



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY
June 15, 2023

Catharine Cummer, Regulatory Counsel, Strategic Planning
Catharine.cummer@duke.edu

Exempt from Review – Acquisition of Facility

Record #: See Attachment A
Date of Request: May 9, 2023
Facility Name: See Attachment A
Type of Facility: See Attachment A
FID #: See Attachment A
Acquisition by: Duke University Health System, Inc.
Business #: 640
County: Alamance, Durham and Wake

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that the project described above is exempt from certificate of need (CON) review in accordance with G.S. 131E-184(a)(8). Therefore, the above referenced business may proceed to acquire the health service facilities identified above without first obtaining a CON. The Agency's determination is limited to the question of whether the above referenced business would have to obtain a CON if the current owners of the health service facilities do in fact sell it to the business listed above. Note that pursuant to G.S. 131E-181(b): "*A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.*"

If the business listed above does acquire the facilities, you should contact the Agency's Acute and Home Care Licensure and Certification Section to obtain instructions for changing ownership of the existing facility.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination regarding whether a certificate of need would be required. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Michael J. McKillip
Team Leader

Micheala Mitchell
Chief

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

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Attachment A

Record #	Name of Private Diagnostic Clinic, PLLC Facility to be Acquired by Duke University Health System, Inc.	Type of Facility	County	FID
4203	Kernodle Clinic Burlington	Diagnostic Center	Alamance	210087
4204	Duke Health Holly Springs	Diagnostic Center	Wake	180516
4205	Duke Health Center Apex	Diagnostic Center	Wake	180515
4206	Duke Health Center South Durham	Diagnostic Center	Durham	170278
4207	Duke Medicine Specialty Care Croasdaile Commons	Diagnostic Center	Durham	120090
4208	Duke Sports Science Institute	Diagnostic Center	Durham	150393
4209	Duke Vascular Specialists of Raleigh	Diagnostic Center	Wake	180318
4210	Duke Health Specialty Care Page Road	Diagnostic Center	Durham	210088
4211	Duke Medicine Specialty Care Page Road	Diagnostic Center	Durham	101140
4212	Duke Medical Plaza Knightdale	Diagnostic Center	Wake	080605
4213	Duke GI at Brier Creek	GI Endo ASF	Wake	150337



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

May 9, 2023

Via Electronic Delivery

Micheala Mitchell
Chief
Health Care Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Dear Ms. Mitchell:

I am writing on behalf of Duke University Health System, Inc. (“DUHS”) regarding a proposed transaction to acquire the assets of the Private Diagnostic Center, PLLC (“PDC”) and to continue the operation of the PDC’s facilities, including CON-approved health service facilities. DUHS is requesting that the Certificate of Need Section issue written confirmation that the transaction and associated acquisition of existing health service facilities is exempt from certificate of need review. DUHS also seeks confirmation that certain certificates of need awarded to the PDC and still under development may be transferred to DUHS for good cause.

Background on the Transaction

DUHS is a North Carolina nonprofit corporation, with its principal place of business in Durham County, North Carolina. Duke owns and operates acute care hospitals, ambulatory surgery centers, diagnostic centers, and other regulated health services, as well as physician practices.

PDC, the existing Duke University School of Medicine faculty practice plan, is one of several closely integrated and highly interdependent components of “Duke Health” with a shared mission of developing breakthrough treatments and providing high quality care to patients. PDC is a professional limited liability company for which a prerequisite of membership for physicians is a faculty appointment in the Duke University School of Medicine. In addition to carrying out cutting-edge research and training the future healthcare workforce as faculty in the Duke School of Medicine, PDC’s members provide patient care through clinics located throughout central and eastern North Carolina under the Duke Health brand.

Ms. Micheala Mitchell
May 9, 2023

In 2022, DUHS and PDC reached an agreement for DUHS's purchase of substantially all of the PDC's assets and assumption of its leases and space obligations, with an anticipated closing date of July 1, 2023. In connection with that transaction, the PDC's member physicians have been offered employment by a new clinical enterprise within the Duke University Health System, through its wholly-controlled affiliate Duke Health Integrated Practice, Inc, a North Carolina nonprofit corporation ("DHIP"). PDC providers and staff have been offered employment in this new, physician-led entity. While DUHS and the PDC have historically been closely aligned in the provision of clinical care, Duke Health will be better able to coordinate its range of patient care, teaching and research activities, and better equipped to improve access and grow with the operation of the faculty practice plan under DHIP. After closing of this transaction, the PDC will be dissolved.

PDC Clinical Operations Subject to the Anticipated Transaction

Upon the closing of this transaction, DHIP intends to continue the clinical operations and continue providing the same care and access at substantially all of the PDC's existing locations.

Existing PDC Health Service Facilities

Currently, PDC clinical sites include the following diagnostic centers developed pursuant to certificates of need:

Facility	FID	CON Issuance Date
Kernodle Clinic Burlington	210087	May 11, 2021
Duke Health Holly Springs	180516	August 17, 2019
Duke Health Center Apex	180515	February 14, 2019
Duke Health Center South Durham	170278	November 6, 2017
Duke Medicine Specialty Care Croasdaile Commons	120090	June 12, 2012
Duke Sports Science Institute	150393	December 1, 2015
Duke Vascular Specialists of Raleigh	180318	October 30, 2018
Duke Health Specialty Care Page Road	210088	June 25, 2021
Duke Medicine Specialty Care Page Road	101140	May 11, 2011
Duke Medical Plaza Knightdale	080605	February 28, 2009

Ms. Micheala Mitchell
May 9, 2023

The PDC also currently operates the following licensed endoscopy center:

Duke GI at Brier Creek
10207 Cerny Street
Suite 210, Raleigh, NC, 27617
License No: AS0115
FID: 150337

PDC Certificates of Need In Development

In addition, the PDC has been awarded the following certificates of need for licensed endoscopy facilities, which facilities are under development:

Facility	Project Number	Date Issued
Duke GI at Green Level	J-11709-19	September 4, 2019
Duke GI at North Durham	J-11708-19	September 4, 2019
Duke Gastroenterology of Raleigh	J-11934-20	December 30, 2020

Notice of Exempt Acquisition

This letter provides notice that DUHS and/or DHIP will acquire the existing health service facilities listed above effective upon the closing of the described transaction. That closing is currently anticipated to occur July 1, 2023. The acquisition of these facilities will allow for continued access to needed clinical services without disruption of existing patient care.

Pursuant to N.C.G.S. 131E-184(a)(8), the acquisition of an existing health service facility (defined in N.C.G.S. 131E-176 to include diagnostic centers and ambulatory surgery/endoscopy facilities) is exempt from certificate of need review.

Request for Transfer for Good Cause Determination

The PDC holds three certificates of need for endoscopy centers which are in varying stages of development.

The transaction described above contemplates the transfer of substantially all of the PDC's assets and assumption of a substantial number of its contracts, and includes the assumption of any space obligations related to the proposed facilities, which were proposed to be developed in space leased from DUHS. Duke GI at Green Level and Duke Gastroenterology of Raleigh are under development in existing DUHS-owned medical office buildings. Duke GI at North Durham will be developed in a future medical office building not yet constructed. The need for the projects, the physicians who intend to refer patients to and provide services at these facilities, and the patients anticipated to be served all remain the same. We would note that none of these projects

Ms. Micheala Mitchell
May 9, 2023

was subject to a need determination and these projects do not affect the opportunity for any other provider to apply to develop similar services.

DUHS commits to the development of the projects in material compliance with the original applications and with their approvals by the state, and this transaction will not cause any delay in their continued development. Duke Health remains committed to offering the proposed services for the benefit of the patients of Wake and Durham Counties and surrounding areas.

Accordingly, we believe that good cause exists within the meaning of N.C. Gen. Stat. § 131E-189(c) for transfer of these CONs. We hereby request that the CON Section find that good cause exists for the proposed CON transfer and the development of these projects by DUHS or an affiliate, and also confirm that it will not withdraw the CONs for the above referenced projects as a result of the transfer.

Conclusion

We appreciate your consideration of this notice of exempt acquisition and request for determination of good cause for transfer of the PDC's CONs. This transaction will enable Duke Health to continue to offer state of the art healthcare to the residents of North Carolina, and these determinations are essential to avoid any disruption to needed patient care. Please let me know if you have any questions. Thank you very much.

Sincerely,

Catharine W. Cummer

Catharine W. Cummer

Cc: Frederick Zufelt, counsel for PDC

From: [Mitchell, Micheala L](#)
To: [Stancil, Tiffany C](#)
Cc: [Waller, Martha K](#)
Subject: FW: [External] Letter of Exempt Acquisition of PDC Assets and Transfer of PDC CONs
Date: Tuesday, May 9, 2023 11:43:26 AM
Attachments: [Letter of Exempt Acquisition of PDC Assets and Transfer of PDC CONs.pdf](#)

Hey Tiffany,

Martha may have already logged this. If she hasn't will you log it as an exemption and assign to Mike?

Thanks,

Micheala Mitchell, JD
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

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From: Catharine Cummer <catharine.cummer@duke.edu>
Sent: Tuesday, May 9, 2023 11:05 AM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Cc: Frederick Zufelt <frederick.zufelt@duke.edu>; Waller, Martha K <martha.waller@dhhs.nc.gov>
Subject: [External] Letter of Exempt Acquisition of PDC Assets and Transfer of PDC CONs

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Ms. Mitchell:

Please see the attached correspondence about a contemplated Duke University Health System transaction with the Private Diagnostic Clinic. I welcome the opportunity to answer any questions you may have. Thank you.

Yours,
Catharine Cummer

Catharine W. Cummer
Regulatory Counsel, Strategic Planning, Duke University Health System
Office 919-668-0857 | Cell 919-423-6928