NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY)
RULING BY STONE INSTITUTE OF)
THE CAROLINAS, LLC)
PROJECT I.D. NO. F-7852-07)

DECLARATORY RULING

I, Robert J. Fitzgerald, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A.0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Stone Institute of the Carolinas, LLC ("Stone Institute") has requested a declaratory ruling allowing for an additional host site for Project I.D. No. F-7852-07 on the grounds that the change does not constitute a material change in physical location or a failure to materially comply with the representations made by Stone Institute in its Certificate of Need ("CON") application for its project. N.C.G.S. §§ 131E-181(a) and (b). This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Douglas M. Surratt, Business Manager, has requested this ruling on behalf of Stone Institute and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Effective 12 October 2007, the CON Section issued a CON to Stone Institute for Project I.D. No. F-7852-07 to acquire a mobile lithotriptor to be located in Mecklenburg County. In its application, Stone Institute provided letters of intent from Presbyterian Hospital and Carolinas HealthCare System to contract with Stone Institute to provide mobile lithotriptor services at the following sites:

- 1. Carolinas Medical Center, Main Campus, Charlotte, NC
- 2. Carolinas Medical Center, Mercy Hospital, Charlotte, NC
- 3. Carolinas Medical Center, University Hospital, Charlotte, NC
- 4. Presbyterian Hospital, Matthews, Matthews, NC
- 5. Presbyterian Orthopaedic Hospital, Charlotte, NC
- 6. Presbyterian Hospital, Huntersville, Huntersville, NC

Stone Institute now seeks to add a new host site at Carolinas Medical Center, NorthCross

Surgery Center ("CMC-NorthCross"), Huntersville, Mecklenburg County. Stone Institute

includes in its Request a proposed schedule that shows 19 equivalent days per year service at

CMC-NorthCross, with a corresponding decrease at CMC-Main.

In its CON application, Stone Institute stated:

Note that all exhibits in this application plan for an equal split between CMC and Presbyterian sites and all Mecklenburg volumes are equally divided between the systems. However, the exact service schedule may be adjusted by mutual consent in the event that one or both of the hospital systems prefer to concentrate their capacity at a fewer number of sites in the future due to staffing or scheduling constraints.

Stone Institute states that the additional site will provide access alternatives to lithotriptor

services for patients and providers within Mecklenburg County.

ANALYSIS

The CON law would require a full review of Stone Institute's proposed addition of a host site if that change were to represent a material change in the physical location or scope of the project. N.C.G.S. § 131E-181(a). The proposed addition of CMC-NorthCross as a host site for Stone Institute's project does not constitute a material change in the physical location or the scope of the proposed project because the use of CMC-NorthCross as a host site will not affect the scope of services offered or the costs and charges to Stone Institute or to the public for the provision of mobile lithotriptor services. The proposed allocation of service time between the Presbyterian and the CMC systems is consistent with Stone Institute's CON application. In addition, there is no proposed change in the person named in the application that would result in a violation of N.C.G.S. § 131E-181(a).

N.C.G.S. § 131E-189(b) allows the Agency to withdraw Stone Institute's CON if Stone Institute fails to develop the service in a manner consistent with the representations made in the application or with any conditions that were placed on the CON. Stone Institute will not be developing its project in a manner that is materially different from the representations made in its application, nor will it be developing its project in a manner that is inconsistent with any of the conditions that were placed on its CON.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the addition of CMC-NorthCross as a host site for Stone Institute's mobile lithotripter, Project I.D. No. F-7852-07, will not constitute a material change in the physical

location or scope of the project, will not violate N.C.G.S. § 131E-181, and will not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b).

This ruling is not intended, and should not be interpreted, to authorize any increases in the approved capital expenditure for this project, a change in the approved timetable, a change in the conditions placed on the certificate of need, or any other change in the approved project.

This the _____ day of _____, 2007.

Robert J. Fitzgerald, Director Division of Health Service Regulation N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Douglas M. Surratt Business Manager Stone Institute of the Carolinas P.O. Box 4509 Davidson, NC 28036

This the _____ day of _____, 2007.

Jeff Horton Chief Operating Officer