

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 24, 2020

Robert A. Leandro
Parker, Poe, Adams & Bernstein, LLP
robbleandro@parkerpoe.com

Exempt from Review – Replacement Equipment

Record #: 3366

Business Name: DLP Cardiac Partners, LLC

Business #: 2314

Project Description: Replace an existing fixed cardiac catheterization lab located at Duke Raleigh

Hospital with a new mobile cardiac catheterization lab

County: Wake

Dear Mr. Leandro:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 17, 2020, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Philips FD20 mobile cardiac catheterization lab to replace the Philips FD10 fixed cardiac catheterization lab (Serial #161). This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you 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.

It should be noted that the 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 office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Michael J. McKillip Project Analyst

Martha J. Frisone

Martha J. Frisone 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



Robert A. Leandro Partnert: 919.835.4636
f: 919.834.4564

robbleandro@parkerpoe.com

Atlanta, GA Charleston, SC Charlotte, NC Columbia, SC Greenville, SC Raleigh, NC Spartanburg, SC Washington, DC

September 17, 2020

ELECTRONIC MAIL

Martha Frisone, Chief Healthcare Planning and Certificate of Need Section North Carolina Department of Health and Human Services Raleigh, NC 27699-2704 Martha.Frisone@dhhs.nc.gov

Re: DLP Cardiac Partners Prior Notice of Replacement of Cardiac Cath Lab

Dear Ms. Frisone:

This letter is intended to provide prior notice to the Healthcare Planning and Certificate of Need Section (the "CON Section" or the "Agency") that our client, DLP Cardiac Partners ("Cardiac Partners") is replacing the cardiac catheterization ('cardiac cath") lab equipment it currently operates at Duke Raleigh Hospital ("Duke Raleigh"). The existing cardiac cath lab at Duke Raleigh is one of the nine mobile cardiac cath labs subject to the 1995 Settlement Agreement with the Department. Pursuant to the Settlement Agreement, these nine mobile cath labs may be operated as either fixed or mobile cath labs. Cardiac Partners is the successor of interest to the 1995 Settlement Agreement based on the 2011 Exemption Decision of this Agency. See Attachment A.

The existing cath lab is a fixed unit. It was originally purchased in 2010. The existing cath lab will be removed from Duke Raleigh and will be sold for parts. It will not be used in North Carolina unless a CON or applicable exemption is obtained.

The replacement lab will be a mobile cath unit, which is permitted under the 1995 Settlement Agreement. The approximate cost of the replacement equipment is \$250,000.00. See Attachment B, Replacement Chart. The replacement equipment will perform similar procedures and have similar capabilities as the existing cath lab equipment. *Id.* Cardiac Partners expects that the replacement lab will be used at various authorized locations throughout North Carolina.

Cardiac Partners requests that the Agency issue a written determination confirming that this replacement acquisition is exempt from CON review. We greatly appreciate your attention to this matter. If you have any questions, please feel free to contact me directly.

Sincerely, RSL a. Lealon

Robb Leandro

RAL:clr

Attachment

ATTACHMENT A



North Carolina Department of Health and Human Services Division of Health Service Regulation Certificate of Need Section 2704 Mail Service Center, Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief Phone: 919-855-3873

Fax: 919-733-8139

Lanier M. Cansier, Secretary

April 29, 2011

Jone Law Koford, Secretary DLP Cardiac Partners, LLC 103 Powell Court, Suite 200 Brentwood, TN 37027

Exempt from Review/ Acquisition of the mobile diagnostic program consisting of the nine RE: units of cardiac catheterization equipment identified in Attachment A owned by MedCath Partners, LLC by DLP Cardiac Partners, LLC

Dear Mr. Koford:

In response to your letter of April 27, 2011, the above referenced proposal is exempt from certificate of need review in accordance with G.S. 131E-184(a)(8). Therefore, DLP Cardiac Partners, LLC may proceed to acquire the above referenced health service facility without first obtaining a certificate of need.

The existing mobile diagnostic program consisting of the nine units of cardiac catheterization equipment identified in Attachment A is authorized by the terms of the August 14, 1995 Settlement Agreement (Attachment B). Operation of the nine units of cardiac catheterization equipment by DLP Cardiac Partners, LLC will also be subject to the terms of the August 14, 1995 Settlement Agreement.

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. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Assistant Chief

Certificate of Need Section

Medical Facilities Planning Section, DHSR

Location: 701 Barbour Drive a Dorothea Dix Hospital Campus a Raleigh, N.C. 37603 An Equal Opportunity Affirmative Action Employer

Attachment A

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	29539VP4	29536VP4	29538VP4*	28538VP4	29S39VP4	29538VP4
- A	Pardee	Pardee	Pardea	Perdos	Pardee	Pardee
	Z77807WICE	338	336.7	336	336	336
Contin	Wilmington Heart Center	Doğum	Dotton	Duka	Duke	Duke
	EDED-AVE-4	BOBZANPA	EDECAPA*	BZBZ4VP4	6570	SSPACEBUR PR
alth Wobie Rie	alth Mobile Ris Pinehurt First Health Mobile Ris First Health	First Health	Pératuret First Health Moolle Rie	the Pinehurst Pirst Health Mobile Rise Interin Lab 73	Interin Lab 73	Prechyterian Hosp Matthews
	977482	877482	8774823	977482	578215818	5752169U6
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Service of the servic	· ·	Critical	Caldwell Memorial	Calchwell Memorial .	Caldwell Marrodal	Caldwell Memorial
	í	4180140	4160340	4180140	576988800	S70550860
	Grace Hospital	Graco	Grace Hospital	Grace Hospital	Grace Hoopital	Gracos Mospital
	SGNOSCYS	SKZBOWPS	S4XXXXXX	SKZBOVPS	SAVOSONPS	# 0728
:Centor	Greensborn Heart Center	GHC	Greenshore Heart Carrier	Greensboro Head Center	Greensborn	ENC Mobile Route
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ofers Mobile	Earthm North Carolina Mebile		ENC Mobile Route	ENC Mobile Route	ENC Mobile Route	ENC Mobile Route

Duke LIFEPOINT HEALTHCARE

April 27, 2011 ·

Via Hand Delivery

Craig R. Smith, Section Chief Certificate of Need Section Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Acquisition of Health Service Facility

Dear Mr. Smith:

We write on behalf of DLP Cardiac Partners, LLC ("DLP"). DLP is wholly owned by DLP Healtheare LLC, a joint venture of the Duke University Health-System and DLP Partner, LLC (a subsidiary of LifePoint Hospitals, Inc.). The purpose of this letter is to provide prior written notice of the acquisition by DLP of the mobile diagnostic program currently owned and operated by MedCath Partners, LLC ("MedCath").

MedCath operates a mobile diagnostic program consisting of 9 cardiac catheterization units operated pursuant to service agreements with various host sites (the "Program"), pursuant to a Settlement Agreement between MedCath Incorporated, Healthtech Corporation, and the State dated August 14, 1995 (the "Settlement Agreement"). We understand from MedCath that pursuant to subsequent corporate reorganizations as previously communicated to the CON Section, MedCath became the authorized operator of the Program under the Settlement Agreement.

Subject to the Certificate of Need Section's confirmation that the acquisition does not require a certificate of need, DLP will acquire substantially all of the assets currently owned by MedCath, including the 9 cardiac catheterization units used in the Program, with the intent to continue operating the Program going forward. Upon learning that MedCath was seeking to divest itself of the Program, DLP pursued this acquisition in order to ensure the continued provision of necessary cardiac catheterization services throughout the state.

Attachment B

STATE OF NORTH CAROLINA COUNTY OF MECKLENBURG

IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION 95 CVS 7908

MEDCATH INCORPORATED, and HEALTHTECH CORPORATION, Plaintiffs,

SETTLEMENT AGREEMENT

NORTH CAROLINA DEPARTMENT OF HUMAN RESOURCES, Defendant.

BY THIS SETTLEMENT AGREEMENT the disputes described herein between Plaintiffs, Medcath Incorporated ("Medcath") and HealthTech Corporation ("HealthTech") (collectively referred to hereinafter as "Plaintiffs") and the North Carolina Department of Human Resources, Division of Facility Services (the "Department") (collectively referred to hereinafter as "the Parties") are hereby resolved.

GENERAL PROVISIONS

- 1. This Action was instituted by Complaint For Declaratory Judgment, filed by Plaintiffs on June 29, 1995.
 - 2. Plaintiffs sought a declaration that, under the current Certificate of Need Law:
- (A) the fifteen mobile cardiac laboratories acquired by Plaintiffs prior to March 18, 1993 are exempt from review;
- (B) each mobile cardiac catheterization laboratory currently operated by Plaintiffs is a "diagnostic center" and a "health service facility"; and,
- (C) the proposed conversion of an existing mobile cardiac catheterization laboratory to a fixed-base unit is not a "new institutional health service."

It is our understanding and belief that the acquisition of the MedCath's cardiac catheterization Program constitutes the acquisition of an existing health care facility exempt from certificate of need review under N.C.G.S. § 131-E-184(a)(8). We request your written confirmation of this exemption. We intend that this correspondence serve as any required statutory notice of the acquisition.

Because DLP will own and operate the Program going forward, we also seek your confirmation that the Settlement Agreement will remain in full force and effect with DLP, and that DLP will be entitled to continue operating the Program, including providing diagnostic and therapeutic cardiac catheterization services at existing and future host sites pursuant to service agreements, under the same terms and conditions that have previously applied to MedCath.

As we would like to move forward with the acquisition as quickly as possible, we would appreciate your early confirmation of our understanding of the effects of this acquisition. Should you require further information, please let me know as soon as feasible.

Thank you for your consideration.

Joné Law Koford

Secretary

DLP Cardiac Partners, LLC

Attachment B

STATE OF NORTH CAROLINA	IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION
COUNTY OF MECKLENBURG	95 CVS 7908
MEDCATH INCORPORATED, and HEALTHTECH CORPORATION, Plaintiffs.	}
ν.	SETTLEMENT AGREEMENT
NORTH CAROLINA DEPARTMENT OF	, · {

HUMAN RESOURCES,

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 - 2. Plaintiffs sought a declaration that, under the current Certificate of Need Law:
- (A) the fifteen mobile cardiac laboratories acquired by Plaintiffs prior to March
 18, 1993 are exempt from review;
- (B) each mobile cardiac catheterization laboratory currently operated by Plaintiffs is a "diagnostic center" and a "health service facility"; and,
- (C) the proposed conversion of an existing mobile cardiac catheterization laboratory to a fixed-base unit is not a "new institutional health service."

- 3. Plaintiffs also sought a declaration that the Department's application of the Certificate of Need Law, insofar as it seeks to prevent Plaintiffs from operating the mobile cardiac catheterization laboratories and/or converting them to fixed-base units in North Carolina, violates Article 1, Section 19 of the North Carolina Constitution and the Commerce Clause of the United States.
 - 4. The Department maintains that:
- (A) Plaintiffs are authorized to operate only those mobile cardlac eatheterization laboratories that were acquired and in use in North Carolina prior to March 18, 1993;
- (B) each individual mobile cardiac catheterization laboratory currently operated by Plaintiffs is not a "diagnostic center" or "mobile diagnostic program" within the definition of "diagnostic center" and/or a "health service facility"; and,
- (C) the conversion of an existing mobile cardiac catheterization laboratory, to a fixed-base unit may be a "new institutional health service."
- 5. The Department also maintains that Plaintiffs have failed to exhaust their administrative remedies and that the Department's application of the Certificate of Need Law which seeks to prevent Plaintiffs from operating the mobile cardiac catheterization laboratories and/or converting them to fixed-base units in North Carolina is not in violation of Article 1, Section 19 of the North Carolina Constitution and the Commerce Clause of the United States.
- 6. Plaintiffs have provided the Department with additional information which relates to the acquisition of the cardiac catheterization equipment prior to March 18, 1993. Plaintiffs have also provided documentation regarding:

- (A) the actual use of mobile cardiac catheterization equipment in North Carolina prior to March 18, 1993;
- (B) binding legal contracts with various persons that relate to the use of the equipment in North Carolina; and,
- (C) conformance with replacement equipment exemption requirements.

 The Plaintiffs have designated certain of the information provided to the Department as "confidential," pursuant to N.C. Gen. Stat. § 132-1,2 and the Department acknowledges that disclosure of information so designated is not required or authorized by N.C. Gen. Stat. § 132-1, et seq.
- 7. In reviewing the above-referenced information provided by Plaintiffs, the Department has found that mobile cardiac catheterization laboratory (identification number 22B203025) that was in use in North Carolina prior to March 18, 1993, was acquired by Plaintiffs after March 18, 1993 without Certificate of Need review. Subsequently, this laboratory was removed from North Carolina and another laboratory (identification number 893750) was brought into North Carolina and put in use without Plaintiffs obtaining a replacement equipment exemption. Plaintiffs do not concede that any violation of applicable laws or rules of the Department have occurred with respect to this equipment and further contend that, if any such violation did in fact, occur it was unintentional and inadvertent.
- 8. Pursuant to N.C. Gen. Stat. § 150B-31, it is the policy of the State to settle disputes between state agencies and other persons whenever possible. The Parties have, therefore, determined that it is in their best interests to settle all issues related to this case upon the terms and conditions stated in this Settlement Agreement.

9. The Parties understand and expressly agree that this Settlement Agreement shall not be construed as an admission of liability on the part of either of the Parties with respect to any issue. Rather, the Parties continue to maintain and do not concede each of their respective contentions.

In consideration of their several and mutual promises, these disputes are hereby resolved in the manner set forth below:

- A. <u>Voluntary Dismissal With Proludice</u>. Within five business days after this Settlement Agreement is fully executed Plaintiffs shall file a notice of voluntary dismissal, with projudice, in case number 95 CVS 7908.
- issue, Plaintiffs shall be authorized to operate in North Carolina the nine (9) mobile cardiac catheterization laboratories identified in Attachment A to this Settlement Agreement. The remaining six (6) mobile cardiac catheterization laboratories shall be removed from the State within 30 days from the date that this Settlement Agreement is fully executed, and shall not be used or operated in North Carolina without first obtaining a certificate of need or exemption. This paragraph shall not apply in the event that, pursuant to judicial action or legislative action, a certificate of need is no longer required for Plaintiffs' services in North Carolina.
- C. Authorized Use. Plaintiffs may operate the authorized nine (9) mobile cardiac catheterization units as either mobile laboratories or fixed-base laboratories at ambulatory surgical centers, hospitals/hospital campuses, professional office buildings, urgent care, centers, and imaging centers.

- D. Transfer of Equipment. Any transfer of ownership or control of any of the individual cardiac catheterization laboratories after the date of this Settlement Agreement shall remain subject to the provisions of the Certificate of Need Law and any applicable rules promulgated by the Department as those provisions may be in effect at the time of any such transfer; provided, however, that nothing in this Settlement Agreement shall place any greater restriction on the ownership, control or operation of any of the individual cardiac catheterization laboratories than is placed on any other comparable equipment by the above-referenced law and rules.
- B. Penalties. In full satisfaction of any sanctions which might be imposed by the Department against Plaintiffs as of the date of this Settlement Agreement under N.C. Gen. Stat. § 131B-190 or any other law or rule of the Department in connection with Plaintiffs' acquisition, ownership or operation of the laboratory referenced in Paragraph 7, the Department will impose a civil penalty of five thousand dollars (\$5,000.00). Without conceding any violation of any law or rule of the Department, Plaintiffs will pay that penalty within ten (10) days of the execution of this Settlement Agreement. This Settlement Agreement will constitute any notice of the above-referenced civil penalty which is required by law and will fully resolve this matter.
- P. Modification or Waiver. No modification or waiver of any provision of this Settlement Agreement shall be effective unless its modification or waiver shall be in writing and signed by the Parties and the same shall be effective only for the period and on the conditions and for the specific instances and purposes specified in such writing.

- G. <u>Title/Preamble</u>. All parts and provisions hereof, including the preamble, are intended to be of substance.
- H. <u>Documentation/Notices</u>. Upon request by the Department or Certificate of Need Section, Plaintiffs shall provide information documenting Plaintiffs' compliance with the provisions of this Settlement Agreement. All documentation, notices, requests, demands, or other communications provided for herein or in any instrument or document delivered pursuant hereto, shall be in writing, shall be deemed to have been given when sent by registered or certified mail, return receipt requested, and at Plaintiffs' option may be designated as "confidential" pursuant to N.C. Gen. Stat. § 132B-1 et seq.
- Agreement sets forth all of the terms and conditions between them concerning the subject matter of this Settlement Agreement, superseding all prior oral and written statements and representations, and that there are no terms or conditions between the Partles except as specifically set forth in this Settlement Agreement.
- J. Expenses. The Parties agree that each Party shall bear its own expenses, including attorney's fees, and that no claim for such costs or expenses shall be made by one Party against the other.
- K. Review of Agreement/Authority to Settle. The Parties have reviewed this document, have had the opportunity to consult with counsel and represent and warrant that they are authorized to enter into this Settlement Agreement on behalf of the Parties to this Agreement. The terms of this Settlement Agreement shall not be construed in favor of or against any of the Parties.

- L. <u>Bffective Date</u>. This Agreement shall be effective as of the day and year on which it is adopted and approved by the Director of the Division of Facility Services.
- M. Mutual Release. Plaintiffs hereby release the Department of Human Resources, the Certificate of Need Section, its officials, employees, and representatives, from any and all liability that has arisen or may arise as a result of this matter or the execution of this Settlement Agreement. The Department hereby releases Plaintiffs, their officers, employees, and representatives, from any and all liability that has arisen or may arise as a result of this matter or the execution of this Settlement Agreement.

(Signature Page to Follow)

IN WITNESS WHEREOF, the Parties have executed duplicate original

copies of this Settlement Agreement, with one original copy being retained by each party.

Stephen R. Puckett, President

HEALTHTECH CORPORATION .

Steplien R. Puckett,

MICHABL F. BASLBY

Attorney General

Sherry Cornett Lindquist Assistant Attorney General N.C. Department of Justice

P.O. Box 629

Raleigh, NC 27602-0629

(919) 733-4512

COUNSEL FOR THE CERTIFICATE OF

NEED-SECTION-

BY: Nool H. Hulltelle III Noah H. Huffstetler II Petree Stockton, L.L.P. 4101 Lake Boone Trail

Suite 400

Raleigh, NC 27607

COUNSEL FOR PETITIONER

This is the ///day of August. 1995.

John M. Syria, Director L'Division of Pacility Services

N.C. Department of Human Resources

701 Barbour Drive

Raleigh, NC 27603-2008

ATTACHMENT A

A Cardiac Catheterization Laboratories to be Registered by Plaintiffs (by Serial Number)	Cardiao Catheterization Laboratories to be Registered by Plaintiffs (by VIN Number)	
9803603201	1PT011JH529001121	
259058WK6	1PT011JH3L9004826	
277607WK8	1PT011JH6M9002232	
28691WK1	. 1T9F80Z26KB021865	
119R013	1PTO 1AH3M9007078	
. 347649WK6	1T9FS0Z24NB021819	
893750	1TT011JH1L9004582	
289378WK2	1T9FS0Z29LB021073	
368093WK1	1T9FS0Z21PB021893	

446-165118

ATTACHMENT B

	EXISTING EQUIPMENT	REPLACEMENT EQUIPME
Type of Equipment (List Each Component)	cardiac cath lab	cardiac cath lab
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	N/A	N/A
Model Number	FD10	FD20
Serial Number	161	TBD
Provider's Method of Identifying Equipment	N/A	N/A
Specify if Mobile or Fixed	Fixed	Mobile
Mobile Trailer Serial Number/VIN#	N/A	1KKVD5327CL232771
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	6/7/2010	TBD
Does Provider Hold Tittle to Equipment or Have a Capital Lea	ase? Holds Tittle	Hold Title
Specify if Equipment Was/Is New or Used When Acquired	Used	Used
Total CapitalCost of Project(IncludingConstructionetc.) *Use attached form*	N/A	N/A
Total Cost of Equipment	125,000	250,000
Fair Market Value of Equipment	125,000	250,000
Net Purchase Price of Equipment	125,000	250,000
Location Where Operated	Duke Raleigh Area Hospita	l Mobile Route
Number days in Use/To be Used in N.C. Per Year	250	250
Percent Change in patient Charges (by Procedure)	N/A	0%
Percent of Changein Per Procedur@peratingExpenses(by Procedure)	N/A	0%
Type of Procedures Currently Performed on Existing equipm	entcardiac catheterizations	N/A
Type of Pricedures New Equipment id Capable of Performing	a N/A	cardiac catheterizations

From: <u>Frisone, Martha</u>
To: <u>Waller, Martha K</u>

Subject: FW: [External] DLP Cardiac Partners Prior Notice of Replacement of Cardiac Cath Lab

Date: Thursday, September 17, 2020 1:58:42 PM
Attachments: Cardiac Partners CON letter 9 17 20.pdf

Martha J. Frisone

Chief

<u>Division of Health Service Regulation</u>, Healthcare Planning and Certificate of Need NC Department of Health and Human Services

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Know the 3 Ws. Wear. Wait. Wash.

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Office: 919-855-3879

martha.frisone@dhhs.nc.gov

809 Ruggles, Edgerton 2704 Mail Service Center Raleigh, NC 27699-2704

Twitter | Facebook | Instagram | YouTube | LinkedIn

From: Reid, Christina L. <christinareid@parkerpoe.com> On Behalf Of Leandro, Robert A.

Sent: Thursday, September 17, 2020 1:49 PM

To: Frisone, Martha <martha.frisone@dhhs.nc.gov>

Cc: Payne, Lindsey H. < lindseypayne@parkerpoe.com>; Leandro, Robert A.

<robbleandro@parkerpoe.com>

Subject: [External] DLP Cardiac Partners Prior Notice of Replacement of Cardiac Cath Lab

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Ms. Frisone,

Please find the attached letter regarding DLP Cardiac Partners Prior Notice of Replacement of Cardiac Cath Lab.

We greatly appreciate your attention to this matter. If you have any questions, please feel free to contact me directly.

Sincerely,

Robb Leandro

Robert Leandro

Partner

Find our latest health care analysis here.



PNC Plaza | 301 Fayetteville Street | Suite 1400 | Raleigh, NC 27601

Office: 919.835.4636 | Fax: 919.834.4564 | vcard | map

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