STATE OF CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H. Commissioner



Dannel P. Malloy Governor Nancy Wyman Lt. Governor

Office of Health Care Access

Certificate of Need Final Decision

Applicants:

Wallingford Endoscopy Center, LLC 863 North Main Street Extension Wallingford, CT 06492

MidState Medical Center 435 Lewis Avenue Meriden, CT 06451

Docket Number: 16-32136-CON

Project Title:

Establishment of an Outpatient Surgical Facility in Wallingford, Connecticut

Project Description: Wallingford Endoscopy Center, LLC ("WEC"), a joint venture between MidState Endoscopy Center Holdings, LLC ("MEC") and MidState Medical Center, is proposing to establish an outpatient surgical facility for gastroenterological services at 863 North Main Street Extension, Wallingford, Connecticut.

Procedural History: The Applicants published notice of their intent to file a Certificate of Need ("CON") application in *The Record-Journal* (Meriden) on September 2, 3 and 4, 2016. On November 30, 2016, the Office of Health Care Access ("OHCA") received the CON application from the Applicants for the above-referenced project and deemed the application complete on March 21, 2017. OHCA received no responses from the public concerning the proposal and no hearing requests from the public per Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(e). Deputy Commissioner Addo considered the entire record in this matter.



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Findings of Fact and Conclusions of Law

- MidState Medical Center ("Hospital"), a wholly owned subsidiary of Hartford HealthCare Corporation, Inc. ("Hartford HealthCare"), is a 156-bed acute care hospital located at 435 Lewis Avenue, Meriden, Connecticut. Annual Report on the Financial Status of Connecticut's Short Term Acute Care Hospitals for Fiscal Year 2015
- 2. MidState Endoscopy Center Holdings, LLC ("MEC") is a new company that will be jointly owned by nine gastroenterology physicians that are currently members of the Hospital's medical staff. Ex. A, pp. 11, 12
- 3. The Hospital and MEC plan to establish an outpatient surgical facility ("OSF") dedicated to gastroenterological services, owned and operated by a Connecticut limited liability company known as Wallingford Endoscopy Center, LLC ("WEC"). Ex. A, p. 12
- 4. WEC will be located at the Wallingford Family Health Center ("WFHC"), 863 North Main Street Extension in Wallingford, Connecticut. Ex. A, p. 12
- 5. The WFHC location was chosen for the proposal for the following reasons:
 - a. Available space for procedure rooms;
 - b. Accessibility for residents of the service area by public transportation; and
 - c. Ease of access from the parking lot to the building via two entry points. Ex. A, p. 20; Ex. C, p. 177
- 6. The Hospital will own a 51% controlling membership interest in WEC, with the remaining 49% ownership to be held by MEC. Ex. A, p. 12
- 7. Initially, WEC will have two fully-equipped and operational procedure rooms. A third procedure room will be shelled for future use to accommodate gastrointestinal ("GI") volume growth. Ex. A, p. 37
- 8. Patients who are at higher risk due to medical complications or comorbidities or who prefer to be treated in a hospital environment will still be able to schedule their procedures at the Hospital. It is estimated that 30% of endoscopy patients will continue to receive services at the Hospital. Ex. A, p. 16

9. WEC will serve the same patient population as the Hospital.

DSTATE MEDICAL CENTER OUTPATIENT GI UTILIZATION BY TOW				
SERVICE AREA	FISCAL YEAR ("FY") PERC 2016 VISITS OF TO			
Meriden	4,351	43%		
Wallingford	1,808	18%		
Cheshire	710	7%		
Southington	473	5%		
New Britain	369	4%		
Waterbury	264	3%		
All Other Towns	2,153	21%		
Total	10,128	100%		

TABLE 1 MIDSTATE MEDICAL CENTER OUTPATIENT GI UTILIZATION BY TOWN

*May not add up due to rounding.

Ex. A, pp. 20, 35

10. The following table summarizes the existing service area providers:

GI SERVICE AREA P	ROVIDERS
PROVIDER	PROVIDER ADDRESS
MidState Medical Center	435 Lewis Avenue, Meriden
MasoniCare Health Center	22 Masonic Avenue, Wallingford
Central Connecticut Endoscopy Center	440 New Britain Avenue, Plainville
Middlesex Endoscopy Center	410 Saybrook Road, Middletown
Ex. A, p. 38	

TABLE 2 GI SERVICE AREA PROVIDERS

11. The utilization rate for inpatient and outpatient GI procedures at the Hospital has steadily increased, reaching 90% in FY 2016.

PROCEDURE ROOM UTILIZ/	TABLE 3 ATION AT MIDST	ATE MEDICAL CE	NTER*
	FY 2014	FY 2015	FY 2016
Number of Cases	10,462	10,548	10,888
Percent Change from Previous Year	-	0.8%	3.2%
Number of Procedure Rooms	4	4	4
**Maximum Number of Cases, Annually	12,000	12,000	12,000
Utilization Rate	87%	88%	90%

*Includes both inpatient and outpatient GI procedures

**Based on existing utilization for the four procedure rooms at the hospital

Ex. C, p. 179; Ex. E, p. 182

12. Between FY 2015 and FY 2016, there was an increase in outpatient GI procedures at the Hospital due to a surge in the number of endoscopic retrograde cholangiopancreatography (ERCP)¹ procedures and the implementation of an outpatient acid reflux clinic. Anticipated growth for the Hospital and WEC is 3% annually, driven by an aging population and increased access to services. Ex. A, pp. 27, 39

TABLE 4
MIDSTATE MEDICAL CENTER AND WEC HISTORICAL AND PROJECTED OUTPATIENT UTILIZATION

	HISTORICA		PROJECTED VOLUME			
PROVIDER	FY 2015	FY 2016	FY 2018	FY 2019	FY 2020	
MidState Medical Center*	8,977	10,128	2,940	3,028	3,119	
Wallingford Endoscopy Center, LLC	-	-	6,860	7,066	7,278	
Total	8,977	10,128	9,800	10,094	10,397	

Fiscal Year is October 1 – September 30

Ex. A, p. 27

13. It is estimated that approximately 70% of the outpatient GI volume will shift from the Hospital to WEC.

TABLE 5 WEC PROJECTED UTILIZATION BY SERVICE				
PROJE	CTED UTILIZ	ATION		
FY 2018	FY 2019	FY 2020		
2,610	2,688	2,769		
4,250	4,378	4,509		
6,860	7,066	7,278		
	ROJECTED UTII PROJE FY 2018 2,610 4,250	ROJECTED UTILIZATION BY 3 PROJECTED UTILIZ FY 2018 FY 2019 2,610 2,688 4,250 4,378		

Ex. A, p. 33

14. The following table summarizes the number of projected procedures (per room) to be performed at WEC:

TABLE 6			
WEC PROJECTED UTILIZATION BY PROCEDURE ROOM			

	FY 2018	FY 2019	FY 2020
Number of Procedures	6,860	7,066	7,278
Number of Procedure Rooms	2	2	2
Number of Procedure Performed Per Room	3,430	3,533	3,639
Maximum Number of Procedures Per Room, Annually*	4,200	4,200	4,200
Utilization Rate	82%	84%	87%

*Based on a maximum of 16-17 procedures per room per eight hour day for 250 days Ex. C, p. 180; Ex. E, p. 182

¹ ERCP procedures are used for the treatment and diagnosis of pancreatic diseases.

- 15. According to 2016 data from the Advisory Board Company², volume for outpatient gastroenterology procedures is expected to increase by 35% nationally and 24% for WEC's primary service area over the ten year period from 2016 to 2026. Within the ambulatory surgery setting, a 51% growth in national volume for outpatient GI procedures is anticipated over the same period. Ex. H, pp. 183, 185-186
- 16. The two factors contributing the most to the overall projected growth in gastroenterology services are an aging population and a rise in the incidence of obesity. Epidemiologic data indicate that obesity is associated with chronic gastrointestinal complaints, many of which overlap with functional gastrointestinal disorders, such as irritable bowel syndrome or dyspepsia. In addition, nearly 50% of the population of the three towns which represent the largest share of utilization for the primary service area (Cheshire, Meriden and Wallingford), is age 45 years or older. This is significant as clinical guidelines suggest that all individuals have an initial colorectal screening at age 50. Ex. A, pp. 14-15, 52
- 17. WEC will operate as a freestanding OSF. As a result, the payment rates paid by payers and patients will be substantially lower than those paid for hospital-based surgical services. Ex. A, p. 13
- 18. A study conducted by the American Journal of Gastroenterology states that ambulatory surgery centers ("ASCs") are paid a fraction of what is paid to hospitals for the same procedures under Medicare and a migration from other settings to ASCs could reduce Medicare spending. The 2016 Medicare rates for outpatient endoscopy services in New Haven County show a 16% to 17% savings to CMS and 36% to 37% savings in patient out-of-pocket costs compared to a hospital-based setting. Ex. A, pp. 22-23; Ex. C, p. 177
- 19. The affiliation of WEC with the Hospital is expected to utilize economies of scale (purchasing of supplies and services), allow consistency among clinical protocols with other Hartford HealthCare facilities, foster sharing of best practices, increase the ability to participate in evolving payer models and improve access to capital. Ex. A, p. 19; Ex. C, p. 78
- 20. WEC will be an EPIC medical record site, connecting WEC to patient records at the Hospital and other Hartford HealthCare facilities. Ex. A, p. 23
- 21. WEC will meet and maintain all national standards required to achieve accreditation by the Accreditation Association for Ambulatory Health Care Centers. Ex. A, p. 17
- 22. WEC will adopt the same charity care policy as the Hospital, which provides for the provision of services to patients covered by Medicare and Medicaid, as well as providing free or reduced charge services to the poor or indigent. Ex. A, pp. 21, 156-158; Ex. C, p. 179
- 23. WEC will execute a transfer agreement with the Hospital that will require both parties to make their facilities available to receive and care for all patients, who in the professional opinion of the patient's physician, would receive more appropriate treatment or care in the receiving institution. Ex. A, p. 150

²The Advisory Board Company is a global research, technology, and consulting firm.

- 24. The proposal has an associated capital expenditure of \$2,788,600; \$598,825 for medical equipment, \$1,683,775 for construction and \$506,000 in pre-opening development expenses. Approximately \$2M of the total will be financed over a 7-year period -- the balance will be funded through an equity contribution. Ex. A, pp. 25, 31, 169
- 25. WEC projects gains from operations in each of the proposal's first three fiscal years.

WEC 3 PROJECTED IN	CREIVIENTAL C		ERATIONS
	FY 2018	FY 2019	FY 2020
Revenue from Operations ¹	\$3,947,648	\$4,132,129	\$4,326,166
Total Operating Expenses ²	\$2,799,668	\$2,907,709	\$2,964,520
Gain/Loss from Operations	\$1,147,980	\$1,224,420	\$ 1,361,646

TABLE 7
WEC'S PROJECTED INCREMENTAL GAIN FROM OPERATIONS

²Total operating expenses are based on salaries/wages, fringe benefits, supplies/drugs and other expenses.

Ex. A, pp. 172,174

¹Net patient revenue is based on a shift in volume from MidState Medical Center and 3% annual growth in procedures.

26. Based on the average historical payer mix for endoscopy and colonoscopy procedures performed at MidState Medical Center, more than 25% of WEC's patients are projected to be Medicaid recipients.

	AFF		SCURRENT					
			Projected ⁴					
Payer	FY 2	016 ²	FY 20	FY 2018 FY 2019 FY 2020		020		
	Visits	% ³	Visits	% ³	Visits	% ³	Visits	% ³
Medicare ¹	4,861	48.0%	2,041	29.8%	2,102	29.8%	2,165	29.8%
Medicaid ¹	2,329	23.0%	1,915	27.9%	1,973	27.9%	2,032	27.9%
CHAMPUS & TriCare	25	0.3%	52	0.8%	54	0.8%	55	0.8%
Total Government	7,216	71.3%	4,008	58.5%	4,129	58.5%	4,252	58.5%
Commercial Insurers	2,507	24.8%	2,802	40.9%	2,886	40.9%	2,972	40.9%
Uninsured	354	3.5%	50	0.7%	52	0.7%	54	0.7%
Workers Compensation	51	0.5%	0	0.0%	0	0.0%	0	0.0%
Total Non- Government	2,912	28.8%	2,852	41.6%	2,938	41.6%	3,025	41.6%
Total Payer Mix	10,128	100%	6,860	100%	7,006	100%	7,278	100%

TABLE 8
APPLICANT'S CURRENT & PROJECTED PAYER MIX

¹Includes managed care activity.

²Represents outpatient volume only for MidState Medical Center.

³May not add up due to rounding. ⁴Projected payer mix reflects MidState's GI payer mix, WEC's geographical location and the exclusion of colorectal surgeons from providing services at the outpatient facility.

Ex. A, p. 34; Ex. C, pp. 178-179; Ex. E, p. 182

- 27. 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 regulations not yet adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)).
- 28. This CON application is consistent with the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2)).
- 29. The Applicants have established that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3)).
- 30. The Applicants have demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)).
- 31. The Applicants have satisfactorily demonstrated that the proposal will improve the accessibility, quality and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat.§ 19a-639(a)(5)).

- 32. The Applicants have shown that there would be no adverse change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6)).
- 33. The Applicants have satisfactorily identified the population to be affected by this proposal. (Conn. Gen. Stat. § 19a-639(a)(7)).
- 34. The Applicants' historical provision of services in the area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8)).
- 35. The Applicants have satisfactorily demonstrated that this proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)).
- 36. The Applicants have demonstrated that there will be increased access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)).
- 37. The Applicants have demonstrated that the proposal will not negatively impact the diversity of health care providers and client choice in the region. (Conn. Gen. Stat. § 19a-639(a)(11)).
- 38. The Applicants have satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or accessibility to care. (Conn. Gen. Stat. § 19a-639(a)(12)).

Discussion

CON 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, OHCA considers the factors set forth in § 19a-639(a) of the Statutes. The Applicants bear the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board, 309 Conn.* 727 (2013).

MidState Medical Center and MEC, a limited liability company that will be jointly owned by nine MidState Medical Center gastroenterologists, are proposing to establish an outpatient surgical facility for gastroenterological services, WEC, in Wallingford, CT. The proposal was developed, in part, in response to current demand and projected future growth for outpatient GI procedures. Between FY 2015 and FY 2016, outpatient GI procedures surged at the Hospital, with an increase of over 11%. Additionally, factors such as an aging population and a rise in the incidence of obesity is expected to accelerate growth in GI procedures in future years. The proposal will help shift GI patients from the Hospital to a lower-cost outpatient setting. *FF1-FF4; FF12-FF13; FF16-FF17*

Access to outpatient GI procedures will improve as WEC will accept Medicare and Medicaid, as well as provide free or reduced charge services to the poor or indigent. Moreover, patients will continue to have the option to receive treatment from any of the four existing service area providers. GI procedures performed at the hospital will be based on patient choice, medical complications or other risk factors. *FF8; FF10; FF22*

Although there is an associated capital expenditure of \$2,788,600, incremental gains exceeding \$1.1 million are projected in each of the first three years of operation. Income from operations, supplemented with capital contributions and lender financing, will fund the WEC, demonstrating financial feasibility. *FF24-FF25*

The affiliation of WEC with the Hospital will help contain costs by utilizing economies of scale, allowing consistency among clinical protocols with other Hartford HealthCare facilities, fostering sharing of best practices, increasing the ability to participate in evolving payer models and improving access to capital. *FF19*

Overall, the proposal demonstrates a clear public need for high quality care at a reduced cost, while increasing access to outpatient GI procedures in the primary service area, both of which are consistent with the Statewide Health Care Facilities and Services Plan.

Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application of Wallingford Endoscopy Center, LLC and MidState Medical Center to establish an outpatient surgical facility for gastroenterological services at 863 North Main Street Extension, Wallingford, Connecticut, is hereby **APPROVED**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the Department of Public Health Office of Health Care Access

yonneaddo

Yvonne T. Addo, MBA Deputy Commissioner

6/8/17

Date