



## Office Of Health Care Access Certificate of Need Application

### Final Decision

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

**Docket Number:** 07-30906-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:** May 23, 2007

**Decision Date:** August 21, 2007

**Default Date:** August 21, 2007

**Staff Assigned:** Alexis G. Fedorjaczenko  
Steven W. Lazarus

**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 May 23, 2007, 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 February 2, 2007.

Pursuant to Section 19a-638, C.G.S., three individuals or an individual representing an entity with five or more people had until June 13, 2007, 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.

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 currently provides infusion therapy services to patients in a home setting. (*January 16, 2007, Letter of Intent, Section IV*)
2. The Applicant is currently a licensed pharmacy that provides specialty admixture pharmacy products to patients in Connecticut. Its nurses and subcontracted home health agencies provide the nursing services related to these pharmacy services. (*May 23, 2007, Completeness Response, page 3*)
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. (*January 16, 2007, Letter of Intent, pages 2 & 9; April 16, 2007, Initial CON Application, page 3; and May 23, Completeness Response, page 3*)
4. The Applicant indicated that the proposed project will address the needs of the following groups of patients:
  - Patients receiving medical outpatient treatments that must be administered by a healthcare provider; and
  - Patients who are unable to self-administer medications or do not have a caregiver to support home self-care.(*April 16, 2007, Initial CON Application, page 6*)

5. The Applicant indicated that there are many biotech medications currently in development that target a wide range of diseases, frequently chronic diseases, and that a majority of these medications must be administered by injection or infusion and require administration by a healthcare provider. *(April 16, 2007, Initial CON Application, exhibit 4-p)*
6. The FDA has mandated that Tysabri, a drug used to treat MS, can only be administered in certified infusion suites and cannot be provided in the home due to risk of adverse reactions.<sup>1</sup> *(January 16, 2007, Letter of Intent, Section IV and April 16, 2007, Initial CON Application, pages 6 and 13)*
7. The Applicant indicated that patients may benefit from receiving infusion therapy at the AIS versus a physician's office or hospital due to easier access and faster throughput, decreased wait times, scheduling that can more easily accommodate weekend and holiday doses of medication, and a safer and more comfortable environment. *(May 23, Completeness Response, pages 3-4 and April 16, 2007, Initial CON Application, page 6)*
8. 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.*(April 16, 2007, Initial CON Application, pages 24-5)*
9. The Applicant identified the following towns to be within 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

*(April 16, 2007, Initial CON Application, page 6)*
10. CASS indicated that the largest expected volume of patients forecasted to be serviced in the AIS would be receiving biotech medicines such as Remicaide, Tysabri, Synagis, Myozyme, IVIG, and Aralast. *(May 23, 2007, Completeness Response, page 9)*

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<sup>1</sup> The Tysabri Outreach Unified Commitment to Health ("TOUCH") certification program was designed by the manufacturer, in consultation with the FDA, to ensure safe administration of Tysabri and to promote "informed benefit-risk decisions between prescribers and patients regarding the use of Tysabri in relapsing MS."

11. 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	202
WH VA	53	55	43	60
Yale-New Haven Hospital	49	42	30	34
Norwalk Hospital	31	43	34	52
Bridgeport Hospital	12	24	1	26
Griffin Hospital	5	7	16	26
Other	121	88	118	90
<b>Total</b>	<b>437</b>	<b>414</b>	<b>380</b>	<b>490</b>

\*Annualized based on January 1 through June 30, 2007 YTD volume of 245 referrals.

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

(May 23, 2007, Completeness Response, page 1 and August 9, 2007, Additional Information)

12. On April 16, 2007, the Applicant reported that the proposed AIS will have the following projected volume:

**Table 3: Projected AIS Volume**

	2007*	2008	2009	2010
Number of Patients	77	102	122	154
Number of Visits	37	50	62	76

\* Annualized

(April 16, 2007, Initial CON Application, page 8)

13. On April 16, 2007, the Applicant reported that the proposed AIS' projected volume would include the following types of infusion therapy:

**Table 4: Projected AIS Volume by Type of Infusion Therapy**

	2007*	2008	2009	2010
Hydration	2	4	6	10
Parenteral nutrition	2	4	6	10
Antibiotics	2	4	6	10
Pain medication	2	4	6	10
Chemotherapy for treatment of cancer	2	4	6	10
Other	77	102	122	154
<b>Total</b>	<b>87</b>	<b>122</b>	<b>152</b>	<b>204</b>

\* Annualized

(August 17, 2007, Additional Information)

14. On August 6, 2007, the Applicant revised its submission and reported that the proposed AIS will have the following projected volume:

**Table 3: Projected AIS Volume**

	2007*	2008	2009	2010
Number of Patients	87	122	152	204
Number of Visits	37	50	62	76

\* Annualized

(August 6, 2007, Additional Information)

15. On August 17, 2007, the Applicant restated its volume projections for the proposed AIS to be the following:

**Table 5: Revised AIS Volume Projections**

	2007*	2008	2009	2010
Number of Patients	87	122	152	204
Number of Visits	148	600	744	912

\* Annualized

(August 17, 2007, Additional Information)

16. The Applicant did not provide a breakdown of the revised volume projections by type of infusion therapy. (August 17, 2007, Additional Information)
17. The Applicant indicated that projected patient volumes are based on a number of factors including disease prevalence data, service area population, drug usage estimates, referral patterns, and contracts with health care insurers, but did not provide calculations to support the projected volume. (May 23, 2007, Completeness Response, page 9)
18. The Applicant did not provide documentation of the needs-based assessment that was identified as a factor in identifying need for the proposal. (April 16, 2007, Initial CON Application, page 20 and May 23, 2007, Completeness Response, page 8)
19. The Applicant is currently accredited by the Accreditation Commission for Healthcare, Inc. (April 16, 2007, Initial CON Application, page 10)

**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**

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

**Table 6: 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>

*(April 16, 2007, Initial CON Application, page 15)*

21. The proposal will be financed with the Applicant's equity from operations. *(April 16, 2007, Initial CON Application, page 18)*

22. On April 16, 2007, the Applicant projected incremental revenue from operations, total operating expense, and gain from operations associated with the CON proposal as follows:

**Table 7: Financial Projections Incremental to the Project**

<b>Description</b>	<b>FY 2007</b>	<b>FY 2008</b>	<b>FY 2009</b>
Incremental Revenue from Operations	\$234,454	\$246,177	\$258,486
Incremental Total Operating Expense	\$136,705	\$143,540	\$150,717
<b>Incremental Gain from Operations</b>	<b>\$97,749</b>	<b>\$102,637</b>	<b>\$107,769</b>

*(April 16, 2007, Initial CON Application, Exhibit 13.c.i)*

23. On August 17, 2007, the Applicant provided revised projected incremental revenue from operations, total operating expense, and gain from operations associated with the CON proposal as follows:

**Table 8: Revised Financial Projections Incremental to the Project**

<b>Description</b>	<b>FY 2007</b>	<b>FY 2008</b>	<b>FY 2009</b>
Incremental Revenue from Operations	\$234,454	\$328,236	\$410,295
Incremental Total Operating Expense	\$136,705	\$191,387	\$239,234
<b>Incremental Gain from Operations</b>	<b>\$97,749</b>	<b>\$136,849</b>	<b>\$171,061</b>

*(August 17, 2007, Additional Information)*

24. The Applicant did not provide any assumptions to justify the revised financial projections. *(August 17, 2007, Additional Information)*

25. On April 16, 2007, the Applicant provided the following current and three year projected payer mix based on Net Patient Revenue:

**Table 9: Current & Three-Year Projected Payer Mix**

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

\*Includes managed care activity.

(April 16, 2007, Initial CON Application, page 20)

26. On August 14, 2007, the Applicant indicated that Medicare, Medicaid, CHAMPUS, and TriCare do not reimburse for AIS services without a physician on-site and that CASS would not have a physician on-site at the proposed AIS. (August 14, 2007, Additional Information)
27. The Applicant did not provide an explanation of the factors considered in determining not to locate a physician on-site in order to be eligible for government reimbursement.
28. On August 14, 2007, the Applicant revised the current and three year projected payer mix based on Net Patient Revenue as follows:

**Table 10: 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%	0%	0%	0%
<b>Total Government</b>	<b>27%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>
Commercial Insurers*	66%	90%	90%	90%
Uninsured	3%	5%	5%	5%
Workers Compensation	4%	5%	5%	5%
<b>Total Non-Government</b>	<b>73%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
<b>Total Payer Mix</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

\*Includes managed care activity.

(August 14, 2007, Additional Information)

29. The Applicant did not provide evidence to support its assertion that most third-party payers are not requiring any modification to CASS' current fee schedules or billing practices as this is an extension of services for which the company is already contracted to provide. (April 16, 2007, Initial CON Application, page 21)

30. There is no State Health Plan in existence at this time. *(April 16, 2007, Initial CON Application, page 4)*
31. The Applicant has adduced evidence that the proposal is consistent with its long-range plan. *(April 16, 2007, Initial CON Application, page 5)*
32. The Applicant has improved productivity and contained costs by participating in activities involving energy conservation, application of new technologies, and group purchasing. *(April 16, 2007, Initial CON Application, page 12)*
33. The proposal will not result in any change to the Applicant's teaching and research responsibilities. *(April 16, 2007, Initial CON Application, page 13)*
34. There are no characteristics that make the Applicant's patient/physician mix unique. *(April 16, 2007, Initial CON Application, page 13)*
35. The Applicant has sufficient technical, financial, and managerial competence and expertise to provide efficient and adequate service to the public. *(May 23, 2007, Completeness Response, Attached resumes and CVs)*

## 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 specialty admixture pharmacy products and infusion therapy services to patients in a home setting. The Applicant is seeking to establish and operate an ambulatory infusion suite (“AIS”) with four chairs at 2 Barnes Industrial Park Road, Wallingford. CASS currently receives referrals from hospitals and other providers throughout Connecticut to provide home infusion services to their patients. However, the Applicant indicated that the proposed project is needed to serve patients receiving new biotech medications that must be administered by a healthcare provider in a controlled environment. The Applicant also indicated that for some patients, an AIS increases access and quality of care compared to similar services rendered in a physician’s office or hospital. For each patient, the Applicant stated that a determination of the most suitable infusion setting will be made based on an assessment of clinical information and other relevant factors.

The Applicant provided inconsistent data regarding the number of patients to be served at the proposed AIS, the total number of visits proposed for the AIS, and the anticipated makeup of the patient population to be served at the AIS. From the Initial CON Application to final data submitted, the number of projected AIS visits increased four times for the first partial year of service and twelve times for the fourth year of service. While the Applicant initially provided only limited documentation and no quantifiable support for the proposed volume, the Applicant subsequently provided no documentation to justify changing the number of proposed visits. Although the Applicant provided a breakdown of proposed volume by type of infusion therapy in the Initial CON Application, the treatment types upon which the Applicant based need for the proposal were combined into an “other” category and were not broken down by type of therapy.

Based on the foregoing reasons, OHCA finds that the Applicant has not demonstrated a need to establish the proposed AIS in Wallingford. While the Applicant has provided some support for the assertion that an AIS would increase options for patients requiring specific biotech medications that must be administered in a controlled setting, the Applicant has not provided consistent evidence to substantiate the scope of need or a lack of comparable services already available in the proposed service area.

The total capital expenditure for the CON proposal is \$30,467. With the proposal, the Applicant initially projected incremental operating gains of \$97,749, \$102,637, and \$107,769 in FYs 2007, 2008, and 2009, respectively. Subsequent to substantially increasing the projected number of patients to be served, the Applicant projected incremental operating gains of \$97,749, \$136,849, and \$171,061 in FYs 2007, 2008, and

2009, respectively. While the Applicant asserted in the CON application that most third-party payers are not requiring any modification to the Applicant's current fee schedules or billing practices, this statement was not supported by evidence in the CON Application. The Applicant also did not provide any documentation to support statements regarding the reimbursement policies of government payers. Without definitive volume projections upon which the revenues and expenditures are based, and without evidence to support the Applicant's statements regarding reimbursement of the proposed service, OHCA cannot evaluate the financial viability of the proposal.

## 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 in Wallingford, is hereby DENIED.

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

*August 21, 2007*

\_\_\_\_\_  
Date

*Signed by Commissioner Vogel*

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Cristine A. Vogel  
Commissioner

CAV: agf : swl