NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

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

May 23, 2019

William F. McDonald
Health Systems Inc.
1804 King Road
Tifton, GA 31793

No Review

Record #:	**2951**
Facility Name:	Wilkes Dialysis Center of Wake Forest University
FID #:	956103
Business Name:	Wake Forest University Baptist Medical Center
Business #:	1324
Project Description:	Add home hemodialysis support services
County:	Wilkes

Dear Mr. McDonald:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request,** the proposal described in that correspondence 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.

You may need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

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,

Lisa Pittman
Assistant Chief

Martha J. Frisone
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

Pittman, Lisa

From:	William McDonald <william@healthsystemsinc.com>
Sent:	Wednesday, May 15, 2019 8:29 AM
To:	Conley, Azzie
Cc:	Mitzi Hutchens; Pittman, Lisa; Debbie Tuttle; Kim Clark
Subject:	[External] Request to Add - Home Hemo-Dialysis Support Services to Wilkes Dialysis Center of WFU
Attachments:	WDC - 34-2724_Wilkes Dialysis Center of Wake Forest University (AMENDED ....pdf; Wilkes Floor Plan - Expanded.pdf; 3427 - Wilkes Dialysis Center of Wake Forest University 5-15-2019 - Sign....pdf

Good Morning Azzie

Per our conversation yesterday afternoon, I have attached the following documents to add Home Hemodialysis support at Wilkes Dialysis Center of Wake Forest University.

Do you need the hard copy mailed to you? If so, will place in the mail today.

1. CMS letter for 34-2724
2. Floor Plan for Wilkes Dialysis Center
3. Signed 3427 for Wilkes Dialysis Center adding Home Hemodialysis Support services only.

After I talked with you, I called Lisa Pittman in the CON Section (she is cc'd on this email). She expressed her opinion that unless you specifically needed a Letter of No Review for Licensure & Certification records to add Home Hemodialysis Support, there was not need to for the CON Section to request or need a letter. The updated services letter from your office will be provided within the next CON application when necessary. **If you need the Letter of No Review – we will submit and request. Your guidance is needed on that issue.**

Please process the Wilkes Dialysis Center request to add Home Hemodialysis support to this location. The patients and staff at Wilkes Dialysis Center greatly appreciate your efforts to help us at this time.

If you have any questions or need any additional information, please let me know.

William

William McDonald
Director of Development
Health Systems Management, Inc.

229-387-3527 – Direct
229-326-3262 – Mobile

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
61 Forsyth Street, SW, Suite 4T20
Atlanta, Georgia 30303-8909

CENTERS FOR MEDICARE & MEDICAID SERVICES

AMENDED LETTER

CMS Certification Number (CCN): **34-2724** •

Administrator
Wilkes Dialysis Center of Wake Forest University
1917 W. Park Dr., Suite A
North Wilkesboro, NC 28659-3585

Record # 2951

Dear Administrator:

We have been notified that the above-named Medicare provider has undergone a change of ownership as defined in 42 C.F.R. § 489.18. According to the information available to this office, the ownership changed from WRMC Hospital Operating Corporation to Wilkes Dialysis Center of Wake Forest University. This change of ownership is effective **July 1, 2017**. Your Medicare year end cost report date is June 30.

FID 956103

Business 1324

Wilkes Dialysis Center of Wake Forest University entered into a provider agreement with the Secretary of Health and Human Services to participate in the Medicare Program as an INDEPENDENT RENAL DIALYSIS FACILITY. Governing regulations specify that when a change of ownership occurs, the existing Medicare agreement is automatically assigned to the new owner per 42 C.F.R. § 489.18(c). The assigned agreement is subject to all applicable statutes and regulations, and is subject to the terms and conditions under which it was originally issued. This includes, but is not limited to, full compliance of the following: all applicable health and safety requirements (including life safety code provisions); full compliance with any existing plan of correction and/or credible allegation of correction/compliance; the ownership and financial interest disclosure requirements of 42 C.F.R. Subpart C; and civil rights requirements set forth in 45 C.F.R. Parts 80, 84, 90, and 42 C.F.R. § 489.18(d). Significantly, therefore, as the new owner you are fully liable for any penalties and sanctions incurred by the previous owner, as well as any Medicare overpayments, (even if such overpayments have yet to be determined). (See 42 U.S.C. § 1395g(a)).

Your facility has been approved as an independent renal dialysis facility to furnish the following service(s): **In-center Hemodialysis (HD) and Home PD (CCPD/CAPD) Training & Support. The total number of approved stations is (24) twenty four.**

Payments will continue to be made for covered services unless evidence is received which indicates your facility is not in compliance with the requirements for participation. You must take steps to maintain required records and information necessary to allocate the costs for furnishing services to beneficiaries. Payments made under Medicare are subject to a final cost report. Your Medicare Administrative Contractor (MAC) will contact you concerning the cost report. They will explain any records and information, which will be needed to validate these costs.

At this time you should submit your Medicare bills and all other routine communications concerning Medicare reimbursement matters to the Part A NC Medicare Administrative Contractor (MAC/FI), **Palmetto GBA (11501)**. Questions concerning billing, claims and other fiscal matters should be directed to Palmetto GBA.

If you are contemplating any further expansion, relocations, renovation, change of ownership, or additions to your renal treatment services, including reuse, after the date of this approval, you must notify the **North Carolina Department of Health and Human Services** as soon as possible, by filing a new application. Your application should include all pertinent information concerning the nature and effect of the proposed change.

If you believe that this determination is incorrect in any respect, you may ask that it be reconsidered. Your request must be submitted in writing to this office within sixty (60) days of receipt of this notice, in accordance with 42 CFR 498.22(b) (c). You may submit with your request for reconsideration any information you believe to be pertinent to the determination.

We look forward to working with you in improving the quality of health care provided to beneficiaries through an efficient and effective administration of the Medicare program.

Sincerely,

Digitally signed by Renee L. Harris -S
Date: 2018.05.10 07:35:51 -04'00'

for Linda D. Smith

Associate Regional Administrator
Division of Survey and Certification

• Replaces letter dated February 16, 2018. Wilkes Dialysis Center of Wake Forest University will qualify as a freestanding Independent Renal Dialysis Facility (34-2724).

cc: NC DHHS / NC Medicaid-ESRD / Network6-Fac#336-667-3762 / PGBA

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0360

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0360. The time required to complete this information collection is estimated to average of 20 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

PART I – APPLICATION – TO BE COMPLETED BY FACILITY

1. Type of Application/Notification (check all that apply, if "Other," specify in "Remarks" section [Item 33]): (V1)
☐ 1. Initial ☐ 2. Recertification ☐ 3. Relocation ☑ 4. Expansion/change of services ☐ 5. Change of ownership
☐ 6. Other, specify

2. Name of Dialysis Facility: Wilkes Dialysis Center of Wake Forest University				3. CCN: 34-2724	
4. Street Address: 1917 W. Park Dr., Suite A				5. NPI: 1760904155	
6. City: North Wilkesboro		7. County: Wilkes		8. Fiscal Year End Date: 06/30	
9. State: NC		10. Zip Code: 28659-3585		11. Administrator's Email Address: dtuttle@wfopd.com	
12. Telephone No: (336) 667-3762		13. Facsimile No: (336) 667-4457		14. Medicare Enrollment (CMS 855A) completed? ☑ Yes ☐ No ☐ NA	

15. Dialysis Facility Administrator Name: Debbie Tuttle, Regional Nurse Administrator
Business Address: PO Box 20459
City: Winston-Salem State: NC Zip Code: 27120 Telephone No: (336) 748-0575

16. Ownership (V2) ☐ 1. For Profit ☑ 2. Not for Profit ☐ 3. Public

17. Is this dialysis facility independent (i.e., not owned or managed by a hospital)? (V3) ☑ 1. Yes ☐ 2. No
Is this dialysis facility owned and managed by a hospital and on the hospital campus (i.e., hospital-based)? (V4) ☐ 1. Yes ☑ 2. No
Is this dialysis facility owned and managed by a hospital and located off the hospital campus (i.e., satellite)? (V5) ☐ 1. Yes ☑ 2. No

18. Is this dialysis facility located in a SNF/NF (LTC) (check one): (V6) ☐ 1. Yes ☑ 2. No
If SNF/NF owned and managed by a hospital: hospital name: (V7)_____ CCN: (V8)_____
If Yes, SNF/NF name: (V9)_____ CCN: (V10)_____

19. Is this dialysis facility owned &/or managed by a multi-facility organization? (V11) ☐ 1. No ☑ 2. Yes, Owned ☐ 3. Yes, Managed
If Yes, name of multi-facility organization: (V12) Wake Forest University Health Sciences
Multi-facility organization's address: Medical Center Blvd., Winston Salem, NC 27157-0001

20. Current modalities/services for dialysis facilities requesting recertification only (check all that apply): (V13)
☑ 1. In-center Hemodialysis (HD) ☐ 2. In-center Peritoneal Dialysis (PD) ☐ 3. In-center Nocturnal HD
☐ 4. Home HD Training & Support ☐ 5. HD in LTC
☑ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse

21. New modalities/services being requested (check all that apply; must have 1 permanent patient for any modality requested): (V14)
☐ 1. In-center HD ☐ 2. In-center PD ☐ 3. In-center Nocturnal HD
☑ 4. Home HD Training & Support ☐ 5. HD in LTC
☐ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse ☑ 9. N/A

NOTE: For dialysis in more than 1 LTC facility, record this same information in the "Remarks" (item 33) section or attach list

22. Does the dialysis facility have any dialysis (PD/HD) patients physically receiving dialysis within long-term care (LTC) facilities? (V15)
☐ 1. Yes ☑ 2. No LTC (SNF/NF) facility name: (V16)_____ CCN: (V17)_____
Staffing for home dialysis in LTC provided by: (V18) ☐ 1. This dialysis facility ☐ 2. LTC staff ☐ 3. Other, specify:_____
Number of dialysis residents by modality receiving dialysis within this LTC facility: (V19) ☐ 1. HD_____ ☐ 2. PD_____

23. Number of dialysis patients currently on census:

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

In-Center HD: (V20) 68 In-Center Nocturnal HD: (V21) ____ In-Center PD: (V22) ____
Home PD: (V23) 15 Home HD <= 3x/week: (V24) ____ Home HD >3x/week: (V25) ____

24. Number of currently approved in-center dialysis stations: (V26) 24 Are onsite home training room(s) provided? (V27) ☑ 1. Yes ☐ 2. N/A

25. Additional in-center stations requested: (V28) ____ or ☑ None

26. How is isolation provided? (V29) ☑ 1. Room ☐ 2. Area (existing 2/9/2009 only) ☐ 3. CMS Waiver/Agreement (Attach copy)

27. If applicable, number of hemodialysis stations designated for isolation: (V30) 1

28. Days/times for in-center shifts or operating hours if home only (check all days that apply and complete time field in military time): (V31)
1st in-center shift starts or home only facility opens: M 06:00 T 06:00 W 06:00 Th 06:00 F 06:00 Sat 06:00 Sun ____
Last in-center shift ends or home only facility closes: M 17:00 T 17:00 W 17:00 Th 17:00 F 17:00 Sat 17:00 Sun ____

29. Dialyzer reprocessing: (V32) ☐ 1. Onsite ☐ 2. Centralized/Offsite ☑ 3. N/A

30. Staff (List full-time equivalents): Registered Nurse: (V33) 7.0 Certified Patient Care Technician (V34) 5
LPN/LVN: (V35) 0 Technical Staff (water, machine): (V36) 1
Registered Dietitian: (V37) .75 Masters Social Worker: (V38) .75
Others: (V39) Clerical - 2.00 PCT - 3.00

31. State license number (if applicable): (V40) ____

32. Certificate of Need required? (V41) ☐ 1. Yes ☐ 2. No ☑ 3. NA

33. Remarks (copy if more and attach additional pages if needed):

21. (4) Provider requests the addition of Home Hemodialysis Support only. Patients will be trained at another location certified to provide home hemodialysis training, but have the option to receive follow up at Wilkes Dialysis Center.

34. The information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my knowledge. I understand that incorrect or erroneous statements may cause the request for approval to be denied, or facility approval to be rescinded, under 42 C.F.R. 494.1 and 488 604 respectively.

I have reviewed this form and it is accurate:

Signature of Administrator/Medical Director	Title	Date
Nellie Gutter	Regional Nurse Administrator	5/14/19

PART II TO BE COMPLETED BY STATE AGENCY

35 Medicare Enrollment (CMS 855A recommended for approval by the Medicare Administrative Contractor)? (V42) ☐ 1. Yes ☐ 2. No
(Note: approved CMS 855A required prior to certification)

36. Type of Survey: (V43) ☐ 1. Initial ☐ 2. Recertification ☐ 3 Relocation ☐ 4. Expansion/change of services
☐ 5. Change of ownership ☐ 6. Complaint ☐ 7. Revisit ☐ 8. Other, specify ____

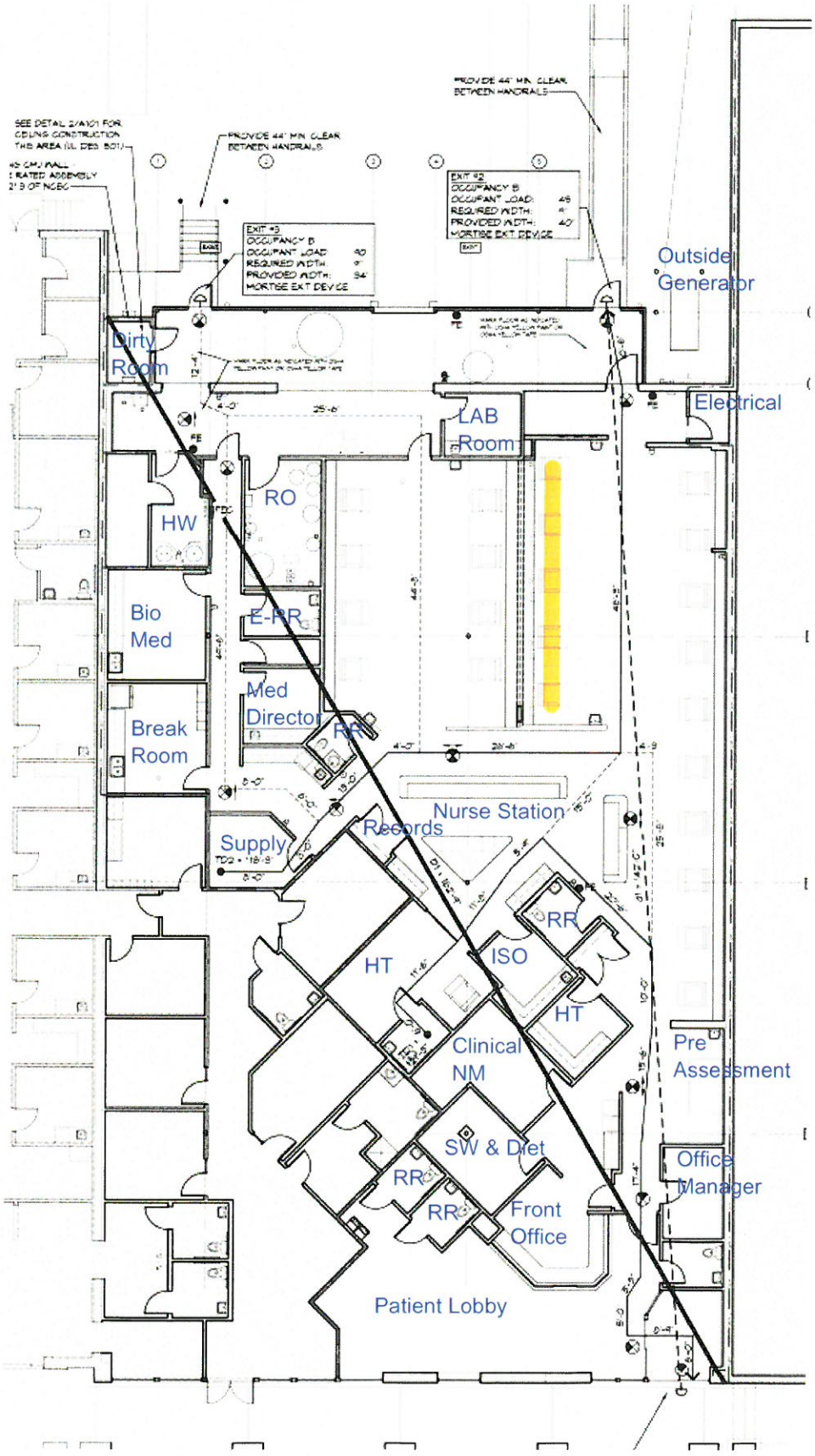
37. State Region: (V44) ____ 38. State County Code (V45) ____

39. Network Number: (V46) ____

My signature below indicates that I have reviewed this form and it is complete.

40 Surveyor Team Leader (sign)	41. Name/Number (print)	42. Professional Discipline *(Print)*	43 Survey Exit Date

INSTRUCTIONS FOR FORM CMS-3427


Outside Generator
Dirty Room
Electrical
LAB Room
RO
HW
Bio Med
E-RR
Med Director
RR
Break Room
Nurse Station
Records
Supply
RR
ISO
HT
HT
Clinical NM
Pre Assessment
SW & Diet
Office Manager
RR
RR
Front Office
Patient Lobby