



MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

MEMORANDUM

TO: Commissioners
FROM: Eileen Fleck *E.F.*
Chief, Acute Care Policy and Planning
DATE: December 20, 2018

RE: Removal of Conditions on Certificates of Need for Suburban Hospital and Western Maryland Regional Medical Center

Maryland Health Care Commission (MHCC) staff recommends that MHCC remove conditions that were part of the Certificate of Need (CON) issued to each of two hospitals. Both CONs authorized the introduction of cardiac surgery services. We recommend removal of one of the conditions on the 1999 CON issued to Western Maryland Regional Medical Center (WMRMC) and removal of two conditions on the 2005 CON issued to Suburban Hospital.

The cardiac surgery programs of WMRMC and Suburban Hospital were established prior to the 2012 changes in statute and the corresponding 2014 changes in regulations that substantially changed the way that regulatory oversight of cardiac surgery is conducted by MHCC. The CON conditions on each hospital address minimum case volume requirements and the manner in which these minimum volume requirements will be enforced. However, with the establishment of the Certificate of Ongoing Performance process and other changes to standards in COMAR 10.24.17, the State Health Plan chapter for cardiac surgery and percutaneous coronary intervention, the conditions are no longer needed. The revised standards in COMAR 10.24.17 do not allow the Commission to withdraw a hospital's authority to provide cardiac surgery services based on a failure of the hospital to reach an annual volume of 200 cases, unless the program is one newly approved that fails to achieve 200 cases by the end of the first two years of operation. However, the conditions on both hospitals' CONs allow or require the cardiac surgery programs at Suburban Hospital and WMRMC to be closed for failure to continuously maintain an annual volume of 200 cases or more.

MHCC staff recommends that all ten of the established cardiac surgery programs in Maryland be subject to the same requirements with respect to case volume and quality. The CON conditions on both Suburban Hospital and WMRMC were included to assure that the cardiac surgery programs would maintain quality standards, using case volume as a proxy for quality.

However, with the establishment of a Certificate of Ongoing Performance process and revisions to the standards of COMAR 10.24.17, the conditions are no longer needed or equitable. Standards in COMAR 10.24.17 allow for closure of any cardiac surgery program for failure to maintain an acceptable level of quality performance, after the program has been given an opportunity to improve. Closure may also be considered for a program that falls below a volume of 100 cardiac surgery cases for two or more consecutive years.

Western Maryland Regional Medical Center

A condition on the CON for Sacred Heart Hospital, now known as WMRMC, provides that Sacred Heart Hospital must “achieve minimum volume standards within 24 months of beginning operation and maintain the minimum utilization level in each subsequent year of operation.” This condition also provides that the Commission “may withdraw the authority granted by this Certificate of Need to operate a cardiac surgery program if the program does not achieve these minimum volume standards, and maintain quality standards acceptable to the Commission.” Staff recommends removal of this condition because it is not consistent with the requirements for most other existing cardiac surgery programs, and the intended purpose of this condition can be achieved through the current regulations for cardiac surgery programs included in COMAR 10.24.17. If removal of this condition is approved by MHCC, then MHCC staff will draft a formal letter to the hospital to notify WMRMC of this change, and this letter will become part of the record for this CON. A copy of the original CON issued to WMRMC is attached.

Suburban Hospital

There are two conditions on the CON for Suburban Hospital that MHCC staff recommends removing. The first condition includes a requirement that, “[i]f Suburban Hospital fails to meet the minimum volume standards within 24 months of beginning operation and maintain the minimum utilization level in each subsequent year of operation, Suburban will close its cardiac surgery program.” Staff recommends removal of this condition because the minimum utilization level for Suburban, 200 cardiac surgery cases, is higher than the minimum volume threshold for most other existing cardiac surgery programs. Except for the two hospitals with CON conditions for their cardiac surgery programs, cardiac surgery volume must fall below 100 cases for two consecutive years before closure may be considered based on case volume. Closure is not automatically required for case volume below 200 cardiac surgery cases at any hospital except Suburban Hospital. MHCC staff has concluded that all existing cardiac surgery programs should be subject to the same requirements.

The second condition on the CON for Suburban Hospital is that Suburban Hospital “submit annually to the Commission, within 150 days after the end of the hospital’s fiscal year, a written report that includes the ongoing evaluation of the benefit and cost of the cardiac surgery program in a format acceptable to the Commission.” MHCC staff has concluded that ongoing reporting of the costs and benefits of the program is no longer useful or necessary and recommends removal of this condition.

A third condition on the CON for Suburban Hospital references information to be included in a written report. This written report is to include “an evaluation of the effectiveness of the hospital’s proposed regional outreach efforts related to cardiovascular disease prevention and [its] early diagnosis program.” This written report also must include Suburban Hospital’s progress in

obtaining new partners to collaborate on regional outreach efforts related to cardiovascular disease prevention, early diagnosis and care, especially for minorities. Lastly, the report must include improvement targets and provide quantitative data documenting Suburban Hospital's progress in serving minorities. MHCC staff notes that one of the reasons that Suburban Hospital was awarded a CON to establish a cardiac surgery program, rather than other competing applicants, was its plans for outreach to minorities. For this reason, MHCC staff recommends keeping this condition.

If removal of conditions on the CON for Suburban Hospital is approved by MHCC, then MHCC staff will draft a formal letter to the hospital to notify Suburban Hospital of this change, and this letter will become part of the record for this CON. A copy of the original CON issued to Suburban Hospital is attached.

MARYLAND HEALTH CARE COMMISSION

Certificate of Need

TO: Brian A. Gragnolati, CEO
Suburban Hospital, Inc.
8600 Old Georgetown Road
Bethesda, Maryland 20814

July 21, 2005
(Date)

RE: Establishment of a Cardiac Surgery
and Percutaneous Coronary Intervention
Program at Suburban Hospital

04-15-2134
(Docket No.)

PROJECT DESCRIPTION

Suburban Hospital, Inc. ("Suburban") is a 231-bed acute general hospital, located at 8600 Old Georgetown Road, Bethesda, Montgomery County, Maryland. Suburban will develop a cardiac surgery, research, education, and training program in conjunction with the National Heart, Lung, and Blood Institute ("NHLBI") of the National Institutes of Health, and Johns Hopkins Medicine. Suburban will accommodate the cardiac surgery procedures in two operating rooms dedicated to this program, and other operating rooms will be renovated and upgraded to accommodate surgical procedures previously performed in the two operating rooms. Suburban will develop three cardiac catheterization laboratories and related space on the third floor of the hospital. The total estimated cost of the project is \$18,617,820, including \$8,301,410 in funding budgeted by the NHLBI to support development of the clinical and research program at Suburban.

ORDER

The Maryland Health Care Commission reviewed the Recommended Decision presented by the Commissioner who served as the Reviewer in this comparative review and, based on this analysis and the record in this review, ordered, on July 21, 2005, that the application of Suburban Hospital for a Certificate of Need to establish a new cardiac surgery and percutaneous coronary intervention program at its facility in Bethesda, Maryland be **APPROVED**, subject to the following conditions:

1. The new cardiac surgery program will achieve minimum volume standards within 24 months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. If Suburban Hospital fails to meet the minimum volume standards within 24 months of beginning operation and maintain the minimum utilization level in each subsequent year of operation, Suburban will close its cardiac surgery program.

2. Suburban Hospital will submit annually to the Commission, within 150 days after the end of the hospital's fiscal year, a written report that includes the ongoing evaluation of the benefit and cost of the cardiac surgery program in a format acceptable to the Commission.
3. Suburban Hospital will submit annually to the Commission, within 150 days after the end of the hospital's fiscal year, a written report that includes an evaluation of the effectiveness of the hospital's proposed regional outreach efforts related to cardiovascular disease prevention and early diagnosis program. The annual report will include Suburban Hospital's progress in obtaining new partners in Prince George's, Calvert, Charles, and St. Mary's Counties to collaborate on regional outreach efforts related to cardiovascular disease prevention, early diagnosis and care, with particular emphasis on outreach to African American and other minority populations. The report shall also specify improvement targets and provide quantitative data documenting Suburban's progress in contacting and serving African American and other minority individuals.
4. Suburban Hospital will continue the rate offset in any future rate reviews with the HSCRC, as long as the HSCRC sets rates for any payer of acute care services in Maryland. If Suburban Hospital fails to comply, Suburban will close its cardiac surgery program.

Performance Requirements

In accordance with COMAR 10.24.01.12, the project is subject to the following performance requirements:

1. Obligation of not less than 51% of the approved capital expenditure, as documented by a binding construction contract and/or equipment purchase order, no later than July 23, 2007, which is 24 months after the July 21, 2005 Certificate of Need approval;
2. Initiation of construction within four (4) months of the effective date of the binding construction contract and/or equipment purchase order; and
3. Documentation from Suburban Hospital that it has completed all renovations for the cardiac surgery and percutaneous coronary intervention services and has met all applicable legal requirements and is providing the approved cardiac surgery and percutaneous coronary intervention services within 24 months of the effective date of the binding construction contract and/or equipment purchase order.

Failure to meet these performance requirements will render this Certificate of Need void, subject to the requirements of COMAR 10.24.01.12.

Proposed Changes To Approved Project

Before making any changes to the facts in the Certificate of Need application approved by the Commission, Suburban Hospital must notify the Commission in writing and receive Commission approval of each proposed change, including the obligation of any funds above those approved by the Commission in this Certificate of Need, in accordance with COMAR 10.24.01.17

Submission Of Project Drawings

The project's architect or engineer is required to contact the Plans Review and Approval section of the Department of Health and Mental Hygiene, to ascertain the specific information concerning the project's drawings and specifications that the law requires to be submitted and approved prior to the initiation of construction.

Quarterly Status Reports

Suburban Hospital must submit quarterly status reports to the Commission, beginning October 21, 2005, three months from the date of this Certificate of Need, and continuing through the completion of the project.

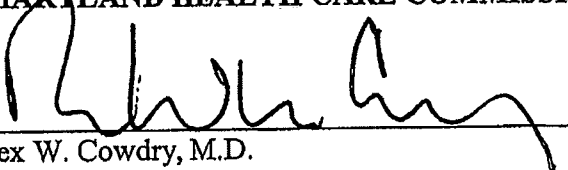
Request For First Use Review

Suburban Hospital must request in writing, not less than 60 days but not more than 120 days before the first use of the newly developed and renovated space for cardiac surgery and percutaneous coronary intervention services, a first use review from the Commission and the Office of Health Care Quality specifying the anticipated date of first use. The Commission will review the request in consultation with the Office of Health Care Quality, in accordance with COMAR 10.24.01.18, to determine whether the project conforms with the Certificate of Need. First use approval remains in effect for 90 days. If the newly developed and renovated space for cardiac surgery and percutaneous coronary intervention services is not occupied within 90 days of approval, Suburban Hospital shall reapply for first use review.

Acknowledgement Of Receipt Of Certificate Of Need

Please acknowledge in writing within thirty days that you have received this Certificate of Need, and that you accept its terms and conditions.

MARYLAND HEALTH CARE COMMISSION


Rex W. Cowdry, M.D.
Executive Director

Docket No. 04-15-2134

July 21, 2005

Page 4 of 4

cc: Robert Murray, Executive Director, Health Services Cost Review Commission
Carol Benner, Director, Office of Health Care Quality
Ulder Tillman, M.D., Health Officer, Montgomery County
Brian Dubey, A.I.A., Office of Plans Review and Approval, DHMH
Gary Terrinoni, Senior Vice President, Finance, Suburban Hospital
Jack C. Tranter, Esq.

RR

MARYLAND HEALTH RESOURCES PLANNING COMMISSION

CERTIFICATE OF NEED

TO: Edward M. Dinan
President and CEO
Sacred Heart Hospital of the Sisters
of Charity, Inc.
900 Seton Drive
Cumberland, Maryland 21502-1874

September 14, 1999
(Date)

RE: Open Heart Surgery and PTCA Services

97-01-2012
(Docket No.)

PROJECT DESCRIPTION:

Sacred Heart Hospital of the Sisters of Charity, Inc. ("Sacred Heart"), a 240-bed non-profit acute care hospital in Cumberland, Allegany County, Maryland, a member of the Western Maryland Health System, Inc. ("WMHS"), currently provides cardiology services with a catheterization laboratory, other diagnostic and cardiovascular support services, intensive care and telemetry monitoring facilities, and a staff well trained in various surgical and nursing capabilities. On April 10, 1996, the Commission approved a merger of Sacred Heart with Memorial Hospital and Medical Center of Cumberland ("Memorial") to form the WMHS. The Maryland Health Resources Planning Commission (the "Commission") has approved a Certificate of Need for Open Heart Services ("OHS") and percutaneous transluminal coronary angioplasty ("PTCA" or "angioplasty") to be developed at Sacred Heart. Sacred Heart has selected the Division of Cardiovascular Surgery, University of Maryland Medical System, to implement its proposed Open Heart Surgery Program.

Capital costs of the project total \$2,215,000, which includes building renovation costs of \$798,000, major movable equipment costs of \$1,000,000, and an inflation allowance of \$161,000. Sacred Heart plans to finance the project with cash.

ORDER

The Recommended Decision in this matter has been reviewed and adopted, with one modification, by the Commission. Based on the evidence in the record, the project is hereby granted a Certificate of Need with the following condition:

- 1. Sacred Heart met the first of two conditions applied to the CON before the Commission's action granting the CON on September 14, 1999. That first condition states as follows: "Prior to the September 14, 1999 Commission Meeting, Sacred Heart Hospital will document its selection of a cardiac surgical group to implement its proposed Open Heart Surgery Program. Furthermore, if the selection of a cardiac surgical group is Drs. Garcia, Mispireta, Corso, Pfister, & Associates, P.A., Sacred Heart Hospital will document the status of negotiations between Washington Hospital Center and Georgetown University Hospital as it affects open heart surgery referrals from Allegany and Garrett Counties going to Georgetown University Hospital." Sacred Heart Hospital met this condition before the Commission's action on September 14, 1999 as documented by the September 10, 1999 letter to Commissioner Row from Francis A. Pommert, Jr., Senior Vice President/Executive Director, Western Maryland Health System. Mr. Pommert stated that Sacred Heart Hospital has selected the Division of Cardiovascular Surgery, University of Maryland Hospital System, to implement its proposed Open Heart Surgery Program.

Pursuant to the State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services, COMAR 10.24.17.04B, Policy 1.3, Sacred Heart Hospital must "achieve minimum volume standards within 24 months of beginning operation and maintain the minimum utilization level in each subsequent year of operation." Policy 1.4 of the same regulation provides that the Commission may withdraw the authority granted by this Certificate of Need to operate a cardiac surgery program if the program does not achieve these minimum volume standards, and maintain quality standards acceptable to the Commission and established by other appropriate agencies [i.e., the Maryland Office of Health Care Quality, formerly the Licensing and Certification Administration, and the Joint Commission on Accreditation of Health Organizations ("JCAHO")].

As required by to COMAR 10.24.17.04C(3)(g)(iii), Sacred Heart Hospital has reached agreement with the Maryland Health Services Cost Review Commission ("HSCRC") that the HSCRC is to receive a 20% net revenue OHS/PTCA giveback on the first 225 cases for each service.

In accordance with Section .12C(2) and (3) of COMAR 10.24.01, the project is subject to the following performance requirements:

1. Obligation of not less than 51% of the certified capital expenditure as documented by a binding construction contract or equipment purchase order within 18 months of the date of certification;
2. Construction shall be initiated within 4 months of the effective date of a binding construction contract; and
3. Documentation that the certified project has been completed, has been licensed, if required, or has otherwise met all applicable legal requirements, and is providing the certified service or services within 12 months of the effective date of a binding contract.

Failure to meet these performance requirements shall render this Certificate of Need null and void.

Certificate of Need is a pre-requirement of the initiation of this service. **This Certificate of Need does not constitute approval for first use of this service.**

If it is necessary to make changes to the certified project before approved first use of the project, the Maryland Health Care Commission ("MHCC"), successor to the Maryland Health Resources Planning Commission, must be notified and MHCC approval of the change must be received prior to implementation of the change/or obligation of any additional funds in accordance with Section .17 of COMAR 10.24.01.

Your architect or engineer is required to contact the Plans Review and Approval Section of the Department of Health and Mental Hygiene in order to ascertain the information on drawings and specifications which is required by law for submission and approval.

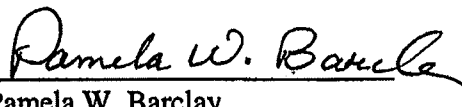
Quarterly status reports must be submitted to the Maryland Health Care Commission beginning three months from the effective date of certification and continuing through the completion of the project.

You must notify the MHCC not less than 60 days nor more than 120 days prior to the planned date of first use of the certified project specifying the anticipated date of first use and indicating that the project conforms with this Certificate of Need. This request for first use will be reviewed in accordance with Section .18 of COMAR 10.24.01. You may not begin operation of this service until the Maryland Health Care Commission has issued first use approval of the service.

Your acknowledgment of your receipt of this Certificate of Need is requested within thirty (30) days.

MARYLAND HEALTH RESOURCES
PLANNING COMMISSION

A majority of Commissioners, including two
consumer members, having concurred in the decision.


Pamela W. Barclay
Acting Executive Director

PWB/RWC/rp

cc: Susan Panek
C. Frederick Ryland, Esquire
Suellen Wideman, Esquire
Rhoda Wolfe-Carr
Robert Murray
Carol Benner
Brian Dubey, AIA
Edward F. Dressman
Jack C. Tranter, Esquire