



STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

July 9, 2013

IN THE MATTER OF:

An Application for a Certificate of Need filed
Pursuant to Section 19a-638, C.G.S. by:

Notice of Agreed Settlement
Office of Health Care Access
Docket Number: 12-31786-CON

Middlesex Hospital & Advanced Colon Care,
Inc. d/b/a Shoreline Colonoscopy Suites, LLC

Transfer of Ownership of the Assets of Advanced
Colon Care, Inc. d/b/a Shoreline Colonoscopy
Suites, LLC, to Middlesex Hospital

To:

Harry Evert
Sr. Vice President
Strategic Planning and Operations
Middlesex Hospital
28 Crescent Street
Middletown, CT 06457-3650

Maurizio D. Nichele, M.D.
President
Advanced Colon Care, Inc. d/b/a
Shoreline Colonoscopy Suites, LLC
929 Boston Post Road, Suite 1
Old Saybrook, CT 06475-2143

Dear Mr. Evert and Dr. Nichele:

This letter will serve as notice of the approved Certificate of Need in the above matter, as provided by Section 19a-638, C.G.S. On July 9, 2013, the Agreed Settlement, attached hereto, was adopted and issued as an Order of the Department of Public Health, Office of Health Care Access.

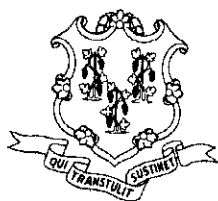
Kimberly R. Martone
Director of Operations

Enclosure
KRM:jah

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(If you require aid/accommodation to participate fully and fairly, contact us either by phone, fax or email)

410 Capitol Ave., MS#13HCA, P.O.Box 340308, Hartford, CT 06134-0308
Telephone: (860) 418-7001 Fax: (860) 418-7053 Email: OHCA@ct.gov



**Department of Public Health
Office of Health Care Access
Certificate of Need Application**

Agreed Settlement

Applicants: Middlesex Hospital
28 Crescent Street, Middletown, CT

Advanced Colon Care, Inc. d/b/a
Shoreline Colonoscopy Suites, LLC
929 Boston Post Road, Old Saybrook, CT

Docket Number: 12-31786-CON

Project Title: Transfer of Ownership of the Assets of
Advanced Colon Care, Inc., d/b/a
Shoreline Colonoscopy Suites, LLC,
to Middlesex Hospital

Project Description: Middlesex Hospital and Advanced Colon Care, Inc. d/b/a Shoreline Colonoscopy Suites, LLC (“Shoreline”) (Middlesex Hospital and Shoreline are hereinafter collectively referred to as the “Applicants”) are seeking Certificate of Need authorization for the transfer of ownership of the assets of Shoreline to Middlesex Hospital. The total capital expenditure associated with the proposed asset purchase is \$1,875,000.

Procedural History: The Applicants published notice of their intent to file the Certificate of Need application in the *New Haven Register* and the *Hartford Courant* on August 15, 16 and 17, 2012. On September 24, 2012, the Office of Health Care Access received the Certificate of Need application from the Applicants for the above-referenced project. On December 5, 2012, the Office of Health Care Access deemed the Certificate of Need application complete.

The Office of Health Care Access received no responses from the public concerning the Applicants' proposal and no hearing requests were received from the public pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a. Deputy Commissioner Lisa A. Davis read the entire record in this matter and issued a Final Decision on May 8, 2013 denying the Application.

On May 23, 2013, the Applicants filed a Request for Reconsideration, pursuant to Conn. Gen. Stat. § 4-181a, claiming the existence of new evidence which materially affected the merits of the case. On or about May 29, 2012, OHCA granted the Applicants' Request for Reconsideration.

FINDINGS OF FACT

1. Middlesex Hospital, a wholly owned subsidiary of Middlesex Health System, Inc., is a not-for-profit, acute care hospital located at 28 Crescent Street in Middletown, Connecticut. Exhibit A, pp. 11, 19, 43 & 46.
2. Shoreline currently operates a licensed outpatient surgical center ("Shoreline Center") located at 929 Boston Post Road, Suite 1, in Old Saybrook, Connecticut. Exhibit A, p. 8.
3. Middlesex Hospital and Shoreline are health care facilities or institutions as defined by Conn. Gen. Stat. §19a-630.
4. The Shoreline Center is a freestanding, one operating room endoscopy center providing gastroenterology and colorectal services to residents of the shoreline area. Exhibit A, p. 8; Shoreline's Report in response to OHCA's Outpatient Surgery Questionnaire for Calendar Year 2010, information received by OHCA on July 20, 2011.
5. Shoreline is currently owned by Maurizio Nichele, M.D., who possesses a 51% ownership share, and Jay Zimmerman, M.D., who possesses a 49% ownership share. Both Shoreline physicians are affiliated with Middlesex Hospital. Exhibit A, pp. 8 & 10.
6. The Applicants are seeking Certificate of Need authorization for the transfer of ownership of the assets of Shoreline to Middlesex Hospital. Exhibit A, p. 8.
7. Middlesex Hospital serves Middlesex County and the shoreline area of Connecticut through a network of community-based outpatient, primary care and emergency care facilities located throughout its service area. Exhibit A, p. 8.
8. The Shoreline Center is located within Middlesex Hospital's primary service area. Exhibit A, p. 9.
9. The proposed transfer of ownership would give Middlesex Hospital sole ownership of the assets of Shoreline after which the Shoreline Center will operate as an outpatient department of Middlesex Hospital. Exhibit A, p. 8.

10. The scope of services currently provided at the Shoreline Center will not change as a result of the proposed asset purchase. Exhibit A, p. 8.
11. Middlesex Hospital plans to enter into a co-management agreement with Dr. Nichele and Dr. Zimmerman to co-manage the Shoreline Center as well as have the doctors continue to provide professional services to the patients at the Shoreline Center. Exhibit A, pp. 8, 11 & 21.
12. Under the Co-Management Agreement, the Shoreline physicians are required to accept Medicaid and provide a reasonable amount of free care. Specifically, they are required to: 1) be participating providers with all health insurers and third party payment plans (including Medicare and Medicaid) with which the hospital contracts, unless such payors are unwilling to contract on commercially reasonable terms; and 2) provide reasonable amounts of charity care to patients of the Shoreline Center. Request for Reconsideration, p. 2 and Exhibit 1 contained therein.
13. Middlesex Hospital accepts all patients without regard to ability to pay, including Medicaid patients and the uninsured, and it provides charity care for those uninsured individuals who meet its guidelines. This policy will apply to patients of the Shoreline Center. This proposal will allow both Medicaid patients and the uninsured to be treated at the Shoreline Center, increasing local access for this population. Request for Reconsideration, p. 4.
14. There are twelve Middlesex Hospital Primary Care physicians in the shoreline area (Old Saybrook, Westbrook, Essex and Madison) who together perform over 3,100 Medicaid visits per year. These physicians cannot currently refer their Medicaid patients to the Shoreline Center because it does not currently accept payment from Medicaid. Instead, these patients have to travel to Middlesex Hospital or another hospital to receive a colonoscopy. This proposal will provide a local center to which those physicians can refer all of their patients. Request for Reconsideration, p. 4.
15. The Co-Management Agreement will allow and require the Shoreline physicians to facilitate the development and operation of the Shoreline Center as a high quality, efficient, cost-effective hospital-based facility and center of excellence without having to spend time on administrative matters that do not require a clinical background. Request for Reconsideration, p. 6.
16. The proposed transfer of ownership will better enable the Shoreline physicians to focus on the professional services they provide to the Shoreline Center's patients, while at the same time allowing the Shoreline Center's patients to continue to receive endoscopy services locally under the auspices of Middlesex Hospital. Exhibit A, pp. 8 & 9.
17. The Co-Management Agreement requires the Shoreline physicians to assist Middlesex Hospital with obtaining and maintaining appropriate regulatory

approvals and accreditation, and to participate in and make recommendations concerning policies regarding pathways and quality standards. Request for Reconsideration, p. 7.

18. Under the Co-Management Agreement, the Shoreline physicians are required to work with Middlesex Hospital to increase productivity at the Shoreline Center by: evaluating and recommending the restructuring of delivery of care processes with the Shoreline Center; evaluating job descriptions and recommending the realignment of responsibilities within the Shoreline center; and establishing and monitoring productivity standards within the Shoreline Center. Request for Reconsideration, Exhibit 1 contained therein.
19. The acquisition of Shoreline's assets will allow Middlesex Hospital to accomplish the following:
 - a. To integrate the Shoreline Center's community-based clinical services into Middlesex Health System's existing network of outpatient service sites to continue meeting the needs of area communities in the future;
 - b. To ensure effective and efficient care coordination for these patients receiving care within the Middlesex Health System; and
 - c. To provide long term sustainability of the outpatient services provided at the Shoreline Center. Exhibit A, pp. 8 & 9; Exhibit E, p. 105.
20. The number of endoscopy procedures performed at the Shoreline Center for fiscal years ("FYs") 2007 through 2012 are as follows:

Table 1: Actual Shoreline Center Volume

Fiscal Year*	Number of Endoscopy Procedures
FY 2007	567
FY 2008	1,014
FY 2009	990
FY 2010	976
FY 2011	1,045
FY 2012	1,126**

Note: *The Shoreline Center's fiscal year operates on a calendar year basis.

**The annualized number of procedures for FY 2012 is based upon nine months of actual data, from January 1 to September 30, 2012.

Exhibit C, p. 49; Exhibit E, 111.

21. Middlesex Hospital projects the following number of endoscopy procedures annually without the proposal, incremental to the proposal and with the proposal.

Table 2: Projected Volume Without, Incremental to and With the Proposal

Fiscal Year	Without the Proposal	Incremental with the Proposal	With the Proposal
FY 2013	1,896	797	2,693
FY 2014	1,915	1,062	2,977
FY 2015	1,934	1,062	2,996

Exhibit A, pp. 15 and 99. Request for Reconsideration, Exhibit 2 contained therein.

22. The Shoreline Center is accredited through the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. Exhibit A, p. 8.
23. The capital expenditure for the proposal is \$1,875,000, representing the asset purchase price for the Shoreline Center. Exhibit A, p. 13.
24. Middlesex Hospital intends to use equity to fund the asset purchase. Exhibit A, p. 13.
25. Shoreline reported the following gains from operations for FYs 2007 through 2011:

Table 3: Actual Gains in Operations from Fiscal Years 2007 through 2011

	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Revenues from Operations	\$402,523	\$549,582	\$561,551	\$534,108	\$621,130
Total Operation Expense	\$362,678	\$538,479	\$530,112	\$528,860	\$601,842
Incremental Gain from Operations	\$39,845	\$11,352	\$31,439	\$5,248	\$19,288

Exhibit E, p. 111.

26. Middlesex Hospital projects the following incremental gains from operations with the proposed project:

Table 4: Projected Incremental Revenues and Expenditures with the Project

Net Patient Revenue	FY 2013*	FY 2014	FY 2015
Non-Government	\$1,989,828	\$2,679,575	\$2,706,312
Medicare	\$141,230	\$190,189	\$192,091
Medicaid & Other Medical Assistance	\$70,989	\$94,652	\$95,599
Other Government	\$0	\$0	\$0
Revenues from Operations	\$2,202,047	\$2,964,416	\$2,994,002
Total Operation Expense	\$793,582	\$832,884	\$849,544
Incremental Gain from Operations**	\$1,408,195	\$2,131,532	\$2,144,457

Note:*FY 2013 reflects commencement of the Center's service at the beginning of the Hospital's second quarter (i.e. 9-months of operation in year 1) and FYs 2014 and 2015 each reflects a full year or 12-month projected impact.

**Increasing revenue for the Shoreline Center in each of the future fiscal years, FYs 2013 through 2015, is attributable to increasing utilization volume when the operation becomes a Hospital outpatient center.

Exhibit C, p. 99.

Request for Reconsideration, Exhibit 2 contained therein.

27. The actual payer mix for the Shoreline Center consists exclusively of Medicare and commercial insurers as is illustrated in the following table.

Table 5: Actual Payer Mix for the Shoreline Center

	Actual FY 2009	Actual FY 2010	Actual FY 2011	Actual FY 2012
Medicare*	22.1%	17.8%	21.3%	21.3%
Medicaid*	-	-	-	-
CHAMPUS & TriCare	-	-	-	-
Total Government	22.1%	17.8%	21.3%	21.3%
Commercial Insurers*	77.9%	82.2%	78.7%	78.7%
Uninsured	-	-	-	-

Workers Compensation	-	-	-	-
Total Non-Government	77.9%	82.2%	78.7%	78.7%
Total Payer Mix	100.0%	100.0%	100.0%	100.0%

Note: * Includes managed care activity.
 Exhibit C, p. 48.

28. Middlesex Hospital's overall projected payer mix with the inclusion of the Shoreline operations is as follows:

Table 6: Projected Payer Mix for the Shoreline Center

	Projected FY 2013	Projected FY 2014	Projected FY 2015
Medicare	19.49%	19.49%	19.49%
Medicaid*	6.93%	6.93%	6.93%
CHAMPUS & TriCare			
Total Government	26.42%	26.42%	26.42%
Commercial Insurers*	71.82%	71.82%	71.82%
Uninsured	1.76%	1.76%	1.76%
Workers Compensation			
Total Non-Government	73.58%	73.58%	73.58%
Total Payer Mix	100.0%	100.0%	100.0%

Request for Reconsideration, Exhibit 2 contained therein.

* Percentage based upon anticipated service to Medicaid and self-pay patients from Chester, Clinton, Deep River, Essex, Madison, Old Saybrook and Westbrook based using ICD 9 codes 45.13; 45.16; 45.23; 45.25; and 45.42.

29. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any policies and standards not yet adopted as regulations by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)).
30. OHCA recently published a statewide facilities and services plan. Since the plan was not in circulation more than ninety days at the time the CON application was deemed complete, OHCA has not made any findings as to this proposal's relationship to the plan. (Conn. Gen. Stat. § 19a-639(a)(2)).
31. The Applicants have established that there is a clear public need for this proposal given the new access for the Medicaid population. (Conn. Gen. Stat. § 19a-639(a)(3)).
32. The Applicants have satisfactorily demonstrated that this proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)).
33. The Applicants have satisfactorily demonstrated that their proposal would improve the accessibility, quality and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5)).

34. The Applicants have shown that there would be a change to the provision of health care services to the relevant populations and payer mix given the new access for the Medicaid population. (Conn. Gen. Stat. § 19a-639(a)(6)).
35. The Applicants have satisfactorily identified the population to be served by their proposal, and have satisfactorily demonstrated that this population currently has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7)).
36. The historical utilization in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8)).
37. The Applicants have satisfactorily demonstrated that their proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)).

DISCUSSION

Certificate of Need applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, the Office of Health Care Access considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicants bear the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services*, 288 Conn. 790 (2008).

The Applicants are seeking Certificate of Need authorization for the transfer of ownership of the assets of Shoreline to Middlesex Hospital with the continued operation of the endoscopy center as an outpatient department of Middlesex Hospital at its current Old Saybrook location. *FF 1, 2, 6, 7*. The scope of services currently provided at the Shoreline Center's single operating room will not change as a result of the proposed transfer of ownership. *FF 4, 8*. Shoreline is currently owned by Maurizio Nichele, M.D., who possesses a 51% ownership share, and Jay Zimmerman, M.D., who possesses a 49% ownership share. *FF 5*. Middlesex Hospital plans to enter into a Co-Management Agreement with Drs. Nichele and Zimmerman to co-manage the Shoreline Center whereby Drs. Nichele and Zimmerman will continue to provide professional services to the patients receiving endoscopy services at the Shoreline Center. *FF 11*. Under the Co-Management Agreement, the Shoreline physicians are required to accept Medicaid and provide a reasonable amount of free care. Specifically, they are required to: 1) be participating providers with all health insurers and third party payment plans (including Medicare and Medicaid) with which the hospital contracts, unless such payors are unwilling to contract on commercially reasonable terms; and 2) provide reasonable amounts of charity care to patients of the Shoreline Center. *FF 12*. Middlesex Hospital accepts all patients without regard to ability to pay, including Medicaid patients and the uninsured, and it provides charity care for those uninsured individuals who meet its guidelines. This policy will apply to patients of the Shoreline Center. This proposal will allow both Medicaid patients and the uninsured to be treated at the Shoreline Center, increasing local access for this population. *FF 13*.

There are twelve Middlesex Hospital Primary Care physicians in the shoreline area (Old Saybrook, Westbrook, Essex and Madison) who together perform over 3,100 Medicaid visits per year. These physicians cannot currently refer their Medicaid patients to the Shoreline Center because it does not currently accept payment from Medicaid. Instead, these patients have to travel to Middlesex Hospital or another hospital to receive a colonoscopy. This proposal will provide a local center to which those physicians can refer all of their patients. *FF 14*.

The proposed transfer of ownership will better enable the Shoreline physicians to focus on the professional services they provide to the Shoreline Center's patients, while at the same time allowing the Shoreline Center's patients to continue to receive endoscopy services locally under the auspices of Middlesex Hospital. *FF 16*.

The Co-Management Agreement will allow and require the Shoreline physicians to facilitate the development and operation of the Shoreline Center as a high quality,

efficient, cost-effective hospital-based facility and center of excellence without having to spend time on administrative matters that do not require a clinical background. *FF 15*. To effectuate this, the Co-Management Agreement requires the Shoreline physicians to assist Middlesex Hospital with obtaining and maintaining appropriate regulatory approvals and accreditation, and to participate in and make recommendations concerning policies regarding pathways and quality standards. *FF 17*. Furthermore, under the Co-Management Agreement, the Shoreline physicians are required to work with Middlesex Hospital to increase productivity at the Shoreline Center by: evaluating and recommending the restructuring of delivery of care processes with the Shoreline Center; evaluating job descriptions and recommending the realignment of responsibilities within the Shoreline Center; and establishing and monitoring productivity standards within the Shoreline Center. *FF 18*.

The Applicants' proposal will allow the Shoreline physicians to concentrate their efforts on serving the Shoreline Center's patient population; ensure effective and efficient care coordination for the patients receiving care within the Middlesex Health System; and provide sustainability of the outpatient services provided at the Shoreline Center. *FF 19*. Moreover, since the Shoreline physicians are required to accept Medicaid and provide a reasonable amount of free care, access would be improved for this population. *FF 12-13*. Consequently, OHCA finds that the Applicants have satisfactorily demonstrated that their proposal would improve the quality, cost-effectiveness and accessibility of health care delivery in the region.

In their Request for Reconsideration, the Applicants provided a copy of the Co-Management Agreement referenced, but not provided, in their initial Application. The Co-Management Agreement contains an extensive amount of new information that was not part of the record for review and consideration prior to the Final Decision being rendered in this matter on May 8, 2013. Moreover, the Applicants' initial Application represented that the Shoreline Center would continue to not serve the Medicaid population if the proposal were to be approved. Such representation contrasts with the Applicants' present representation that the Shoreline Center will in fact serve the Medicaid population upon approval of the proposal. Based upon the foregoing notable new information, OHCA concludes that the Applicants have demonstrated a clear public need for the proposed transfer of ownership of Advanced Colon Care, Inc. d/b/a Shoreline Colonoscopy Suites, LLC, to Middlesex Hospital.

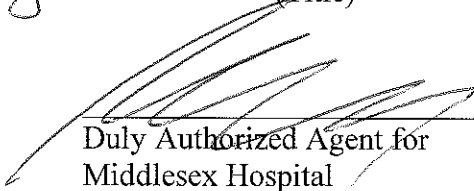
ORDER

NOW, THEREFORE, the Department of Public Health, Office of Health Care Access, Middlesex Hospital and Advanced Colon Care, Inc. d/b/a Shoreline Colonoscopy Suites, LLC (Middlesex Hospital and Shoreline are hereinafter collectively referred to as the "Applicants") hereby stipulate and agree to the terms of settlement with respect to the transfer of ownership of Shoreline as follows:

1. The Applicants shall provide the Office of Health Care Access with a fully executed copy of the Co-Management Agreement, provided as Exhibit 1 within the Request for Reconsideration and as subsequently revised, including any and all attachments or exhibits, within thirty (30) days of execution.
2. The Applicants shall provide the Office of Health Care Access with a copy of the approval of Dr. Maurizio Nichele and Dr. Jay Zimmerman to be enrolled as providers in the Connecticut Medical Assistance Program thereby allowing them to accept Medicaid patients. The approvals must be filed with OHCA within thirty (30) days of receipt by the Applicants.
3. Upon receipt of the approval to accept Medicaid patients, the Applicants shall issue a notification directly to physicians and other practitioners in the Shoreline Center's service area announcing that its physicians are now enrolled in the State Medical Assistance program and are actively accepting Medicaid referrals. Within thirty (30) days of its release, the Applicants shall provide OHCA with a copy of the notification as well as an affidavit affirming that the notification was released to physicians and other practitioners in the Shoreline Center's service area.
4. The Office of Health Care Access and the Applicants agree that this Agreed Settlement represents a final agreement between the Office of Health Care Access and the Applicants with respect to Docket No. 12-31786-CON. The execution of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Applicants with regard to Docket Number 12-31786-CON.
5. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement under the provisions of Conn. Gen. Stat. §§ 19a-642 and 19a-653 with all fees and costs of such enforcement being the responsibility of the Applicants.
6. This Agreed Settlement shall be binding upon the Applicants and their successors and assigns.


Signed by Paul Knog, Counsel for Middlesex Hospital
(Print name) (Title)

7/8/13
Date



Duly Authorized Agent for
Middlesex Hospital

Signed by Stephen M. Cowherd, Counsel for ACC, Inc.
(Print name) (Title)

7/3/13
Date


Duly Authorized Agent for
Advanced Colon Care, Inc. d/b/a Shoreline
Colonoscopy Suites, LLC

The above Agreed Settlement is hereby accepted and so ordered by the Department of
Public Health Office of Health Care Access on July 9, 2013.


Lisa A. Davis, MBA, BSN, RN
OHCA Commissioner