



## Office of Health Care Access Certificate of Need Application

### Final Decision

**Applicant:** Coram Alternate Site Services, Inc.

**Docket Number:** 07-31035-CON

**Project Title:** Establishment and Operation of an Ambulatory Infusion Suite in Wallingford

**Statutory Reference:** Section 19a-638 of the Connecticut General Statutes

**Filing Date:** March 25, 2008

**Hearing Date:** May 14, 2008

**Presiding Officer:** Cristine A. Vogel, Commissioner

**Decision Date:** June 10, 2008

**Default Date:** June 23, 2008

**Staff Assigned:** Alexis G. Fedorjaczenko

**Project Description:** Coram Alternate Site Services, Inc. (“Applicant”) proposes to establish and operate an Ambulatory Infusion Suite in Wallingford, Connecticut, at a total capital expenditure of \$30,467.

**Nature of Proceedings:** On March 25, 2008, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from the Applicant seeking authorization to establish and operate an Ambulatory Infusion Suite in Wallingford, Connecticut, at a total capital expenditure of \$30,467.

Pursuant to Section 19a-638 of the Connecticut General Statutes (“C.G.S.”), a notice to the public concerning OHCA’s receipt of the Applicant’s Letter of Intent was published in the *Record Journal* on September 28, 2007. Pursuant to Section 19a-638, C.G.S., three individuals or an individual representing an entity with five or more people had until April 15, 2008, the twenty-first calendar day following the filing of the Applicant’s CON application, to request that OHCA hold a public hearing on the Applicant’s proposal. OHCA received no hearing requests from the public.

Pursuant to Section 19a-638, C.G.S., a public hearing regarding the CON application was held on May 14, 2008. On April 23, 2008, the Applicants were notified of the date, time, and place of the hearing. On April 25, 2008, a notice to the public announcing the hearing was published in *The Record Journal*. Commissioner Cristine A. Vogel served as Presiding Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-638, C.G.S.

OHCA’s authority to review and approve, modify or deny the CON application is established by Section 19a-638, C.G.S. The provisions of this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

## **Findings of Fact**

### **Clear Public Need**

#### **Impact of the Proposal on the Applicant’s Current Utilization Statistics Proposal’s Contribution to the Quality of Health Care Delivery in the Region Proposal’s Contribution to the Accessibility of Health Care Delivery in the Region**

1. Coram Alternate Site Services, Inc. (“Applicant” or “CASS”) is a Connecticut Corporation that provides home infusion therapy and specialty pharmacy services based out of Wallingford. (*January 4, 2008, Initial CON Application, pages 3 and 17*)
2. CASS is also a national provider of home infusion and specialty pharmacy distribution services, with more than 70 branch locations throughout the United States. CASS also operates more than 50 infusion suites in the United States. (*September 7, 2007, Letter of Intent, March 25, 2008, Completeness Response, pages 5 and 11, and May 14, 2008, Public Hearing Testimony*)
3. The Applicant is seeking to establish and operate an ambulatory infusion suite (“AIS”) at 2 Barnes Industrial Park Road in Wallingford, Connecticut. The proposed AIS will have four chairs and will utilize the services of CASS’ existing pharmacy to provide infusion services in an outpatient setting. (*September 7, 2007, Letter of Intent and January 4, 2008, Initial CON Application, page 29*)

4. The proposed AIS will allow RNs to infuse intravenous medications prepared in CASS' on-site pharmacy, which contains a USP 797 clean room, and is licensed by the State of Connecticut's Board of Pharmacy (License Number PCY.0001335). *(January 4, 2008, Initial CON Application, page 19)*
5. The proposed AIS would serve a wide range of patients, many with neurological, infectious, gastrointestinal, dermatological, metabolic, and autoimmune diseases/conditions. *(January 4, 2008, Initial CON Application, page 7)*
6. The Applicant indicated that the proposed project will address the needs of the following groups of patients:
  - Patients receiving outpatient treatments that must be administered with medical oversight;
  - Patients who are unable to self-administer medications or do not have a caregiver to support home self-care; and
  - Patients who will be receiving the therapy for the rest of their lifetime.*(January 4, 2008, Initial CON Application, page 6 and March 25, 2008, Completeness Response, page 5)*
7. CASS stated that the Wallingford branch has received inquiries from patients and payers regarding the provision of services in the AIS. CASS also stated that Centocor, the maker of the pharmaceutical Remicade, indicated that patients are requesting a centrally located AIS within a reasonable proximity to their work places in the New Haven, Wallingford, North Haven, Cheshire, and Meriden areas where they can receive treatments immediately before or after their shifts at work. *(January 4, 2008, Initial CON Application, page 9 and May 14, 2008, Public Hearing Testimony)*
8. The Applicant indicated that there are many biopharmaceuticals currently under development that target a wide range of diseases, require a lifetime commitment by the patient, and require healthcare provider administration and monitoring. *(January 4, 2008, Initial CON Application, page 6)*
9. The Applicant indicated that the benefits of therapy at the AIS versus a the patient's home, a hospital outpatient facility, or a physician's office include the following:
  - Lower overhead costs at the AIS than a hospital setting;
  - Flexible hours of operation at the AIS, in order to accommodate multiple patient schedules compared to most Hospital clinics which are restricted to business hours;
  - Decreased wait times at the AIS, both in-office and before beginning first round of treatment after a referral; and
  - Clean, comfortable setting with personalized care and availability of full clinical team, compared to Hospital setting which may be less private, or patients home which may not be conducive to home infusions.*(March 25, 2008, Completeness Response, pages 2-4)*

10. The Applicant identified the following towns as the service area for the proposed AIS:

Primary: Wallingford and New Haven  
Secondary: North Haven, West Haven, East Haven, Cheshire, Rocky Hill,  
Southington, Meriden, Middletown, Berlin, Hamden, North Branford,  
Durham, and Guilford

*(January 4, 2008, Initial CON Application, pages 6-7)*

11. CASS indicated that providers in the service area that offer similar services to the AIS, such as chemotherapy infusions, hydration, iron infusions, and blood transfusions include the following:

**Table 1: Existing Providers in the Proposed Service Area**

<u>City</u>	<u>Provider Name</u>
New Haven	Hospital of Saint Raphael Yale-New Haven Hospital
Wallingford	None
West Haven	VA Hospital
Meriden	MidState Hospital
Middletown	Middlesex Hospital
Southington	Hospital of Central Connecticut
Derby	Griffin Hospital

*(January 4, 2008, Initial CON Application, page 11)*

12. The Applicant indicated that the majority of referrals for long-term chronic therapies will come directly from a physician's office rather than the hospital setting. *(January 4, 2008, Initial CON Application, page 8 and March 25, 2008, Completeness Response, page 9)*

13. CASS indicated that due to the existing pharmacy and home care services, the Wallingford branch has pre-established relationships with many local physicians. CASS also stated that there are 72 physician specialty groups within a 20 mile radius of the proposed AIS, including specialties likely to refer patients for infusion therapy such as rheumatologists, dermatologists, and neurologists. *(March 25, 2008, Completeness Response, page 1 and May 14, 2008, Public Hearing Testimony)*

14. The following table summarizes hospital referrals to CASS for home infusion therapy in FYs 2004-2007:

**Table 2: Home Infusion Therapy Referrals, 2004-2007**

Referring Hospital	FY 2004	FY 2005	FY 2006	FY 2007*
Hospital St. Raphael	166	155	138	178
WH VA	53	55	43	46
Yale-New Haven Hospital	49	42	30	27
Norwalk Hospital	31	43	34	36
Bridgeport Hospital	12	24	1	22
Griffin Hospital	5	7	16	17
Other	121	88	118	82
<b>Total</b>	<b>437</b>	<b>414</b>	<b>380</b>	<b>408</b>

\*Annualized based on January 1 through December 21, 2007

Note: 2004-2006 volume declines represent a shift in focus to more biologic therapies and less traditional infusion therapies.

(January 4, 2008, Initial CON Application, page 29)

15. The Applicant reported that CASS' home infusion therapy operation in Connecticut had the following volume for 2004 through 2007:

**Table 3: Historical CASS Home Infusion Therapy Volume**

	2004	2005	2006	2007*
Number of Patients	1,156	939	1,038	947
Number of Visits	4,680	4,037	3,907	4,097
Patients suitable for AIS Therapy	176	109	96	79

\* Year to date, as of 12/31/2007

(January 4, 2008, Initial CON Application, page 9)

16. The Applicant reported that projected volume for the proposed AIS is as follows:

**Table 4: Projected AIS Volume**

	2008*	2009	2010	2011
Number of Patients	79	114	135	173
Number of Visits	831	1248	1664	2080

\* Annualized

Note: The number of visits per patient varies depending on the type of infusion therapy administered. Patient volume is based on service area population (excluding Medicare beneficiaries); disease prevalence data for conditions treated with the infusion therapies to be administered at the AIS; and market share. (March 25, 2008, Completeness Response, page 9 and May 29, 2008, Late File Response)

17. The Applicant indicated that capacity was calculated based on 4 chairs x 2 shifts per day x 52 weeks x number of days per week in operation. The proposed site will phase in the program with 2 days per week in the initial year (831 visits), increasing to 3 days per week in year two (1,248 visits) and 4 days per week in year 3 (1,664 visits), reaching capacity at 5 days per week in year 4 (2,080 visits). (January 4, 2008, Initial CON Application, page Appendix 4D)
18. The proposed AIS will operate Monday through Friday from 8:00 am to 5:30 pm. The Applicants will also accommodate patients' needs for flexibility with evening and weekend hours. (January 4, 2008, Initial CON Application, page 8 and May 14, 2008, Public Hearing Testimony)

19. A determination of each patients' suitability for infusion therapies rendered in the home versus the AIS will be made based on several factors, including the patient's baseline clinical data, as well as whether:

- The prescribed injectible therapy requires a controlled setting;
- The patient prefers a particular setting;
- The patient is homebound or travel is an issue;
- Nursing visits are required more frequently than weekly or the patient requires nurse administered medications;
- The patient is receiving their first dosing of a prescribed medication; and/or
- The patient/caregiver is unable or unwilling to learn self infusion.

*(January 4, 2008, Initial CON Application, pages 29-30)*

20. The Applicant is currently accredited by the Accreditation Commission for Healthcare, Inc. for their home infusion and specialty pharmacy services, and proposes to follow the core sections of these standards, as well as the Infusion Nursing, Pharmacy, and Ambulatory Infusion Center sections. *(January 4, 2008, Initial CON Application, page 8)*

21. AIS services are not currently licensed in the State of Connecticut. *(January 4, 2008, Initial CON Application, page 16)*

**Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the Applicant's Rates and Financial Condition  
Impact of the Proposal on the Interests of Consumers of Health Care Services and the Payers for Such Services  
Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

22. The estimated total capital expenditure of the CON proposal is \$30,467 and includes the following components:

**Table 5: Capital Expenditure Components**

<b>Description:</b>	<b>Cost</b>
Major Medical Equipment (Purchase)	\$5,960
Non-Medical Equipment (Purchase) (Infusion chairs)	\$5,007
Construction/Renovation	\$19,500
<b>Total Capital Expenditure</b>	<b>\$30,467</b>

*(January 4, 2008, Initial CON Application, page 18)*

23. The proposal will be financed with the Applicant's equity from operations. *(January 4, 2008, Initial CON Application, page 21)*

24. The total area for the AIS is 656 square feet, which includes private restrooms for patients and private areas for individual chairs. It meets ADA accessibility standards and is located near the facility's front entryway. There is a waiting area for AIS patients that is distinct from the pharmacy and administrative office areas. *(January 4, 2008, Initial CON Application, page 19)*

25. The Applicant provided the following incremental revenue from operations, total operating expense, and gain from operations associated with the CON proposal:

**Table 6: Revised Financial Projections Incremental to the Project**

Description	FY 2008	FY 2009	FY 2010	FY 2011
Incremental Revenue from Operations	\$807,936	\$1,165,882	\$1,380,650	\$1,759,050
Incremental Total Operating Expense	\$606,049	\$935,743	\$1,132,503	\$1,453,699
<b>Incremental Gain from Operations</b>	<b>\$201,887</b>	<b>\$230,139</b>	<b>\$248,147</b>	<b>\$305,351</b>

(March 25, 2008, Completeness Response, Financial Attachment 13 B i)

26. CASS, Wallingford is the entity that will bill for the proposed service. CASS bills third party payers using per diem coding. The Applicant stated that this is more cost effective than the CPT codes used in physician's offices and hospital outpatient settings. (January 4, 2008, Initial CON Application, pages 17, and 24-26)

27. The Applicant's current and three year projected payer mix based on Net Patient Revenue are as follows:

**Table 7: Current & Three-Year Projected Payer Mix**

Description	Current (Home Infusion)	Year 1 (AIS)	Year 2 (AIS)	Year 3 (AIS)
Medicare*	15%	0%	0%	0%
Medicaid*	9%	0%	0%	0%
CHAMPUS and TriCare	3%	1%	1%	1%
<b>Total Government</b>	<b>27%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>
Commercial Insurers*	66%	90%	90%	90%
Uninsured	3%	5%	5%	5%
Workers Compensation	4%	4%	4%	4%
<b>Total Non-Government</b>	<b>73%</b>	<b>99%</b>	<b>99%</b>	<b>99%</b>
<b>Total Payer Mix</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

\*Includes managed care activity.

(January 4, 2008, Initial CON Application, page 23)

28. The Applicant indicated that Medicare and Medicaid do not reimburse for freestanding AIS facilities. (January 4, 2008, Initial CON Application, page 23)
29. There is no State Health Plan in existence at this time. (January 4, 2008, Initial CON Application, page 4)
30. The Applicant has adduced evidence that the proposal is consistent with its long-range plan. (January 4, 2008, Initial CON Application, page 5)
31. The Applicant has improved productivity and contained costs by participating in activities involving energy conservation, application of new technologies, and group purchasing. (January 4, 2008, Initial CON Application, page 15)
32. The proposal will not result in any change to the Applicant's teaching and research responsibilities. (January 4, 2008, Initial CON Application, page 16)

33. There are no characteristics of the Applicant's patient/physician mix that make the proposal unique. *(January 4, 2008, Initial CON Application, page 16)*
34. The Applicant has sufficient technical, financial, and managerial competence and expertise to provide efficient and adequate service to the public. *(January 4, 2008, Initial CON Application, page 14 and Appendix 5D)*

## Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for Certificate of Need (“CON”) proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g. the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

Coram Alternate Site Services, Inc. (“Applicant” or “CASS”) is a Connecticut corporation that provides home infusion therapy and specialty admixture pharmacy services based out of Wallingford. CASS is also a national provider of home infusion, ambulatory infusion, and specialty pharmacy services. CASS is seeking to establish and operate an ambulatory infusion suite (“AIS”) at 2 Barnes Industrial Park Road, Wallingford. The proposed AIS will have four chairs and will utilize the services of CASS’ existing pharmacy to provide infusion services in an outpatient setting. It will serve a range of patients, many with neurological, infectious, gastrointestinal, dermatological, metabolic, and autoimmune diseases and conditions.

The Applicant indicated that need for the proposal is driven by the increasing availability of treatments that involve a lifetime commitment by patients and require healthcare provider administration and monitoring. CASS stated that the Wallingford branch has received inquiries from patients and payers regarding the provision of outpatient infusion services in order to meet this need. According to CASS, the benefits of therapy at the AIS versus at the patient’s home, a hospital outpatient facility, or a physician’s office include more flexible accommodation of patient schedules, particularly before and after work; decreased wait times; and a clean, comfortable, and private setting with personalized care. A determination of the each patient’s suitability for infusion therapies rendered in the home versus the AIS will be based on several factors, including the patient’s clinical data, the prescribed injectable therapy, and patient preference and ability to travel to the AIS. OHCA concludes that establishment of the proposed AIS will enhance the range of options available to patients requiring infusion therapy, and will improve the quality and accessibility of outpatient infusion services in the Wallingford area.

The proposal has a total capital expenditure of \$30,467, which will be financed with equity from operations. With the proposal, the Applicant projects incremental operating gains of \$201,887, \$203,139, \$248,147, and \$305,351 in FYs 2008, 2009, 2010 and 2011, respectively. The Applicant’s financial projections, and volumes upon which they are based, appear to be reasonable and achievable. Therefore, OHCA concludes that the CON proposal is financially feasible and will improve access to quality ambulatory infusion therapy services.

## Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Coram Alternate Site Services, Inc. ("Applicant") to establish and operate an ambulatory infusion suite ("AIS") in Wallingford, is hereby GRANTED, subject to the following conditions:

1. This authorization shall expire on June 10, 2009. Should the Applicant's ambulatory infusion suite not be operational by that date, the Applicant must seek further approval from OHCA to complete the project beyond that date.
2. The Applicant shall not exceed the approved total capital expenditure of \$30,467. In the event that the Applicant learns of potential cost increases or expects that final project costs will exceed those approved, the Applicant shall notify OHCA immediately.

Should the Hospital fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional action as authorized by law.

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

By Order of the  
Office of Health Care Access

*Signed by Commissioner Vogel on June 10, 2008*

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Date

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Cristine A. Vogel  
Commissioner

CAV: agf