Cardiac Catheterization Services Comments

April 9, 2025

Mr. James Falahee, JD
Chairperson, Certificate of Need Commission
Michigan Department of Health and Human Services
South Grand Building, 4th Floor
P.O. Box 30195
Lansing, Michigan 48909

Re: Public Hearing for CC SAC Recommended Changes

Chairperson Falahee,

As chair of the Cardiac Catheterization Standards Advisory Committee (CC SAC) I am reaching out regarding a non-substantive change I would respectfully ask the Commission to consider making to the definition of "Elective PCI services without on-site open heart surgery (OHS)". It has recently come to my attention that the wording in this definition relative to coronary atherectomy is confusing and I'd like to suggest a simple revision that could alleviate any potential for misinterpretation. Let me start by clarifying unequivocally that it was the SACs intention to allow coronary atherectomy in facilities with elective PCI without on-site OHS, as this recommendation would align with contemporary guidance provided by the Society of Cardiovascular Angiography and Interventions (SCAI). In fact, we added language in the project delivery requirements to include specific volume requirements for these procedures in these types of facilities. However, when coronary atherectomy was added into the definition it was put at the end of the sentence expanding the services allowed at these sites, immediately following cardiac ablations. However, cardiac ablations have one exception that is not allowed in hospital with elective PCI without on-site OHS and so the coronary atherectomy as added after the "exception" which has created some confusion.

In order to eliminate that confusion I am requesting the Commission to edit the currently drafted definition just slightly be reordering the additional services these facilities can provide in order to make it clear that coronary atherectomy can be performed in hospitals with elective PCI services without on-site OHS as was intended by the SAC. The current draft of the definition reads as follows:

> "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI EXPERT CONSENSUS STATEMENT ON PERCUTANEOUS CORONARY INTERVENTION WITHOUT ON-SITE SURGICAL BACKUP (GRINES CL ET AL, JSCAI GRINES, JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS, VOLUME 2, ISSUE 2, 2023) ~~SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in Circulation 2014, 129:2610-2626~~ and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform LEADLESS PACEMAKER PROCEDURES AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS AND CORONARY ATHERECTOMY. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT. right-sided

cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation." (emphasis added)

Because "coronary atherectomy" is listed after the "except" it makes it possible that the "except" also applies to coronary atherectomy and not just ventricular tachycardia ablations. Instead the definition should be modified to move "coronary atherectomy" before "cardiac ablation" in order to remove any confusion created by the "except" in the sentence. More specifically, I recommend the following updated definition:

> "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI EXPERT CONSENSUS STATEMENT ON PERCUTANEOUS CORONARY INTERVENTION WITHOUT ON-SITE SURGICAL BACKUP (GRINES CL ET AL, JSCAI GRINES, JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS, VOLUME 2, ISSUE 2, 2023) SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in Circulation 2014, 129:2610-2626 and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform LEADLESS PACEMAKER PROCEDURES, CORONARY ATHERECTOMY, AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT. right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation." (emphasis added)

This change would not impact the intent of the standards and would clearly be considered technical in nature, alleviating the need for an additional public hearing. I appreciate your time in considering this request.

Respectfully,

Ryan Madder

Dr. Ryan Madder, MD
Cardiac Cath SAC Chair

HENRY FORD HEALTH℠

April 9, 2025

Mr. James Falahee, JD
Chairperson, Certificate of Need Commission
Michigan Department of Health and Human Services
South Grand Building, 4th Floor
P.O. Box 30195
Lansing, Michigan 48909

Re: Public Hearing for CON Standards for Cardiac Cath Services

Chairperson Falahee,

We appreciate the opportunity to provide public comments regarding the CON Review Standards for Cardiac Catheterization Services approved by the Commission at the March meeting. Henry Ford Health supports the SAC recommended changes; however, we would like to request a minor, non-substantive tweak that would provide more clarity regarding coronary atherectomy services provided in a facility with elective PCI services without on-site open heart surgery.

We request that the Commission edit the currently drafted definition just slightly be reordering the additional services these facilities can provide to make it clear that coronary atherectomy can be performed in these facilities as was intended by the SAC. The current draft of the definition reads as follows:

> "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI EXPERT CONSENSUS STATEMENT ON PERCUTANEOUS CORONARY INTERVENTION WITHOUT ON-SITE SURGICAL BACKUP (GRINES CL ET AL, JSCAI GRINES, JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS, VOLUME 2, ISSUE 2, 2023) ~~SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in Circulation 2014, 129:2610-2626~~ and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform LEADLESS PACEMAKER PROCEDURES AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS AND CORONARY ATHERECTOMY. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT. right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation." (emphasis added)

Because "coronary atherectomy" is listed after the "except" it makes it possible that the "except" also applies to coronary atherectomy and not just ventricular tachycardia ablations. The SAC intentions to allow coronary atherectomy at these facilities as is clear in the Cardiac Cath SAC report presented at the March meeting. We would respectfully request that the definition be modified to move "coronary atherectomy" before "cardiac ablation" in order to remove any confusion created by the "except" in the sentence. More specifically, we recommend the following updated definition:

"Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI EXPERT CONSENSUS STATEMENT ON PERCUTANEOUS CORONARY INTERVENTION WITHOUT ON-SITE SURGICAL BACKUP (GRINES CL ET AL, JSCAI GRINES, JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS, VOLUME 2, ISSUE 2, 2023) SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in Circulation 2014, 129:2610-2626 and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform LEADLESS PACEMAKER PROCEDURES, CORONARY ATHERECTOMY, AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT. right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation." (emphasis added)

This change would not impact the intent of the standards and would clearly be considered technical in nature, alleviating the need for an additional public hearing. We appreciate your time in considering our request.

Respectfully,

Tracey Dietz

Tracey Dietz
Directory, Strategic Planning
Henry Ford Health

April 9, 2025

Mr. James Falahee, JD
Chairperson, Certificate of Need Commission
Michigan Department of Health and Human Services
South Grand Building, 4th Floor
P.O. Box 30195
Lansing, Michigan 48909

Re: Public Hearing for CON Review Standards for Cardiac Catheterization Services

Chairperson Falahee,

Thank you for this opportunity to provide public comments regarding the CON Review Standards for Cardiac Catherization Services presented by the Standards Advisory Committee at the March Commission meeting. MyMichigan Health supports the SAC recommended standards, however, we would like to offer a suggestion of a minor, non-substantive tweak that would remove some confusion in the way the definition of "Elective PCI services without on-site open heart surgery (OHS)" is currently drafted.

Specifically, we request that the Commission edit the currently drafted definition just slightly be reordering the additional services these facilities can provide in order to make it clear that coronary atherectomy can be performed in these facilities as was the clear intention of the SAC. The current draft of the definition reads as follows:

> "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI EXPERT CONSENSUS STATEMENT ON PERCUTANEOUS CORONARY INTERVENTION WITHOUT ON-SITE SURGICAL BACKUP (GRINES CL ET AL, JSCAI GRINES, JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS, VOLUME 2, ISSUE 2, 2023) ~~SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in Circulation 2014, 129:2610-2626~~ and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform LEADLESS PACEMAKER PROCEDURES AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS AND CORONARY ATHERECTOMY. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT. ~~right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.~~" (emphasis added)

Because "coronary atherectomy" is listed after the "except" it is unclear if the except applies only to ventricular tachycardia ablations or also applies to coronary atherectomy. We know that the SAC intended to allow coronary atherectomy at these facilities as is noted in the Cardiac Cath SAC report presented to the Commission at the March meeting. We would respectfully suggest that the definition be modified slightly to move "coronary atherectomy" before "cardiac ablation" in order to remove any confusion created by the "except" in the sentence. More specifically, we recommend the following updated definition:

"Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI EXPERT CONSENSUS STATEMENT ON PERCUTANEOUS CORONARY INTERVENTION WITHOUT ON-SITE SURGICAL BACKUP (GRINES CL ET AL, JSCAI GRINES, JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS, VOLUME 2, ISSUE 2, 2023) SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in Circulation 2014, 129:2610-2626 and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform LEADLESS PACEMAKER PROCEDURES, CORONARY ATHERECTOMY, AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT. ~~right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.~~" (emphasis added)

We would also like to take this opportunity to address public comment that was provided by St. Francis Hospital at the March Commission meeting related to these standards. As explained by Dr. Madder, chair of the SAC, St. Francis brought forward their proposal to both the Rural Subcommittee of the SAC and the full SAC. Neither the subcommittee nor the full SAC supported their proposal, raising many concerns. One of the main concerns we have with the proposal is that it allows the facility to provide elective PCI without requiring 24/7/365 primary (emergent) PCI at the same time. Instead, it allows the facility to only provide primary PCI on the days and times they have staff to perform elective PCI. While other rural hospitals have invested in the staff needed to offer primary PCI 24/7/365 as is currently required, this change could incentive existing full-time primary PCI programs to transition to the same schedule which would greatly reduce access to primary PCI services in rural Michigan. Since primary PCIs are the only PCI that is crucial to have local, we feel this would be a tremendous disservice to rural Michiganders.

As St. Francis has shown in the data they provided, UPers are traveling to both Marquette and several sites in Wisconsin to receive elective PCI care. Since elective PCIs are scheduled and typically require just one visit, having patients travel for that care is not a public health concern. What the UP really needs is additional access to primary PCI, allowing patients who are in an emergency situation to get access to a PCI in shorter time, reducing the travel time and door-to-balloon time for those patients. The St. Francis proposal does nothing to improve access to this time-sensitive care. In fact, we believe their proposal, in the long run, could result in decreased access to primary PCI services as it would draw the most profitable patients away from the facility in the UP that is providing primary PCI and could jeopardize that program both from a volume perspective and a financial one.

Although the St. Francis proposal does require the facility to expand primary PCI services to 24/7/365 once the elective PCI service reaches 300 total PCIs per year, the reality is that a service the size of St. Francis' will never reach those volumes. Including that provision is just an empty promise. St. Francis has premised their entire proposal on the concept of wanting to keep Michigan patients in Michigan. However, it would seem to us that in fact this proposal will

just solidify the referral patterns into Wisconsin and perhaps even increase the flow of patients from the UP into Wisconsin as Bellin Health increases their presence.

We do agree with St. Francis that requiring duplication of primary PCI services within a defined geographic area adds costs to the health care system unnecessarily, but to propose that primary PCI services do not need to be within 120 miles of each other is completely unreasonable. Considering that studies show time is muscle, putting in place a public policy that states we do not need primary PCI services any closer than 120 miles sets a dangerous precedent. A previous SAC implied 60 miles as the minimum when putting into place the provision in Section 4(1)(m)(iii) and we would agree that 60 miles is the absolute maximum.

If the Commission feels that a UP specific provision needs to be added, we would caution you from adopting the current proposal as the provisions included in it have not been appropriately vetted. These provisions were thrown together without evidence-based data and best practices considered. Significantly more time would be needed to create a provision that would ensure patient safety and truly improved access.

We appreciate your time in considering our comments. We would be happy to discuss this further as well as participate in a SAC or workgroup addressing these issues in the future.

Respectfully,

Sunita Vadakath, MD, FRCA, MPA
Senior VP & CSO
MyMichigan Health
989-839-1345

April 18, 2025

Mr. Chip Falahee, Chairperson
Certificate of Need Commission
South Grand Building, 5th Floor
333 S. Grand Ave, Lansing, Michigan 48933

Subject: Request Clarification of the Definition of Elective PCI services without on-site OHS

On behalf of McLaren Health Care, I would like to respectfully request that the Commission clarify the definition of "Elective PCI services without on-side open heart surgery (OHS)" as it relates to coronary atherectomy.

The Cardiac Cath Standard Advisory Committee ("SAC") clarified that a hospital that provides elective PCI without on-site OHS may perform cardiac ablation procedures except ventricular tachycardia ablations. Coronary atherectomy was also added by the SAC as a procedure that can be performed by a hospital that provides elective PCI services without OHS. However, the language was added after the exclusion of ventricular tachycardia ablations. There is some concern that the current drafting of the language may cause confusion as to whether coronary atherectomy is also part of the exclusion list or if it is an authorized procedure. It is our understanding that the SAC intended coronary atherectomy to be included as a procedure that a hospital that provides elective PCI without on-site OHS may perform.

McLaren respectfully requests that the Commission clarifies the language under the definition of "Elective PCI services without on-site OHS" to avoid any confusion.

Current Proposed Language under Subsection 2(s):
… A hospital that provides elective PCI without on-site OHS may also perform **LEADLESS PACEMAKER PROCEDURES AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS**; ~~right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.~~ **AND CORONARY ATHERECTOMY. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT**. ~~right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.~~

Requested Clarified Language under Subsection 2(s):
… A hospital that provides elective PCI without on-site OHS may also **perform LEADLESS PACEMAKER PROCEDURES; CORONARY ATHERECTOY; AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT.** ~~right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.~~

We appreciate your time and consideration of this clarification within the Cardiac Cath Standards.

Thank you,

Chris Candela
President and Chief Executive Officer
McLaren Flint

December 2, 2024

Mr. Chip Falahee, Chair
Certificate of Need Commission
South Grand Building, 4th Floor
333 S. Grand Ave, Lansing, Michigan 48933

Subject: Support Cardiac Cath SAC Recommendations

On behalf of McLaren Oakland, I would like to submit written support for the Cardiac Cath ("CC") SAC Recommendations that are before the CON Commission. McLaren Oakland appreciates the thorough and robust discussions that the CC SAC members engaged in and appreciate the willingness from the Chair, Dr. Ryan Madder, to allow McLaren Oakland to discuss what it believes is an outdated provision that limits certain hospitals after 2015 from providing elective PCI services.

Charge 4 had the CC SAC "[c]onsider whether revisions to the Standards are appropriate to allow certain cardiac catheterization procedures to be performed in hospitals without on-site, open-heart surgery, and under what conditions/requirements." McLaren Oakland is one of two hospitals in the State of Michigan that offer primary PCI services without elective PCI. However, because the Standards prohibits any hospital that offers a primary PCI service after 2015 from being within a PCI or OHS service within 60 miles or 60 minutes travel time, McLaren Oakland is unable to have the opportunity to apply for an elective PCI program. The CC Standards before the Commission from the SAC would allow us to have that opportunity.

An Ambulatory Surgical Center or Freestanding Surgical Outpatient Facility that wants to initiate elective PCI programs must be within 30 minutes of an OHS program. However, a hospital that offers primary PCI after 2015 that wants to offer elective PCI cannot be within 60 minutes of an OHS program. Eliminating the 60 miles or 60-minute radius language would align this criteria. Additionally, we believe it is in the patient's best care to allow elective PCI services at a primary PCI location as long as the rest of the Standards can be met.

We appreciate your time and consideration of this proposal and look forward to showing our continued support for the CC SAC Recommendations.

Thank you.

Lorenzo Suter
CEO/President
McLaren Oakland

OSF HEALTHCARE

April 9, 2025

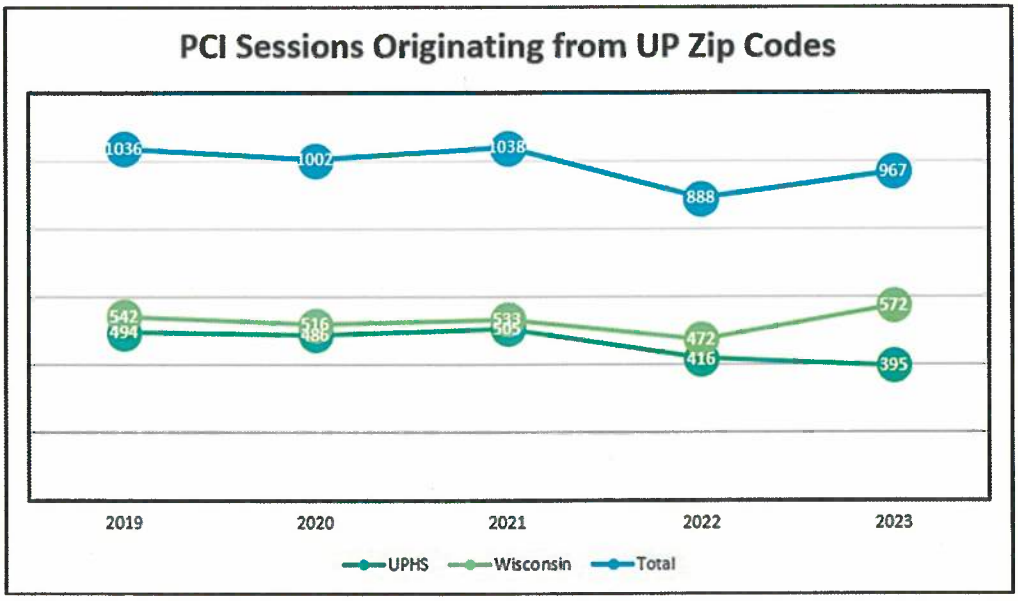
Dear Certificate of Need Commissioners,

The purpose of this letter is to provide public comment related to the draft cardiac catheterization services (CCS) standards revisions that were accepted at the March 2025 Certificate of Need Commission (CON) meeting.

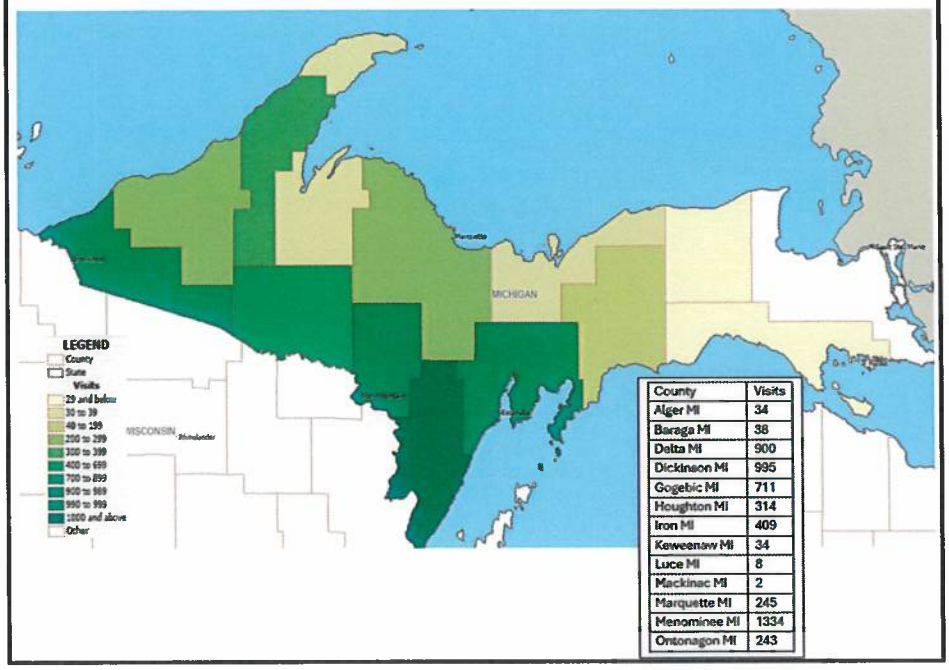
I would like to begin by thanking you for assembling a Standards Advisory Committee for the review of CCS standards. I support the draft changes that were accepted by the Commission, but do not feel that the approved revisions went far enough in addressing access to CCS in the Upper Peninsula (UP).

Access to interventional CCS in rural areas is a point of concern in the UP. Currently, there are two CCS labs in the UP. One at UPHS Marquette, performing both diagnostic catheterizations and PCI, and the other at OSF St. Francis Hospital (SFH) in Escanaba, performing diagnostic catheterizations only which recently opened in July of 2024.

In the trending graph below of PCI sessions performed on individuals originating from a UP zip code, you will see that access to PCI services in the UP is a long-standing issue. In this five-year lookback each year more than 50% of the PCI sessions occurred in Wisconsin, with the attached map showing that the majority of these individuals were from Delta and Menominee Counties, which are both served by OSF St. Francis Hospital.



All Cath Lab Cases Performed in Wisconsin from 2019 to 2023 on Patients Originating from a UP Zip Code



County	Visits
Alger MI	34
Baraga MI	38
Delta MI	900
Dickinson MI	995
Gogebic MI	711
Houghton MI	314
Iron MI	409
Keweenaw MI	34
Luce MI	8
Mackinac MI	2
Marquette MI	245
Menominee MI	1334
Ontonagon MI	243

Access to PCI services in the UP is not improving, and there is no hope that it will ever improve given the historical trends without changes to the existing CCS CON standards. We must be open to new models of care that will provide opportunities to improve access to care in rural areas like the UP. Committed partnerships, like the one OSF has established with Emplify Health, can bring PCI services to the UP while ensuring that care is provided by highly skilled teams who perform these procedures at the volume necessary to build and maintain competence and meet quality standards.

Where else in our state is it acceptable to have so few resources for such expansive geography? It is frustrating to our care team to know that we have the equipment and resources needed to care for PCI patients who far too frequently remain in the SFH emergency department waiting for transfer for extended periods due to lack of bed availability at other PCI centers.

We are eager to be a part of the solution and are well positioned to do so if given the opportunity. I respectfully request that the Commission consider establishing a Standards Advisory Committee or Workgroup to address the unique challenges related to access to PCI services in the UP as soon as possible, but no later than the next review period. Alternatively, I request that the Commission consider including a UP PCI pilot program to expand access in the 2025 standards recommendations.

Sincerely,

Kelly Jefferson
President
OSF St. Francis Hospital & Medical Group

Trinity Health

Trinity Health Michigan

April 16, 2025

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Cardiac Catheterization Services

Dear Chairman Falahee:

As requested by the CON Commission at its March 13 meeting, Trinity Health Michigan would like to comment on the proposed language for the Certificate of Need Standards for Cardiac Catheterization Services. Trinity Health Michigan participated in the Cardiac Catheterization SAC and believes the SAC was effective and collaborative while covering a large number of proposed changes.

With regards to the proposed language, Trinity Health believes the proposed definition for Elective PCI Hospital may be confusing. Specifically, it was the SAC's intent to allow elective PCI hospitals to perform Atherectomy. Trinity Health would recommend the inclusion of parenthesis around the words "except ventricular tachycardiac ablations" in the definition (r) "Elective PCI services without on-site open heart surgery (OHS)" to be clear that Atherectomy is intended to be an allowed procedure.

> "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI Expert Consensus Statement on Percutaneous Coronary Intervention without On-Site Surgical Backup (Grines CL et al, JSCAI Grines, Journal of the Society for Cardiovascular Angiography & Intervention, Volume 2, Issue 2, 2023) and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform leadless pacemaker procedures and cardiac ablation procedures **(**except Ventricular Tachycardia Ablations**)** and Coronary Atherectomy. A facility that provides elective PCI without on-site OHS may also perform myocardial biopsy only on patients who have undergone a previous heart transplant.

Trinity Health supports the other proposed changes. We appreciate the CON Commission's consideration of our comments.

Sincerely,

Shannon D. Striebich
President and CEO
Trinity Health Michigan Market

Magnetic Resonance Imaging (MRI) Services Comments

HENRY FORD HEALTH

April 15, 2025

Mr. James Falahee, JD
Chairperson, Certificate of Need Commission
Michigan Department of Health and Human Services
South Grand Building, 4th Floor
P.O. Box 30195
Lansing, Michigan 48909

Re: Public Hearing for CON Standards for Magnetic Resonance Imaging (MRI) Services

Chairperson Falahee,

We appreciate the opportunity to provide public comments regarding the CON Review Standards for MRI Services approved by the Commission at the March meeting, with questions. Henry Ford Health supports the SAC recommended changes. Additionally, we strongly support the language added to clarify which facilities qualify for the teaching facility adjustment, as follows:

> (ww) "Teaching facility" means a licensed hospital site, or other location, that provides either fixed or mobile MRI services and at which residents or fellows of a training program in diagnostic radiology ENGAGE IN THE CARE OF A PATIENT (INCLUDING PROTOCOLING/INTERPRETATIONS OF STUDIES), AND that is approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association, are assigned. A TEACHING FACILITY SHALL BE IDENTIFIED AS MEETING THE DEFINITION IF AT LEAST ONE (1) OF THE FOLLOWING IS TRUE:
>
> (i) THE PARTICIPATING HOSPITAL SITE OR OTHER LOCATION'S FACILITY NAME IS LISTED ON THE ACCREDITATION COUNCIL ON GRADUATE MEDICAL EDUCATION OR AMERICAN OSTEOPATHIC ASSOCIATION'S ACCREDITATION LETTER AS HAVING A TRAINING PROGRAM IN DIAGNOSTIC RADIOLOGY.
>
> (ii) (ii) THE PARTICIPATING HOSPITAL SITE OR OTHER LOCATION IS OWNED BY AN ENTITY THAT IS LISTED ON THE ACCREDITATION COUNCIL ON GRADUATE MEDICAL EDUCATION OR AMERICAN OSTEOPATHIC ASSOCIATION'S ACCREDITATION LETTER AS HAVING A TRAINING PROGRAM IN DIAGNOSTIC RADIOLOGY.

Henry Ford Health feels these are appropriate changes for the following reasons:

1. The changes specifically require protocoling/interpretation of studies to be read by residents assigned as part of their training per ACGME or AOA, which is more specific than current language. Given the expectations of training, this responsibility is part of a resident's everyday training and workflow.
2. Given the evolution of technology, remote reading of studies/scans are now the standard of practice in most health systems.
3. Having a resident physically onsite is not feasible or practical. It would restrict how quickly a study could be interpreted. A remote standard of practice is cost effective and efficient,

HENRY FORD HEALTH

allowing more studies be completed daily. Additionally, there are not enough residents to be onsite at every facility offering MRI Services.

These change would not impact the intent of the standards and is only clarifying the current definition of a "teaching facility". We appreciate your time in considering our request.

Respectfully,

Dr. Brent Griffith
Vice Chair, Department of Radiology, Henry Ford Health
Associate Professor of Radiology, Michigan State University College of Human Medicine

Dr. Sabala Mandava
Chair, Department of Radiology, Henry Ford Health
Associate Professor of Radiology, Michigan State University College of Human Medicine

UNIVERSITY OF MICHIGAN HEALTH
MICHIGAN MEDICINE

T. Anthony Denton, JD, MHSA
Senior Vice-President & Chief Environmental, Social and Governance Officer

300 N. Ingalls St, SPC 5474
Ann Arbor MI 48109-5474

T: (734) 764-1505

tadpole@med.umich.edu

April 9, 2025

James Falahee - CON Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Intraoperative Magnetic Resonance Imaging (IMRI) – Cost Questions

Dear Chairperson Falahee:

The CON Commission, at their March 13, 2025 meeting, requested public comment addressing questions concerning the cost implications of utilizing the IMRI technology within a licensed operative environment for the expanded procedures as proposed by the MRI Workgroup.

It is important to note that performing outpatient MRI-guided procedures in the IMRI surgical suite does not create additional costs compared to traditional MRI settings. The processes and resources required remain consistent with standard MRI procedures, ensuring that cost-efficiency is maintained.

Moreover, the use of the IMRI surgical suite in this capacity does not necessitate the operation of additional personnel or equipment beyond what is already established, thus not impacting the overall cost structure. As such, the transition of these procedures to the IMRI surgical suite should not influence the financial aspects of their delivery. If anything, the increased utilization of equipment for interventions, which an IMRI surgical suite is explicitly designed for, should improve access to diagnostic scans for patients.

In terms of logistical operation, the primary effect of utilizing the IMRI surgical suite for these procedures is the limitation it imposes on the ability to count MRI adjusted procedures used in support of the MRI service expansion volume requirement within the CON Standards. This procedural choice reflects a strategic decision to optimize existing resources rather than expanding the service unnecessarily, which aligns with the principles of cost containment and resource efficiency that the Commission endorses.

We hope this clarification addresses your concerns. Should you have further inquiries or require additional information during the public comment period, please feel free to reach out. A representative from the University of Michigan Health Radiology Department will also be in attendance at the June 12, 2025 CON Commission meeting and will be available to answer any additional questions you may have at that time.

Thank you for your attention and the opportunity to provide this explanation for consideration.

Respectfully submitted,

T. Anthony Denton, JD, MHSA
Senior Vice-President & Chief ESG Officer
University of Michigan Health
Michigan Medicine

Vikas Gulani, MD
Fred Jenner Hodges Professor of Radiology
Chair, Department of Radiology
University of Michigan Medical School
Michigan Medicine

UNIVERSITY OF MICHIGAN HEALTH
MICHIGAN MEDICINE

T. Anthony Denton, JD, MHSA
Senior Vice-President & Chief Environmental, Social and Governance Officer

300 N. Ingalls St, SPC 5474
Ann Arbor MI 48109-5474

T: (734) 764-1505

tadpole@med.umich.edu

April 18, 2025

James Falahee - CON Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: MRI Contrast-Enhanced Procedures

Dear Chairperson Falahee:

The CON Commission, at their March 13, 2025 meeting, requested public comment addressing questions concerning registered nurse supervision of intravenous contrast material administration as proposed by the MRI Workgroup.

University of Michigan Health is requesting consideration and support for the recognition of registered nurses (RNs) as qualified personnel to monitor patients for adverse reactions during MRI contrast-enhanced procedures, in alignment with established national standards of care.

The **American College of Radiology (ACR)**, in its **ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media**, specifically permits RNs to provide direct supervision of intravenous contrast material administration when under the general supervision of a radiologist. The document clearly outlines that:

"Registered nurses may provide direct supervision following a symptom- and sign-driven treatment algorithm."

This evidence-based approach ensures patient safety while expanding flexibility in clinical operations, particularly in settings with increasing imaging volumes and staffing constraints.

Further, the **subgroup tasked with reviewing this topic** has unanimously agreed that adherence to the **ACR–SPR Practice Parameter**, including Section E: *Supervising Radiologist or Other Supervising Provider*, is both appropriate and responsible. This section supports that under general supervision by a radiologist (MD/DO), direct supervision may also be carried out by:

1. Nonradiologist physicians (MD/DO)
2. Advanced practice providers (NP, PA)
3. Registered nurses using an approved algorithmic approach

While we acknowledge that **CMS guidelines outlined in 42 CFR parts 410, 414, 415, 423, 424, and 425** (specifically referenced on page 123 regarding supervision of diagnostic services) do not explicitly name RNs as supervisors, this omission does not preclude the opportunity for state-level interpretation or legislative refinement to align with current, nationally endorsed clinical standards.

We hope this clarification addresses your concerns. Should you have further inquiries or require additional information during the public comment period, please feel free to reach out. A representative from the University of Michigan Health Radiology Department will also be in attendance at the June 12, 2025 CON Commission meeting and will be available to answer any additional questions you may have at that time.

Thank you for your attention and the opportunity to provide this explanation for consideration.

Respectfully submitted,

T. Anthony Denton, JD, MHSA
Senior Vice-President & Chief ESG Officer
University of Michigan Health
Michigan Medicine

Vikas Gulani, MD
Fred Jenner Hodges Professor of Radiology
Chair, Department of Radiology
University of Michigan Medical School
Michigan Medicine

Trinity Health

Trinity Health Michigan

April 16, 2025

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Magnetic Resonance Imaging (MRI) Services

Dear Chairman Falahee:

As requested by the CON Commission at its March 13 meeting, Trinity Health Michigan would like to comment on the proposed language for the Certificate of Need Standards for Magnetic Resonance Imaging (MRI) Services. Trinity Health Michigan participated in the MRI workgroup and believes the workgroup was effective and collaborative in discussing proposed changes.

With regards to the proposed change to the onsite supervisory requirements for MRI studies, the proposed language does align with the American College of Radiology SPR Practice Parameter guidelines by allowing Registered Nurses as supervising providers. Trinity Health does not believe the workgroup considered whether the proposed language aligns with CMS' Conditions of Participation; upon further research, it appears the proposed language may not align with CMS. If the CON Commission chooses to retain Registered Nurses in the definition, the language would continue to meet ACR's guidelines regarding quality. Providers would be responsible for meeting applicable payor requirements (as they do today).

During the MRI workgroup, Trinity Health did not support the proposed definition of teaching facility due to concerns with the breadth of the language. Trinity Health agrees the presence of a teaching program may cause additional room time, and for those scans a higher MRI weight is appropriate. However, all MRI departments routinely pause MRI scans to consult with Radiologists regarding scanning protocols, regardless of whether those consultations are with a staff radiologist or a radiologist-in-training. We believe the proposed language is more sweeping than the actual impact of teaching programs, providing disproportionate benefit to health systems with training programs. As presented, the proposed language would apply a 0.10 factor to 100% of scans at all locations within a health system that has a training program. Trinity Health would support the CON Commission delaying this specific change related to the teaching facility definition to allow for later review.

Trinity Health supports the other proposed changes. We appreciate the CON Commission's consideration of our comments.

Sincerely,

Shannon D. Striebich

Shannon D. Striebich
President and CEO
Trinity Health Michigan Market