



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

June 17, 2021

Kenneth Burgess
kburgess@poynerspruill.com

No Review

Record #: 3590
Date of Request: June 7, 2021
Facility Name: Mission Hospital
FID #: 943349
Business Name: MH Mission Hospital, LLLP
Business #: 3045
Project Description: Acquire dialysis equipment
County: Buncombe

Dear Mr. Burgess:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law in effect on the date of this response to your request, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Ena Lightbourne
Project Analyst

Gloria C. Hale

for
Lisa Pittman
Acting Chief, Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHS
NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

June 7, 2021

Kenneth L. Burgess
Partner
D: 919.783.2917
F: 252.783.1075
kburgess@poynerspruill.com

VIA E-MAIL

Lisa Pittman, Assistant Chief
N.C. Department of Health and Human Services
N.C. Division of Health Service Regulation
Certificate of Need Section
809 Ruggles Drive, Raleigh, N.C. 27603
Via email to: lisa.pittman@dhhs.nc.gov

RE: ***Request for "No Review" Determination: Replacement of Existing Dialysis Equipment at Mission Hospital, Facility I.D. No. 943349, and at CarePartners Rehabilitation Hospital, Facility I.D. No. 923508***

Dear Lisa:

I am writing on behalf of our clients MH Mission Hospital, LLLP ("Mission" or "the Hospital") and CarePartners Rehabilitation Hospital, LLLP ("CarePartners") to provide the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section ("the CON Section" or "the Agency") with prior written notice of Mission's intent to replace certain dialysis equipment (the "Equipment") which is currently in use at Mission and CarePartners (the "Proposed Project"). The equipment being replaced, described in detail below, does not qualify as a "new institutional health service" under the CON Statute at N.C. Gen. Stat. section 131E-175 *et seq.*; is not therefore subject to review by the CON Section; and neither Mission nor CarePartners are required to obtain a certificate of need ("CON") before proceeding to replace the equipment. I am writing to request a "No Review" determination by the CON Section with respect to replacement of the Equipment.

Background and Project Description

Mission Hospital and CarePartners Rehabilitation Hospital are both entities housed within the North Carolina Division of HCA Healthcare, Inc. Both corporate entities are limited liability limited partnerships. The upstream members of both the Mission Hospital and CarePartners Rehabilitation Hospital limited liability limited partnerships are MH Master, LLC and MH Master Holdings, LLLP.

Since approximately 2000, Mission has provided acute inpatient dialysis services to its hospital patients via a contract with Davita, Inc.¹ Since approximately 2016, CarePartners has provided acute inpatient dialysis services to its patients, via an amendment to Mission's contract with DaVita which added the CarePartners Rehabilitation Hospital as an additional site of service under the original Mission / DaVita contract. Neither Mission nor CarePartners are "kidney disease treatment centers" as that term is defined in the CON Statute. Specifically, neither Mission nor CarePartners are "certified as an end-stage renal disease facility by the Centers for Medicare and Medicaid Services of the Department of Health and Human Services pursuant to 42 C.F.R. section 405." See N.C. Gen. Stat. 131E-176(14e) (CON Statute's definition of "kidney disease treatment center).

¹ DaVita, Inc. was formerly known as Total Renal Care of North Carolina, LLC.

Lisa Pittman
June 7, 2021
Page 2

Effective in June of 2021, Mission and CarePartners will be terminating their agreements with DaVita and both Mission and CarePartners will provide acute inpatient dialysis to their respective patients directly, rather than through a contract with an outside dialysis vendor. As part of that transition of services, Mission and CarePartners will acquire the following Tablo dialysis machines to replace those currently being provided by DaVita under its agreement with Mission and CarePartners.

Specifically, Mission and CarePartners will acquire the following replacement dialysis machines:

- Mission will acquire 18 Tablo units to replace dialysis machines currently being provided by DaVita under its contract with Mission to provide inpatient dialysis services; and
- CarePartners will acquire 2 Tablo units to replace dialysis machines currently being provided by DaVita under its contract with CarePartners to provide inpatient dialysis services.

The Tablo Dialysis Machines Being Acquired by Mission and CarePartners do not Constitute “New Institutional Health Services” Within the Meaning of the CON Statute

The CON Law precludes any person from offering or developing a “new institutional health service” without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of “new institutional health service” includes, *inter alia*, the following:

- Incurring an obligation for a capital expenditure that exceeds \$2,000,000.00 to develop or expand a health service or health service facility, or which “relates” to the provision of a health service (N.C. Gen. Stat. section 131E-176(16)(b));
- Developing a new “health service facility” which includes developing a new “kidney disease treatment center” (N.C. Gen. Stat. section 131E-176(16)(a) and N.C. Gen. Stat. section 131E-176(9b));
- The offering of dialysis services . . . by or on behalf of a health service facility if those services were not offered within the previous 12 months by or behalf of the facility (N.C. Gen. Stat. section 131E-176(16)(d)); and
- The acquisition of “major medical equipment” (N.C. Gen. Stat. section 131E-176(16)(p)).²

For the reasons set forth below, the Proposed Project does not qualify as a new institutional health service under any of these provisions or under any other provision of the CON Statute and thus neither Mission nor CarePartners are required to apply for and obtain a CON to proceed with the Proposed Project. Further, the Proposed Project is not a “new institutional health service” which would nonetheless be exempt from CON review by virtue of a statutory exception to N.C. Gen. Stat. section 131E-178(a), cited above. Instead, the Proposed Project is simply not subject to CON Section review, no CON is required to proceed with the Project, and thus a No Review Determination is appropriate in this case.

The Project Does Not Involve the Expenditure of Over \$2,000,000.00

Based on our discussions with personnel from the CON Section, and based on prior Exemption Notices and No Review Determination Requests we have filed, it is our understanding that each unit of dialysis equipment being acquired as part of this project should be evaluated independently in terms of determining

² We have addressed the major definitional elements of “new institutional health service” which one might consider when analyzing whether this Proposed Project requires a CON.

whether the Equipment exceeds any of the CON Statute's designated capital expenditure thresholds (e.g. the \$2,000,000 "new institutional health service capital expenditure"; the "major medical equipment" capital expenditure threshold; etc.). The dialysis machines being acquired are each individual items of equipment and are not part of an integrated system of medical equipment components which rely upon one another to operate. The vendor quote attached as **Exhibit A** reflects the following:

- Mission is acquiring a total of 18 Tablo units, as follows:
 - 16 Tablo Hemodialysis System units, each at a cost of \$42,500.00; and
 - 2 Tablo Hemodialysis System XT units, each at a cost of \$52,500.00.
- CarePartners is acquiring 2 Tablo Hemodialysis System units, each at a cost of \$42,500.00 and 1 unit of Treatment Bundle Tablo Cartridges and Straws (which are likely not required to be included in the units' total capital cost but which we are including to be conservative) at a cost of \$2,400.00.³

None of the dialysis units being acquired, even including the ancillary service and support plans, come close to exceeding the \$2,000,000.00 "new institutional health service" capital expenditure threshold. Further, even if all costs for the entire suite of dialysis units being acquired is totaled together, they do not exceed the \$2,000,000.00 "new institutional health service" capital expenditure threshold. The total costs for all of the 20 dialysis units, even including their related service plans, are \$972,400.00.⁴

The Project Does Not Involve the Development of a Kidney Disease Treatment Center

As noted in prior sections of this No Review Determination Request, both Mission and CarePartners have provided inpatient dialysis to their patients for several years now, albeit through a contractual arrangement with DaVita. During that time, neither Mission nor CarePartners have ever sought Medicare certification to qualify as a "kidney disease treatment center" as that term is defined at N.C. Gen. Stat. section 131E-176(14e), nor are they required to do so. As part of this Proposed Project, neither Mission nor CarePartners will seek certification from the Medicare program as an "end-stage renal disease facility" pursuant to 42 C.F.R. section 405, which is the CON Statute's definition of a kidney disease treatment center. Rather, both Mission and CarePartners have been providing, and will continue to provide, inpatient dialysis to their patients who are at one of those two hospitals for other purposes, but also need dialysis during their hospital stay at either Mission or CarePartners.

The Project Does Not Involve the Offering of Dialysis Services by or on Behalf of a Health Service Facility That did not Offer Such Services Within the Prior 12 Months

As previously noted herein, Mission has been providing inpatient dialysis services since at least 2000, via its contractual arrangement with DaVita. Likewise, CarePartners has been providing inpatient dialysis services to its patients via a contract with Davita since approximately 2016. This Proposed Project only

³ The attached vendor quote also reflects a 1-year Product and Program Support component at a total cost of \$10,000 (for 2 units for CarePartners and \$90,000 for 18 units for Mission). Based on prior filings with the CON Section, we understand that these service plans are not required to be included in a capital cost calculation since they are not necessarily required to make the units function, but are a typical add-on to maximize ongoing performance of the machines.

⁴ As previously noted, each individual dialysis unit must be evaluated individually for purposes of assessing whether each unit meets or exceeds any capital expenditure threshold set forth in the CON Statute. We are simply showing this total for all machines and attendant service plans to show that, even combined, all units do not exceed the new institutional health service capital expenditure threshold.

Lisa Pittman
June 7, 2021
Page 4

involves the replacement of Davita's dialysis equipment with equipment owned by Mission and CarePartners respectively. The inpatient dialysis services which Mission and CarePartners have been providing since 2000 and 2016 will remain the same after the Proposed Project is implemented. As such, the Project does not involve the offering of dialysis services by or on behalf of a health service facility that did not offer such services within the prior 12 months.

The Equipment To Be Acquired And Installed As Part Of The Proposed Project Does Not Constitute Major Medical Equipment Under The CON Statute

The CON Statute treats as a "new institutional health service" requiring a CON the acquisition of major medical equipment. N.C. Gen. Stat. § 131E-176(16)p. Major medical equipment is defined as "a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars ("750,000)." N.C. Gen. Stat. 131E-176(14o).

Mission's Proposed Project does not involve the acquisition of medical equipment which meets the definition of "major medical equipment" under the CON Statute. Please see the discussion at the top of page 3 of this correspondence for a detailed explanation of the medical equipment costs which are part of the Proposed Project. As noted there, none of the individual dialysis machines being acquired as part of the Proposed Project cost more than \$750,000.00 and thus none of them qualify as "major medical equipment" within the meaning of the CON Statute.

Also, the Proposed Project does not include the acquisition of any of the equipment defined at N.C. Gen. Stat. § 131E-176(16)f1 as a "new institutional health service" which, if listed there, would require Mission to obtain a CON before acquiring the equipment regardless of the equipment's cost.

The Proposed Project Is Not A New Institutional Health Service Under Any Other Provision Of N.C. Gen. Stat. § 131E-176(16)

The Proposed Project also does not qualify as a new institutional health service under any other provision of the CON statute. Specifically, the project does not involve a change in bed capacity as defined by N.C. Gen. Stat. § 131E-176(5). That section defines "change in bed capacity" in pertinent part as: (i) any relocation of health service facility beds from one licensed facility or campus to another, or (ii) any redistribution of health service facility bed capacity among the categories of health service facility beds defined in N.C. Gen. Stat. § 131E-176(9c), or (iii) any increase in the number of health service facility beds. The Project does not involve any relocation of health service facility beds from one licensed campus to another, any increase in the number of health service beds or any redistribution of health service facility beds among the categories identified at N.C. Gen. Stat. § 131E-176(9c). Further, the Project does not involve the development or addition of any bed capacity, operating rooms, health services or facilities that fall within the definition of "new institutional health services" at N.C. Gen. Stat. section 131E-176(16).

The Proposed Project does not qualify as a "new institutional health service" under any other provision of the CON Statute, specifically including N.C. Gen. Stat. section 131E1-17(16). In short, there are no "new institutional health service" definitional elements that apply to the Proposed Project.

Lisa Pittman
June 7, 2021
Page 5

Conclusion

We would appreciate the CON Section acknowledging at its earliest opportunity that the Proposed Project, as described herein, is not subject to CON Section Review and that Mission and CarePartners may proceed with the Project without first obtaining a CON.

Please let me know if you have questions or need further information regarding this notice.

Very truly yours,



Kenneth L. Burgess
Partner

cc: Joseph R. Rudisill
Cathi Durham
Sondra Smith
Exhibit

EXHIBIT A



This Quote shall expire after 30 days, or at the end of Outset Medical, Inc.'s current fiscal quarter, whichever is earlier.

This quote is non-contractual, non-binding and is being provided for informational purposes only.

Company Address 3052 Orchard Dr
San Jose, California 95134
United States

Created Date 3/30/2021
Expiration Date 3/31/2021
Quote Number 00000414

Prepared By Jonathan Limbert
Email jlimbert@outsetmedical.com

Account Name Mission Health System
Address 509 Biltmore Ave
Asheville, North Carolina 28801
United States

Product Code	Product Name	Quantity	List Price	Sales Price	Total Price
1006001	Tablo Hemodialysis System (1006001)	16.00	\$45,000.00	\$42,500.00	\$680,000.00
1007001	Tablo Hemodialysis System XT (1007001)	2.00	\$55,000.00	\$52,500.00	\$105,000.00

Product Name	Quantity	List Price	Sales Price	Total Price
1 Year Tablo Product and Program Support ("Service")	18	\$5,000.00	\$5,000.00	\$90,000.00

Total Console \$785,000.00
Total Service \$90,000.00



This Quote shall expire after 30 days, or at the end of Outset Medical, Inc.'s current fiscal quarter, whichever is earlier.

This quote is non-contractual, non-binding and is being provided for informational purposes only.

Company Address 3052 Orchard Dr
San Jose, California 95134
United States

Created Date 3/22/2021
Expiration Date 3/31/2021
Quote Number 00000409

Prepared By Jonathan Limbert
Email jlimbert@outsetmedical.com

Account Name CarePartners Rehabilitation Hospital
Address 68 Sweeten Creek Rd
Asheville, North Carolina 28803
United States

Product Code	Product	Sales Price	Quantity	Total Price
	1 Year Tablo Product and Program Support ("Service")	\$5,000.00	2.00	\$10,000.00
1000480	48 Treatment Bundle Tablo Cartidges & Straws (1000480)	\$2,400.00	1.00	\$2,400.00
1006001	Tablo Hemodialysis System (1006001)	\$42,500.00	2.00	\$85,000.00

Total Console \$85,000.00
Total Service \$10,000.00
Total Treatment \$2,400.00
Total Other \$0.00
Grand Total \$97,400.00