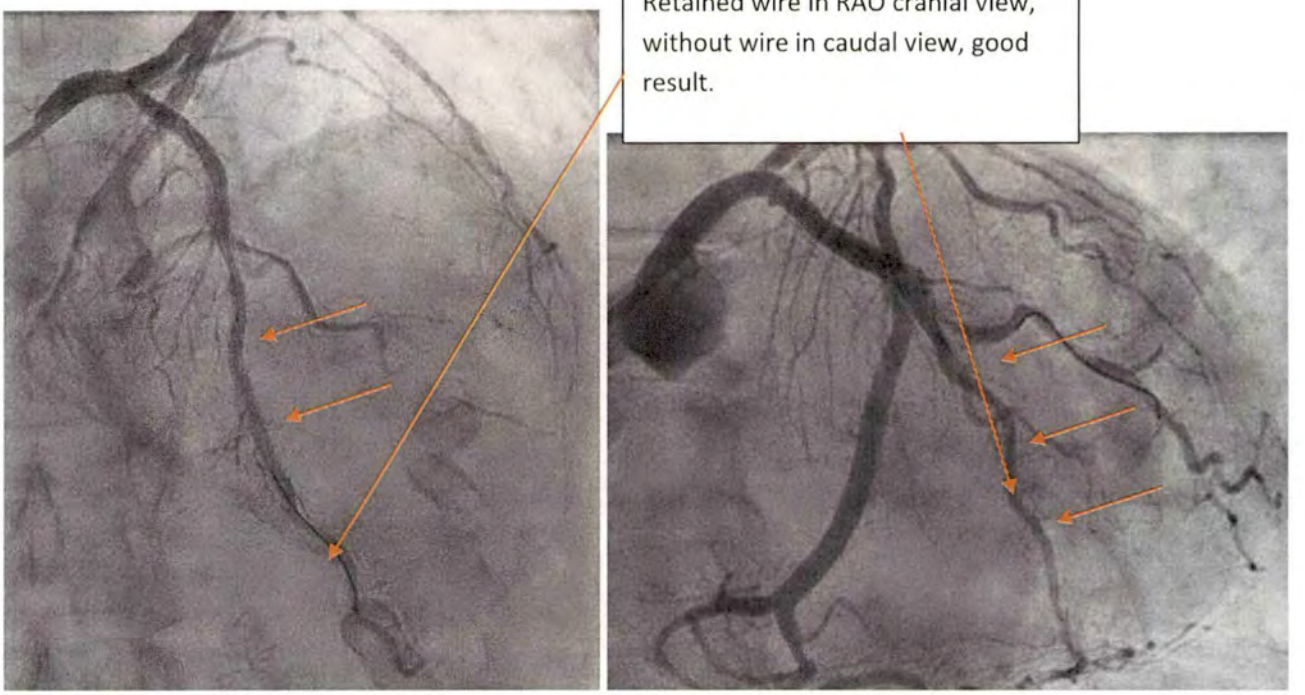
Reviewer 2: Diabetic with reportedly reduced LV function. Despite age and some comorbidities labs are normal. She is not anemic and has good kidneys. A surgical drum roll would have been appropriate. Targets are good

Technical comment:

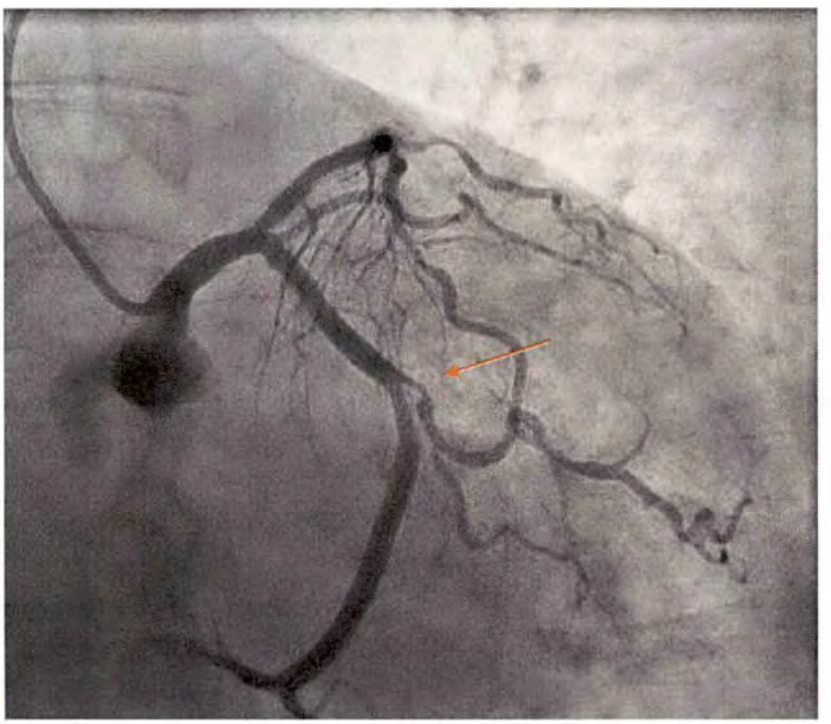
The Operator pre-dilated the difficult OM1 lesion with 2.0 balloon then tried to deliver a stent which would not cross - likely due to tortuosity, calcium and residual stenosis. There was still significant stenosis after balloon dilation. The lesion will likely require calcium modification or more aggressive pre-dilation/guide support/ wire support to deliver a stent.

Pre-LAD PCI:

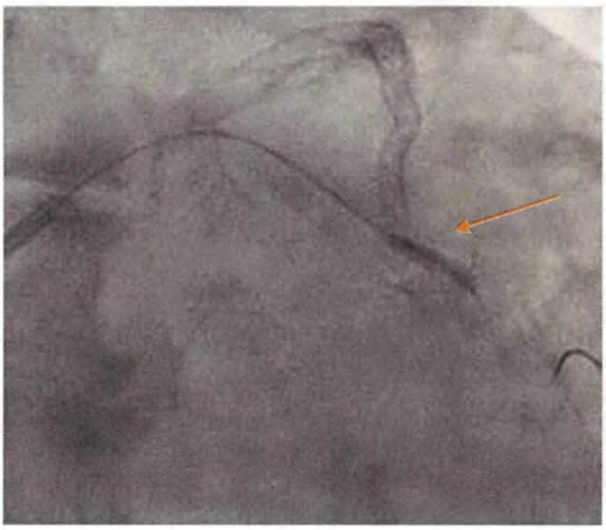
Post LAD PCI:



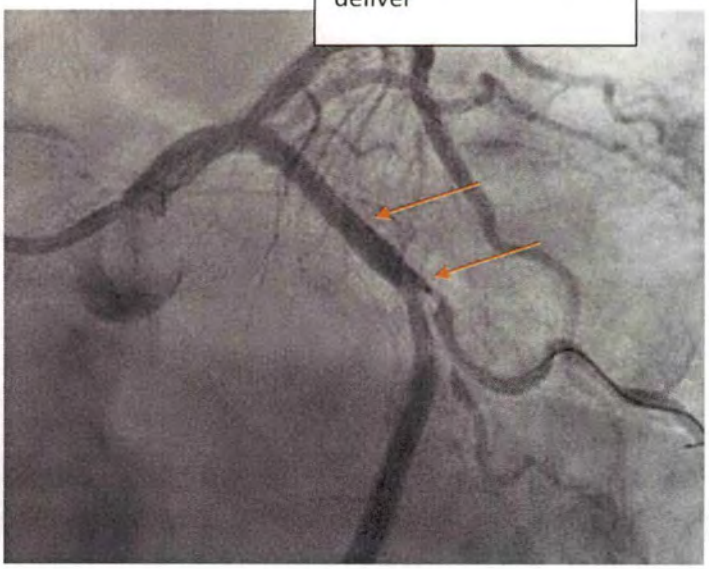
Pre LCx PCI:



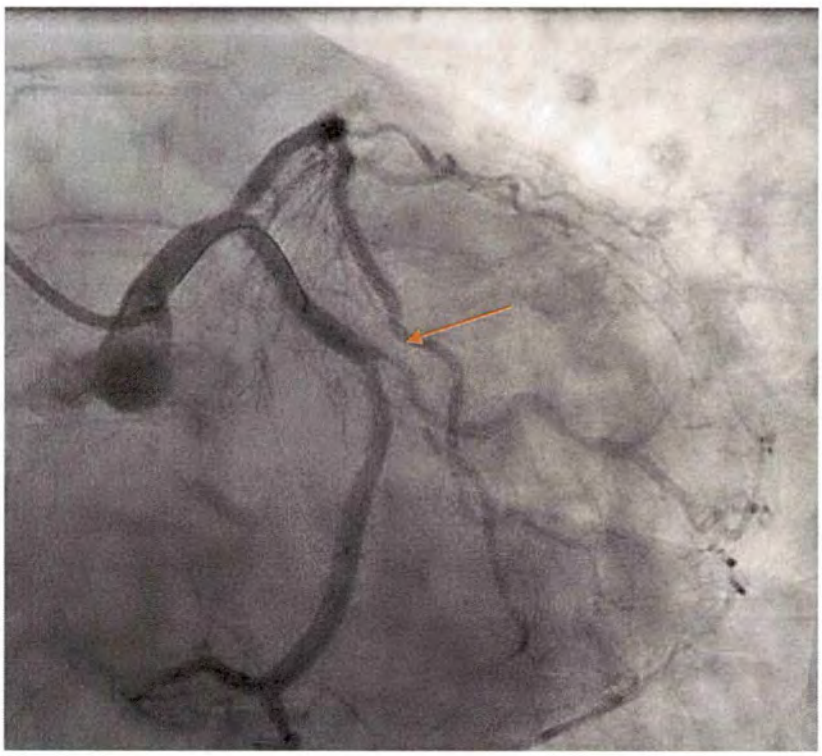
POBA, stent would not cross post POBA



Stent attempt, could not deliver



Post POBA PCI: >50% residual stenosis.



Identifier: **FGC072**

Clinical history: A 72-year woman with a history of hypertension, diabetes elevated cholesterol and known coronary artery disease with accelerating angina and abnormal stress nuclear scan showed ischemia in the anterior wall.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
12 = Proximal left anterior descending	90	85	Yes
13 = Mid Left anterior descending artery	50*	50-60	Yes
20 = 1st Obtuse marginal	80-90	85	Yes

**** DFR/IFR was performed for stenosis severity and met obstructive criteria (0.76 DFR)***

PCI Appropriateness

Location	Angiographic	Clinical	AUC
12 = Proximal left anterior descending	Appropriate	Appropriate	Appropriate
13 = Mid Left anterior descending artery	Maybe appropriate*	Maybe appropriate+	Maybe appropriate
20 = 1st Obtuse marginal	Appropriate	Maybe appropriate	Maybe appropriate

+ DFR used post proximal stent to assess mid lesion. DRF was obstructive, however Reviewer could not exclude a contribution by a residual more proximal lesion leading to positive DFR.

	Successful Stent		
PCI result:	Successful Stent		
	Partially Successful stent		
Complications:	None	None	None

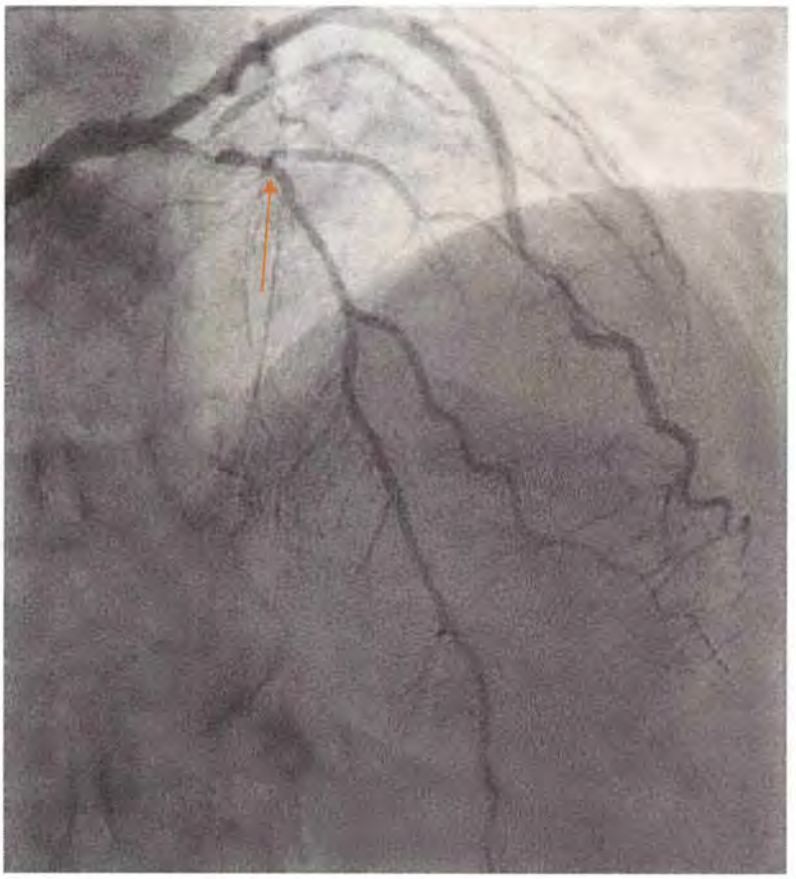
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	No

Reviewer agrees with the operator's ACS diagnosis	Not Applicable
Type of ACS:	Not Applicable
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	No

Reviewers Comments:

Good use of FFR post PCI for second mid LAD lesion. Proximal LAD stent doesn`t seem fully expanded or more likely there was geographic miss of the most proximal portion of the lesion or plaque shift proximal to the newly deployed stent. IVUS could have been helpful to define this with or without an additional angiographic view. This residual stenosis or plaque may have contributed to the positive DFR, so clinical appropriateness is still "may be appropriate", though using DFR was an excellent idea. Follow mid LAD2.5 mm stent overlap nicely post dilated with a 3.0 balloon to ensure stent overlap apposition.

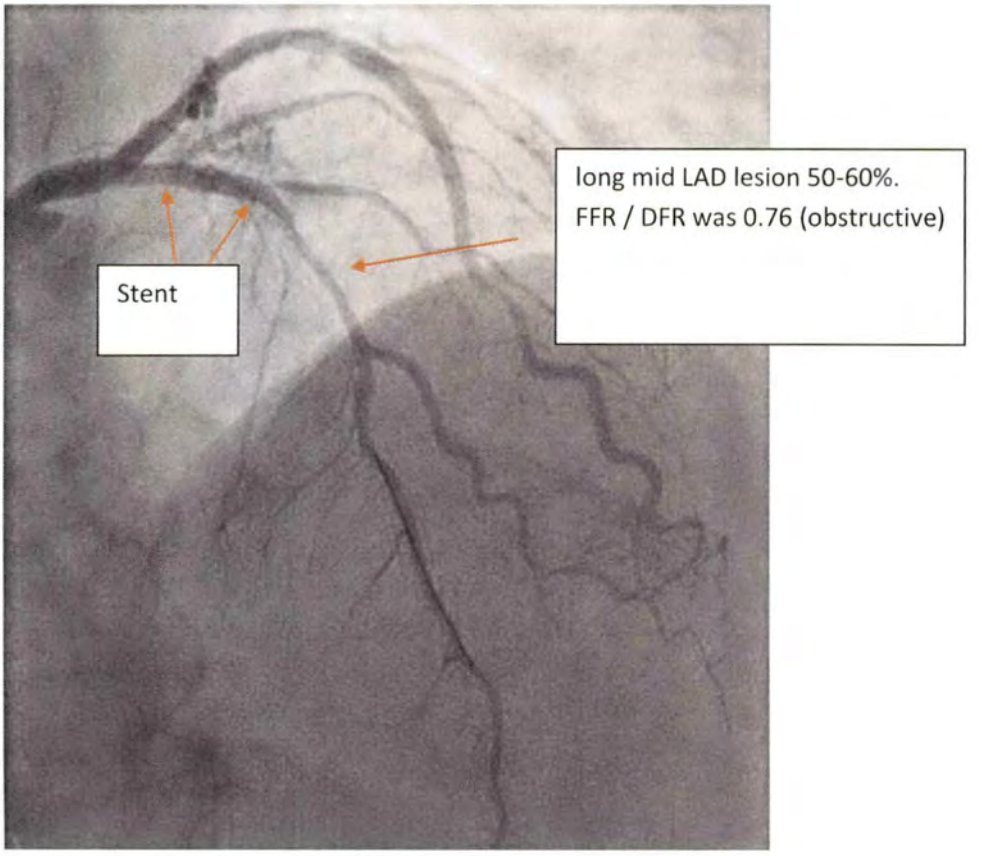
Pre PCI of proximal LAD

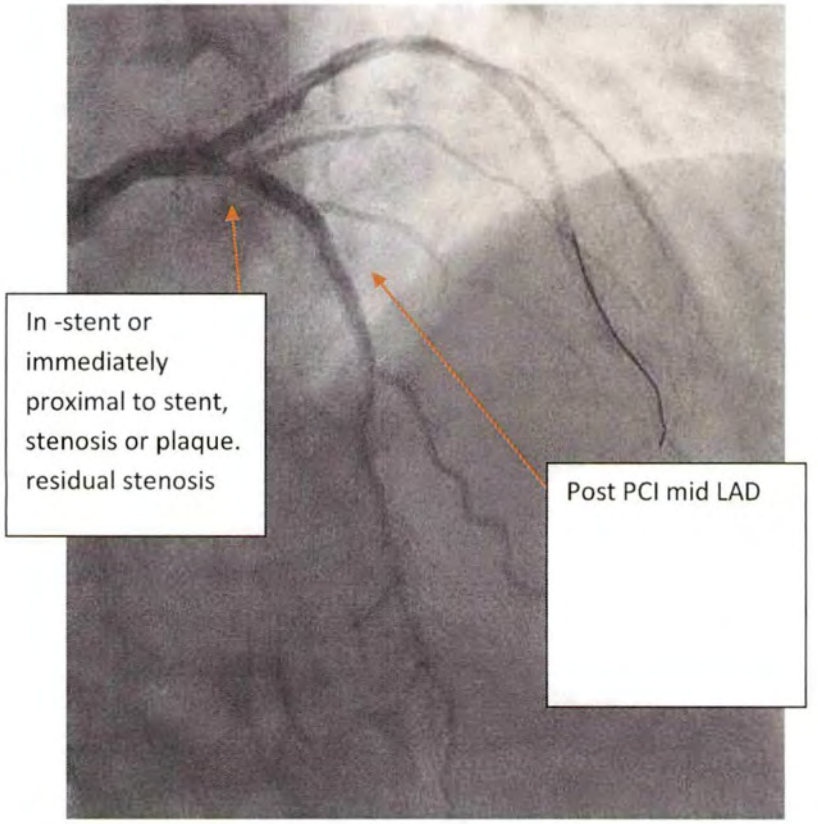


Pre-stent, balloon of diagonal

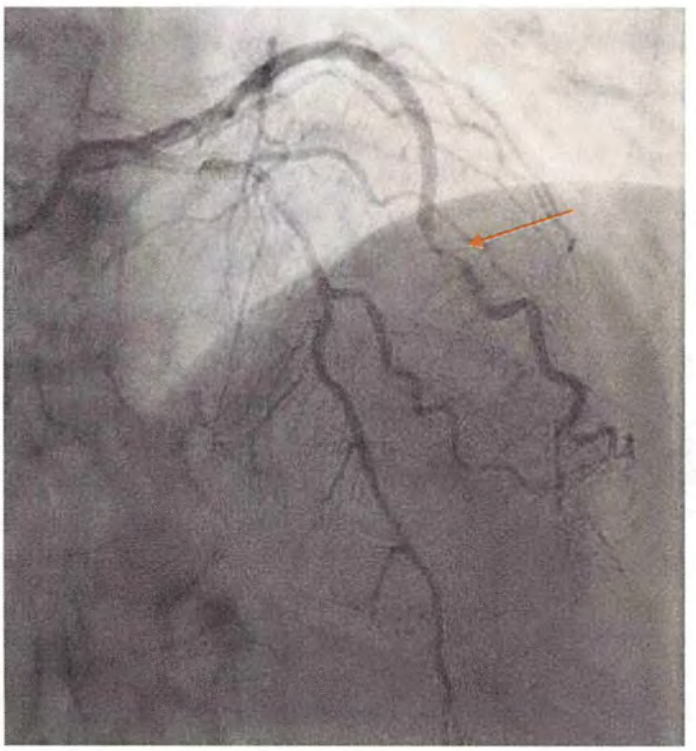
Stent deployment location of proximal LAD: partial geographic miss of more proximal disease

Post proximal LAD PCI, note mid LAD Pre- PCI mid LAD

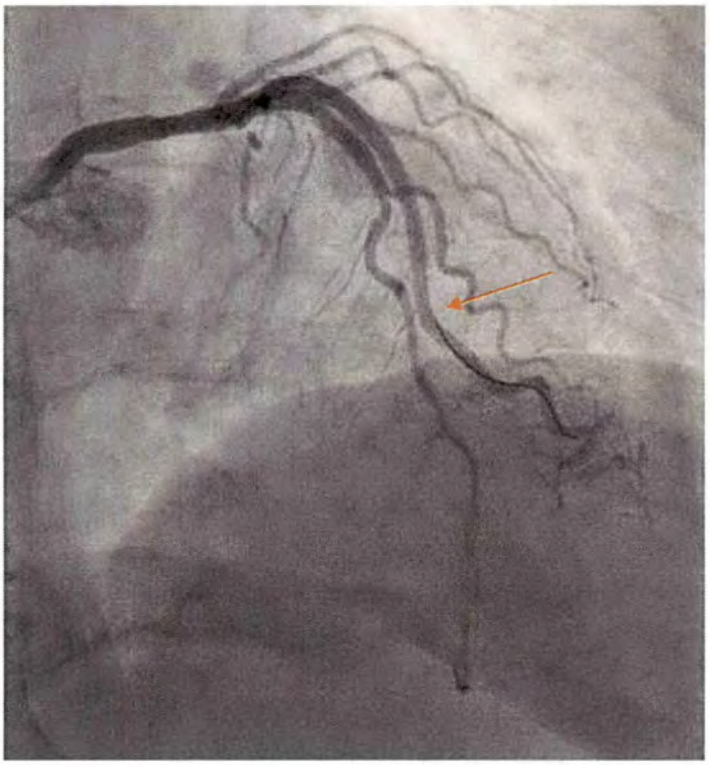



In -stent or immediately proximal to stent, stenosis or plaque. residual stenosis
Post PCI mid LAD

Pre PCI LCX:



Post PCI:



Identifier: DRT795

Clinical history: 61-year-old Caucasian male with multiple risk factors for coronary disease who presents the hospital with several days of recurrent indigestion. The patient developed significant substernal chest pain several hours prior to presenting to the emergency room. An EKG revealed ST elevation inferior STEMI. The patient was referred for emergent invasive coronary angiography.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
3 = Distal RCA	100	100	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
3 = Distal RCA	Appropriate	Appropriate	Appropriate

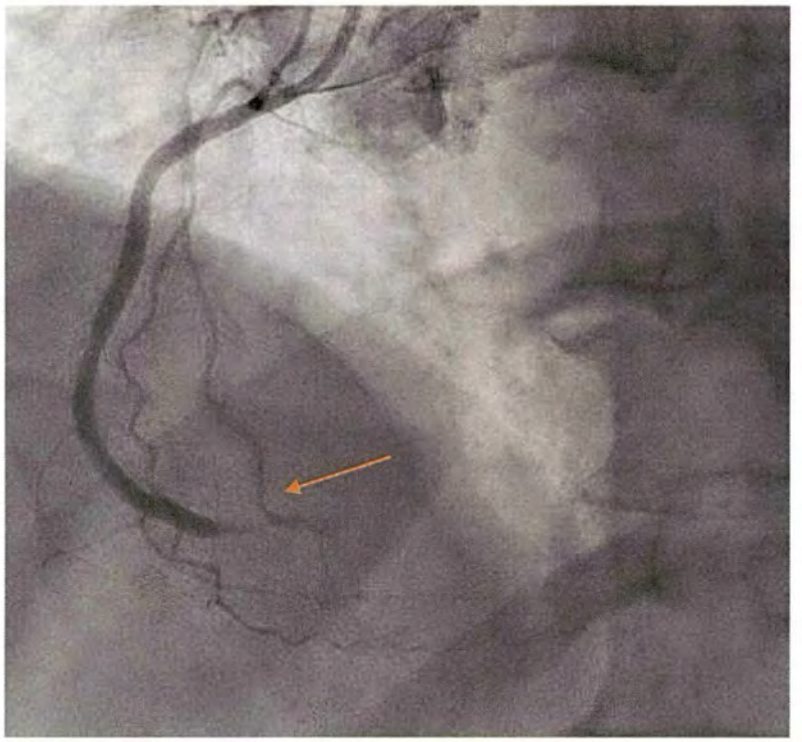
PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Not Applicable
Type of ACS:	ST-Elevation Myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

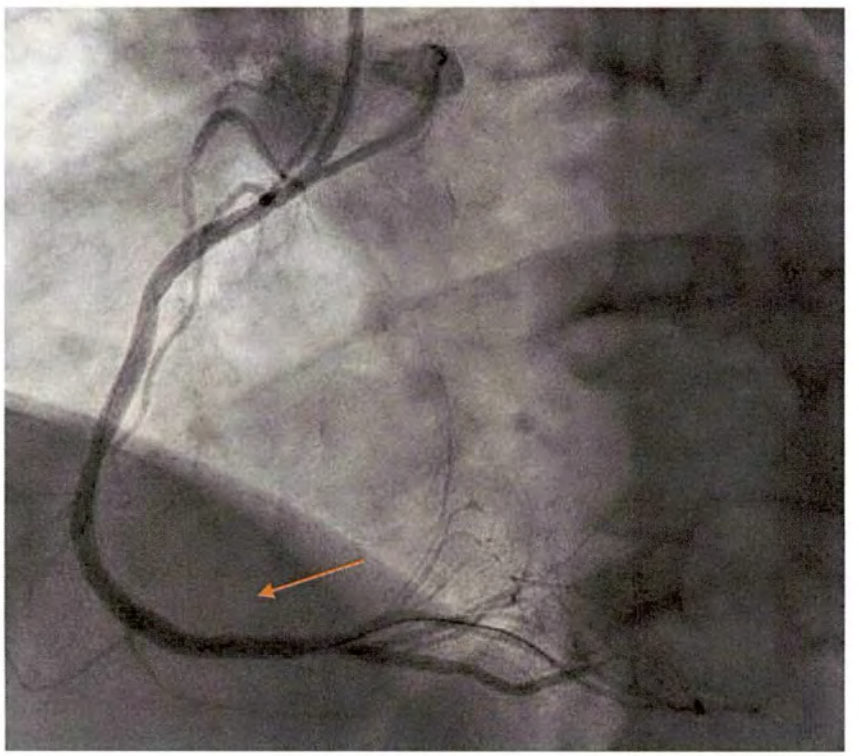
Reviewers Comments:

Appropriate PCI for inferior STEMI. Appropriate PCI for inferior STEMI.

Pre PCI:



Post PCI:



Identifier: EME553

Clinical history: A 52-year-old man with a history of hypertension, elevated cholesterol, diabetes, and coronary artery disease with previous coronary artery bypass x 2, previous PCIs. Now with ongoing severe angina, hypotensive, in cardiogenic shock and acute ST elevation in the infero-lateral leads presenting with chest pain. . He was referred for emergent LHC and PCI

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
11 = Left main	90	90	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
11 = Left main	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	ST-Elevation Myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:

Inferolateral ST elevation MI with hypotension. Appropriate PCI. The culprit was thrombus in the terminal LM and into a large non-grafted ramus intermedius and LCX, and involving the ostium of the large LCX, which also does not appear to be bypassed, with large OM and appears left dominant. Intervention is performed prior to knowledge of entire anatomy, which sometimes is necessary in STEMI. A PDA was never clearly seen in this patient with inferior STEMI. The patient was reportedly in shock on pressors. Given this, consideration of an IABP at the end of the procedure may have been beneficial. The Operator states that ventriculography was normal, but no image was provided. Follow up echo showed preserved LV function.

Technical comment: The Interventional cardiologist started with a single wire in the large ramus. I would

have likely put a second wire down into the circumflex, and balloon the ostium to establish flow and assess the anatomy and dominance. Following stenting of the ramus, if single stent approach was chosen to be used, final kissing balloon of the side branch to improve flow into the circ. Restenosis will likely occur at the ostium of the circumflex and there appears to be residual thrombus/ lesion.

Reviewer 2: The LCX is large, and appears dominant. The left PDA appears occluded also, which may have been able to be addressed prior to LM -to-ramus PCI. In the second image after wiring of the LM into the large ramus, the thrombus is dramatically improved and the ramus does not really appear to be diseased, suggesting the culprit was the LM plaque and thrombus. Aspiration thrombectomy followed by IVUS may have been able to define the culprit lesion and avoid having to stent from the LM into the ramus and compromising/jailing the LCX. That said, in STEMI with shock, circumstances can certainly necessitating immediate stenting based on the Operators judgement of the situation.

Pre- PCI image of RCA: unable to engage, but likely non-dominant

Pre PCI:

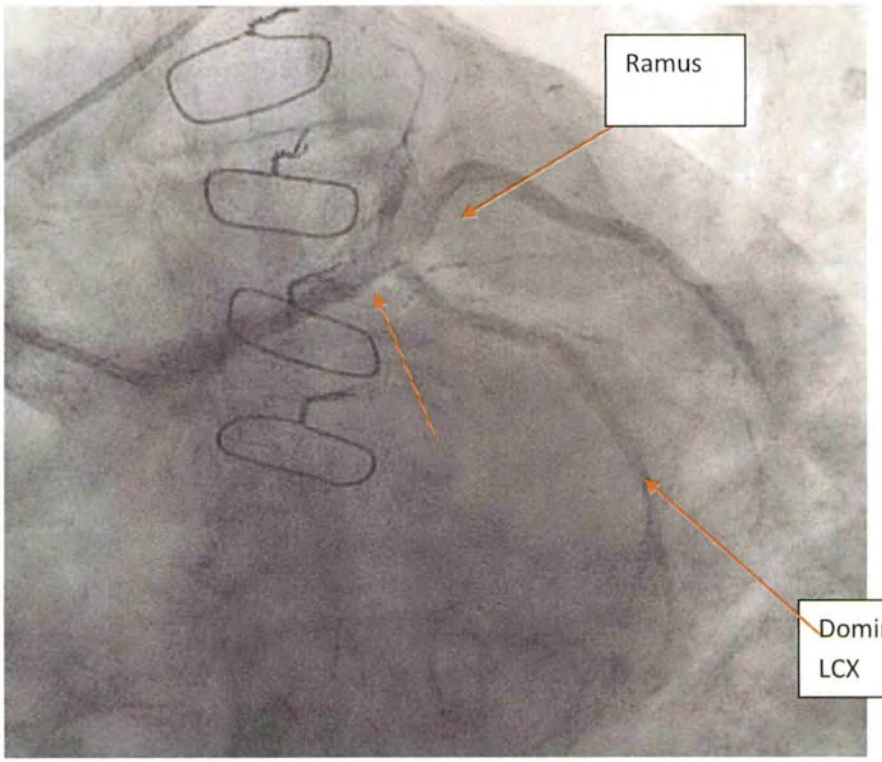
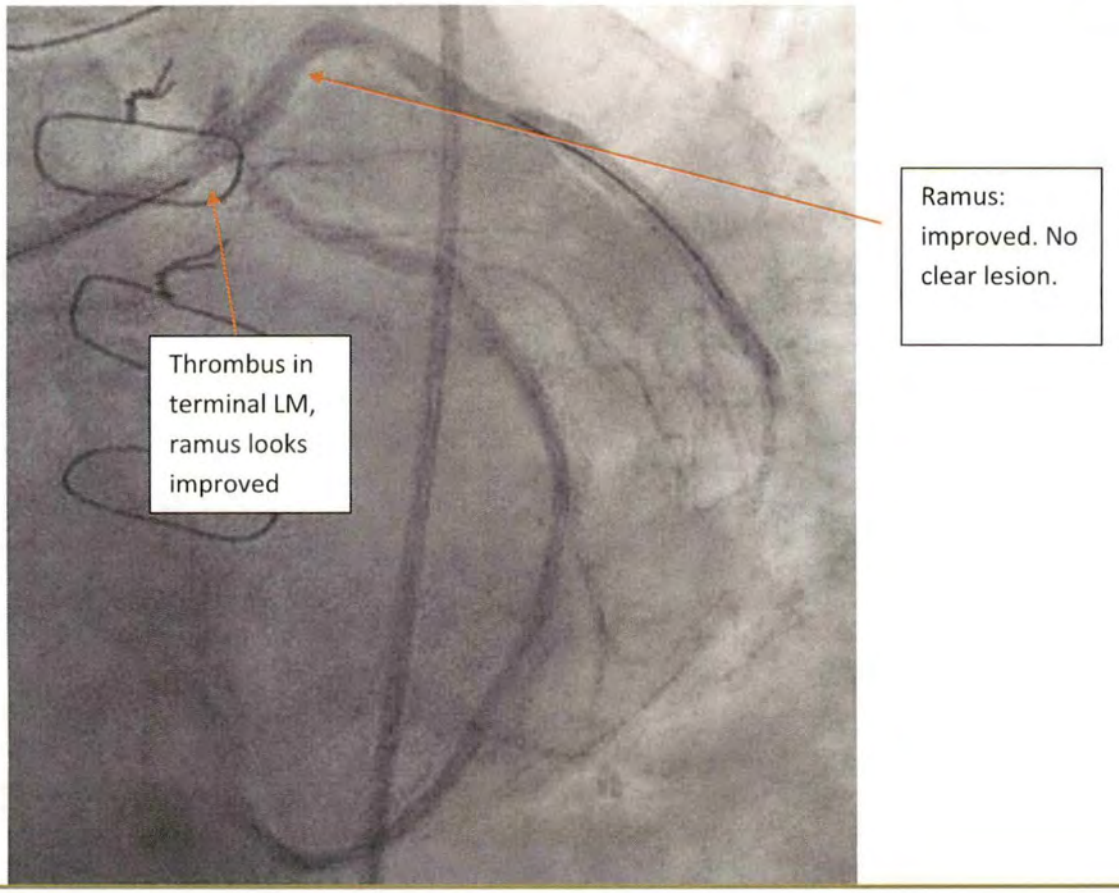
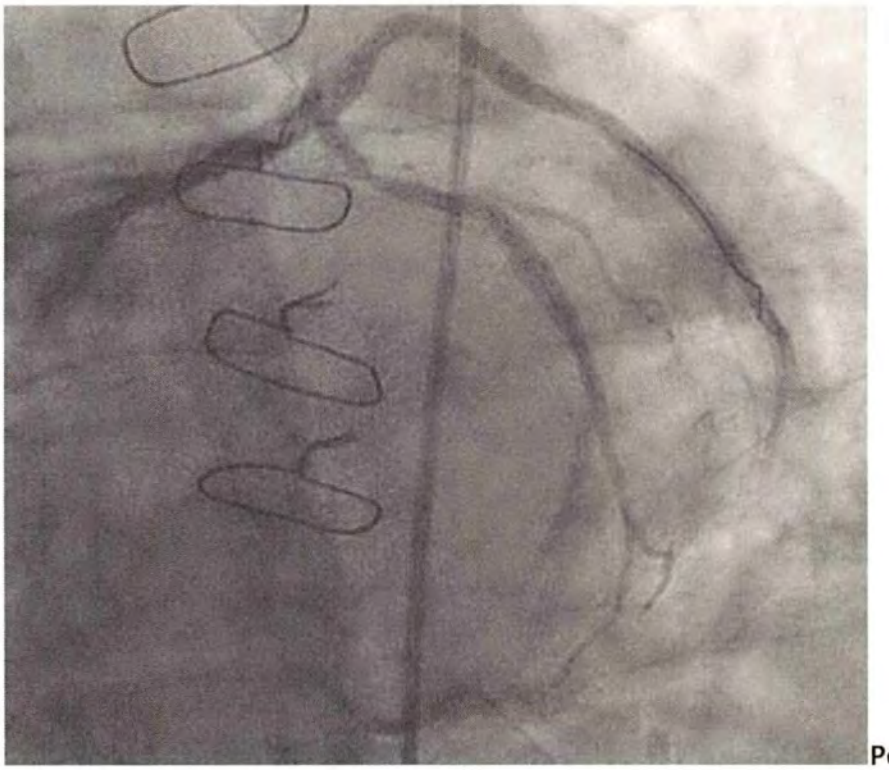


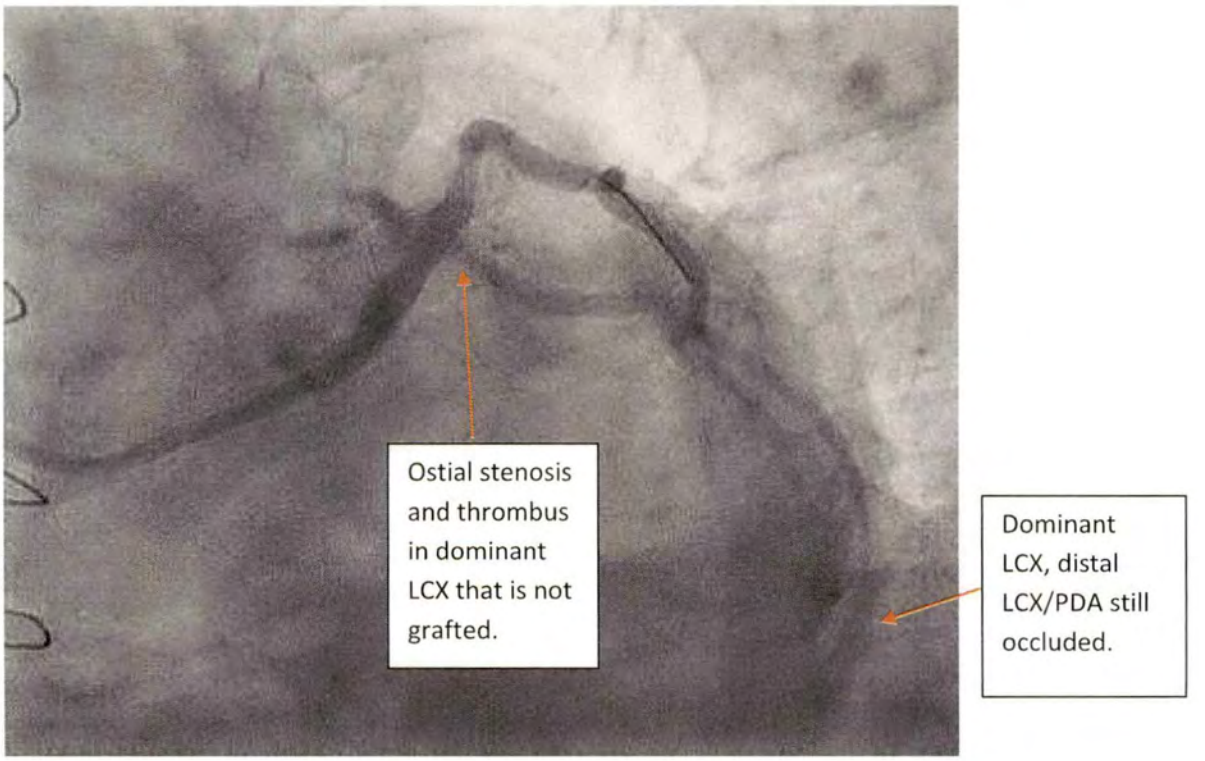
Image after wiring, improved thrombus and visualization of the LCX, occluded distal LCX likely into PDA



Post PCI, occlusion of distal LCX into left PDA

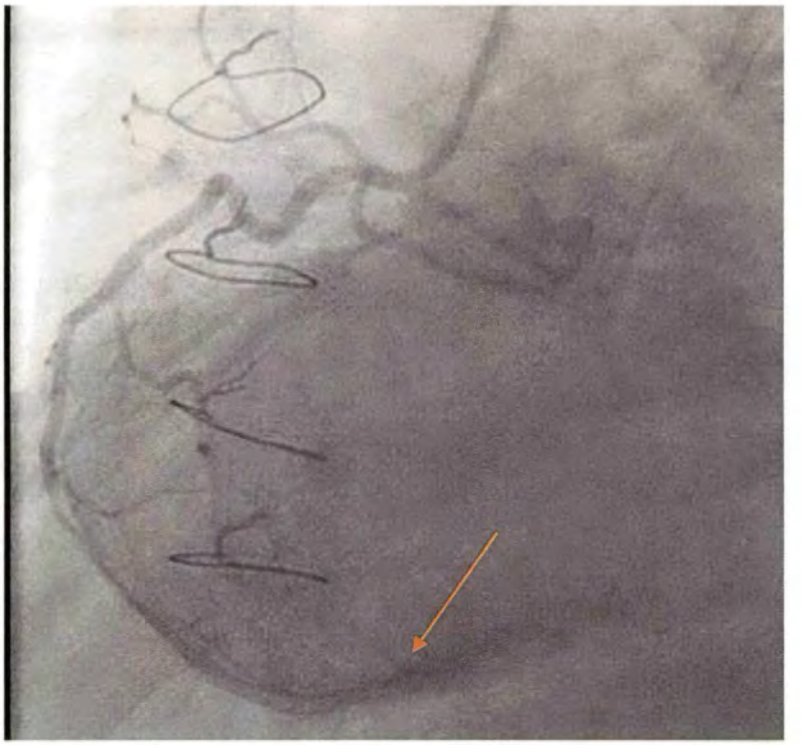


Post PCI:

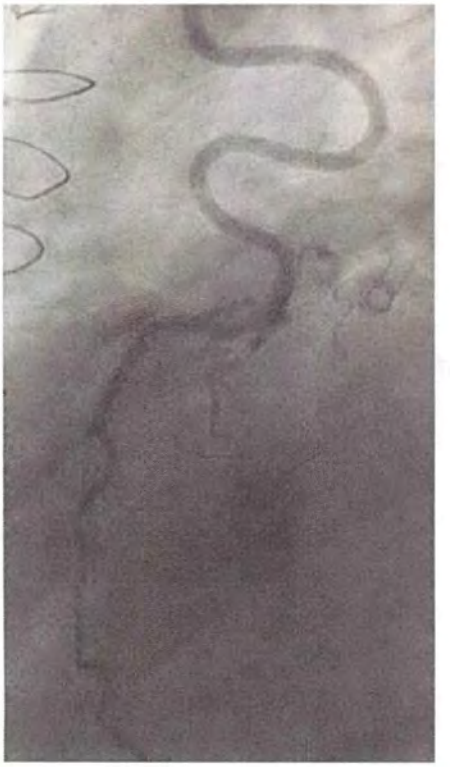


Following PCI, images of RCA and LIMA

RCA: Likely non-dominant with few collaterals to distal left sided PCI



LIMA to diagonal and LAD (CABG x 2 – distal anastamosis)



Identifier: NQT448

Clinical history: A 57-year-old Caucasian male with history of elevated cholesterol, coronary artery disease and HIV who presented the hospital with severe substernal chest pain. The patient's myocardial perfusion image study was notable for reversible defect in the apical septum. The patient develops episodes of rest substernal chest pain consistent with unstable angina. EKG showed inverted T waves in the inferior leads. He was brought urgently to the cardiac catheterization laboratory.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
13 = Mid left anterior descending	90	90	Yes

PCI Appropriateness

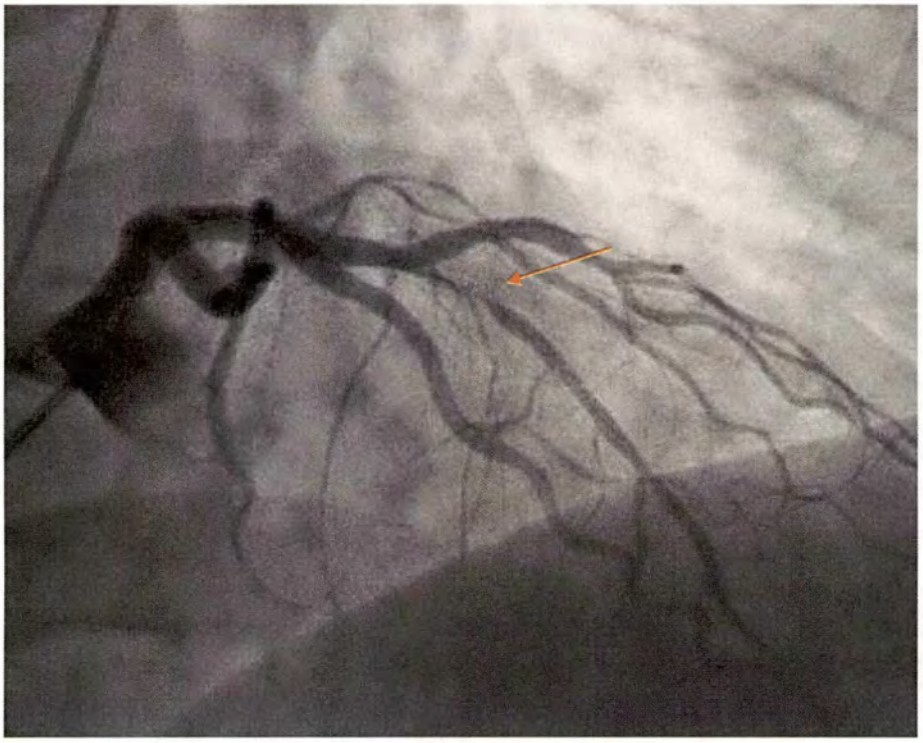
Location	Angiographic	Clinical	AUC
13 = Mid left anterior descending	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Non-Q-Wave myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:
good case. Not sure this patient required a stress test to qualify for cath since cardiac enzymes were elevated. Technical comment: technically sound

Pre PCI:



Post PCI:

Identifier: **ADT722**

Clinical history: An 89-year-old man with history of hypertension, chronic kidney disease who presented to the hospital several weeks ago with acute coronary syndrome. An angiogram was performed which by report was noted to show severe coronary artery disease. The patient was noted to have significant COPD and chronic renal disease. His films were reviewed by interventional cardiology and cardiothoracic surgery. It was felt that he was a high risk for open heart surgery and their recommendation was to proceed with coronary artery intervention.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
3 = Distal RCA	90	90	Yes
13 = Mid Left anterior descending artery	90	90	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
3 = Distal RCA	Appropriate	Appropriate	Appropriate
13 = Mid Left anterior descending artery	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)

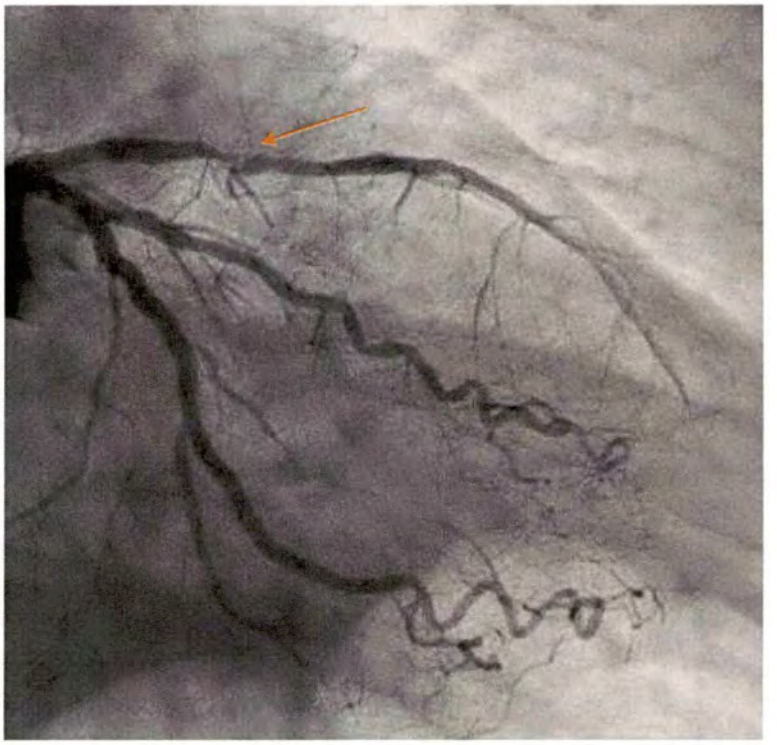
Complications: None None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Non-Q-Wave myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

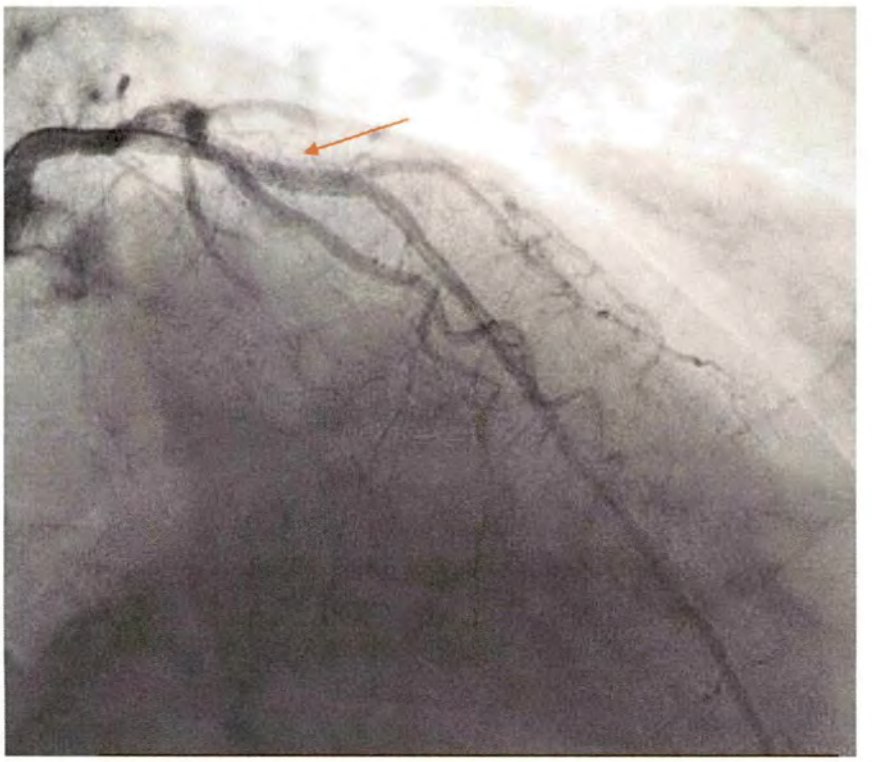
Reviewers Comments:

Reasonable MV PCI for ACS w multiple potential culprits.

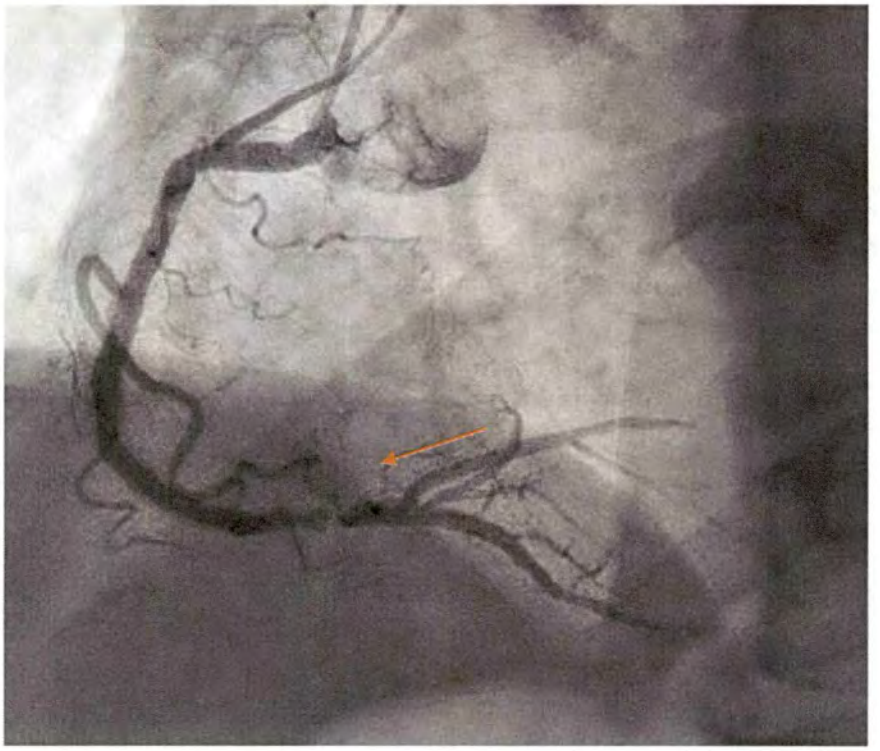
Pre PCI:



Post PCI:



Pre PCI:



Post PCI:

Identifier: **APF293**

Clinical history: A 36-year-old woman with a 30-year history of diabetes, stable bicuspid aortic valve with moderate aortic stenosis admitted with chest pain. Echocardiogram demonstrated a mean gradient on last echo was 30 mmHg with evidence of moderate aortic stenosis and a valve area of approximately 1 to 1.1 cm2. The patient ruled in for a NSTEMI.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
21 = 2 nd Obtuse marginal	70*	70	Yes

* DFR/IFR was performed for stenosis severity and met obstructive criteria

PCI Appropriateness

Location	Angiographic	Clinical	AUC
21 = 2 nd Obtuse marginal	Appropriate	Maybe appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)

Complications: None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Non-Q-Wave myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

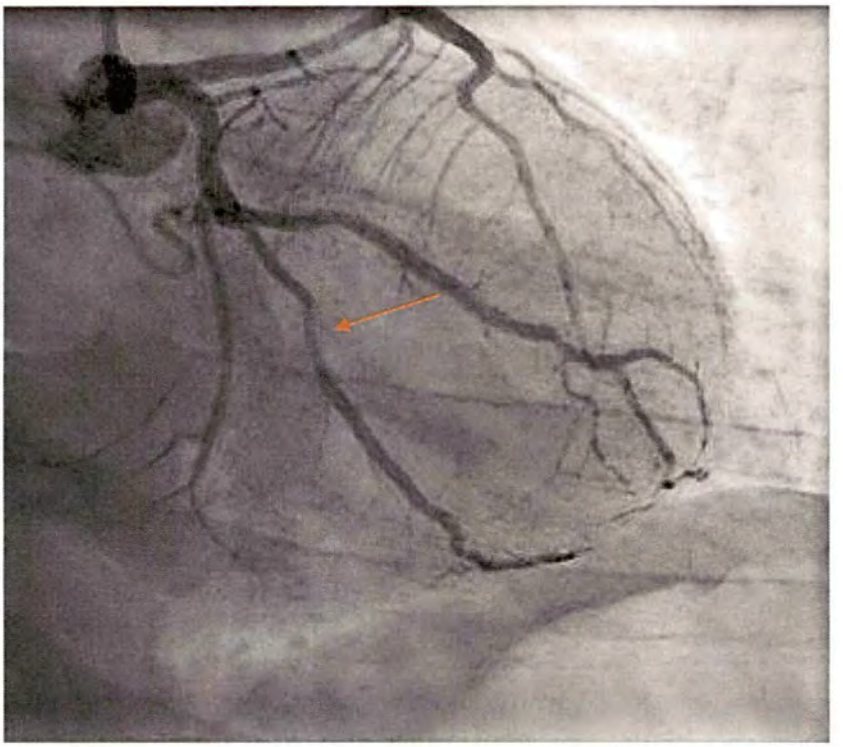
Reviewers Comments:

A 36-year-old woman admitted with diabetic ketoacidosis now with evidence of elevated troponin. Her picture is consistent with a type 2 myocardial infarction related to marked hypotension, dehydration related to diabetic ketoacidosis. There was one episode of chest pain the prior week. The Operator performed DFR which confirmed the angiographically obstructive lesion at 0.85. Successful PCI. It would have also been reasonable to try to treat medically.

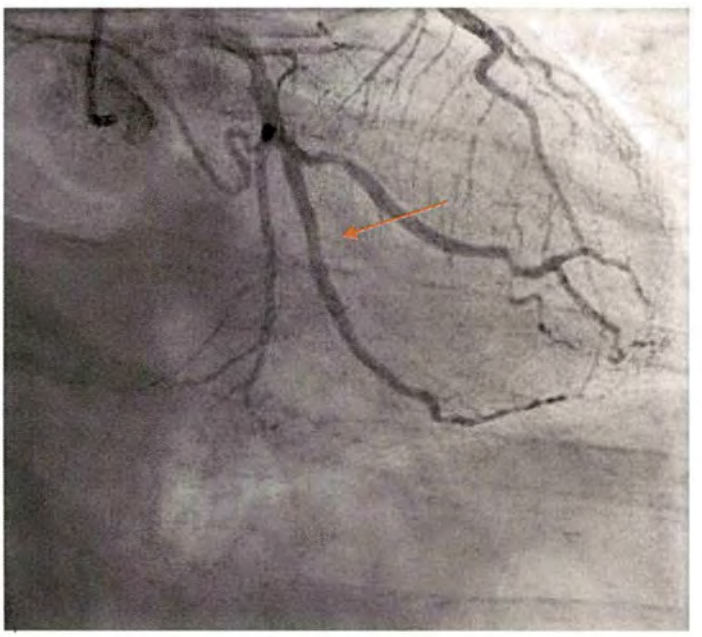
Reviewer 2

Positive iFR not withstanding and regardless of history of CP 1 week prior this pts acute issue was related to DKA. Especially given young age and a reason for troponemia, cath could have been deferred

Pre PCI:



Post PCI:



Identifier: AQC719

Clinical history:
An 87-year-old man with known coronary artery disease including RCA stenting, previous MI, hypertension who presented to ER with chest pain and recent ACID firing.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
15 = 1 st Diagonal branch	80	80	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
15 = 1 st Diagonal branch	Appropriate	Appropriate	Appropriate

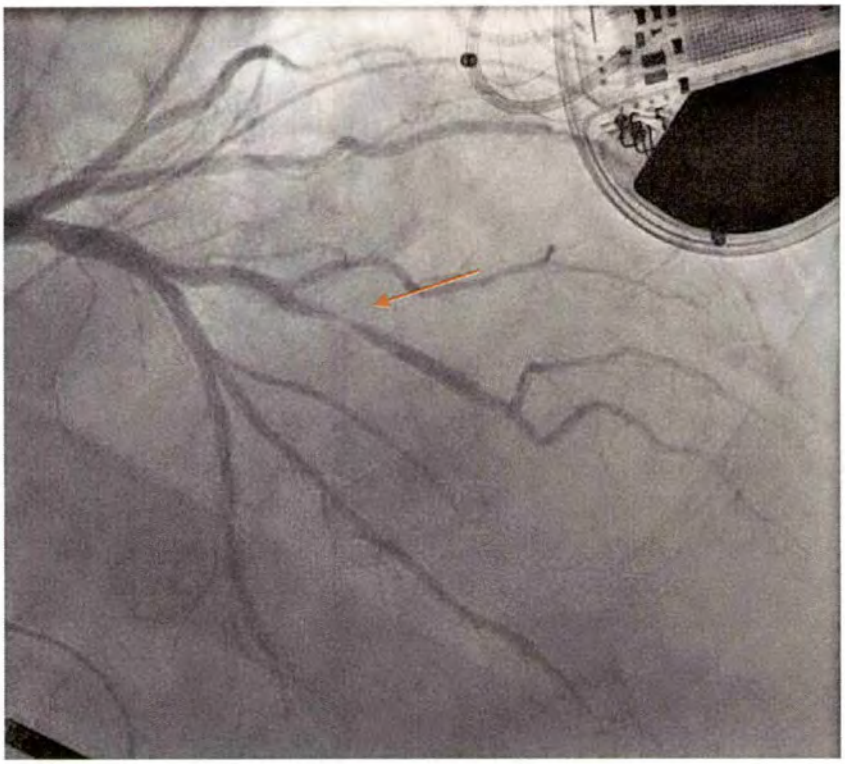
PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)

Complications: None

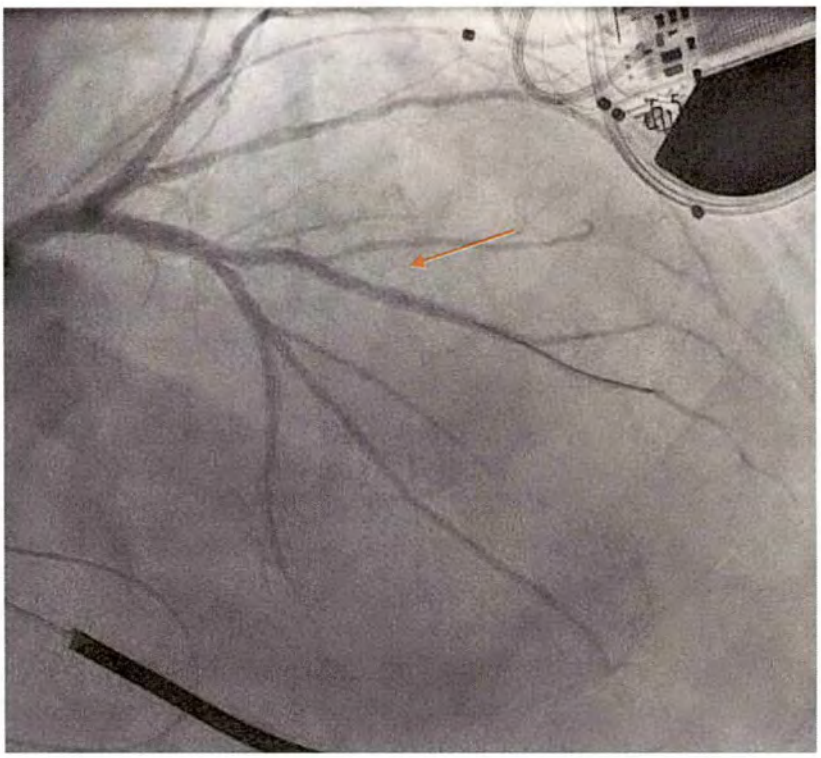
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Unstable Angina
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:
Appropriate PCI for UAP w possible ischemia mediated VT w ICD shock. Diagonal is actually bigger than LAD.

Pre PCI:



Post PCI:



Identifier: FYG874

Clinical history: A 53-year-old woman with a history of hypertension congestive heart failure with admitted with progressive chest discomfort over the past few weeks. Initial [presentation was respiratory felt to be due to volume overload. An echocardiogram demonstrated markedly reduced LV function of 30-35%.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
13 = Mid left anterior descending	75	75	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
13 = Mid left anterior descending	Appropriate	Appropriate	Appropriate

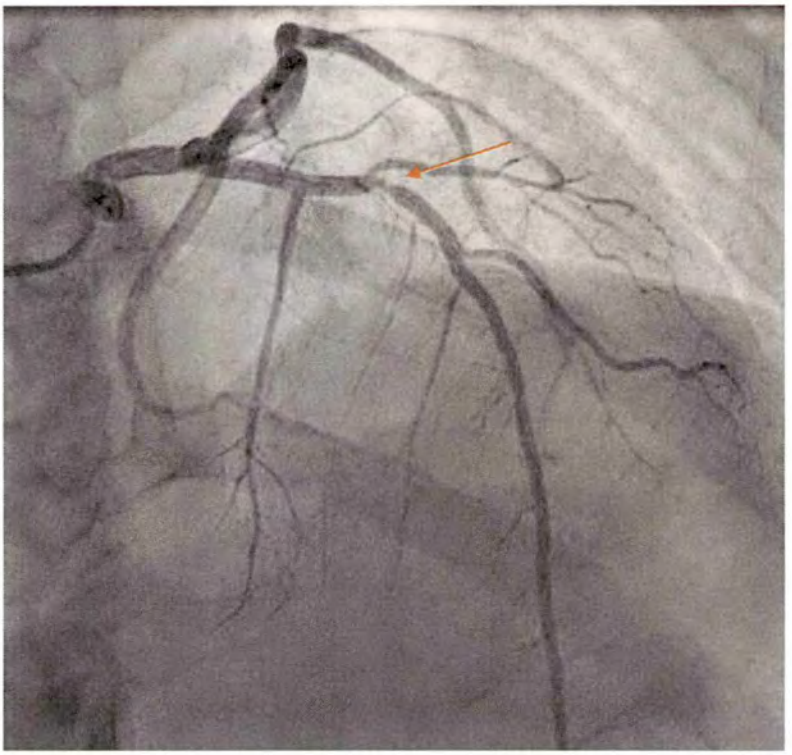
PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Unstable Angina
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:
Reasonable PCI for presumptive ischemia mediated pulmonary edema (though global LV dysfunction speaks to multifactorial CHF.

Technical comment:
Sad reflection of the world in which we live that the operator felt obligated to perform FFR to justify PCI

Pre PCI:



Post PCI:

Identifier: ESQ447

Clinical history:
An 68-year-old woman with medical history significant for coronary artery disease s/p DES, hypertension and HLD who presented to the ER complaining of atypical chest pain. Work up in the ER showed normal trop and elevated BNP at 343. EKG showed nonspecific ST-T wave changes.

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
2 = Mid RCA	90	90	Yes

PCI Appropriateness

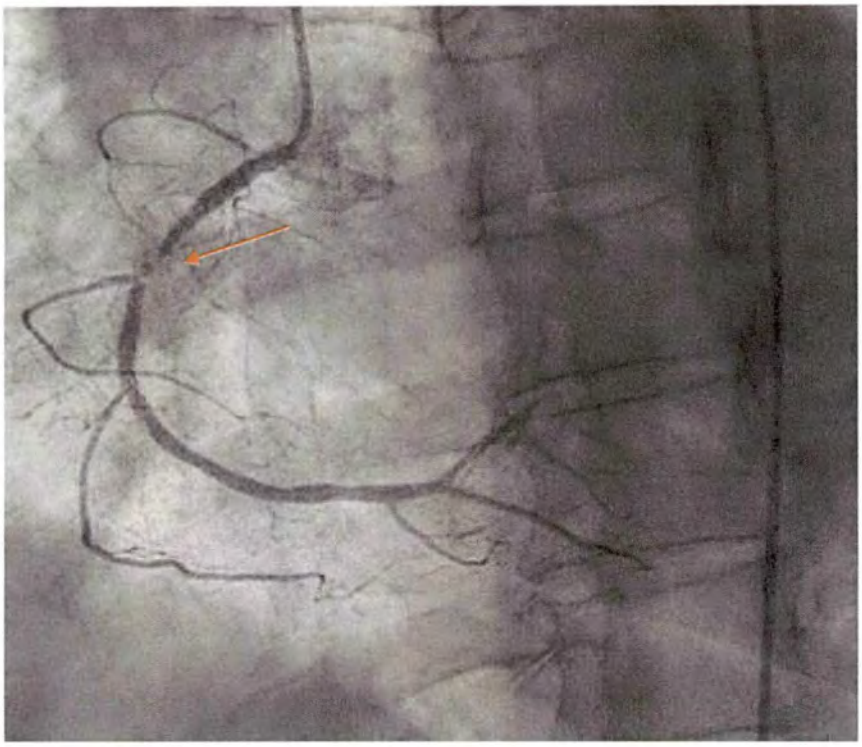
Location	Angiographic	Clinical	AUC
2 = Mid RCA	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)
Complications: None

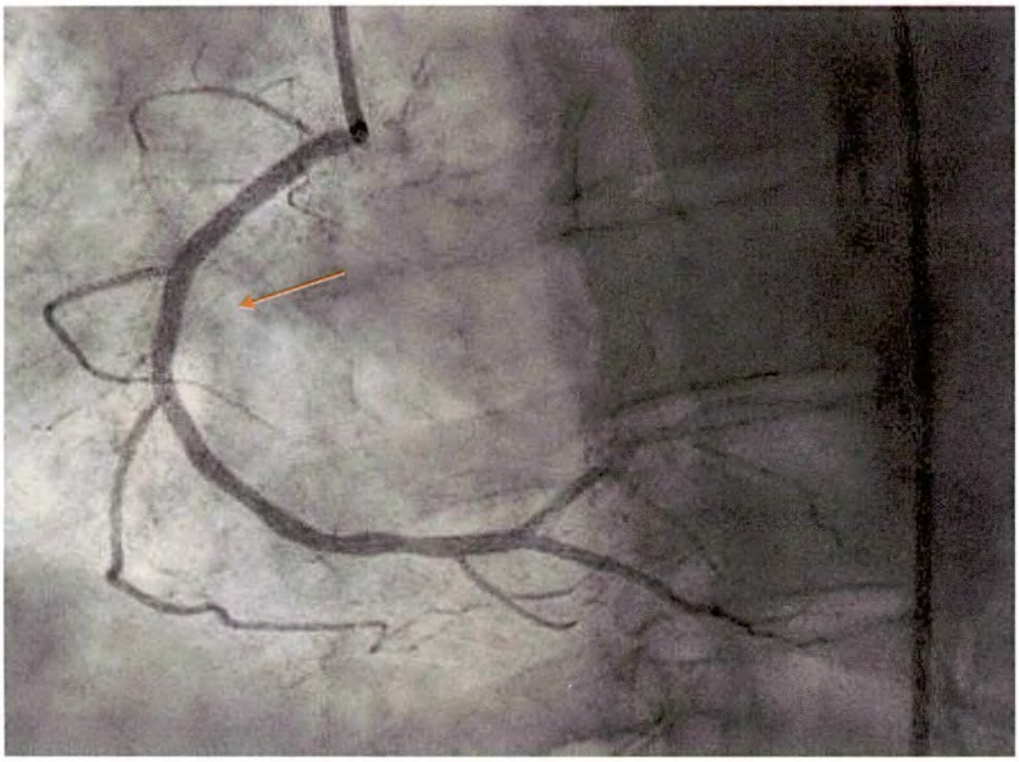
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Unstable Angina
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:
Appropriate PCI for acute coronary syndrome with positive exercise treadmill test.

Pre PCI:



Post PCI:



Identifier: ZTN007

Clinical history: A 66-year-old man male with history of hypertension and TIA with significant dyspnea on exertion and chest heaviness with activity. An EKG demonstrated ST-T changes compatible with ischemia. Cardiac enzymes were within in normal limits

MACPAQ Review Results:

Visual assessment of percent stenosis of PCI lesion

Location	Reviewer	Operator	Agreement?
21 = 2 nd Obtuse marginal	90	90	Yes

PCI Appropriateness

Location	Angiographic	Clinical	AUC
21 = 2 nd Obtuse marginal	Appropriate	Appropriate	Appropriate

PCI result: Successful Stent (<10% residual stenosis AND TIMI 3 flow)

Complications: None

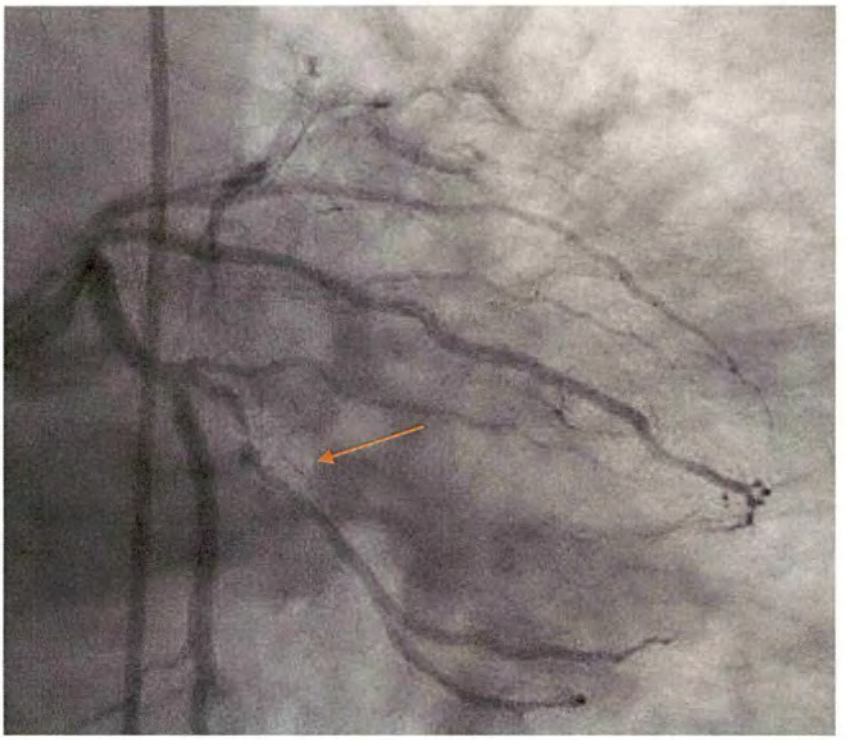
Catheterization Lab Report Documentation:	Reviewer Agrees
Agree with stenosis severity of PCI lesion?	Yes
Agree with stenosis severity of non-intervened vessels?	Yes
Agree with documented Cath Report Outcome?	Yes
Clinical Presentation Driving Intervention	
Was PCI done for ACS?	Yes
Reviewer agrees with the operator's ACS diagnosis	Yes= agree
Type of ACS:	Non-Q-Wave myocardial Infarction
Documentation of consideration of other possible treatment	
(such as cardiac surgery or medical therapy):	Does NOT apply

Reviewers Comments:

Appropriate PCI for NSTEMI with obvious culprit.

A lot of retained guide wires

Pre PCI:



Post PCI:

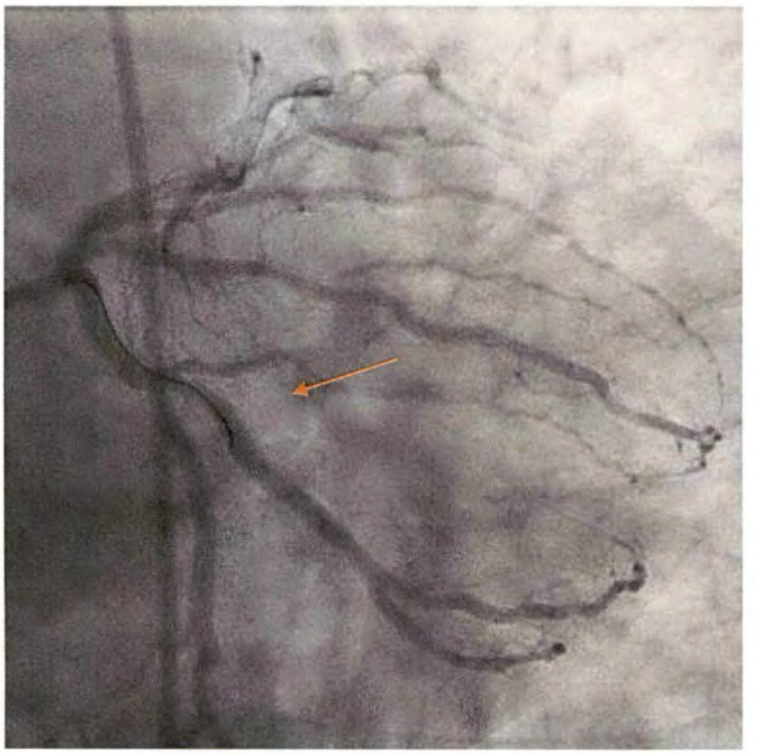


EXHIBIT 13

UNIVERSITY of MARYLAND
SHORE REGIONAL HEALTH

January 6, 2023

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21225

Dear Mr. Steffen,

As part of our modified CON application seeking replacement of University of Maryland Shore Medical Center at Easton ("UMSMC-E"), we are seeking a Certificate of Conformance to move our primary and elective PCI program to the replacement hospital. I am submitting this letter of commitment that if University of Maryland Shore Regional Health (UM SRH) obtains Commission approval to establish a primary PCI Program at the replacement hospital, the replacement hospital will evaluate the performance of each interventionalist through an internal or external review as described in COMAR 10.24.17.07C(4)(d).

Sincerely,

Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

EXHIBIT 14

UNIVERSITY of MARYLAND
SHORE REGIONAL HEALTH

January 6, 2023

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21225

Dear Mr. Steffen,

As part of our modified CON application seeking replacement of University of Maryland Shore Medical Center at Easton ("UMSMC-E"), we are seeking a Certificate of Conformance to move our primary and elective PCI program to the replacement hospital. I am submitting this letter of commitment that if University of Maryland Shore Regional Health (UM SRH) obtains Commission approval to establish a primary PCI program at the replacement hospital, each physician who performs primary PCI services at UM SRH (a hospital without on-site cardiac surgery) shall achieve an average annual case volume of 50 PCI cases over a twenty-four month period. UM SRH will track physicians' volume on a rolling eight quarter basis and report the results to the Commission on a quarterly basis.

UM SRH will submit documentation that demonstrates compliance with this standard 90 days prior to first use at the replacement hospital. UM SRH, as part of the application, using Form C, is submitting to the Commission the staff roster of all physicians who will be performing primary PCI services at the existing facility with documentation showing that each currently meets the case volume requirement.

Sincerely,

Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

EXHIBIT 15

UNIVERSITY of MARYLAND
SHORE REGIONAL HEALTH

January 6, 2023

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21225

Dear Mr. Steffen,

As part of our modified CON application seeking replacement of University of Maryland Shore Medical Center at Easton ("UMSMC-E"), we are seeking a Certificate of Conformance to move our primary and elective PCI program to the replacement hospital. I am submitting this letter of commitment to provide PCI services at the replacement hospital only for suitable patients. Suitable patients are patients described as appropriate for primary PCI in the Expert Guidelines of the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) for Management of Patients with Acute Myocardial Infarction or in the Guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) for Percutaneous Coronary Intervention. The replacement hospital will not provide PCI services to patients at high procedural risk, as described in the Expert Guidelines, as such patients are not suitable patients for elective PCI programs without cardiac surgery on-site.

Sincerely,

Kenneth D. Kozel, MBA, FACHE
President and CEO
UM Shore Regional Health

Jeffrey Etherton, M.D.
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