Petition to the State Health Coordinating Council
Regarding Special Need Adjustment for Cardiac Catheterization
for Iredell County
2022 State Medical Facilities Plan

July 28, 2021

Petitioner:		***Contact:***	
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STATEMENT OF REQUESTED ADJUSTMENT

Iredell Health requests the following change to the *Proposed 2022 State Medical Facilities Plan* (*SMFP*) to address a special need for shared fixed cardiac catheterization equipment in Iredell County. For discussion purposes, Iredell Health proposes the following wording:

Table ##: Shared Fixed Cardiac Catheterization Need Determination
(Scheduled for Certificate of Need Review Commencing in 2022)

It is determined that the service areas listed in the table below need shared fixed cardiac catherization capacity.

Service Areas	Shared Fixed Cardiac Catheterization Need Determination	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Iredell County	1***	TBD	TBD

* *Need determination shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).*

** *Application due dates are absolute deadlines. The filing deadline is 5:00 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).*

*** ***Provided that in response to this need, the applicant shall be in an acute care hospital that reported at least 1,100 weighted cardiac catheterization procedures in Table 17A-3 of the 2021 SMFP***

REASONS FOR THE PROPOSED ADJUSTMENT

BACKGROUND

Current Situation

Iredell Memorial Hospital has one CON-approved fixed cardiac catheterization laboratory and second laboratory that is capable of doing cardiac catheterizations, but has CON approval for angiography and vascular procedures only. During the COVID Emergency, under Executive Order 139, the Agency approved a temporary exemption. This emergency approval enables the hospital to use the second laboratory equipment as what in SMFP terms is "a shared fixed cardiac catherization laboratory." With permission to schedule cardiac catheterizations in the second laboratory, the hospital saw immediate positive results in patient service, operational efficiency, and physician satisfaction. The hospital wishes to continue that program, but needs CON approval to do so. The SMFP has a specific methodology that limits CON approval the number and quantity of cardiac catheterization equipment. In this case, the 2022 SMFP, must show a need for shared fixed cardiac catheterization equipment in Iredell County. Two other cardiac catheterization laboratories in Iredell County have equipment that operates at far below the SMFP threshold for generating need for additional cardiac catheterization capacity in Iredell County.

State Medical Facilities Plan Methodologies for Cardiac Catheterization Laboratories

To calculate need for cardiac catheterization equipment, the *Proposed 2022* SMFP provides two need determination methodologies. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment; and Methodology Two is the methodology for determining need for shared fixed cardiac catheterization equipment. Shared fixed cardiac catheterization equipment is defined in the SMFP as "fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures." Application of these methodologies to utilization data reported on hospital license renewals and summarized in Table 17A-1, on page 314, of the *Proposed 2022 SMFP* does not generate a need determination for fixed cardiac catheterization equipment or for shared fixed cardiac catheterization equipment in Iredell County.

Methodology One automatically generates a need for one additional cardiac catheterization laboratory in a county that averages 1200 weighted cardiac catheterization procedures per unit of catheterization equipment in the county. That will not happen in Iredell County for a long time, because the county has three hospitals, and each has a cardiac catheterization laboratory. The numbers were no better pre-COVID. According to Table 17A-3 of the 2021 SMFP, which contains data from fiscal year 2019, use at the other two hospitals was still very low, 404 and 271 annual weighted procedures. Use is even less in the same table in the *Proposed 2022 SMFP* (318 and 130 weighted procedures).

Methodology Two applies only to cardiac catheterization service areas that do not offer fixed cardiac catheterization equipment.

Chapter 17 of the 2022 SMFP states, "For cardiac catheterization equipment service areas in which a unit of fixed cardiac catheterization equipment is not located, need exists for one shared cardiac catheterization equipment (i.e., fixed equipment that is used to perform both cardiac catheterization procedures and angiography procedures) when:

a) *The number of cardiac catheterization procedures as defined in 10A NCAC 14C .1601 (5) performed at any mobile site in the cardiac catheterization service area exceeds 240 (300 procedures X 80 percent) procedures per year for eight hours per week the mobile equipment is operated at the site during the current reporting year (Table 17A-2); and*

b) *No other fixed or mobile cardiac catheterization service is provided within the same cardiac catheterization equipment service area. (Emphasis added)"*

Methodology Two, as written, does not apply to Iredell County, which has three operational fixed cardiac catheterization labs: one each at Iredell Memorial Hospital (IMH), Davis Regional Medical Center (DRMC), and Lake Norman Regional Medical Center (LNRMC).

Methodology Two is ideal for a small cardiac catheterization program, because it permits a hospital to use a single piece of equipment for both cardiac and vascular procedures. Today, because of technology advances, the same piece of equipment can do either procedure, with a simple change of aperture, camera speed and display settings.

Examples of the applicability of Methodology Two are the adjusted need determination for a shared fixed cardiac catheterization lab in Lee County in the 2011 SMFP; for Carteret County in 2013; and for Harnett County in 2016. Prior to the adjusted need determination approval, these counties did not have a fixed unit; county residents received *mobile* cardiac catheterization services at hospitals in these counties.

The SMFP has no methodology to address the needs of a community cardiac catheterization program that reaches capacity of one cardiac catheterization lab, but will not likely need two full labs.

PRE-COVID, IREDELL HEALTH CARDIAC CATHETERIZATION GROWTH PATTERN

Had the COVID pandemic not occurred, IMH cardiac catheterization laboratory would have operated at or above the Methodology One threshold in 2020, the data year used for the 2022 SMFP.

In 2016, recognizing that heart and vascular disease rates are extremely high in Iredell County, Iredell Memorial expanded its cardiovascular program to include acute heart attack response in a formal ST-segment elevation myocardial infarction ("STEMI") program in 2016. Iredell was the first community hospital in the state without a full open heart surgery program to take this initiative. The success was remarkable. Supported by open heart surgeons who are on-call for every interventional procedure, the hospital now offers scheduled and unscheduled interventional cardiac catheterization services. Following that initiative, use of the lab increased steadily, reaching 1,124.5 weighted cardiac catheterization procedures in 2019, as illustrated in Table 1, below.

Table 1—History of Weighted Cardiac Catheterization Procedures, Iredell Memorial

Fiscal Year	Diagnostic Cath Procedures	Interventional Cath Procedures	Weighted Caths	% of 1200 threshold for additional lab
2017	662	203	1,017.25	85%
2018	646	163	931.25	78%
2019	729	226	1,124.50	94%
2020	507	130	734.5	61%

Source: Iredell Memorial Hospital License Renewal applications. Weighted = 1.0 x Diagnostic +1.75 x Interventional

Numbers dropped in FY 2020, when COVID patients occupied 64 percent of Iredell Memorial beds and Governor Cooper's orders mandated the hospital to cease elective procedures. However, this year (2021) demand is on track to match 2019 rates by the fourth quarter of calendar 2021. By March 2022, internal data trends show the lab will be operating at a monthly rate that exceeds 1200 annualized weighted procedures (Attachment B).

Forecasting is an inexact science, especially in the midst of a second COVID surge. However, IMH looked at conservative trendlines that included the tail of the first surge. In FY 2022, Iredell Health expects to provide about 1200 weighted cardiac catheterization procedures. More importantly, it will be operating at a rate above 1300 procedures for the last fiscal quarter. These forecasts are based on actual data for the months of November 2020 through June 2021 (Attachment C). They are trended data that include a step up only for the portion of Statesville procedures that IMH expects Dr. Allen to bring. New cases associated with Dr. Allen start in August 2021. Dr. Allen actually began work on June 28, 2021. Even these conservative trends show annual weighted cardiac catheterizations beyond capacity by the end of FY2022 and above threshold for new equipment by July 2022. A CON filed for the 2022 Plan will not typically be available until FY2023.

Iredell Memorial Hospital cardiac catheterization patients travel long distances for care. They do not show up for "after dark" schedules. When they do, the late hours often result in preventable overnight stays. Seven, and, soon to be eight, physicians are credentialled to and actually do cardiac catheterization procedures; five are employees of Iredell Health. Each physician schedules patients in at least one clinic location in addition to the cardiac catheterization lab. As the cardiac catheterization lab gets full, juggling patient, physician and STEMI emergencies becomes extremely difficult.

CARDIOVASCULAR PROGRAM

Quality of care is a top priority for the IMH Board of Directors. The Iredell Memorial Catheterization lab equipment is one critical part of the high-quality IMH cardiovascular program. IMH is a Joint Commission certified Primary Stroke Center. The Cardiac program has been accredited by the Society of Cardiovascular Patient Care for our Chest Pain Programs since 2011. Today IMH offers patients world class times for acute MI interventions as evidenced by "door to artery open" STEMI times consistently ranking in the top 10% percent nationally.

Iredell Health is fully committed to patient outcomes. The Board has adopted a philosophy of whole patent care; and outcomes data reflect the commitment. Iredell outcomes are stellar, as demonstrated on our most recent NCQC report card, (Attachment A). Iredell Health outcomes are in the top quintile statewide.

IMH currently offers a full STEMI program 50 hours a week; on average 40 patients per year are able to receive emergency treatment within the first two hours of heart attack diagnosis. Treatment during this critical window prevents acute injury of the heart muscle. Otherwise, these patients would risk critical delay associated with an emergency trip to Hickory, Winston Salem, or Charlotte in the midst of an acute and damaging heart attack.

CREDENTIALLED PHYSICIANS

As noted above, seven physicians are credentialled to use IMH's cardiac catheterization lab. The seventh, Dr Allen, an invasive cardiologist, joined the IMH medical staff, in July 2020, bringing, an active practice of 300 annual catheterization procedures from our service area with him. He previously took his cases to one of the other two Iredell County cardiac catheterization labs. In the past, cardiologists also worked in all of the cardiac catherization labs in the county. This is no longer the case. Most now work exclusively, or primarily at Iredell Memorial.

In September 2021, Dr. Rajpur, an interventional cardiologist will join the Iredell Health medical staff. He will replace an invasive cardiologist who retired in 2019. An interventional cardiologist can do therapeutic cardiac catheterizations. An invasive cardiologist can do only diagnostic catheterizations. Dr. Rajpur will bring IMH cardiovascular medical staff complement to eight, three of whom are credentialled for interventional procedures.

With Dr. Rajpur as the third interventional cardiologist, Iredell Health can begin moving toward 7 days/ week, 12-hour-a-day STEMI coverage. This will be possible if IMH can obtain permanent approval to use both labs.

HEALTH STATUS

Evidence supports continued community need for cardiac catheterization. According 2021 County Health Rankings, Iredell residents overall are healthy, but a significant segment of people served by IMH are not[1]:

- 19 percent of resident adults smoke tobacco
- 35 percent are obese
- One third lack access to exercise opportunities
- 22 percent are excessive drinkers

County Health Rankings is a national, statistically uniform, county health status database developed and maintained by the University of Wisconsin and supported with funds from The Robert Wood Johnson Foundation.

[1] County Health Rankings 2021 Iredell County NC https://www.countyhealthrankings.org/app/north-carolina/2021/rankings/iredell/county/outcomes/overall/snapshot

The reported county data represent risk factor percentages for heart attack. IMH cardiac catheterization lab statistics show that these risks convert to disease and demand for services that is increasing as the county population increases.

EQUIPMENT ALREADY AVAILABLE INSTALLED, IN USE AND SUCCESSFUL

Why act this year? Why not wait? The simple answer, is that loss of permission would mean dismantling a very successful, cost effective program that is meeting a community need well. IMH is efficiently using one full cardiac catheterization laboratory and one shared fixed cardiac catheterization laboratory today. With simple permission to use existing equipment, the results are already very positive. Physicians have better schedules; STEMIs are easier to accommodate. Techs and nurses are happier operating with less stress, and IMH is on track to save about $150,000 to $175,000 a year from the staffing efficiency alone.

The same person who is at risk for a heart attack has a very high likelihood of vascular problems. Some physicians who do cardiac catheterizations also do vascular procedures. However, most vascular procedures are done by vascular specialists. At IMH, a vascular surgeon does these procedures. Regardless, the cardiac and vascular physicians and techs work together to design the best outcomes for the individual at risk.

Data for the combined IMH cardiac and vascular programs indicate that a shared fixed lab is the perfect solution. The following Table 2 shows IMH near-term forecasts of procedures in the combined program. It also compares productivity in two scenarios, one with two full catheterization labs and the other with one full fixed and one shared fixed lab.

By 2022, IMH internal data indicate that the combined program will reach 103 percent of the 1200 weighted procedures required to justify a new cardiac catheterization lab according to Methodology One. (Table 2, Column c). If IMH had a second full lab, Column g shows that IMH would be at 68 percent catheterization performance standard set by 10NCAC14C.1603(a)(1) for the third full operating year. However, the hospital would have an extra piece of equipment it does not need.

Table 2, Column h shows that IMH would easily meet the cardiac catheterization performance standard for one full and one shared lab. And Column (i) shows that the program of one shared and one fixed cardiac catheterization equipment would function at 72 percent of the full capacity benchmark of 1500 weighted procedures per fixed unit and 225 for each shared unit. Column I accords a weight of 1.75 to Device Cases, which is the same weight accorded to therapeutic cardiac catheterization procedures. IMH has demonstrated that this is an efficient program. Importantly, it requires no net change in equipment inventory

In reading this table, be aware that the SMFP sets a threshold for new equipment at 1200 weighted catheterizations, but the cardiac catheterization performance standard for the third year is based on 60 percent of capacity or 900 procedures for fixed and 225 procedures for shared equipment.

Table 2—Iredell Memorial Hospital Historical Cardiac Catheterization Procedures: FY17 to FY20 and Forecast through FY22

Fiscal Year	Weighted Caths	% Catheterization Capacity (1500)	% New Catheterization unit Threshold (1200)	Weighted Vascular Cases	Device Cases	Total Weighted Procedures (Cath + Vascular)	Two Labs (Full Catheterization and Shared)		Full +Shared % Capacity (3000).
							Two Full % Required Cath Performance (1800)	Full +Shared % Required Cath Performance 1231(1,125)	
Notes	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)
ACTUAL									
FY 2017	1017.25	68%	85%	553	243	1,814	**57%**	**90%**	60%
FY 2018	931.25	62%	78%	553	257	1,742	**52%**	**83%**	58%
FY 2019	1124.5	75%	94%	625	282	2,031	**62%**	**100%**	68%
FY 2020 (Covid)	734.5	49%	61%	574	266	1,575	**41%**	**65%**	52%
FORECAST									
FY 2021 (March to May Annualized)	960	64%	80%	602	322	1,884	53%	**85%**	63%
Projected FY 22 (j)	1,231	82%	103%	602	322	2,155	68%	109%	**72%**

Notes

- *(a) Per SMFP weights 1.75 per interventional; and 1.0 per diagnostic*
- *(b) 1500 annual weighted procedures (total room capacity)*
- *(c) 1200 annual weighted capacity (80% room capacity)*
- *(d) Schedule 2 hours per case; 95% involve diagnostic and intervention (1.75 equivalents per case)*
- *(e) Schedule 2 hours per case; (1.75 equivalents per case)*
- *(f) Sum of weighted procedures (all modalities)*
- *(g) (a)/1800 (2 rooms at 60% capacity as required by 10NCAC.1603(a)(1). = 1800 weighted catheterizations)*
- *(h) (a)/1,125 (1 room at 60% capacity and one room at 225 catheterizations per 10ANCAC14C.1603(d)(1)*
- (i) *(f)/3000 (2 rooms at full capacity (3000 equivalents)*
- (j) *Forecast trend for cardiac catheterizations based on Nov 2020 – June 2021*

EFFICIENCY IS ESSENTIAL TO COST CONTROL

Clearly IMH needs more capacity than its current CON's permit. Based on state average cardiac catheterization rates, need of the primary IMH user population will not reach full second catheterization lab utilization for a long time. Sadly, the SMFP has no provision for a hospital to grow bigger than one but less than two full labs.

Iredell Memorial has the equipment with trained and high proficiency staff teams in place. The two labs share one control room; and during the COVID emergency, under Executive Order 139, IMH is using the equipment today in a high-quality cardiovascular program, providing both cardiac catheterization and vascular procedures to the same at-risk population.

Unfortunately, 30 days after the Covid Emergency officially ends, IMH will be required to cease using the shared fixed lab for cardiac procedures.

Iredell Memorial is just asking to make the exemption permanent.

By using both a cardiac catheterization and angiography functions on the approved angio / vascular equipment, Iredell Health now saves 20 minutes between cases. This reduces overtime and produces a cost savings of about $175,000 a year. Just as important, IMH staff are happier, because they get time with their families. IMH patients are happier because Iredell Health is not asking them to come in early in the morning and late at night for diagnostic cardiac catheterizations. IMH physicians are happier because their clinic schedules are more predictable and they have less competition for the cardiac catheterization lab slots. The arrangement works for the vascular program as well. It is busy, but it was not using all of the available equipment time.

LABOR SHORTAGE RELIEVED BY EFFICIENT SCHEDULING CAPACITY

Recruiting highly qualified cardiac catheterization physicians and techs is difficult. It took Iredell Memorial two years to replace one cardiologist; specially trained and willing to do complex procedures. Today, IMH schedules tech and nursing staff on overlapping shifts that cover 11-12 hours a day, 7A to 5P, even with two units in service. And staff are willing to work this schedule. It is more difficult to recruit staff to work a regular later schedule and take STEMI call. It is important to note that today, nurses and techs are just as difficult to recruit and retain as physicians. Maintaining high quality outcomes requires that IMH retain these highly qualified staff. The proposed solution accomplishes that goal.

With sudden loss of flexibility in the schedules, Iredell Memorial risks loss of physicians, nurses, and tech staff. All are in short supply nationally and are heavily recruited.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS NOT MADE

If the SHCC does not grant the petition for adjusted need, then, 30 days after the Emergency Order ends, IMH will lose everything gained. Patients, staff, and physicians will lose critical access equipment and staff that are in place and paid for. History already provides evidence that other cardiac catheterization laboratories in Iredell County will not necessarily gain more patients. Those programs have had low volumes, or declining cardiac catheterization procedures while the IMH grew.

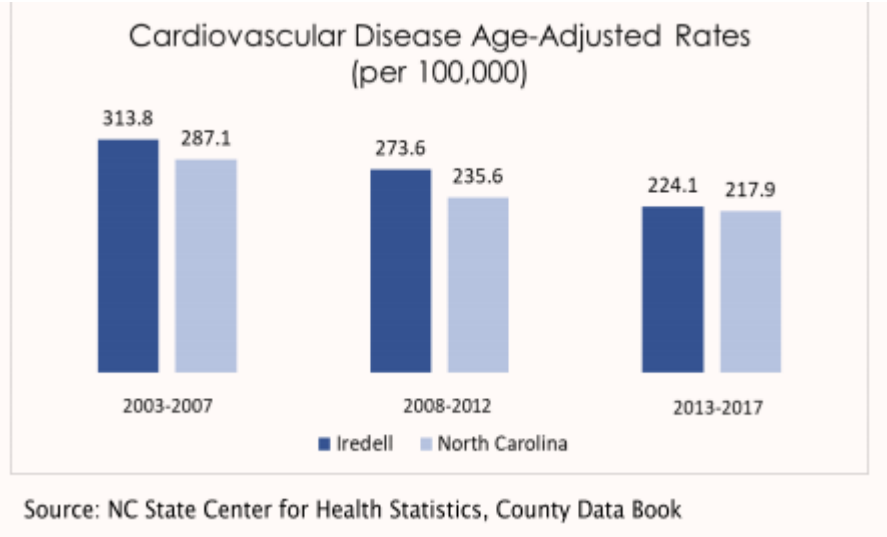
LOSS OF EFFICIENT INNOVATION DEVELOPED IN RESPONSE TO PANDEMIC

Without the requested adjustment, the innovation associated with the EO 139 Exemption will be lost after the COVID emergency ends. Eight cardiologists will be forced to schedule all cardiac catheterization procedures in one room. Staff will be required to work overtime. Patients will compete for daylight appointments and scheduled cases will be moved for emergencies. Rescheduling will be a frequent inconvenience for non-emergent patients.

HEART DISEASE AND VASCULAR DISEASE IN IREDELL COUNTY

Looking at county cardiovascular disease rates alone (Figure 1 below) might lead the reader to think that declines in need for cardiac catheterization equipment are imminent. Such is not the case. Iredell County cardiovascular disease rates are dropping, but NC Office of Budget and Management and Census data in Table 3 indicate that Iredell County population is increasing. Together, these indicate that the cases are not going away. Figure 1, shows that from 2013-2017, 224.1 Iredell County residents per 100,000 population had higher cardiovascular disease rates than the state as a whole.

Figure 1—NC Cardiovascular Disease Age-Adjusted Rates per 100,000 population



Source: NC State Center for Health Statistics, County Data Book

Table 3—Iredell County Population Forecast 2020-2025

	July 2020	July 2021	July 2022	July 2023	July 2024	July 2025
Population	183,309	185,011	187,525	18,9994	192,458	194,916
Percent Change		0.9%	1.4%	1.3%	1.3%	1.3%

Source: NCOSBM July 2021

Iredell County residents alone will need more than 1500 weighted cardiac catheterizations in 2022. This assumes the population will use cardiac catheterization at the average NC 2019 rate of 6.93 caths per 1,000 residents[2]. Also, Iredell County's population is older than the state, with a median age of 40.7 years compared to 39.5 years.

[2] DHSR Medical Facilities Database

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

ALTERNATIVE 1: STATUS QUO

In this case, the Status Quo permitted under the Executive Order 139 Exemption is the most effective alternative. However, the only way to make it permanent is for the 2022 SMFP to include the proposed adjustment. With COVID rates increasing, the Executive Order may extend into 2022, but it will eventually end.

ALTERNATIVE 2: RETURN TO SINGLE FIXED CARDIAC CATHETERIZATION LABORATORY

As discussed, this is not an effective alternative. Other facilities in the county do not offer the same high standard cardiovascular program, and there will not be enough flexibility in Iredell Health's schedule for physicians to efficiently care for patients. Equipment and staff use will be inefficient and more costly to operate, over time will increase and labor costs will go up proportionately. Patients may be referred out of county to obtain comparable quality care.

ALTERNATIVE 3: CONSIDER ADDITIONAL CATHETERIZATION ONLY LAB

Population based need forecasts indicate that another full fixed catheterization lab is more than the county needs. If the 2022 SMFP included an adjusted need for one more dedicated fixed catheterization lab, the resultant Certificate of Need could involve inefficient use of capital; this is unnecessary at this time.

ALTERNATIVE 4: MOVE SUITE TO AMBULATORY SURGERY CENTER

In 2019, CMS began permitting and paying for cardiac catheterization procedures in ambulatory surgery centers. Though moving the program out of the hospital, or moving some cardiac catheterization procedures out of the hospital, might seem to be a less costly alternative, because billing rates would be lower, it is not more effective in Iredell County. The level of need in the county is too small to support efficiency in both a strong hospital program and a freestanding program. Both would suffer. A freestanding program would not offer emergency STEMI care, and the STEMI care alone will not support a cardiac catheterization program at the hospital. Hence, moving cardiac catheterization to a new laboratory in a surgery center is a less effective alternative. It would not have emergency capacity, would not have same hours; might not have volume to sustain cost of the operation.

ALTERNATIVE 5: DROP THE CONDITIONAL VOLUME REQUIREMENT

Similarly, without the proposed restrictive volume condition, another provider could enter the county and offer outpatient only cardiac catheterization services. This might reduce charges for some

patients, but the gain required to support that program would require significant reduction of procedures at IMH and could jeopardize the STEMI program. This is not an effective alternative. Without that wording, an existing provider could propose to build a program that would compete for the limited number of catheterization procedures in the service area.

EVIDENCE OF NO UNNECESSARY DUPLICATION OF SERVICES

Approval of this proposed adjustment requires no capital Investment in equipment or labor. As such it would involve no unnecessary duplication. The workload has already developed in the IMH program. The petition requests only permission to continue using it.

Existing equipment has the technology to do either cardiac catheterization or angiography procedures by changing the settings. This capability came with the equipment at no extra cost.

Precedent for an adjusted cardiac catheterization equipment need determination in a county with excess cardiac catheterization laboratory capacity was set in the 2017 SMFP. That SMFP has a special need for an additional fixed cardiac catheterization lab for Wake County. The SHCC agreed that

> *using the capacity definitions in the SMFP, Rex [the petitioner] had a deficit of 1.78 cardiac catheterization labs, which indicates a need for two additional labs.*

The petition noted:

> *"Of utmost importance, Rex's capacity issues have a negative impact on patients including long wait times, cancelled procedures, unnecessary overnight stays, and more. These procedures are needed to improve the health of patients and the delays that result from equipment operating above its optimal capacity also delay their recovery and return to normal life.*
>
> *While the overall growth trends in Wake County can be accommodated by each of the other providers in the county with excess capacity, it is Rex's remarkable and unique growth, which has not been experienced by other cardiac catheterization providers in the state, that drives the need for an adjusted need determination for two additional units of cardiac catheterization equipment in Wake County.*
>
> *Despite these expanded hours, scheduled cases often finish after 9:30pm. These last patients must fast for an extended period prior to their procedure and then stay in the hospital overnight for observation.[3]"*

Following substantial debate, the SHCC supported the petition and accepted the petitioner's arguments that:

- shared equipment Use Agreements do not really solve capacity issues in quality cardiac catheterization programs that are operating at capacity.
- the current reimbursement landscape of bundled payments is most efficiently addressed

[3] UNC Rex Petition for Fixed Cardiac Cath Lab, 2016]

when the entire program operates in a single facility,
- evidence in the SMFP's demonstrate that excess capacity does not relieve high utilization at other providers; and
- addition of capacity in a service area does change the situation at existing providers.

Iredell County nor IMH is at the same scale as Wake County and Rex Hospital. However, Iredell faces the same patient care issues.

The SHCC denied Iredell Memorial's 2011 request for this same adjusted need determination, because Iredell Memorial's program history showed declining procedures. Table 1 in this petition and internal data indicate procedures are trending up today. Had the COVID pandemic not occurred, Iredell Memorial Hospital cardiac catheterization laboratory would have operated at or above 1,200 procedures in 2020 and will operate at that rate in 2022, even with conservative trends that include COVID months.

EVIDENCE OF CONSISTENCY WITH NORTH CAROLINA STATE MEDICAL FACILITIES PLAN

BASIC GOVERNING PRINCIPLES

1. Safety and Quality

This basic principle notes:

> "*…priority should be given to safety, followed by clinical outcomes, followed by satisfaction.*
>
> *"…As experience with the application of quality and safety metrics grows, the SHCC should regularly review policies and need methodologies and revise them as needed to address any persistent and significant deficiencies in safety and quality in a particular service area*."

Iredell Health has demonstrated that it can sustain high quality on shared fixed equipment through its current arrangements. Outpatients are now 65 percent of patients. Trying to maintain the program by scheduling later hours will risk losing patients, who may forego critical procedures. It will risk losing critical staff retention, may cause physician burnout.

Data in Attachment A demonstrate that Quality has been achieved.

Further, physicians and cardiac catheterization programs have learned that when physicians can work with a consistent staff at a single location, they can better maintain the number of procedures required to maintain quality proficiency.

2. Access

This basic principle notes:

> "*…The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.*
>
> *"…The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards."*

When Iredell Heath cannot accommodate a patient, the nearest facilities with the experience recommended by the AHA/ ASC Guidelines for Cardiac Catheterization are in Hickory, Charlotte, and Winston Salem. Automobile travel is the only transportation option for non-emergencies. For some people, travel on I-40 and I-77 represent sufficient risks to avoid the trip and skip the procedure.

Finally, Iredell Health's mission to be accessible to all residents of the county is demonstrated in its high combined charity, self-pay Medicare, and Medicaid statistics. According to 2021 Licensure Renewal Reports, 72 percent of IMH emergency room visits were associated with these groups of medically underserved residents.

3. Value

This basic principle notes:

> *"The SHCC defines health care value as the maximum health care benefit per dollar expended.*
>
> *"…Cost per unit of service is an appropriate metric…*
>
> *" …At the same time overutilization of more costly and/or highly specialized low-volume services without evidence-based medical indication may contribute to escalating health costs without commensurate population-based health benefit."*

This request requires zero capital investment.

Iredell Health has demonstrated that it can save $150,000 to $175,000 annually, in labor costs alone with this arrangement. With staff and equipment already paid for, costs go down as volume goes up.

CONCLUSION

The proposed changes are consistent with and support the Basic Principles that govern the *SMFP*. This is a unique opportunity to grant a petition for a special need in the SMFP that will require no capital expenditure. It would grant residents of Iredell County continued access to an efficient cardiovascular program that has demonstrated a cost savings and high-quality ratings.

ATTACHMENTS:

Attachment A

NC Quality Center Heart Program Dashboard Report

Quality Dashboard for Iredell Health System

HCAHPS Patient Perceptions Survey	7/13 - 6/14
Rate 9 or 10 Overall	71.0%
Always Clean and Quiet	62.5%

PSO Member


This report developed by
the North Carolina Quality Center.

Conditions	Optimal Care Score	Mortality Rate	Readmission Rate
	7/13 - 12/13	7/10 - 6/13	7/10 - 6/13
Heart Attack (HA)[a]	97.9%	14.7%	17.1%
Heart Failure (HF)[a]	95.2%	9.8%	23.8%
Pneumonia (PN)	96.5%	12.8%	18.3%
Surgical Care (SCIP10)	97.2%		

Color Coding
Top Quartile
2nd Quartile
3rd Quartile
Lowest Quartile
No Data

Measure Benchmarks	NC 25th %-ile Score[b]	NC 50th %-ile Score[c]	NC 75th %-ile Score[d]
Rate 9 or 10 Overall	66.0%	71.0%	75.0%
Always Clean and Quiet	63.8%	67.0%	70.5%
Optimal Care HA Score	96.9%	100.0%	100.0%
Optimal Care HF Score	92.5%	97.9%	100.0%
Optimal Care PN Score	95.0%	97.0%	99.2%
Optimal Care SCIP Score	94.5%	96.7%	98.5%
HA 30-Day Mortality Rate	15.7%	14.9%	14.3%
HF 30-Day Mortality Rate	12.9%	12.1%	11.3%
PN 30-Day Mortality Rate	13.7%	12.4%	11.2%
HA 30-Day Readmit Rate	18.2%	17.7%	17.1%
HF 30-Day Readmit Rate	23.4%	22.6%	21.7%
PN 30-Day Readmit Rate	18.1%	17.2%	16.6%

The PSO MEMBER box represents membership in ANY federally listed Patient Safety Organization (PSO) as reported to the North Carolina Quality Center.

[a]Optimal Care Scores do not use quartiles: Red 0%-89.9%, Yellow 90.0%-94.9%, Green 95.0%-97.9%, and Blue 98.0%-100%.

[b]Hospitals with a score worse than the NC 25th %-ile score/threshold fall in the lowest 4th quartile.

[c]Hospitals with a score equal to or better than the 25th %-ile but worse than the 50th %-ile fall in the 3rd quartile.

[d]Hospitals with a score equal to or better than the 50th %-ile but worse than the NC 75th %-ile threshold fall in the 2nd quartile.
A score equal to or better than the 75th %-ile puts a hospital in the top, most favorable quartile.
A hospital with apparently equal scores to a quartile threshold may fall to a lower quartile because rounded scores are displayed.

Attachment B

Iredell Memorial Hospital Monthly Actual and Forecast Cardiac Cath Procedures

Actual and Forecast Cardiac Catheterization Procedures by Month FY 2021 through FY 2023 - Plus Dr. Allen Only

Fiscal Year	Calendar Year	Month	Actual IMH Cardiac Caths					Cum tot Weighted Caths	annualized rate	Nov-Jun 2021 Linear Trend			Dr Allen	
			Dx cath	Cath Eqiv	Pci/DES	Cath Equiv	TOTAL			Mo total	cum tot wt caths	annual rate	wt caths	cum tot
2021	2020	October	56	56	12	21	77		924					
		November	37	37	8	14	51	128	612					
		December	38	38	11	19	57	108.25	687					
	2021	January	36	36	12	21	57	114.25	684					
		February	47	47	13	23	70	126.75	837					
		March	64	64	20	35	99	168.75	1188					
		April	53	53	16	28	81	180.000	972					
		May	39	39	12	21	60	141.000	720					
		June	51	51	9	16	67	618.750	801					
		July	63	63	12	21	84	702.422	1004					
		August								82	785	990	30.667	816
		September								85	870	1022	30.667	901
2022		October								88	88	1054	30.7	118.5
		November								91	178	1086	30.7	239.7
		December								93	272	1118	30.7	363.5
	2022	January								96	367	1150	30.7	490.1
		February								99	466	1183	30.7	619.3
		March								101	567	1215	30.7	751.2
		April								104	671	1247	30.7	885.8
		May								107	778	1279	30.7	1023.1
		June								109	887	1311	30.7	1163.0
		July								112	999	1344	30.7	1305.6
		August								115	1114	1376	30.7	1450.9
		September								117	1231	1408	30.7	1598.9
2023		October								120	120	1440	30.7	150.7
		November								123	243	1472	30.7	304.0
		December								125	368	1504	30.7	460.1
	2023	January								128	496	1537	30.7	618.8
		February								131	627	1569	30.7	780.2
		March								133	760	1601	30.7	944.3
		April								136	896	1633	30.7	1111.0
		May								139	1035	1665	30.7	1280.5
		June								141	1177	1698	30.7	1452.6
		July								144	1321	1730	30.7	1627.4
		August								147	1468	1762	30.7	1804.9
		September								150	1617	1794	30.7	1985.1

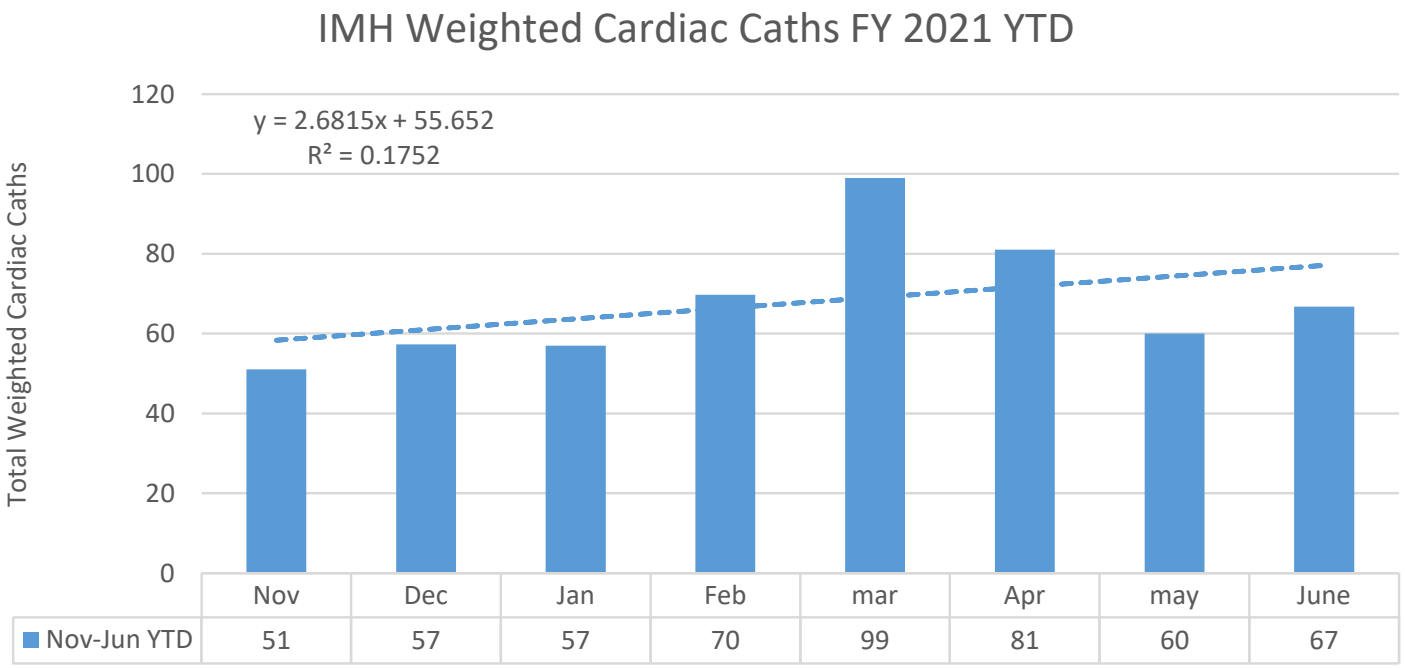
a Weights 1.75 per PCI

b Dr. Allen brings 368 wt caths per year to IMH, which represents 80 percent of his historical Statesville only practice

c Trendline based on Nov-June only

Attachment C

IMH Nov 2020 – June 2021 Cath Trendline


IMH Weighted Cardiac Caths FY 2021 YTD
Total Weighted Cardiac Caths
y = 2.6815x + 55.652
R² = 0.1752
120
100
80
60
40
20
0
Nov
Dec
Jan
Feb
mar
Apr
may
June
Nov-Jun YTD
51
57
57
70
99
81
60
67