REQUIRED STATE AGENCY FINDINGS
FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date:	January 27, 2023
Findings Date:	February 3, 2023
Project Analyst:	Donna Donihi
Co-Signer:	Micheala L. Mitchell
Project ID #:	F-12267-22
Facility:	Iredell Memorial Hospital
FID #:	933284
County:	Iredell
Applicant:	Iredell Memorial Hospital, Incorporated
Project:	Develop a hospital-based outpatient dialysis center with no more than 4 stations pursuant to Policy ESRD-3.

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Iredell Memorial Hospital, Inc. (hereinafter referred to as IMH, or "the applicant") proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and outpatients classified as "observation" patients.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2022 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2022 SMFP, on pages 22-23, which is applicable to this review: *Policy ESRD-3: Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus* which states:

> *"Licensed acute care hospitals (see stipulations in G.S. 131E-77 (e1) may apply for a certificate of need to develop or expand an existing Medicare-certified kidney disease treatment center (outpatient dialysis facility) without regard to a county or facility need determination if all the following are true:*
>
> 1. *The hospital proposes to develop or expand the facility on any campus on its license where general acute beds are located.*
> 2. *The hospital must own the outpatient dialysis facility, but the hospital may contract with another legal entity to operate the facility.*
> 3. *The hospital must document that the patients it proposes to serve in an outpatient dialysis facility developed or expanded pursuant to this policy are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus.*
> 4. *The hospital must establish a relationship with a community-based outpatient dialysis facility to assist in the transition of patients from the hospital outpatient dialysis facility to a community-based facility wherever possible.*
>
> *The hospital shall propose to develop at least the minimum number of stations allowed for Medicare certification by the Centers for Medicare and Medicaid Services (CMS). Certificate of need will impose a condition requiring the hospital to document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need."*
>
> *The performance standards in 10A NCAC 14C .2203 do not apply to a proposal submitted by a hospital pursuant to this policy."*

In Section B.6, pages 19-20, the applicant explains why it believes its application is consistent with Policy ESRD-3. The applicant states the following:

- The proposed project involves the development of an outpatient dialysis facility located on the campus of IMH, an acute care facility with general acute care beds.

- The applicant certifies that the proposed outpatient dialysis facility will be owned by IMH.

- The applicant documents that the patients proposed to be served are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus. On page 20, the applicant defines these patients as:

    - *Patients whose usual outpatient renal dialysis provider may be miles away in another county.*
    - *Patients who are, by definition, too ill to travel alone to an outpatient dialysis facility.*
    - *Patients that have wounds that would be at risk of harm with multiple transfers from bed to stretcher to dialysis facility and back.*
    - *Patients that are still healing from surgeries. In the hospital, these patients can remain in their beds and be wheeled directly to the Dialysis Unit and back without transfer risks.*

- The applicant documents its relationship with Statesville Dialysis Center and other community-based outpatient facilities. Exhibit I.2 contains a letter from the Nurse Administrator of Statesville Dialysis Center, confirming Statesville's relationship with IMH to transition patients to community providers in the area as well as other community-based outpatient facilities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion. The applicant adequately demonstrates that the proposal is consistent with Policy ESRD-3 based on the following:

- The applicant adequately demonstrates a plan to retain its outpatient dialysis facility located at an acute care facility with general acute care beds on the main campus of IMH.

- The applicant certifies that IMH will own the outpatient dialysis facility.
- The acuity of the applicant's patients is inappropriate for outpatient dialysis services in the community.
- The applicant adequately demonstrates its relationship with the outpatient community dialysis in the service area and their support in transitioning patients to community providers in the area.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, low-income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center with no more than four stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The Applicant proposes to obtain approval to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as "observation" patients.

Patient Origin

On page 115, the 2022 SMFP defines the service area for dialysis stations as *"The service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties*." Thus, the service area for this facility consists of Iredell County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 21-22, the applicant states it has been certified to provide ESRD renal dialysis for years. On December 21, 2021, IMH obtained CMS certification to provide outpatient dialysis services, so that it could be reimbursed to provide routine renal dialysis to patients in its Skilled Nursing Facility (SNF) Unit who have ESRD. The proposed project involves the development of a new hospital-based, outpatient dialysis center. The applicant has been providing services as referenced in the application since obtaining CMS certification. In

supplemental information the applicant provides the tables below that illustrate the historical and projected patient origin for IMH dialysis patients as summarized below.

County	Iredell Memorial Hospital Historical Dialysis Patient Origin					
	Last Full FY 10/1/2020 to 09/30/2021					
	# of In-Patients not Peritoneal	% of Total	# of Home Hemodialysis Patients (SNF)	% of Total	# of Peritoneal Dialysis Patients	% of Total
*Iredell**	*535*	*77.5%*	*54*	*89%*	*126*	*77.5%*
Rowan	38	5.5%	0	0%	9	5.5%
*Alexander**	*47*	*6.8%*	*5*	*7%*	*11*	*6.8%*
Davie	-	0.0%	0	0%	0	0.0%
Wilkes	17	2.4%	0	0%	4	2.4%
Cabarrus	12	1.8%	2	4%	3	1.8%
Caldwell	-	0.0%	0	0%	0	0.0%
Catawba	26	3.8%	0	0%	6	3.8%
Stanly	3	0.4%	0	0%	1	0.4%
Surry	5	0.7%	0	0%	1	0.7%
Yadkin	3	0.4%	0	0%	1	0.4%
Lexington	3	0.4%	0	0%	1	0.4%
Lincoln	2	0.2%	0	0%	0	0.2%
Total	**691**	**100%**	**61**	**100%**	**162**	**100%**

*Source: Section C, page 23 *SNF. Data are from IMH internal database. Nursing home patients were treated as inpatients and not billed. Peritoneal patients are not included in the Inpatient count.*
** italicized identify primary service area.*

The following table summarizes the projected patient origin at IMH in the second full fiscal year (FY) of operations, calendar year (CY) 10/1/2024- 9/30/2025.

Iredell Memorial Hospital Projected Patient Origin						
County	Second Full FY 10/01/2024 to 09/30/2025					
	# of Inpatient Patients	% of Total	# of Home Hemodialysis Patients	% of Total	# of Peritoneal Dialysis Patients	# of Home
Iredell	641	75.8%	29	89%	130	76%
Rowan	107	12.6%	0	0%	22	13%
Alexander	59	7.0%	2	7%	12	7%
Davie	15	1.8%	1	0%	3	2%
Wilkes	6	0.7%	0	0%	1	1%
Cabarrus	2	0.2%	0	4%	0	0%
Caldwell	2	0.2%	0	0%	0	0%
Catawba	2	0.2%	0	0%	0	0%
Forsyth	2	0.2%	0	0%	0	0%
Gaston	2	0.2%	1	0%	0	0%
Hampshire	2	0.2%	0	0%	0	0%
Montgomery	2	0.2%	0	0%	0	0%
Stanly	2	0.2%	0	0%	0	0%
Surry	2	0.2%	0	0%	0	0%
Total	**846**	**100.0%**	**60**	**100%**	**171**	**100%**

Source: Section C, page 24

In Section C, pages 22 and 26, and in supplemental information, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant based its projected patient origin on the historical number of dialysis patients at IMH by county.
- The applicant has the only existing hospital-based outpatient dialysis center in the service area.
- The applicant assumes that the patient origin percentages will mirror that of its existing inpatient dialysis operations.

Analysis of Need

In Section C, pages 26-28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

To demonstrate the need for the proposed project, the applicant begins by identifying the proposed service area for the new outpatient dialysis center. In Section C page 23, the applicant states that IMH is the only provider of inpatient dialysis provided, 24/7 in Iredell County. The applicant's 48-bed Distinct Part SNF provides services to 480-560 patients per year, of which 12% have ESRD. IMH serves patients from all over the state. IMH's historical patient origin serves a 30-county service area, which includes a primary and secondary service area, as shown in the table below.

SNF Patient Origin 2019-2021	
Primary	
Iredell	
Alexander's	
Secondary	
Rowan	Stanley
Davy	Surry
Catawba	Brunswick
Yadkin	Buncombe
Mecklenburg	Burke
Wilkes	Cherokee
Other	Haywood
Caldwell	McDowell
Wilson	Orange
Gaston	Person
Lincoln	Union
South Carolina	Wake
Cabarrus	Georgia
New Hanover	Virginia

Source: Exhibit C.5a page 3

In section C. pages 27-28, the applicant used data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the need based on the population growth trends in the service area. The applicant states that between 2020 and 2024, the primary service area is projected to increase at a compound annual growth rate ("CAGR") of 0.84 percent. The applicant states, 97 percent of their SNF residents, originate from Iredell and adjacent counties: Alexander, Rowan, Davie, Catawba, Yadkin, and Wilkes.

Service Area Total Population Growth

County	CY20	CY21	CY22	CY23	CY24	CY25	CY26	CY27
Iredell	*187,694*	*191,180*	*194,835*	*198,674*	*202,512*	*206,348*	*210,187*	*214,025*
Alexander	*36,372*	*36,145*	*35,984*	*35,916*	*35,863*	*35,864*	*35,866*	*35,869*
Rowan	147,281	147,817	148,685	149,010	149,662	150,169	151,166	152,164
Catawba	160,924	161,909	163,042	164,334	165,619	166,910	168,195	169,485
Davie	42,822	43,283	43,738	44,211	44,211	45,164	45,637	46,113
Wilkes	65,827	65,378	64,988	64,665	64,342	64,021	63,708	63,397
Yadkin	37,187	37,081	37,015	36,996	36,982	36,970	36,961	36,958
Total	678,107	682,793	688,287	693,806	699,667	705,446	711,720	718,011

Source: Section C, page 32; 2019 NCOSBM Italicized font indicates primary service area

Age 45-64 Population Growth by County

County	**CY20**	**CY21**	**CY22**	**CY23**	**CY24**	**CY25**	**CY26**	**CY27**
Iredell	*54,967*	*55,755*	*56,494*	*57,096*	*57,584*	*58,060*	*58,651*	*59,309*
Alexander	*10,264*	*10,065*	*9,925*	*9,846*	*9,756*	*9,674*	*9,582*	*9,482*
Rowan	38,976	38,652	38,471	38,136	37,854	37,504	37,395	37,263
Catawba	44,926	44,772	44,735	44,738	44,704	44,550	44,353	44,188
Davie	12,135	12,167	44,735	12,111	12,120	12,154	12,165	12,204
Wilkes	17,803	17,453	17,132	16,769	16,086	16,086	15,741	15,398
Yadkin	10,447	10,289	10,142	10,001	9,668	9,668	9,512	9,392
Total	**189,518**	**189,153**	**189,060**	**188,697**	**187,696**	**187,696**	**187,399**	**187,236**

Source: Section C, page 33; 2019 NCOSBM Italicized font indicates primary service area

Age 65+ Population Growth by County

County	**CY20**	**CY21**	**CY22**	**CY23**	**CY24**	**CY25**	**CY26**	**CY27**
Iredell	*31,029*	*32,236*	*33,513*	*35,019*	*36,511*	*38,083*	*39,609*	*41,142*
Alexander	*7,452*	*7,564*	*7,653*	*7,760*	*7,860*	*7,996*	*8,133*	*8,277*
Rowan	26,981	27,627	28,365	29,057	29,808	30,643	31,407	32,163
Catawba	29,936	30,845	31,784	32,780	33,722	34,786	35,765	36,723
Davie	14,523	14,523	14,523	9,997	10,275	10,557	10,848	11,120
Wilkes	14,523	14,523	14,523	14,523	14,627	14,744	14,868	14,978
Yadkin	7,475	7,564	7,641	7,747	7,877	8,019	8,134	8,250
Total	**126,233**	**129,516**	**133,006**	**136,883**	**140,680**	**144,828**	**148,764**	**152,653**

Source: Section C, page 33; 2019 NCOSBM Italicized font indicates primary service area

To demonstrate the need for the proposed project, the applicant refers to the growing needs of ESRD patients. ESRD is common among the middle-aged and elderly. The applicant states that the Distinct SNF unit population is age 50 plus, of which 12% require dialysis. The 65+ population is showing the highest growth projections. Based on data from the NCOSBM, the table demonstrates the percentage of growth by age group and county in the proposed service area, across five years the population 65 years of age and older will increase by 2 percent, adding 26,300 people by 2026 in Iredell County.

Growing Needs of ESRD Patients

To demonstrate the need for the proposed project, the applicant refers to the growing needs of ESRD patients The applicant calculates the 4 years (CAGR) for the population aged 65 from (2022-2026). Iredell County dialysis patients would increase by 4.27% and Alexander County by 1.53%. The total primary population will increase by 3.77% CAGR. The historical trends for dialysis will continue for acute care and SNF. IMH assumes that the patient population will increase with the rate of change for Iredell and Alexander counties. The following tables illustrate these growth trends.

The applicant projects that the prevalence of ESRD in the proposed service area will continue to grow at a similar rate. The applicant also refers to the number of ESRD patients using in-center dialysis services at a community dialysis center in the service area where the proposed outpatient dialysis center will be located. The following tables illustrate the growth trends stated below.

Incidence and Prevalence of ESRD by Age in North Carolina								
Age	**2019**	**2018**	**2017**	**2016**	**2015**	**2014**	**2013**	**2012**
0-17	13.4	12.8	12.2	10.6	11.3	11.5	11.9	11.1
18-29	9.9	10.3	10.2	10.7	10.3	9.7	10.0	10.7
30-39	10.7	10.1	9.8	10.0	9.9	9.9	9.8	10.0
40-49	9.8	9.8	9.7	9.8	9.8	9.9	9.8	10.1
50-59	10.8	10.8	10.8	10.8	10.6	10.7	10.8	11.3
60-64	11.6	11.4	11.4	11.4	11.6	11.5	11.6	12.1
65+	57.1	58.1	58.8	58.4	59.6	58.5	61.2	63.9

Source Exhibit C.5c

The applicant refers to the incidence count and prevalence of ESRD in North Carolina and the growing need for ESRD patients in the proposed service area. The applicant states that the growth in North Carolina is mirrored in IMH's 30-county service area. According to data from USRDS, incidence of ESRD in IMH's service area from 2012 to 2019

Estimated ESRD Patients in the Counties that Refer to IMH SNF

	FY20	FY21	FY22	FY23	FY24	FY25
7-County ESRD Patient Estimate	1,308	1,319	1,330	1,341	1,353	1,364

Source: Section C page 27.
a. Prior year times 1.0084
b. Population CAGR for 2022 through 2026 is 0.84% for the 7 counties.

Primary Service Area Population	**CY 2022**	**CY 2023**	**CY 2024**	**CY 2025**	**CY 2026**	**CAGR 65+**
Iredell	33,513	35,019	36,511	38,083	39,069	4.23%
Alexander	7,653	7,760	7,860	7,996	8,133	1.53%
Service Area Population	41,166	42,779	44,371	46,079	47,742	3.77%

Source: Section Q page 88

The applicant states, 97 percent of their SNF residents, originate from Iredell and adjacent counties: Alexander, Rowan, Davie, Catawba, Yadkin, and Wilkes. The population 65 years

of age and older will increase by 2 percent, adding 26,300 people by 2026 in Iredell County. In section C page 26, the applicant states: IMH, Distinct SNF unit population is age 50 plus, of which 12% require dialysis. IMH has four fixed and three mobile dialysis stations already in service at IMH. The applicant calculates the 4 years (CAGR) for the population age 65 from (2022-2026). Iredell County dialysis patients would increase by 4.27% and Alexander County by 1.53%. The total primary population will increase by 3.77% CAGR. The historical trends for dialysis will continue for acute care and SNF. IMH assumes that the patient population will increase with the rate of change for Iredell and Alexander counties.

The information is reasonable and adequately supported based on the following:

- The applicant applies the North Carolina Office of State Budget and Management predictions of a compound annual growth rate ("CAGR") of 0.61 percent between 2022 and 2027.
- The applicant provides data showing the population growth in the service area, particular those 65 and over who tend to utilize more health resources, including ESRD services.
- The applicant's proposal is in response to ESRD patients who are inappropriate for treatment, or unable to receive treatment, in a community setting.
- The applicant relies on growth trends and historical utilization of its existing inpatient dialysis unit to justify the need
- The applicant uses the NCOSBM, to predict the population 65 and over will increase by a CAGR of two percent growth for the patients from all counties being served at IMH.

Forecast Need

In Section Q, page 82, the applicant provides historical and projected utilization based on its historical patient origin. The applicant applies two methods to forecast the need for ESRD at IMH. The need is determined by applying forecast population increases to the population of Iredell and Alexander County, as forecast by the North Carolina Office of Budget and Management ("NCOSBM") to IMH total and SNF dialysis patients in its 48-bed SNF.

Iredell Memorial Hospital Projected Utilization			
Utilization	**Last FFY 10/01/2020-09/30/21**	**1st FFY 10/01/23-9/30/24**	**2nd FFY 10/01/24-9/30/25**
In Center Patients			
Average # of Patients during the Year	535	681	692
Ave. # of Treatments/ Patients/Year	2.12	2.11	2.11
Total # of Treatments	1,136	1,440	1,463
Home Hemodialysis Patients			
Average # of Patients during the Year	55	53	54
Ave. # of Treatments/ Patients/Year	4.6	4.58	4.58
Total # of Treatments	253	119	246
Peritoneal Dialysis Patients			
Average # of Patients during the Year	162	84	174

Ave. # of Treatments/ Patients/Year	2.63	2.69	2.69
Total # of Treatments	426	226	467
Total Patients			
Average # of Patients during the Year	752	905	920
Ave. # of Treatments/ Patients/Year	2.41	2.37	2.37
Total # of Treatments	**1,815**	**2,142**	**2,176**

Source Section Q page 79

In Section Q, Form C. page 79, the applicant projects to serve, ESRD, Home Hemodialysis, and Peritoneal Dialysis Patients in its last FFY and in the first two operating years, FFY 2024 (10/1/2023-9/30/2024) and FFY 2025 (10/1/2024-9/30/2025).

The applicant calculates the 4 years (CAGR) for the population age 65 from (2022-2026). Iredell County dialysis patients would increase by 4.27% and Alexander County by 1.53%. The total primary population will increase by 3.77% CAGR. The historical trends of patients on dialysis will continue for the acute care and SNF patients on its existing dialysis stations. IMH assumes that the patient population will increase with the rate of change for Iredell and Alexander counties.

The information is reasonable and adequately supported by the applicant.

Step 1: Identify the Population to be Served by County Through the First Two Fiscal Operating Years.

In section C page 27, the applicant states, "*Most, about 90 percent, come from Iredell and Alexander Counties."* Ninety-seven percent of IMH SNF residents originate from Iredell and adjacent counties: Alexander, Rowan, Davie, Catawba, Yadkin, and Wilkes. The remaining IMH, and SNF residents historically originate from counties in and out of state.

The applicant states from 2019- 2021, with the exception of COVID year 2020, 85 percent of the IMH SNF census is age 65 and older, however, in the Dialysis Unit Census have been more consistent with changes in the total population. Considering this, the applicant estimates the total annual population and that of persons aged 65 and older for these two counties from the North Carolina Office of State Budget and Management("NCOSBM").

As illustrated in the table below, in the second full project fiscal year, the projected population to be served will exceed 242,000 and those over 65 will reach 46,079.

Table 1 **Key population growth 2022 through 2026***

Primary Service Area Counties	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	CAGR 65+
Iredell	33,513	35,019	36,511	38,083	39,069	4.23%
Alexander	7,653	7,760	7,860	7,996	8,133	1.53%
Service Area Population	41,166	42,779	44,371	46,079	47,742	3.77%

Source: NCOSBM Population Forecast by County, accessed 07.28.22
**As a precaution, the applicant extended forecasts to 2026*

Step 2: Calculate Population Growth Rates for the Primary Service Area Counties

In Section Q page 82, the applicant states, the compound annual growth rates (CAGR) for the population age 65 and older for RRI over four years (2022-2026) are:

Table 2

CAGR Age 65 and Older	
Iredell	4.27%
Alexander	1.53%
Total Primary Population	3.77%

Source: Page 82, of the application

Step 3: Project SNF Admissions Cases and Procedures in Proposed Service Area

In Section Q, pages 82-83 the applicant projects SNF admissions by calculating the total population of the service area using NCOSBM data and then calculating the CAGR for the total primary service area using the excel formula for RRI between 2022-2026 as illustrated below.

Table 3

Total Population 2022 through 2026					
Primary Service Area Counties	**2022**	**2023**	**2024**	**2025**	**2026**
Iredell	194,835	198,674	202,512	206,348	210,187
Alexander	35,984	35,916	35,863	35,864	35,866
Service Area Population	**230,819**	**234,590**	**238,375**	**242,212**	**246,053**

Source: Page 82, of the application

Table 4

CAGR for Total Primary Service Area Population	
Iredell	1.9%
Alexander	0.08%
Total Primary Population	1.61%

Source: Page 82, of the application.

In Section Q, page 83, the applicant states, IMH SNF beds are included in the SMFP nursing home need methodology. The county use rates for nursing homes in Iredell County increased between 2020, the COVID impact year, and 2021. In 2021 Iredell's rate was 2.3067 versus a state-wide average of 3.1539 per 1000 population. Although Iredell's growth rate was lower, the upward trend in 2021 was consistent statewide. In the proposed 2023 SMFP, the use rate forecast is 2.108 in FY2026 with a county average use rate of 62.9 percent. The 2022 SMFP applies a lower use rate of (1.924) and forecasts that in 2025, the county occupancy rate will be 75.4%. There is consistency in the Medicare use rates, and because its patients are medically complex with shorter average lengths of stay, SNF admission rates will increase with total population CAGR as indicated in the table.

Table 5

		Estimated IMH SNF Admissions and Days							
		2019	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
a	Admissions	561	495	482	482	490	498	506	514
b	Days	9,726	9,727	9,728	10,402	10,569	10,739	10,912	11,088
c	ALOS	17.3	19.7	20.2	21.6	21.6	21.6	21.6	21.6
d	Days available	17,520	17,520	17,520	17,520	17,520	17,520	17,520	17,520
e	Percent Occupied	56%	56%	56%	59%	60%	61%	62%	63%

Source: Section Q page NCOSBM Population Forecast by County, accessed 07.28.22

**2022 data annualized from 10 months Oct through July.*

Notes:

a. DHSR Facilities database for history to 2021; 10 months FY 2022 annualized from IMH data; 2023 forward= prior year * (1+ population growth CAGR of 1.61%. see Table 4)

b. IMH License renewal applications through 2021; 10 months FY 2022 annualized from IMH data; 2023 forward = Admissions * ALOS

c. Row b divided by row a through 2022; all future years = 2022

d. 48 beds times 365 days (no leap year adjustments)

e. Row b divided by row d.

In Section Q. page 84, the applicant states that given the forecast county use rates in the SMFP and IMH history, these forecasts are reasonable. Using the total population rather than the over-65 population growth to forecast SNF admissions. COVID-19 temporarily decreased admissions and transfers. The applicant assumes that the continued forecast will return to annualized projections moving forward.

Step 4: Project ESRD Cases in Proposed Primary Service Area

In Section Q, page 85, the applicant states that although there was a shift to peritoneal dialysis from in-center, the number of total patients increased from 2020 to 2021.

Table 6

	Estimated Dialysis Patients in Primary Service Area								
		2019	2020	2021	2022	2023	2024	2025	2026
A	Iredell	242	249	247	257	261	265	270	274
B	In Center	213	200	197	212	216	219	233	276
C	Peritoneal	29	49	50	45	45	46	47	48
D	Alexander	54	53	65	60	61	62	63	64
E	In Center	48	48	56	53	54	55	56	56
F	Peritoneal	6	5	9	7	7	7	7	7
G	Primary Service Area	296	302	312	317	322	327	333	338

Source: Section Q page 85.
*Notes: a-f: DHSR Patient County of Origin Reports through 2021. For 2022 forward multiply row g by the average 3-year historic percent of total cases in the primary service area from the table below e.g., Iredell County 2022 = 0.81 * 317=257*

Three-year Average Distribution of Dialysis Patients in Primary Service Area Counties

Iredell	81%
In Center	67%
Peritoneal	14%
Alexander	19%
In Center	17%
Peritoneal	2%
Total Iredell + Alexander	100%

Source: application page 85
g. Total for both counties through 2021, future years forecast at prior year times (1 + 1.61%, the population growth CAGR from Table 4

Step 5: Project ESRD Cases Admitted to Hospital SNF in Primary Service Area

In Section, Q page 86, the applicant states that in 2019, the average admission rate for dialysis patients' admissions is 1.6 -1.8 times a year including observation. The return to hospital rate was an average of 21.5 percent in a 30-day period. The average length of stay is 22 to 44 days per year. Which is an increase from 2019 m of 11.2 days for SNF ESRD admissions. The applicant assumes that 10 percent of acute care patient admissions could become SNF ESRD admissions. The applicant demonstrates in the table below that 60 potential ESRD patients will need SNF following acute admissions in 2025. The applicant calculated the total SNF admissions by dividing the admissions from the tables below by 0.924 as 92 percent of IMH SNF patients are from the primary service area, and then rounding to the nearest whole number.

Table 7

Estimated Annual Hospitalized Dialysis Patients Discharged to SNF Level of Care in Primary Service Area Counties									
		2019	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
a	Hospitalizations	533	544	562	571	580	589	599	608
b	SNF Admissions from Acute	53	54	56	57	58	59	60	61

Source: Section Q page 86

Notes:

a. Dialysis patients from Table 6 row g times 1.8 acute admissions per year.

b. Row times 10 percent discharged to SNF.

Table 8

Estimate Annual Hospitalized Dialysis Patients Discharged to SNF Level of Care in Primary Service Area Counties									
		2019	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
A	SNF ESRD Pts from Primary SA	53	54	56	57	58	59	60	61
B	Total SNF ESRD patients	58	58	61	62	63	64	65	66

Notes:

a. Row b, Table 7

b. Row a divided by 0.924

In section Q page 87, the applicant states, "*Future in-migration will be in constant proportion to historical."*

Conclusion

The forecasted needs for dialysis will continue for the SNF. IMH assumes that the patient population will increase with the rate of change for Iredell and Alexander counties.

The information is reasonable and adequately supported based on the following:

- Dialysis patients are hospitalized 1.8 times a year.
- Acute ESRD patients will continue to transfer to SNF to decrease LOS.
- Future SNF mitigation will remain proportionate to historical.
- The forecast county use rates and IMH history, using the total population rather than the over-65 population growth to forecast SNF admissions.
- The applicant's methodology accounted for the impact of COVID-19 on admissions and transfers.
- The continued forecast will return to annualized projections.

The applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

Forecast Utilization

Step 1: Estimate Annual IMH Nursing Home Admissions for Persons on Dialysis

In Section Q. page 88, IMH uses its past three years' nursing home census and the CAGR for population growth in the primary service area to estimate future nursing home patients. The range for the last three years was 9.3 to 12.7 percent. IMH applies the 2022 rate of 12 percent to the annual SNF resident estimate to estimate future nursing home patients who require dialysis. The applicant assumes that nursing home and dialysis admissions will increase with population CAGR and that readmission rates for dialysis patients will stay constant.

Table 9

	Estimated IMH Nursing Home Bed Patients on Dialysis							
	Estimated Patients Origin *(numbers differ from patient origin data due to readmissions)*	**History**			**Future**			
		2020	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
a	Annual NH Pts. Admitted	495	482	482	490	498	506	514
b	Annual NH Dialysis Admissions	46	61	58	59	60	61	62
c	Percent NH on Dialysis	9.3%	12.7%	12.0%	12.0%	12.0%	12.0%	12.0%

*Source: Section Q page 88 *Row a: 2022 data annualized from 10 months actual YTD; row b 2022 data annualized from 11 months actuals YTD*

Notes:

a. Through 2021 from LRA p 8; 2022 estimated from 10 months actual YTD July 2021, Future years from the formula: prior year times (1+ Population CAGR of 1.61 percent from Table 4).
b. Through 2021 from IMH internal data; 2022 estimated from 11 months actual YTD August 2022, future years = row a times row
c. History = Row b divided by row a; Future held constant at 2022 percentage

Table 10

	Estimated IMH SNF ESRD Readmission Rates							
	Annual NH Dialysis Pts. Admitted	**History**			**Future**			
		2020	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
a	Annual NH Dialysis Admissions	46	61	58	59	60	61	62
b	Unique SHF Dialysis Patients	22	27	29	33	33	34	34
c	Readmission Rate	2.1	2.3	1.8	1.8	1.8	1.8	1.8

Notes:
a. Table 9 row b
b. History: IMH data, future: row a / row c
c. History: a / b; Future constant in 2022

Step 2: Estimate Annual SNF Dialysis Treatments and Stations Needed

In section Q page 90, the applicant states that the dialysis unit schedule operates 6 days per week and as needed for emergencies. The applicant estimates daily dialysis treatments by assuming that a single dialysis station could treat two SNF patients a day, 3 times per week for with an efficiency factor of 75%.

Table 11

	Annual and Forecast SNF ESRD Treatments and Stations Needed							
	Metric	**History**			**Future**			
		2020	**2021**	**2022 ***	**2023**	**2024**	**2025**	**2026**
a	Annual NH Dialysis patients	46	61	58	59	60	61	62
b	Annual ESRD NH Treatments	250	302	278	283	287	292	297
c	Average Annual ESRD NH Treatments per Patient	5.43	4.95	4.81	4.81	4.81	4.81	4.81
d	Days of service per year	312	312	312	312	312	312	312
e	Treatments per day	0.80	0.97	0.89	0.91	0.92	0.94	0.95
f	Efficiency Factor	75%	75%	75%	75%	75%	75%	75%
g	Average Daily Station Use	1.07	1.29	1.19	1.21	1.23	1.25	1.27

Source Section Q. page 90. **2022 data annualized from 11 months actual YTD*

Notes:

a. From Table 9, row b
b. History from IMH internal data; Future = row a times row c.
c. History = row b divided by row a; Future is held constant at 2022 percentage.
d. Assumes 6 days per week times 52 weeks.
e. Row b divided by row d.
f. 2022 SMFP pg. 116, Small station performance standard ESRD Methodology.
g. Row e divided by row f.

In Section Q page 90, the applicant states, the IMH dialysis program has the efficiency of a small dialysis program.

Step 3: Estimate All IMH, Inpatient, SNF, and Peritoneal ESRD

In Section Q. page 91, the applicant uses forecast treatments and historical data to forecast peritoneal treatments for inpatients and SNF patients. As indicated in the tables below, the applicant first calculates the total patients and treatments and estimates inpatients; peritoneal patients, "in-center" patients and treatments, home hemodialysis or SNF patients and treatments. The number of total peritoneal patients is derived by adding the number of "in-center" peritoneal patients and treatments with SNF peritoneal patients and treatments.

Table 12

	All IMH Patients and Treatments and IMH Inpatient Patients							
	Metric	**History**			**Future**			
		2020	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
a	Total Patients	533	752	841	891	905	920	935
b	Total Patient Increase Percentage		41.1%	11.8%	5.92%	1.61%	1.61%	1.61%
c	Total IMH All ESRD Treatments	1,362	1,815	1,990	2,108	2,142	2,176	2,211
d	Average Treatments per Patient	2.56	2.41	2.37	2.37	2.37	2.37	2.37
e	Nursing Home Dialysis Patients	46	61	58	59	60	61	62
f	Inpatient Dialysis Patients	487	691	783	832	846	859	873

Source: Section Q page 91 **2022 data annualized from 11 months actual YTD*

Notes:

a. History from IMH internal data; future = prior year row a times current year row b

b. History = current year / prior year - 1; 2023 = half of 2022 increase, 2024-2025 = population four-year CAGR of 1.61%

c. History from IMH internal data; future = row a times row d

d. History = row c divided by row a; future held constant at 2022 rate

e. From table 11 row a

f. History through 2022 per IMH data, future = row a less row e

Table 13

	Inpatient ("In-Center") Peritoneal Patients and Treatments							
	Metric	History			Future			
		2020	2021	2022	2023	2024	2025	2026
a	Inpatient Treatments All	1,112	1,513	1,712	1,825	1,854	1,884	1,915
b	Inpatient Peritoneal & Peritoneal Complex Tx	126	377	383	408	415	422	428
c	% Peritoneal	11%	25%	22%	22%	22%	22%	22%
d	Inpatient Peritoneal Pts	50	156	152	162	164	167	170
e	Inpatient Peritoneal Tx/Pt	2.52	2.42	2.53	2.53	2.53	2.53	2.53

Source: Section Q page92 **2022 data annualized from 11 months actual YTD*

Notes

1. History from IMH internal data; Future, Table 12 row c less Table 11 row b

2. History from IMH internal data; future = row a times row c

3. History = row b divided by row a; future held at 2022 percentage

4. History from IMH internal data; future = row b divided by row e

5. History = row b divided by row d; future assumed to be 2022 rate

Table 14

Calculate Inpatient ("In-Center") Patients and Treatments for Form C Excludes In-Center Peritoneal								
Metrix		History			Future			
		2020	2021	2022	2023	2024	2025	2026
a	In-Center patients (not peritoneal)	437	535	632	670	681	692	703
b	In-Center Tx (not peritoneal)	986	1,136	1,329	1,417	1,440	1,463	1,486
c	In-Center Tx/Pt (not peritoneal)	2.26	2.12	2.10	2.11	2.11	2.11	2.11

Source: Section Q page92 **2022 data annualized from 11 months actual YTD*

Notes:

1. Table 12 row f less Table 13 row d
2. Table 13 row a less Table 13 row b
3. Row b divided by row a

Table 15

	SNF Peritoneal Patients and Treatments							
	Metrix	History			Future			
		2020	2021	2022	2023	2024	2025	2026
a	SNF Treatments All	250	302	278	283	287	292	297
b	SNF Peritoneal & Peritoneal Complex Tx	30	49	44	44	45	46	47
c	% Peritoneal	12%	16%	16%	16%	16%	16%	16%
d	SNF Peritoneal Pts	4	6	7	7	7	7	7
e	SNF Peritoneal Tx/Pt	4.5	8.17	4.0	6.56	6.56	6.56	6.56

Source: Section Q page 93 *022 data annualized from 11 months actual YTD*

Notes

1. Table 11, row b
2. History from IMH internal data; future = row a times row c
3. History = row b divided by row a; future held constant at 2022 percentage
4. History from IMH internal data; future = row b divided by row e
5. History = row b divided by row d; future is the average of 2020 through 2022

Table 16

	SNF ("Home Hemodialysis") Patients and Treatments for Form C							
	Metric	History			Future			
		2020	2021	2022	2023	2024	2025	2026
a	SNF patients (not peritoneal)	42	55	47	52	53	54	55
b	SNF Treatments (not peritoneal)	220	253	235	238	242	246	250
c	SNF Tx/Pt (not peritoneal)	5.24	4.60	5.00	4.54	4.54	4.54	4.54

Source: Section Q page 93 **2022 data annualized from 11-month actuals YTD.*

Notes:

a. Table 11 row a less table 15 row d
b. Table 11 row b less table

Table 17

	Total Peritoneal Patients and Treatments for Form C							
	Metric	History			Future			
		2020	2021	2022	2023	2024	2025	2026
a	Total Peritoneal Patients	54	162	163	168	171	174	177
b	Total Peritoneal Tx	156	426	427	453	460	467	475
c	Average Peritoneal TX/Peritoneal Patients	2.89	2.63	2.62	2.69	2.69	2.69	2.69

Source: Section Q. page 94 **2022 data annualized from 11 months actual YTD*

Notes:

a. Table 13 row d plus Table 15 row d
b. Table 13 row b plus Table 15 row b
c. Row b divided by row a

Project utilization is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the projected growth of the Iredell County ESRD population and how this growth will result in dialysis patients requiring inpatient care during the period that they are receiving ESRD treatments.

- The applicant adequately demonstrates how this project allows IMH to offer inpatient dialysis services while containing cost without interruption of care or causing more injury of a frail patient with multiple complex comorbidities to another facility providing dialysis.

Access to Medically Underserved Groups

In Section C page 42, the applicant states:

> *"IMH accepts all patients regardless of their ability to pay. IMH does not discriminate based on race. MH does not discriminate based on gender or gender preference. IMH facilities are designed for compliance with the Americans with Disabilities Act and other federal and state regulations related to persons with disabilities. IMH does not discriminate based on age."*

In Section L, pages 68-69, the applicant projects the following payor mix during the second full fiscal year of operation following the completion of the project, as illustrated in the following table.

Projected Payor Mix 2nd Full FY Estimated Percentage of Total Patients						
Primary Payor Source at Admission	**In Center Dialysis**		**Home Hemodialysis**		**Peritoneal Dialysis**	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Medicare	692	100%	54	100%	174	100%
Charity Care	412					
Estimated total IMH Patients	83,081					

Source: Pages 68 & 69

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.

(3a) In the case of a reduction or elimination of service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low-income persons, racial and ethnic minorities, women, … persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

Section E, page 41, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in the application. The alternatives considered were:

- Maintaining the Status Quo – The applicant concluded that given the identified need for inpatient dialysis services, maintaining the status quo would not be in the best interest of the patients served at IMH.
- Outsourcing – This alternative was not cost-effective as the applicant's staff is trained to utilize the equipment currently owned by the applicant.
- Transporting patients to outpatient dialysis decreased staff availability as the applicant was required to send staff on the transport; additionally, transportation options were costly and limited.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Patients will be served in a lower-cost setting without gaps in their dialysis treatments.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is conforming to this criterion and is approved subject to the following conditions:

1. **Iredell Memorial Hospital and Iredell memorial hospital, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **Iredell Memorial Hospital and Iredell Memorial Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section F of the application and that would otherwise require a certificate of need.**

3. **Iredell Memorial Hospital and Iredell Memorial Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

4. **Progress Reports:**
   a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.**
   b. **The certificate holder shall complete all sections of the Progress Report form.**
   c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
   d. **The first progress report shall be due on 06/1/2023.**

5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of any charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

Capital and Working Capital Costs

In Section Q, Form F.1(a), The applicant states there will be no capital cost, no start-up or initial operating expenses associated with the proposed project. The applicant has provided contingency money of $150,000 in case a need arises.
In Section Q, page 95, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the information on projected capital costs provided by the applicant in Form F.1(a) and in the assumptions.

Iredell Memorial Hospital Outpatient Dialysis Center Capital Costs	
Medical Equipment	$0
Furniture	$0
Contingency	$150,000
Total	**$150,000**

Source Section F.2a page 43

Availability of Funds

In Section F, page 44, the applicant states, that the capital cost will be funded as shown below.

Iredell Memorial Hospital Outpatient Dialysis Center Sources of Capital Cost Financing	
Accumulated reserves or OE*	$150,000
Total	**$150,000**

Source: Exhibit F.2 *Owners' Equity

In Exhibit F.2, the applicant provides a letter from the Chief Financial Officer of Iredell Memorial Hospital, Inc. that confirms the applicant has sufficient cash reserves to fund the capital needs of the project and agrees to commit the necessary funds to the capital cost of the project. In Exhibit F.2 the applicant provides copies of the audited financial statements for Iredell Memorial Hospital, Inc., which indicate that as of September 15, 2022, Iredell Memorial

Hospital, Inc., had current assets totaling $48 million and cash and cash equivalents totaling $285 million.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the applicant's documentation of IMH's accumulated funds and its willingness to fund the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following the completion of the project. In Section Q, Forms F.2 and F.4, the applicant projects that revenues will exceed operating expenses in the first and second operating years of the project.

In Section Q, Form F.2 and F.4, the applicant explains that the projected reimbursement for IMH inpatient dialysis services indicates there is positive net revenue for inpatient dialysis at IMH independently of the outpatient dialysis center as indicated in the tables below:

Total SNF Dialysis Gross Revenue	Last Full FY F: 10/01/2020 T: 9/30/2021	Partial FY F: 04/01/2023 T: 09/30/2023	1st Full FY F: 10/01/2023 T: 09/30/2024	2nd Full FY F: 10/01/2023 T: 09/30/2025
Total # of Treatments (from Assumptions	**302**	**141**	**287**	**292**
Total Gross Revenue (2)	$0	$300,470	$610,619	$620,454
Total Gross Revenue / Treatment *	$0.00	$2,126.00	$2,126.00	$2,126.00
Total Net Revenue / Treatment *	$0	$82,329	$167,310	$170,004
Total Operating Costs (from Form F.4)	$162,939	$75,706	$156,760	$162,216
Net Income	**$162,939**	**$6,623**	**$10,550**	**$7,788**

Source Section Q. Form F.2 page 98

The assumptions used by the applicant in the preparation of the pro forma financial statements are provided in Section Q pages, 98. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation for Form F.2, and F.4.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:
- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as "observation" patients.

On page 115, the 2022 SMFP defines the service area for dialysis stations as "*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties*." Thus, the service area for this facility consists of Iredell County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Iredell County as illustrated in table 9A of the 2023 SMFP.

Iredell County Dialysis Facilities					
Facility	**Certified Stations as of 12/31/2022**	**Number of Incenter Patients as of 12/31/2021**	**Utilization by Percent as of 12/31/2021**	**Patients per Station as of 12/31/2021**	**Number of Additional Stations Approved**
Lake Norman Dialysis Center of WFU	31	81	65.32%	2.61	0
Statesville Dialysis Center of WFU	27	83	76.85%	3.07	0
West Iredell Dialysis Center of WFU	24	66	68.75%	2.75	2
Total	**82**	**230**			

* From Column K in Table 9A. Proposed 2023 SMFP
** From Column L in Table 9A.
*** From Column M in Table 9A.
^ The sum of Column G CON Issued/Not Certified and Column H Decision Rendered (Conditional Approval) in Table 9A.

In Section G, page 49 the applicant states there are 3 dialysis facilities in Iredell County, however, the closest facility is located 30 minutes away. Other facilities locally do not offer the same services as IMH. In Section G, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved inpatient dialysis services in Iredell County. The applicant states in Section G page, 50:

> *"The hospital can provide better continuity with fewer disruptions and less risk to fragile patients when the dialysis care is provided in the hospital and integrated with all other care in the hospital's patient care electronic record.*"

The applicant adequately demonstrates that the proposal will not result in unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal will not result in an increase in hospital-based outpatient dialysis centers or community-based dialysis centers in Iredell County.
- The applicant adequately demonstrates that the proposed inpatient dialysis services are needed for IMH patients.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as "observation" patients. In Section Q, Form H, In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current Positions (9/7/22)	Projected 1st Year	Projected 2nd Year
Registered Nurse	5	5	5
RN Certified in Nephrology	1	1	1
CNAs	0.1	0.1	0.1
CCHT PRN	0.03	0.03	0.03
CCHT	1	2	2
Total	**7**	**8**	**8**

Source: Section Q, Form H, page 106

The assumptions and methodology used to project staffing are provided in Section Q. There are adequate operating expenses for the health manpower and management positions proposed by the applicant. In Section H, pages 52-53, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant will offer salaries/benefits and recruit staff through traditional methods, from their internal HR department.
- All IMH employees are provided orientation specific to their positions and ongoing education.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing healthcare system.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3. IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as "observation" patients.

Ancillary and Support Services

In Section, I, page 54, the applicant identifies the necessary ancillary and support services for the proposed dialysis services. On pages 55-56, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1 pages 55-56 and Exhibit I.1.

Coordination

In Section I.2, page 57, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant provides copies of support letters submitted by physicians and community health professionals in Exhibit I.2. The

applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2 and Exhibit I.2 as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina counties in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed to represent the most reasonable alternative and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy-saving features have been incorporated into the construction plans.

NA

The applicant does not propose any construction or renovations. Therefore, Criterion (12) is not applicable to this review.

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low-income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and persons with disabilities, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as “observation” patients.

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved.

In Section L, page 64, the applicant provides the historical payor mix during the last full FY before submission of the application for the proposed services, as shown in the table below.

Primary Payor Source at Admission Days	Iredell Memorial Hospital Historical Payor Mix					
	FY2019		FY2020		FY2021	
	# of Patient	% of Patients	# of Patients	% of Patients	# of Patients	# of Patients
Medicare	7,271	59.6%	6320	52.8%	162	46.2%
Medicaid	714	5.9%	1,321	11.0%	1,500	15.4%
Private	862	7.1	556	4.6%	206	2.1%
Other	3,334	27.4	3,782	31.6%	3,524	36.2%

Source: Exhibit C.5

SNF ESRD Payor at admission	Iredell Memorial Hospital Historical Payor Mix Full FY, 10/01/2020 to 9/30/202					
Medicare	535	100%	55***	100%	162	100%

Source: Section L, page 64

In Section L., page 65 the applicant provides the following comparison:

IMH	Percent of Total Patients Served	Percent of the Population of the Service Area
Female	73%	50.6%
Male	27%	49.4%
64 and Younger	15%	81.9%
65 and Older	85%	19.1%
American Indian	Unknown	0.4%
Asian	Unknown	2.5%
Black or African American	Unknown	9.4%
White or Caucasian	Unknown	80.5%
Other Race	Unknown	4.8%

Source: Section L page 65

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring the provision of uncompensated care, community service, or access by minorities and … persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant.

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 67, the applicant states that the facility is obligated to provide uncompensated care and/or community service. IMH is subject to compliance with Internal Revenue Service Section 501(r) and all requirements imposed by the Affordable Care Act.

In Section L.2b, page 67, the applicant states there have been no civil rights access complaints filed against any of the applicant's facilities within the last 18 months.

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 69, the applicant projects that it will serve only Medicare and indigent patients. The applicant states that approximately 4.78 percent of all IMH patients will receive care at a reduced cost. To estimate the number of reduced-cost patients, the applicant multiplied the estimated total patients by 4.78 percent. The applicant assumes the total number of patients will increase by 1.17 percent annually.

On pages 68-69, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following the completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's projected patient payor mix is based on the applicant's research regarding the incidence of dialysis patients who are Medicare and Medicaid recipients, and the applicant's historical provision of charity care to its patients.

The Agency reviewed the:

- Application

- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by staff, and admission by personal physicians.

C

In Section L, page 88, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as "observation" patients.

In Section M, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 71, and Exhibit M.1 as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact on the cost-effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as "observation" patients.

On page 115, the 2022 SMFP defines the service area for dialysis stations as "*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties*." Thus, the service area for this facility consists of Iredell County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Iredell County as illustrated in table 9A of the 2023 SMFP.

Iredell County Dialysis Facilities					
Facility	**Certified Stations as of 12/31/2022**	**Number of In-center Patients as of 12/31/2021**	**Utilization by Percent as of 12/31/2021**	**Patients per Station as of 12/31/2021**	**Number of Additional Stations Approved**
Lake Norman Dialysis Center of WFU	31	81	65.32%	2.61	0
Statesville Dialysis Center of WFU	27	83	76.85%	3.07	0
West Iredell Dialysis Center of WFU	24	66	68.75%	2.75	2
Total	**82**	**230**			

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 72, the applicant states:

> *"The project will extend IMH's limited competition with existing outpatient dialysis providers in Iredell County. One outpatient community dialysis provider, Statesville Dialysis Center of Wake Forest University offers home dialysis, is in the same city as the applicant, and **does not** provide routine dialysis to IMH nursing home patients"*

Regarding the impact of the proposal on cost-effectiveness, in Section N, page 72, the applicant states:

> *"Approval of this project will enable IMH to continue offering routine renal dialysis with its equipment and staff to residents of its nursing home beds. It will avoid the cost of coordinating essential life maintaining care with an external provider. It will also increase the use of existing equipment, thus reducing unit costs of care. Effectively, the only new costs associated with the service will be the cost of supplies and pharmaceuticals for each patient."*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 73, the applicant states*:*

> *"By providing routine dialysis for nursing home patients with its own staff and equipment, IMH will eliminate as many as six handoffs in care a week for affected patients. According to The Joint Commission ("TJC"), a hand-off is a transfer and acceptance of patient care responsibility achieved through. effective communication TJC warns that even the most diligent processes can falter when the patient is handed off to another health care provider. It warns that "while it sounds simple, a high-quality hand-off is complex. Failed hand-offs are a longstanding common problem in health care."*

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 73, the applicant states:

> *"As noted in Section L, IMH has a long history of serving medically underserved groups. Ownership of the building and grounds by the county and governance of IMH by County-appointed Trustees assures continuous oversight of its mission to serve all residents. Residents of other counties benefit from policies that are built on this mission."*

See also Sections L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

1) The proposal is cost-effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.

3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as "observation" patients.

The applicant, Iredell Memorial Hospital is the only facility owned by the applicant or a related entity that offers 24/7 renal dialysis services.

In Section O, page 75, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any these facilities The applicant is an existing operational hospital (license H0164). According to the files in the Acute and Home Care Licensure and Certification Section, DHSR. IMH operates in conformance with all applicable Federal, State, and local laws, regulations, codes, and ordinances, and in conformance with all material representations of this CON application.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to develop a hospital-based, outpatient dialysis center to be located at IMH, an existing acute care hospital with a total of no more than 4 stations pursuant to Policy ESRD-3.

IMH began providing these services under a COVID-19 Executive Order Waiver, EO 130, which was approved by the DHHS on December 11, 2021. The applicant proposes to use the four fixed and three mobile dialysis stations already in service at IMH to provide routine outpatient dialysis services to patients of the IMH distinct part skilled nursing facility unit and to outpatients classified as "observation" patients.

There are no administrative rules that are applicable to proposals for a hospital-based, outpatient dialysis center pursuant to Policy ESRD-3.