

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 5, 2016

Findings Date: February 5, 2016

Project Analyst: Mike McKillip

Assistant Chief: Martha Frisone

Project ID #: N-11077-15

Facility: Maxton Dialysis

FID #: 140332

County: Robeson

Applicant: Total Renal Care of North Carolina, LLC

Project: Add four dialysis stations by relocating four stations from Dialysis Care of Hoke County for a total of 14 stations upon completion of this project and Project I.D. # N-10321-14

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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

Total Renal Care of North Carolina, LLC d/b/a Maxton Dialysis [Maxton Dialysis] proposes to add four dialysis stations by relocating four stations from Dialysis Care of Hoke County for a total of 14 certified dialysis stations upon completion of this project and Project I.D. # N-10321-14 (Relocate St. Pauls Dialysis Center, a 10 station dialysis facility, to Maxton and rename it Maxton Dialysis).

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Robeson County. Also, the applicant is not eligible to apply for additional stations in its existing facility based on the facility need methodology. The applicant does not propose to add new dialysis stations to an existing facility. Therefore, neither of the two need methodologies in the 2015 SMFP are applicable to the review.

Policies

Policy GEN-3 is not applicable to this review since there is no identified need for additional dialysis stations in Robeson County based on the county need methodology, nor is there a need for new dialysis stations at Maxton Dialysis based on the facility need methodology.

Policy ESRD-2 is applicable to this review. Policy ESRD-2 of the 2015 SMFP states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations to contiguous counties shall:

- (A) Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- (B) Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate four existing dialysis stations from Hoke County to Robeson County. Therefore, the dialysis station inventory in Hoke County would decrease by four stations and the dialysis station inventory in Robeson County would increase by four stations. Hoke and Robeson Counties are contiguous to each other.

The applicant proposes to relocate four dialysis stations from Dialysis Care of Hoke County, located in Raeford, to Maxton Dialysis in Robeson County. According to the July 2015

SDR, Table B, there is a surplus of five dialysis stations in Hoke County. Therefore, after the proposed relocation of four dialysis stations from Dialysis Care of Hoke County, there will still be a surplus of one dialysis station in Hoke County. According to the July 2015 SDR, Table B, there is a deficit of 13 dialysis stations in Robeson County. Therefore, after the proposed relocation of four dialysis stations from Dialysis Care of Hoke County to Maxton Dialysis, there will still be a deficit of nine dialysis stations in Robeson County. The applicant adequately demonstrates that the proposal will not result in a deficit in the number of dialysis stations in Hoke County, the county that would be losing stations as a result of the proposed project. Furthermore, the applicant adequately demonstrates that the proposal will not result in a surplus of dialysis stations in Robeson County, the county that would gain stations as a result of the proposed project. As of June 30, 2015, 12 residents of Robeson County were receiving in-center dialysis services as Dialysis Care of Hoke County. Therefore, the application is conforming to Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2. Therefore, the application is conforming to this criterion.

- (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, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

On October 29, 2014, the applicant was conditionally approved (Project I.D. # N-10321-14) to relocate St. Pauls Dialysis Center, a 10 station dialysis facility, to Maxton, and rename it Maxton Dialysis. However, the approval of Project I.D. # N-10321-14 was appealed by Fresenius Medical Care, and the Certificate of Need has not yet been issued pending resolution of the contested case. On page 13, the applicant states,

“As soon as the certificate of need is issued for the relocation of the facility from St. Pauls to Maxton, development of the project will begin. The application to relocate the facility projected the project would be complete on January 1, 2016. However, since Fresenius appealed the conditional approval of the project, we are adjusting the completion date of the project to January 1, 2017.”

In this application, the applicant proposes to add four dialysis stations at Maxton Dialysis by relocating four stations from Dialysis Care of Hoke County for a total of 14 certified dialysis stations upon completion of the project.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Robeson County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 21, the applicant provides the historical patient origin for St. Pauls Dialysis Center in-center patients as of December 31, 2014, which is summarized in the following table:

St. Pauls Dialysis Center County of Residence	In-Center Patients	Percent
Robeson	14	64%
Cumberland	6	26%
Bladen	1	5%
Other States	1	5%
Total	22	100%

In Section C.1, page 13, the applicant provides the projected patient origin for Maxton Dialysis for in-center patients for the first two years of operation following completion of the project as follows:

	OPERATING YEAR 1 CY2017		OPERATING YEAR 2 CY2018		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN- CENTER	HOME*	IN-CENTER	HOME*	YEAR 1	YEAR 2
Robeson	16	3	17	4	36.5%	38.9%
Scotland	29	4	29	4	63.5%	61.1%
Total	45	7	46	8	100.0%	100.0%

*The “Home” category includes peritoneal dialysis patients.

The applicant provides the assumptions and methodology used to project patient origin on pages 13-16. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.1, page 14, the applicant describes the need for the proposed project as follows:

“The certificate of need application to relocate the facility from St. Pauls to Maxton did not call for the station expansion of the facility. There were fifty-one (51) letters of support from in-center patients living in Robeson and Scotland Counties that indicated they would consider transferring their care from the facility where they were currently receiving services to the newly relocated and named Maxton Dialysis. We indicated in the application a projection that 16 patients from Robeson County and 16 patients from Scotland County would transfer their care to Maxton Dialysis.

An addition of four stations to Maxton Dialysis is warranted for the following reasons:

- *There is a 13-station deficit of stations in Robeson County as cited in the July 2015 SDR.*
- *The Robeson County station deficit needs to be reduced so that there will be enough dialysis stations in Robeson County to meet the needs of patients living in Robeson County and for patients living in contiguous counties who prefer to receive their dialysis services in Robeson County.*
- *There are 25 patients being treated at DaVita facilities contiguous to Robeson County who live in Robeson County. The additional stations will give these patients the opportunity to receive services at a DaVita facility in their home county. This information is found in the Patient Origin Report published by the Healthcare Planning Section.*
- *This application contains thirteen letters of support signed by patients who are receiving dialysis services at DaVita owned facilities in counties contiguous to Robison [sic] County and by patients receiving dialysis services at Dialysis Care of Richmond County, which is not contiguous to Robison [sic] County. Most of these patients signed letters of support that were included in the relocation of St. Pauls Dialysis Center to Maxton. See Exhibit C-1 for a copy of the patient letters.*
- *The Maxton location offers a provider alternative to the patients living on the southwest side of Robeson County and the east side of Scotland County that has not been available in the past.”*

Projected Utilization

The applicant projects that Operating Years One and Two for the proposed project will be CY2017 and CY2018, respectively. On pages 14-15, the applicant describes its methodology for projecting utilization as follows:

“Since this certificate of need application deals with the relocation of stations from a contiguous county and patients living in Robeson and Scotland Counties receiving services at several DaVita facilities, we have started the growth of the facility the day Maxton Dialysis relocation/expansion is certified and used the five year average annual change rate for Robeson and Scotland Counties as stated in the July SDR to grow the facility census projections during the first two years of operation.

The growth of the patient census during the first two years of operation is based on 16 in-center patients living in Robeson County. Since the growth rate in Scotland County is a negative 1.4%, no growth will be calculated for the projected 29 in-center patients.

Robeson County in-center patient growth projection based on the Average Annual Change Rate for the Past Five Years of 4.9%:

January 1, 2017-December 31, 2017 – 16 X 1.049 = 16.784

January 1, 2018-December 31, 2018 – 16.784 X 1.049 = 17.606416”

On page 15, the applicant states,

“For the purpose of the chart below there will be no growth shown for 2015 or the interim year. The facility had 22 in-center patients on December 31, 2014.

		Start Date	# of SA Patients	X	Growth Rate	=	SA Year End Census	+	# out-of-SA existing patients	=	Total Year End Census	Year End Date
(a)	Beginning Service area (SA) census SA: Maxton	12/31/2014	14									
(b)	Current Year	1/1/2015	14	X	1.0	=	14	+	8	=	22	12/31/2015
(c)	Interim Year	1/1/2016	14	X	1.0	=	14	+	8	=	22	12/31/2016
(e)	Census OY1	1/1/2017	16	X	1.049	=	16.784	+	29	=	45.784	12/31/2017
(f)	Census OY 2	1/1/2018	16.784	X	1.049	=	17.606	+	29	=	46.606	12/31/2018

The table below summarizes the beginning and end of year census for each of the years in the period of growth and lists the average number of patients for each year. The number of patients shown below (beginning and end of year) were rounded down to the nearest whole number.

	Start Date	# of pts -begin of year	# of pts – end of year	Avg # of pts in year	pts per station	Utilization Rate
	12/31/2014	22	22	22		
Current Year	1/1/2015	22	22	22		
Interim Period	1/1/2016	22	22	22		
Operating Year 1	1/1/2017	45	45	45	3.214	80.4%
Operating Year 2	1/1/2018	45	46	45.5	3.286	82.1%

The applicant projects to serve 45 in-center patients or 3.2 patients per station ($45/14 = 3.2$) by the end of Operating Year 1 and 46 in-center patients or 3.3 patients per station ($46/14 = 3.3$) by the end of Operating Year 2 for the proposed 14-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

The applicant assumes a projected annual rate of growth of 4.9% for the Robeson County in-center patient census at Maxton Dialysis, which is consistent with the Robeson County Five Year Average Annual Change Rate (2010-2014). Also, the applicant’s projections of Robeson County in-center patients proposed to be served at Maxton Dialysis are consistent with the patient origin projections for in-center patients for the first two years of operation following completion of the project in the previously approved project (Project I.D. # N-10321-14), which are summarized in the table below:

**Patient Origin Projections for the Previously Approved Application
 (Project I.D. # N-10321-14)**

	OPERATING YEAR 1 CY2016		OPERATING YEAR 2 CY2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME*	IN-CENTER	HOME*	YEAR 1	YEAR 2
Robeson	16	5	17	6	36.5%	38.9%
Scotland	16	1	16	1	63.5%	61.1%
Total	32	6	33	7	100.0%	100.0%

*The “Home” category includes peritoneal dialysis patients.

In the previously approved application for Maxton Dialysis (Project I.D. # N-10321-14), the applicant provided 51 letters of support from in-center patients living in Robeson and

Scotland Counties that indicated they would consider transferring their care from the facility where they were currently receiving services to the proposed Maxton Dialysis facility. Of the 51 patient support letters, 15 patients were residents of Robeson County and 36 were residents of Scotland County, as shown in the table below.

Patient's County of Residence	# of In-Center Patients	# of Home Patients	Total # of Patients	Percent Total
Robeson	14	1	15	29.4%
Scotland	33	3	36	70.6%
Total	47	4	51	100.0%

As shown in the table above, 14 in-center patients identified as being a Robeson County resident and 33 in-center patients identified as being a Scotland County resident.

In Section G.2, page 34, the applicant states,

“The additional four stations will help meet the need that was identified in the relocation application, where 51 total patients indicated an interest in transferring their care to Maxton Dialysis. This application contains thirteen letter [sic] of support signed by patients who are receiving dialysis services at DaVita owned facilities in counties contiguous to Robinson [sic] County and by patients receiving dialysis services at Dialysis Care of Richmond County, which is not contiguous to Robison [sic] County.”

In this application, the applicant projects to serve the identical number of in-center patients from Robeson County in the first two operating years (16 Robeson County patients in OY1 and 17 Robeson County patients in OY2) as it projected in the previously approved application for Maxton Dialysis (Project I.D. # N-10321-14). In addition to the Robeson County patients, the applicant projects to serve 29 in-center patients from Scotland County in each of the first two operating years, which is an increase of 13 Scotland County patients in each of the first two operating years over what the applicant projected in the previously approved application for Maxton Dialysis (Project I.D. # N-10321-14). Exhibit C-1 contains copies of letters, dated September 2015, from 13 patients who are currently receiving dialysis services at other DaVita dialysis facilities expressing support for the proposed project and their intention to utilize the Maxton Dialysis facility. Of the thirteen patient letters of support in Exhibit C-1, eight of the patients identify themselves as residents of Scotland County, and five patients identify themselves as residents of Robeson County. Projected utilization is based on reasonable and adequately supported assumptions.

Access

In Section L.1(a), pages 49-53, the applicant states that Maxton Dialysis (currently d/b/a St. Pauls Dialysis Center) makes its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects 91% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for four additional stations at Maxton Dialysis, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a 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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

On October 29, 2014, the applicant was conditionally approved (Project I.D. # N-10321-14) to relocate St. Pauls Dialysis Center, a 10 station dialysis facility, to Maxton, and rename it Maxton Dialysis. However, the approval of Project I.D. # N-10321-14 was appealed by Fresenius Medical Care, and the Certificate of Need for the project has not yet been issued pending resolution of the contested case. In this application, the applicant proposes to add four dialysis stations at Maxton Dialysis by relocating four stations from Dialysis Care of Hoke County for a total of 14 certified dialysis stations upon completion of the project. The applicant also projects that four in-center dialysis patients from Dialysis Care of Hoke County will transfer their care to Maxton Dialysis as part of the project. In Section D.1, page 24, the applicant describes the impact of the proposed transfer of stations from Dialysis Care of Hoke County as follows:

“This application calls for the relocation of four stations from Dialysis Care of Hoke County, located in Raeford in Hoke County. The July 2015 SDR indicated that Dialysis Care of Hoke County had 27 certified dialysis stations. However, an additional dialysis station was certified on July 28, 2015. This application also calls for the transfer of four of the in-center patients from Dialysis Care of Hoke County to Maxton Dialysis.”

The calculations below grow the December 31, 2014 Dialysis Care of Hoke County in-center patient population by the five-year average annual change rate of 4.1% as indicated in the July 2015 SDR for 2015 and 2016 patients. Dialysis Care of Hoke County was dialyzing 80 of the 105 in-center patients who lived in Hoke County as of December 31, 2014.

*January 1, 2015-December 31, 2015 – 80 in-center patients X 1.041 = 83.28
January 1, 2016-December 31, 2016 – 83.28 in-center patients X 1.041 = 86.69448*

Dialysis Care of Hoke County is projected to have 111 in-center patients (86 Dialysis Care of Hoke County resident patients + 25 in-center patients who live outside of Hoke County = 111 in-center patients) as of December 31, 2016. Maxton Dialysis is projected to become certified on January 1, 2017. Dialysis Care of Hoke County will transfer 4 dialysis stations and 4 in-center patients leaving the facility with 24 stations and 107 in-center patients. On January 1, 2017 Dialysis Care of Hoke County is projected to have a utilization rate of 111.5% or 4.46 patients per station. However, Dialysis Care of Hoke County will submit a CON application to increase the number of stations utilizing the Facility Need Methodology to expand the stations so that no patient has to revert to a third shift for their dialysis treatments.”

The applicant proposes to relocate four existing dialysis stations from Dialysis Care of Hoke County, and four existing patients are projected to transfer to Maxton Dialysis as of January 1, 2017. Following the certification of one additional station in July 2015 (Project I.D. # N-10345-14, Relocate one station from Dialysis Care of Richmond County to Dialysis Care of Hoke County for a total of 28 stations), Dialysis Care of Hoke County currently operates 28 certified dialysis stations.

As shown above, based on a December 31, 2014 census of 105 in-center patients, the applicant projects that Dialysis Care of Hoke County would be serving 107 in-center patients on 24 certified stations on January 1, 2017, when the four stations and four patients are projected to transfer to Maxton Dialysis, for a projected utilization of 4.46 patients per station or 112%. However, according to the January 2016 SDR, Dialysis Care of Hoke County had 95 in-center patients dialyzing on 27 stations as of June 30, 2015, for a utilization rate of 3.5 patients per stations or 88%. Therefore, in contrast to the applicant’s projections, the in-center patient census and utilization for Dialysis Care of Hoke County decreased during the most recent reporting period. Consequently, the applicant’s utilization projections for Dialysis Care of Hoke County appear to be overstated. Also, the applicant states that Dialysis Care of Hoke County intends to apply for additional dialysis stations as permitted by the Facility Need Methodology in the SMFP. The applicant demonstrates that the needs of the

population presently served at Dialysis Care of Hoke County will continue to be adequately met.

The applicant adequately demonstrates that the facility from which dialysis stations would be transferred has sufficient capacity following the transfer of stations to the proposed Maxton Dialysis facility. Thus, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation of dialysis stations. Therefore, the application is conforming to this criterion.

- (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.

CA

In Section E.1, page 26, the applicant states the only other alternative to the proposed project that was considered prior to submitting this application was to maintain the status quo. However, the applicant states that maintaining the status quo is not an effective alternative *“given the number of dialysis patients who have indicated that they will consider transferring to the newly relocated Maxton Dialysis.”*

After considering the alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Total Renal Care of North Carolina, LLC d/b/a Maxton Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Maxton Dialysis shall develop and operate no more than four additional dialysis stations for a total of no more than 14 certified stations upon completion of this project and Project I.D. # N-10321-14, which shall include any isolation or home hemodialysis stations.**

3. **Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify four stations at Dialysis Care of Hoke County for a total of no more than 24 stations upon completion of this project.**
 4. **Total Renal Care of North Carolina, LLC d/b/a Maxton Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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 and charges for providing health services by the person proposing the service.

C

In Section F.1, page 28, the applicant states that it projects \$71,016 in capital costs to develop this project. In Sections F.10-F.12, page 31, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project. These costs were proposed in the previously approved Project I.D. # N-10321-14 (\$978,757).

Availability of Funds

In Section F.2, page 29, the applicant states it will finance the capital costs with accumulated reserves. Exhibit F-5 contains a letter dated September 10, 2015 from the Vice President of Tax for DaVita HealthCare Partners, Inc. (DHP), the parent company for the applicant, which states the applicant has adequate funds for the proposed project. Exhibit F-7 contains the Securities and Exchange Commission Form 10-K for DHP which indicates that it had \$965 million in cash and cash equivalents as of December 31, 2014. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	CY2017	CY2018
Total Net Revenue	\$2,159,151	\$2,243,929
Total Operating Expenses	\$1,819,026	\$1,882,403
Net Income	\$340,125	\$361,526

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion of projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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

On October 29, 2014, the applicant was conditionally approved (Project I.D. # N-10321-14) to relocate St. Pauls Dialysis Center, a 10 station dialysis facility, to Maxton, and rename it Maxton Dialysis. In this application, the applicant proposes to add four dialysis stations at Maxton Dialysis by relocating four stations from Dialysis Care of Hoke County for a total of 14 certified dialysis stations upon completion of the project.

On page 361, the 2015 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Robeson County. Facilities may serve residents of counties not included in their service area.

The applicant operates one dialysis facility in Robeson County. BMA is the only other provider of dialysis services in Robeson County, and currently operates five dialysis centers, as shown in the table below.

Existing and Approved Robeson County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/15	% Utilization	Patients Per Station
BMA of Red Springs	12	91.67%	3.7
FMC Dialysis of Robeson County (BMA)	23	77.17%	3.1
FMC Pembroke (BMA)	15	88.33%	3.5
FMC St. Pauls (BMA)	15	95.00%	3.8
Lumberton Dialysis (BMA)	35	85.71%	3.4
St. Pauls Dialysis Center (DaVita)	10	40.00%	1.6
Maxton Dialysis (DaVita)*	0	NA	NA

Source: January 2016 SDR, Table A.

*DaVita has been approved to relocate the 10 dialysis stations at St. Pauls Dialysis Center to a new facility, Maxton Dialysis (Project I.D. # N-10321-14).

As shown in the table above, four of the six Robeson County dialysis facilities are operating above 80% utilization (3.2 patients per station), and five of the six facilities are operating above 75% utilization (3.0 patients per station). According to the July 2015 SDR, Table B, there is a deficit of 13 dialysis stations in Robeson County.

The applicant, Maxton Dialysis, proposes to add four dialysis stations by relocating four stations from Dialysis Care of Hoke County for a total of 14 dialysis stations upon project completion. The applicant does not propose to establish a new facility.

Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant projects to serve 45 in-center patients or 3.2 patients per station ($45/14 = 3.2$) by the end of Operating Year 1. At the end of Operating Year Two, Maxton Dialysis projects the utilization will be 3.3 in-center patients per station ($46 \text{ patients} / 14 \text{ dialysis stations} = 3.3$), which is 83% of capacity. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 13-16 of the application. The utilization projections are based on a projected 4.9% average annual growth rate in the number of Robeson County dialysis patients at the Maxton Dialysis facility. The projections are also based on the number of existing in-center patients served by the applicant at other existing facilities that have expressed an interest in transferring their care to the proposed Maxton Dialysis facility. The applicant adequately demonstrates the need to add four additional dialysis stations at the proposed facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

- (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

In Section H.1, page 35, the applicant provides the current and proposed staffing for the facility. The applicant proposes to add one full-time equivalent (FTE) technician as a result of this project, for a total of 11.5 FTEs. In Section H.3, pages 36-37, the applicant describes its experience and process for recruiting and retaining staff. In Section H.2, page 36, the applicant identifies the medical director as Jonathan Nestor, M.D., and Exhibit I-3 contains a copy of a letter from Dr. Nestor expressing his support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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 health care system.

C

In Section I.1, page 40, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-3 contains a copy of a letter from the medical director for the facility expressing his support for the proposed project, and describing the facility's established relationships with other healthcare providers. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (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

- (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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed 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

- (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 handicapped persons, 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:
 - (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;

C

In Section L.7, page 53, the applicant projects that 91% of the patients who receive treatments at Maxton Dialysis will have some or all of their services paid for by Medicare or Medicaid. Projections are based on the historical payment sources at Dialysis Care of Richmond as shown in the table below:

Payment Source (CY2014)	Percent of Total Patients
Commercial Insurance	5.9%
Medicare	27.7%
Medicaid	3.0%
Medicare/Medicaid	28.7%
VA	3.0%
Medicare/Commercial	31.7%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Robeson and Scotland counties and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Robeson	31%	13.2%	23.9%
Scotland	30%	12.9%	21.5%
Statewide	17%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

The applicant demonstrates that it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In Section L.3, page 52, the applicant states:

“Maxton Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.”

In Section L.6, page 53, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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.1, page 50, the applicant projects that 91% of the patients who will receive treatments at Maxton Dialysis in the second operating year (CY2018) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility:

Payment Source	Percent of Total Patients
Commercial Insurance	5.9%
Medicare	27.7%
Medicaid	3.0%
Medicare/Medicaid	28.7%
VA	3.0%
Medicare/Commercial	31.7%
Total	100.00%

In Section L.1, page 50, the applicant states,

“The projected payor mix is based on the sources of patient payment that have been received by the existing facility in the last full operating year at Dialysis Care of Richmond County. It is the closest facility to the Maxton Dialysis site.”

The applicant demonstrated that medically underserved groups will have adequate access to the services offered at Maxton Dialysis. Therefore, 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 house staff, and admission by personal physicians.

C

In Section L.4, page 52, the applicant describes the range of means by which a person will have access to the dialysis services at Maxton Dialysis, including referrals from nephrologists. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, 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

In Section M.1, page 54, the applicant states that Maxton Dialysis has established relationships with local community training programs. Exhibit M-2 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as a clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (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 upon 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

On October 29, 2014, the applicant was conditionally approved (Project I.D. # N-10321-14) to relocate St. Pauls Dialysis Center, a 10 station dialysis facility, to Maxton, and rename it Maxton Dialysis. In this application, the applicant proposes to add four dialysis stations at

Maxton Dialysis by relocating four stations from Dialysis Care of Hoke County for a total of 14 certified dialysis stations upon completion of the project.

On page 361, the 2015 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Robeson County. Facilities may serve residents of counties not included in their service area.

The applicant operates one dialysis facility in Robeson County. BMA is the only other provider of dialysis services in Robeson County, and currently operates five dialysis centers, as shown in the table below.

Existing and Approved Robeson County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/15	% Utilization	Patients Per Station
BMA of Red Springs	12	91.67%	3.7
FMC Dialysis of Robeson County (BMA)	23	77.17%	3.1
FMC Pembroke (BMA)	15	88.33%	3.5
FMC St. Pauls (BMA)	15	95.00%	3.8
Lumberton Dialysis (BMA)	35	85.71%	3.4
St. Pauls Dialysis Center (DaVita)	10	40.00%	1.6
Maxton Dialysis (DaVita)*	0	NA	NA

Source: January 2016 SDR, Table A.

*DaVita has been approved to relocate the 10 dialysis stations at St. Pauls Dialysis Center to a new facility, Maxton Dialysis (Project I.D. # N-10321-14).

As shown in the table above, four of the six Robeson County dialysis facilities are operating above 80% utilization (3.2 patients per station), and five of the six facilities are operating above 75% utilization (3.0 patients per station).

In Section N.1, page 55, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The expansion of the Maxton Dialysis will have no effect on competition in Robeson County. The addition of four stations at this facility serves to address the needs of a population already identified to be served, based on letters of support.

The expansion of Maxton Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will

enhance the quality and effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services at a DaVita facility.

The expansion of this facility is not expected to have any impact on competition since Fresenius operates five facilities in Robeson County and two facilities in Scotland County and serves most of the patients in both Robeson and Scotland Counties. DaVita does not have a facility in Scotland County.”

See also Sections B, C, E, F, G, H and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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

In Exhibit O-3, the applicant identifies three kidney disease treatment centers located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O.3, page 56, the applicant states all three facilities are back in compliance with CMS Guidelines as of the date of submission of this application. Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by the Centers for Medicare and

Medicaid Services and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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 in order 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.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:*

.2202(a)(1) Utilization rates;

- C- In Section G.1, page 34, the applicant reports the facility had a 55% utilization rate as of December 31, 2014.

.2202(a)(2) Mortality rates;

- C- In Section C.9, page 22, the applicant reports 2012, 2013, and 2014 facility mortality rates of 4.8%, 30.8% and 19.0%, respectively.

.2202(a)(3) The number of patients that are home trained and the number of patients on Home dialysis;

- NA- In Section C.8, page 21, the applicant reports no home dialysis patients.

.2202(a)(4) *The number of transplants performed or referred;*

-C- In Section C.10, page 22, the applicant reports one patient was referred for transplant evaluation in 2014.

.2202(a)(5) *The number of patients currently on the transplant waiting list;*

-C- In Section C.10, page 22, the applicant states two patients on the transplant waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus Non-dialysis related;*

-C- In Section C.11, page 22, the applicant reports a total of 25 hospital admissions, of which 19 were non-dialysis related and 6 were dialysis-related.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section C.10, page 22, the applicant reports that in 2014 there were no patients with an infectious disease, and no patients converted to infectious status.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*

-NA- The applicant is not proposing a new facility in this application.

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

(A) *timeframe for initial assessment and evaluation of patients for transplantation,*

(B) *composition of the assessment/evaluation team at the transplant center,*

- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically Re-evaluated for transplantation, and,*
- (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- The applicant is not proposing a new facility in this application.

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- The applicant is not proposing a new or replacement facility in this application.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- Exhibit K-1 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- The applicant is not proposing a new facility in this application.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section K.1, page 45, the applicant states the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

- C- In Section C.1, page 13, Maxton Dialysis provides projected patient origin for the first two years of operation following completion of the project. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- The applicant is not proposing a new facility in this application.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section L.3, page 51, the applicant states, “*Maxton Dialysis admits and provides dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant is not proposing to establish a new facility in this application.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C.1, page 13, the applicant projects to serve 45 in-center patients by the end of Operating Year 1, which is 3.2 patients per station ($45 / 14 = 3.2$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C.1, pages 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

.2204(1) *Diagnostic and evaluation services;*

-C- These services are provided by Scotland Memorial Hospital. See Section I.1, page 40.

.2204(2) *Maintenance dialysis;*

-C- Provided by Maxton Dialysis. See Section I.1, page 40.

.2204(3) *Accessible self-care training;*

-C- Provided by Maxton Dialysis. See Section I.1, page 40.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- Provided by Maxton Dialysis. See Section I.1, page 40.

.2204(5) *X-ray services;*

-C- These services are provided by Scotland Memorial Hospital. See Section I.1, page 40.

.2204(6) *Laboratory services;*

-C- Provided by DaVita Laboratory Services, Inc. See Section I.1, page 40.

.2204(7) *Blood bank services;*

-C- Provided by Scotland Memorial Hospital. See Section I.1, page 40.

.2204(8) *Emergency care;*

-C- Provided by Scotland Memorial Hospital. See Section I.1, page 40.

.2204(9) *Acute dialysis in an acute care setting;*

-C- Provided by Scotland Memorial Hospital. See Section I.1, page 40.

.2204(10) *Vascular surgery for dialysis treatment patients*

-C- Provided by referral to Dr. Chu. See Section I.1, page 40.

.2204(11) *Transplantation services;*

-C- Provided by Carolinas Medical Center. See Section I.1, page 40.

.2204(12) *Vocational rehabilitation counseling and services; and,*

-C- Provided by referral to North Carolina Division of Vocational Rehabilitation. See Section I.1, page 40.

.2204(13) *Transportation*

-C- Provided by Robeson County DSS. See Section I.1, page 40.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*

-C- In Section H.1, page 35, the applicant provides the proposed staffing. In Section H.2, page 36, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 494 (formerly 405.2100). The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- See Section H.4, page 37, and Exhibits H-2 and H-4.