



## Office Of Health Care Access Certificate of Need Application

### Final Decision

**Applicant:** Professional Home Care Services, Inc.

**Docket Number:** 05-30609-CON

**Project Title:** Establishment and Operation of an Outpatient Infusion Therapy Center in Vernon

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

**Filing Date:** April 10, 2007

**Decision Date:** June 27, 2007

**Default Date:** July 9, 2007

**Staff Assigned:** Alexis G. Fedorjaczenko  
Laurie K. Greci

**Project Description:** Professional Home Care Services, Inc. ("Applicant") proposes to establish and operate an Outpatient Infusion Therapy center in Vernon, Connecticut, at a total capital expenditure of \$6,000.

**Nature of Proceedings:** On April 10, 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 outpatient infusion therapy center in Vernon, Connecticut, at a total capital expenditure of \$6,000.

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 October 22-23, 2005 issue of the *Journal Inquirer*.

Pursuant to Section 19a-638, C.G.S., three individuals or an individual representing an entity with five or more people had until May 1, 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 Hospital’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 Hospital’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. Professional Home Care Services, Inc. (“Applicant” or “PHCS”) is a Connecticut corporation that provides home infusion and respiratory therapy services in Connecticut. (*October 18, 2005, Letter of Intent, page 5 and February 10, 2006, Initial CON Application, p.2*)
2. PHCS has four locations in Connecticut as noted below: (*April 11, 2007, Completeness Response, page 6*)

**Table 1: PHCS Locations and Services in Connecticut**

PHCS Location	Services
104 Sebeth Drive Cromwell, CT 06416	Compounding pharmacy, durable medical equipment, and respiratory therapy/equipment
216 Christian Lane Berlin, CT 06037	Compounding pharmacy, durable medical equipment, and respiratory therapy/equipment
225 Research Drive, Suite 7 Milford, CT 06460	Durable medical equipment and home respiratory therapy/equipment
400 Talcottville Road Vernon, CT 06066	Durable medical equipment and home respiratory therapy/equipment

3. PHCS is licensed as a pharmacy and has been providing specialty infusion therapy in the home for 16 years. PHCS pharmacists compound intravenous medications and nurses administer intravenous therapies. (*November 9, 2006, Completeness Response, page 3, and February 10, 2006, Initial CON Application, page 8*)
4. The Applicant is seeking to establish and operate an outpatient infusion therapy center, or ambulatory infusion suite (“AIS”), in Vernon, Connecticut. The proposed AIS will

have four chairs. (*October 18, 2005, Letter of Intent, page 5, and November 9, 2006, Completeness Response, page 12*)

5. The proposed AIS would serve a wide range of patients, many with the following diseases and conditions: (*November 9, 2006, Completeness Response, page 4*)
  - Cancer;
  - Infections diseases (e.g. Lyme's Disease, Hepatitis, AIDS);
  - Neurological conditions;
  - Autoimmune diseases (e.g. Rheumatoid Arthritis); and
  - Gastrointestinal conditions (e.g. Inflammatory Bowel Disease).
6. The proposed AIS would administer treatments such as the following: (*November 9, 2006, Completeness Response, page 4*)
  - Chemotherapy/Hydration;
  - Antibiotics and Anti-infectives;
  - Immunological therapy;
  - Monoclonal antibody therapy; and
  - A small amount of parenteral therapy.
7. PHCS based the need for the proposed AIS on the following: (*April 11, 2007, Completeness Response, pages 2, 3, & 7*)
  - New pharmaceutical agents and/or new uses for existing pharmaceutical agents which have led to an increase in the size of the population appropriate for outpatient infusion therapy;
  - Capacity problems at hospital-based infusion centers; and
  - Benefits for certain patients of receiving infusion therapy at the AIS rather than in a hospital or in the home.
8. New infusion therapies, classified as biologicals, have been introduced for the treatment of certain chronic diseases. It is forecast that 50% of these biologicals in the future will be given intravenously. (*February 10, 2006, Initial CON Application, page 3*)
9. Although the specific pharmaceutical therapy to be delivered at the AIS would be the same as that delivered by the Hospital or at home, the Applicant has identified the following possible benefits to patients of receiving infusion therapy at the AIS: (*April 11, 2007, Completeness Response, page 7*)
  - Smaller, more personal environment than a hospital;
  - Easier access and faster throughput and than a hospital; and
  - Safer environment and nursing care throughout the infusion compared to home.
10. Whether a patient will receive treatment in their home or access the AIS will be determined after a complete intake assessment and all relevant factors (e.g. type of treatment, length of treatment, location and condition of home, patient's physical condition, health insurance, patient/physician preference, etc) have been considered. (*November 9, 2006, Completeness Response, page 10*)

11. The Applicant indicated that Eastern Connecticut Health Network, Inc. (“ECHN”), which consists of Manchester Hospital and Rockville Hospital, provides similar services in the proposed service area. Manchester Hospital has an ambulatory medical unit with ten stations and provides a variety of services in this area including infusions, bone marrow biopsies, liver biopsies, and other minor procedures. Rockville Hospital does not have a dedicated outpatient infusion area and provides this service in an outpatient procedure area. Outpatient chemotherapy is not offered at Rockville Hospital. *(February 10, 2006, Initial CON Application, page 3, and April 11, 2007, Completeness Response, page 3)*
12. ECHN stated in a letter supporting the proposal that: “Over the past two years there has been increasing demand for infusion services that has challenged outpatient capacity at both hospitals.” The Hospitals further state that “Without additional capacity, our patients will experience increasing difficulty in accessing timely, convenient care in a comfortable setting that meets their needs and desires.” *(April 11, 2007, Completeness Response, page 11)*
13. The ECHN Hospitals have indicated that they will refer patients to the proposed infusion suite and the Applicant expects that they will be the main referral source. *(April 11, 2007, Completeness Response, page 4, and November 9, 2006, Completeness Response, page 3)*
14. The Applicant identified the following towns to be within the service area for the proposed AIS: *(November 9, 2006, Completeness Response, page 7)*  
  
Primary: Ellington, Manchester, Tolland, Vernon/Rockville  
Secondary: Bolton, East Hartford, East Windsor, South Windsor, Windsor  
Extended: Andover, Coventry, Marlborough, Stafford Springs
15. The following table summarizes outpatient drug administration volumes performed at both ECHN hospitals for the time period 2003-2006. *(April 11, 2007, Completeness Response, page 3)*

**Table 2: ECHN Outpatient Drug Administration Volumes, 2003-2006**

FY 2003	FY 2004	FY 2005	FY 2006
17,290	19,045	19,958	21,790

16. ECHN identified the specific infusion medications that would be appropriate and most likely to be referred to the proposed AIS because they can be safely administered in an AIS, they can be administered more cost effectively in an AIS as opposed to a hospital-based unit, and there is a significant volume of patients requiring these infusions. *(April 11, 2007, Completeness Response, page 4)*

**Table 3: Infusion Medications**

Generic Drug Name	Trade Drug Name	Type/Use of Drug
Darbepoetin	Aranesp	Anti-anemia drug
Enoxaparin	Lovenox	Anti-coagulant
Epoetin Alfa	Procrit	Treat anemia
Filgrastim	Neupogen	Growth factor – promotes growth of white blood cells
Immune Globulin		Help fight infection/boost immune system
Infliximab	Remicade	Monoclonal antibody – treats auto-immune conditions
Omalizumab	Xolair	Treat asthma
Pegfilgrastim	Neulasta	Growth factor – promotes growth of white blood cells
Rituximab	Rituxan	Monoclonal antibody – treats auto-immune conditions
Zoledronic Acid	Zometa	Cancer treatment/treatment for hypercalcemia

17. The Applicant indicated that the proposed AIS will have the following projected volume with three days of service per week, 50 weeks annually: (*April 11, 2007, Completeness Response, page 22, and November 9, 2006, Completeness Response, page 8*)

**Table 4: Projected Patient Encounters by Service Area for Operating Years 1-3**

	Baseline Visits <sup>1</sup>	Capture Rates Year 1	Year 2	Year 3	Projected Visits Year 1	Year 2	Year 3
ECHN PSA <sup>2</sup>	674	60%	75%	90%	404	506	607
ECHN SSA <sup>2</sup>	239	50%	60%	75%	120	143	179
ECHN ESA <sup>2</sup>	52	20%	40%	50%	10	21	26
PHCS <sup>3</sup>	768	20%	35%	50%	154	269	384
<b>Total</b>	<b>1,733</b>	<b>--</b>	<b>--</b>	<b>--</b>	<b>688</b>	<b>939</b>	<b>1,196</b>

1. Baseline visits represent visit statistics rather than patient volumes. The assumption is six visits per patient.
2. ECHN identified the target patient population for the proposed service area for referrals. These patients are currently receiving infusion therapy that would be appropriate for the AIS and could be adequately reimbursed at the AIS (See Table 4). These patients are broken out by location in the Applicant's Primary Service Area, Secondary Service Area, and Extended Service Area.
3. In addition to the ECHN patients, it is expected that a small number of current home care patients will be shifted to the AIS because of location, safety, clinical reasons, or patient preference.

18. The Applicant indicated that the proposed AIS will have the following volume distribution by service type: (*April 11, 2007, Completeness Response, page 22*)

**Table 5: Volume Estimates by Type of Therapy**

Type of Therapy	% Distribution	Year 1 Visits
Chemotherapy/Hydration	5.0%	34
Parenteral Nutrition	0.5%	3
Antibiotics/Anti-infectives	19.5%	134
Immunological Therapy	30.0%	206
Monoclonal Antibody	45.0%	310
<b>Total</b>	<b>100.0%</b>	<b>688</b>

19. The Applicant projects AIS capacity of 1,867 visits per year, based on 3 days per week of service, seven hours per day, with an average visit time of 2.25 hours. *(April 11, 2007, Completeness Response, page 22)*
20. PHCS carries malpractice insurance for all of its nurses. *(November 9, 2006, Completeness Response, page 15)*
21. PHCS is currently JCAHO<sup>1</sup> accredited for home infusion therapy, and will pursue JCAHO accreditation for the proposed AIS. *(November 9, 2006, Completeness Response, page 4)*
22. PHCS bills for infusion therapy services in three parts: the drug, a per diem, and a nursing charge. The same billing structure would apply for the AIS. *(November 9, 2006, Completeness Response, page 4)*
23. That Applicant stated that other home-infusion providers in the proposed service area include Apria, Coram, Collins IV Care (Genox Home Care), and Option Care. The Applicant stated that the proposed AIS is not expected to have any impact on these providers because the AIS will primarily treat patients who otherwise would have been treated in a hospital infusion suite or a physician's office. *(November 9, 2006, Completeness Response, page 6, and April 11, 2007, Completeness Response, page 5)*
24. The Applicant stated that Drs. Davis, Posteraro, and Wasser, MDs, LLP is a medical oncology practice that administers chemotherapy in the office to some of their patients in the proposed service area. *(November 9, 2006, Completeness Response, page 11)*

**Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the  
Hospital'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**

25. The estimated total capital expenditure of the CON proposal is \$6,000 and includes the following components: *(February 10, 2006, Initial CON Application, page 9)*

**Table 6: Capital Expenditure Components**

<b>Description:</b>	<b>Cost</b>
Major Medical Equipment (Purchase)	\$1,000
Non-Medical Equipment (Purchase) (Infusion chairs)	\$3,000
Construction/Renovation	\$2,000
<b>Total Capital Expenditure</b>	<b>\$6,000</b>

26. This infusion suite will be installed in a space that is currently leased and occupied by PHCS's Vernon office. *(November 9, 2006, Completeness Response, page 17)*

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<sup>1</sup> Joint Commission on Accreditation of Healthcare Organizations

27. The Applicant indicates that renovations will commence as soon as the CON and Outpatient Clinic Licensure are approved, and that construction will be completed and operations will commence 2-4 weeks later. *(February 10, 2006, Initial CON Application, page 10)*
28. The proposal will be financed with the Applicant's equity from operations. *(February 10, 2006, Initial CON Application, page 11)*
29. The Applicant's projected incremental revenue from operations, total operating expense, and gain/(loss) from operations associated with the CON proposal are as follows: *(April 11, 2007, Completeness Response, page 21)*

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

Description	FY 2007	FY 2008	FY 2009
Incremental Revenue from Operations	\$648,406	\$1,769,237	\$2,254,387
Incremental Total Operating Expense	\$652,955	\$1,737,363	\$2,180,890
<b>Incremental Gain from Operations</b>	<b>(\$4,549)</b>	<b>\$31,874</b>	<b>\$73,496</b>

30. The current and three year projected payer mix percentages of the Applicant are as follows. *(February 10, 2006, Initial CON Application, page 12)*

**Table 8: Current & Three-Year Projected Payer Mix**

Description	Current	Year 1	Year 2	Year 3
Medicare	12%	13%	15%	20%
Medicaid	17%	17%	17%	17%
<b>Total Government</b>	<b>29%</b>	<b>30%</b>	<b>32%</b>	<b>36%</b>
Commercial Insurers	70%	69%	67%	63%
Uninsured	1%	1%	1%	1%
<b>Total Non-Government</b>	<b>71%</b>	<b>70%</b>	<b>68%</b>	<b>64%</b>
<b>Total Payer Mix</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

31. There is no State Health Plan in existence at this time. *(February 10, 2006, Initial CON Application, page 2)*
32. The Applicant has adduced evidence that the proposal is consistent with its long-range plan. *(February 10, 2006, Initial CON Application, page 12)*
33. The Applicant's proposal will improve productivity and contain costs. *(February 10, 2006, Initial CON Application, page 7)*
34. The Applicant states that the proposed AIS offers a more cost effective setting than hospital outpatient infusion suites or home infusion therapy services because the AIS does not have the overhead costs of a hospital and enjoys certain efficiencies compared to home services. *(November 9, 2006, Completeness Response, page 3)*
35. The proposal will not result in any change to the Applicant's teaching and research responsibilities. *(February 10, 2006, Initial CON Application, page 8)*

36. There are no characteristics that make the Applicant's patient/physician mix unique. *(February 10, 2006, Initial CON Application, page 8)*
37. The Applicant has sufficient technical, financial, and managerial competence and expertise to provide efficient and adequate service to the public. *(April 11, 2007, Completeness Response, pages 28-41)*
38. The Applicant's rates are sufficient to cover the proposed capital and operating costs associated with the proposal. *(April 11, 2007, Completeness Response, page 21)*

## 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.

Professional Home Care Services, Inc. ("Applicant" or "PHCS") is a Connecticut corporation that provides home infusion and respiratory therapy services in Connecticut based out of offices in Cromwell, Berlin, Milford, and Vernon. PHCS is licensed as a pharmacy and has been providing specialty infusion therapy in the home for 16 years. The Applicant's pharmacists compound intravenous medications and its nurses administer the intravenous therapies.

The Applicant is seeking to establish and operate an outpatient infusion therapy center, or ambulatory infusion suite ("AIS"), at 400 Talcottville Road, Vernon. The proposed AIS will have four chairs and will provide a range of treatments to patients with conditions including cancer, infectious diseases, neurological conditions, autoimmune diseases, and gastrointestinal conditions. The Applicant based the need for the proposed AIS on new pharmaceutical agents and/or new uses for existing pharmaceutical agents which have led to an increase in the size of the population appropriate for outpatient infusion therapy; the benefits to certain patients of receiving infusion therapy at the AIS rather than in a hospital or in the home; and capacity problems at hospital-based infusion centers.

New infusion therapies classified as biologicals have been introduced for the treatment of certain chronic diseases. It is forecast that 50% of these biologicals in the future will be given intravenously, creating a significant demand for infusible services. While infusion therapy can be administered in several settings—inpatient hospital, hospital-based outpatient infusion center, physician's office, patient's home, or AIS—and the specific pharmaceutical therapy to be delivered would be the same irrespective of location, the Applicant has identified a number of possible benefits to patients who receive treatment in the AIS. They are able to receive care in a smaller, more personal environment with easier access and faster throughput than in the Hospital. They are also provided with a safer environment than may be available in the home, along with the benefit of nursing care



throughout the infusion. A determination of the most appropriate location for treatment of each patient will be determined by the Applicant after a complete intake assessment and consideration of all relevant factors.

Manchester and Rockville Hospitals, which make up Eastern Connecticut Health Network, Inc. ("ECHN"), provide similar services in the proposed service area. However, they have indicated that increasing demand for infusion services has created capacity challenges and that the proposed AIS will benefit their patients by improving access to timely and convenient care. The Hospitals support the proposed AIS and will serve as the main referral source of patients to this new service. Based on the foregoing reasons, OHCA finds that the Applicant has provided sufficient evidence to support the establishment of the AIS in Vernon. The Applicant's proposal will improve both the accessibility and quality of infusion therapy treatment for patients located in the greater Vernon service area.

The total capital expenditure of \$6,000 for the CON proposal will be financed with PHCS's equity from operations. With the proposal, PHCS projects a small incremental loss from operations of (\$4,549) in FY 2007, and incremental operating gains of \$31,874 and \$73,496 in FYs 2008 and 2009, respectively. Although OHCA cannot draw any conclusions, the Hospital's volume and financial projections upon which they are based appear to be reasonable and achievable.

In summary, OHCA finds that there is clear public need for the Applicant's proposed outpatient infusion therapy center, as the CON proposal will enhance the range of options available to patients requiring infusion therapy treatment and will help address existing capacity challenges in the proposed service area.

## Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Professional Home Care Services, Inc. to establish and operate an outpatient infusion therapy center at 400 Talcottville Road, Vernon, Connecticut, is hereby GRANTED, subject to the following conditions:

1. This authorization shall expire on June 27, 2009. Should the Applicant's outpatient infusion therapy center 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 \$6,000. 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

\_\_\_\_\_  
Date

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Cristine A. Vogel  
Commissioner

CAV: lkg : agf