

COMMONWEALTH OF VIRGINIA

APPLICATION FOR A

MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

(CHAPTER 4, ARTICLE 1:1 OF TITLE 32.1,

SECTIONS 32.1 – 102.1 THROUGH 32.1 – 102.12 OF

THE CODE OF VIRGINIA OF 1950, AS AMENDED)

OUTPATIENT FACILITIES

SECTION I FACILITY ORGANIZATION AND IDENTIFICATION

- A. Woodburn Nuclear Medicine/Metro Region PET Center
Official Name of Facility
3289 Woodburn Rd. Suite 60
Address
Annandale, VA 22003
City State Zip
703-698-0666
Telephone
- B. Woodburn Nuclear Medicine, LTD
Legal Name of Applicant
3289 Woodburn Rd. Suite 60
Address
Annandale, VA 22003
City State Zip
- C. Chief Administrative Officer
Nancy Harty
Name
3289 Woodburn Rd. Suite 60
Address
Annandale, VA 22003
City State Zip
703-663-8579
Telephone
- D. Person(s) to whom questions regarding application should be directed:
Mark S. Goldstein
Name
3289 Woodburn Rd. Suite 60
Address
Annandale, VA 22003
City State Zip
703-608-8209 703-698-5630
Telephone Facsimile

E. Type of Control and Ownership (Complete appropriate section for both owner and operator.)

Will the facility be operated by the owner?

Yes



No

Owner of the Facility
(Check one)

Proprietary

Operator of Facility
(Check one)

(1) _____

(1) Individual

(1) _____

(2) _____

(2) Partnership-attach copy of Partnership Agreement and receipt showing that agreement has been recorded

(2) _____

(3) ☒ _____

(3) Corporate-attach copy of Articles of Incorporation and Certificate of Incorporation

(3) ☒ _____

Refer to binder
Sections
5 and 6

(4) _____

(4) Other _____ Identify (4) _____

Non-Profit

(5) _____

(5) Corporation-attach copy of Articles of Incorporation and Certificate of Incorporation

(5) _____

(6) _____

(6) Other _____ Identify (6) _____

Governmental

(7) _____

(6) State

(7) _____

(8) _____

(8) County

(8) _____

(9) _____

(9) City

(9) _____

(10) _____

(10) City/County

(10) _____

(11) _____

(11) Hospital Authority or Commission

(11) _____

(12) _____

(12) Other _____ Identify (12) _____

F. Ownership of the Site (Check one and attach copy of document) *Refer to binder Section 7*

- (1) _____ Fee simple title held by the applicant
- (2) _____ Option to purchase held by the applicant
- (3) _____ leasehold interest for not less than _____ years
- (4) ☒ Renewable lease, renewable every 11 years
- (5) _____ Other _____ Identify

G. Attach a list of names and addresses of all owners or persons having a financial interest of five percent (5%) or more in the medical care facility.

(a) In the case of proprietary corporation also attach:

- (1) A list of the names and addresses of the board of directors of the corporation.
- (2) A list of the officers of the corporation.
- (3) The name and address of the registered agent for the corporation.

Refer to binder Section 4, page 1

(b) In the case of a non-profit corporation also attach: **N/A**

- (1) A list of the names and addresses of the board of directors of the corporation
- (2) A list of the officers of the corporation
- (3) The name and address of the registered agent for the corporation

(c) In the case of a partnership also attach: **N/A**

- (1) A list of the names and addresses of all partners.
- (2) The name and address of the general or managing partner.

(d) In the case of other types of ownership, also attach such documents as will clearly identify the owner. **N/A**

H. List all subsidiaries wholly or partially owned by the applicant. **N/A**

I. List all organizations of which the applicant is wholly or partially owned subsidiary. **N/A**

J. If the operator is other than the owner, attach a list of the names(s) and addresses of the operator(s) of the medical care facility project. In the case of a corporate operator, specify the name and address of the Registered Agent. In the case of the partnership operator, specify the name and address of the general or managing partner. **N/A**

K. If the operator is other than the owner, attach an executed copy of the contract or agreement between the owner and the operator of the medical care facility. **N/A**

SECTION II

ARCHITECTURE AND DESIGN

A. Location of the Proposed Project

1. Size of site: 650 acres sq. ft.
2. Located in Annandale/Fairfax/PD8 City/County/Planning District
3. Address or directions 3289 Woodburn Rd., Suite 60
Annandale, VA 22003
4. Has site been zoned for type of use proposed:
☒ Yes (attach copy of zoning or use permit) Refer to binder Section 8
☐ No
 If no, explain status _____

B. Type of project for which Certificate of Public Need is requested. (Check one)

- (1) ☐ New construction
- (2) ☒ Remodeling/modernization of an existing facility
- (3) ☐ No construction or remodeling/modernization
- (4) ☐ Other _____ (Identify)

C. Design of the facility

- (1) Does the facility have a long range plan? If yes, attach a copy.
- (2) Briefly describe the proposed project with respect to location, style and major design features, and the relationship of the current proposal to the long range plan.
- (3) Describe the relationship of the facility to public transportation and highway access.
- (4) Relate the size, shape, contour and location of the site to such problems as future expansion, parking, zoning and the provision of water, sewer and solid waste services.

Refer to
binder
Section
4
page 2

- (5) If this proposal is to replace an existing facility, specify what use will be made of the existing facility after the new facility is completed. *N/A*

- (6) Describe any design features which will make the proposed project more efficient in terms of construction costs, operating costs, or energy conservation. *Refer to binder Section 4, page 3*

Refer to binder Section 4, page 3

D. Describe and document in detail how the facility will be provided with water, sewer and solid waste services. Also describe power source to be used for heating and cooling purposes. Documentation should include, but is not limited to:

- (1) Letters from appropriate governmental agencies verifying the availability and adequacy of utilities, *N/A*
- (2) National Pollution Discharge Elimination System permits, *N/A*
- (3) Septic tank permits, or *N/A*
- (4) Receipts for water and sewer connection and sewer connection fees. *N/A*

E. Space tabulation – (show in tabular form)

1. If Item #1 was checked in II-B, specify:

- a. The total number of square feet (both gross and net) in the proposed facility.
- b. The total number of square feet (both gross and net) by department and each type of patient room (the sum of the square footage in this part should equal the sum of the square footage in (a) above and should be consistent with any preliminary drawings, if available).

2. If Item #2 was checked in II-B, specify: *Refer to binder section 9*

- a. The total number of square feet (both gross and net) by department and each type of patient room in the existing facility.
- b. The total number of square feet (both gross and net) to be added to the facility. *None as this is an existing space.*
- c. The total number square feet (both gross and net) to be remodeled, modernized, or converted to another use.
- d. The total number of square feet (both gross and net) by department and each type of patient room in the facility upon completion. (The sum of square footage in this part should equal the sum of the square footages in parts (a) and (b) above and should be consistent

with any preliminary drawings, if available. (The department breakdown should be the same as in (a) above.)

3. Specify design criteria used or rationale for determining the size of the total facility and each department within the facility. *Refer to binder Section 4, page 3*
- F. Attach a plot plan of the site which includes at least the following: *N/A*
1. The courses and distances of the property line.
 2. Dimensions and location of any buildings, structures, roads, parking areas, walkways, easements, right-of-way or encroachments on the site.
- G. Attach a preliminary design drawing drawn to a scale of not less than 1/16"-1'0" showing the functional layout of the proposed project which indicates at least the following: *Refer to binder section 9*
1. The layout of each typical functional unit.
 2. The spatial relationship of separate functional components to each other.
 3. Circulatory spaces (halls, stairwells, elevators, etc.) and mechanical spaces.
- H. Construction Time Estimates
1. Date of Drawings: Preliminary 10.2.23 Final 1.4.24
 2. Date of Construction: Begin 6.20.24 Completion 10.15.24
 3. Target Date of Opening: 11.1.24

SECTION III

SERVICE DATA

- Refer to binder section 4, page 3
- A. In brief narrative form describe the kind of services now provided and and/or the kind of services to be available after completion of the proposed construction or equipment installation.
 - B. Describe measures used or steps taken to assure continuity of care.
 - C. What procedures are utilized in quality care assessment?
 - D. Describe the plan for obtaining additional medical, nursing and paramedical personnel required to staff the project following completion and identify the sources from which such personnel are expected to be obtained.
 - E. Facilities and Services to be Provided (Check)

		<u>Existing</u>	<u>This Project To be Added</u>	<u>This Project to to be Discontinued</u>
1.	Outpatient Surgery	_____	_____	_____
2.	Post Operative Recovery Room	_____	_____	_____
3.	Pharmacy with full-time pharmacists	_____	_____	_____
	part-time pharmacists	_____	_____	_____
4.	Diagnostic Radio- logical Services	_____	_____	_____
	x-ray	_____	_____	_____
	radioisotope	_____	_____	_____
	CT scanning	_____	_____	_____
5.	Therapeutic Radio- logical Services	_____	_____	_____
	Specify Source(s) or Type(s) or Equipment Used	_____	_____	_____
		_____	_____	_____
		_____	_____	_____
		_____	_____	_____

3. Is (will) there (be) an arrangement whereby medical records can readily be transferred between this outpatient facility and an inpatient facility (ies)?
☒ Yes (give name of facility) *Refer to binder section 4, page 4*
☐ No
4. Outpatient services are (will be) available from 7 a.m. to 5 p.m. 5 days of week.
5. Does (will) the facility operate scheduled clinics?
☐ Yes (Attach clinic schedule list)
☒ No
6. Are there other organized outpatient services in your primary service area?
☒ Yes ☐ No
7. The outpatient facility is (will be) staffed:
 (a) Only by physicians on call: ☐ Yes ☒ No
 (b) By full time physicians: ☒ Yes ☐ No
 (c) By physicians who limit their practice to this outpatient service? ☒ Yes ☐ No
8. State specifically any limitations or restrictions for participation in the services of the facility. *None*

G. Please provide historical and/or project utilization statistics for the facility including number of patients, number of patient visits and number of patient services.
Refer to binder section 16

H. Staffing of Existing and/or Proposed Facility

In the following categories, indicate the number of full time equivalent personnel (at least 35 hours per week).

	Current	Additional	Needed	
	Full Time	Vacant Positions	Full Time	TOTAL
Total number of Full-time staff	<u>39</u>	<u>0</u>	<u>0</u>	<u>39</u>
Administration-Business Office	<u>25</u>	<u>0</u>	<u>0</u>	<u>25</u>
Registered Nurses	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Licensed Practical Nurses, Nurses Aides, Orderlies/Attendants	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Registered Medical Records Librarian	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Registered Pharmacists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Laboratory Medical Technologists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
ADA Dieticians	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Radiologic Technologists	<u>7</u>	<u> </u>	<u> </u>	<u>7</u>
Occupational Therapists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Physical Therapists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Psychologists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Psychiatric Social Workers	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Recreational Therapists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Inhalation Therapists	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Medical Social Workers	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Other Health

Professionals, Identify _____

All Other Personnel (Exclude Physicians and Dentists)

- I. Present a plan for obtaining all additional personnel required to staff the project following completion and identify the sources from which such personnel are expected to be obtained. *The facility is already fully staffed for this project.*
- J. Describe the anticipated impact that the project will have on the staffing of other facilities in the service area. *none*
- K. Attach the following information or documents:
1. Copy of most recent licensing report from State Agency (existing facilities, excluding public health centers).
Refer to RAM License, binder section 17
 2. Current accreditation status and copy of latest accreditation report from Joint Commission on Accreditation of Hospitals (existing facilities excluding public health centers).
Refer to ACR Accreditation, binder section 18
 3. Roster of medical staff (existing facilities). Indicate their specialty, Board Certification, Board eligibility and staff privileges (active, associate, etc.).
Refer to binder, section 10
 4. Copies of letters of commitment or statement of intent from physicians indicating they will staff the proposed new facility or service upon completion (existing and proposed facilities).
Refer to binder, section 11

SECTION IV

PROJECT JUSTIFICATION AND IDENTIFICATION OF
COMMUNITY NEED

- A. Please provide a comprehensive narrative description of the proposed project.

Refer to binder, section 4, page 4

- B. Identification of Community Need

1. Describe the geographic boundaries of the facility's primary service area. (Note: Primary service area may be considered to be geographic area from which 75% of patients are expected to originate.)

Refer to binder, section 4, page 5

2. Provide patient origin, discharge diagnosis or utilization data appropriate for the type of project proposed. *N/A*

- C. 1. Is (are) the service(s) to be offered presently being offered by any other existing facility(ies) in the Health Planning Region?

Refer to binder section 4 page 5

2. If Yes,

- a. Identify the facility(ies)
- b. Discuss the extent to which the facility(ies) satisfy(ies) the current demand for the service(s).
- c. Discuss the extent to which the facility(ies) will satisfy the demand for services in five years.

Refer to binder, section 4, page 6

- D. Discuss how project will fill an unmet need in the delivery of health care in the service area including, where applicable, geographic barriers to access.

- E. Discuss the consistency of the proposed project with applicable Regional Health Plan, State Health Plan, State Medical Facilities Plan, or other plans promulgated by State agencies.

- F. Show the method and assumptions used in determining the need for additional beds, new services or deletion of service in the proposed project's service area. *N/A*

- G. Coordination and Affiliation with Other Facilities. *N/A*

Describe any existing or proposed formal agreements or affiliations to share personnel, facilities, services or equipment. (Attach copies of any formal agreements with another health or medical care facility.)

Refer to binder, section 4, page 7

H. Attach copies of the following documents:

1. A map of the service area indicating: *Refer to binder section 12*
 - a. Location of proposed project.
 - b. Location of other existing medical facilities (by name, type (hospital, nursing home, outpatient clinic, etc.) and number of beds in each inpatient facility).
2. Any material which indicates community and professional support for this project; i.e. letter of endorsement from physicians, community organizations, local government, Chamber of Commerce, medical society, etc. *Refer to binder section 13*
3. Letters to other area facilities advising of the scope of the proposed project. *Refer to binder section 14*

SECTION V

FINANCIAL DATA

It will be the responsibility of the applicant to show sufficient evidence of adequate financial resources to complete construction of the proposed project and provide sufficient working capital and operating income for a period of not less than one (1) year after the date of opening:

- A. Specify the per diem rate for all existing negotiated reimbursement contracts and proposed contracts for patient care with state and federal governmental agencies, Blue Cross/Blue Shield Plans, labor organizations such as health and welfare funds and membership associations. N/A

- B. Does the facility participate in a regional program which provides a means for facilities to compare its costs and operations with similar institutions?

_____ Yes ☒ No

If yes, specify program _____
Provide a copy of report(s) which provide(s) the basis for comparison.

- C. Estimated Capital Costs

Please see "Instructions for Completing Estimated Capital Costs" Section of the Certificate of Need application for detailed instructions for completing this question (attached)

Part I – Direct Construction Costs

- | | | |
|----|---|-------------------------|
| 1. | Cost of materials | \$ <u>~ 75,000</u> |
| 2. | Cost of labor | \$ <u>~ 125,000</u> |
| 3. | Equipment included in construction contract | \$ <u>0</u> |
| 4. | Builder's overhead | \$ <u>Not available</u> |
| 5. | Builder's profit | \$ <u>Not available</u> |
| 6. | Allocation for contingencies | \$ <u>~ 50,000</u> |
| 7. | Sub-total (add lines 1 thru 6) | \$ <u>250,000</u> |

Part II – Equipment Not Included in Construction Contract

If leasehold, lease expense over entire term of lease

(List each separately)

8. a. Siemens Biograph Horizon \$ 850,000
PET/CT scanner

- b. _____ \$ 0
- c. _____ \$ 0
- d. _____ \$ 0
- e. _____ \$ 0

9. Sub-total (add lines 8a thru 8e)

\$ 850,000

Part III – Site Acquisition Costs

10. Full purchase price \$ 0
11. For sites with standing structures \$ 0
- a. purchase price allocable to structures \$ 0
- b. purchase price allocable to land \$ 0
12. Closing costs \$ 0
13. If leasehold, lease expense over entire term of lease \$ 3,381,312
over 11 years
14. Additional expenses paid or accrued:
- a. _____ \$ 0
- b. _____ \$ 0
- c. _____ \$ 0
15. Sub-total (add lines 10 thru 14c) \$ 0

Part IV – Site Preparation Costs

16. Earth work \$ 0
17. Site utilities \$ 0
18. Roads and walks \$ 0
19. Lawns and planting \$ 0
20. Unusual site conditions:

a. _____
 \$ 0 _____ b. _____
 \$ 0 _____

21. Accessory structures \$ 0 _____
 22. Demolition costs \$ 0 _____
 23. Sub-total (add lines 16 thru 22) \$ 0 _____

Part V – Off-site Costs (List each separately)

24. _____ \$ 0 _____
 25. _____ \$ 0 _____
 26. _____ \$ 0 _____
 27. _____ \$ 0 _____
 28. Sub-total (add lines 24 thru 27) \$ 0 _____

Part VI – Architectural and Engineering Fees

29. Architect's design fee \$ 14,800 _____
 30. Architect's supervision fee \$ 6,600 _____
 31. Engineering fees \$ 750 _____
 32. Consultant's fees \$ 0 _____
 33. Sub-total (add lines 29 thru 32) \$ 22,150 _____

Part VII – Other Consultant Fees (List each separately)

34. a. Project Consultant \$ 15,000 _____
 b. _____ \$ 0 _____
 c. _____ \$ 0 _____
 35. Sub-total (add lines 34a thru 34c) \$ 15,000 _____

Part VIII – Taxes During Construction

36. Property taxes during construction \$ 0
37. List other taxes:
- a. _____ \$ 0
- b. _____ \$ 0
38. Sub-total (add lines 36 thru 37b) \$ 0

Part IX-A – HUD Section 232 Financing

39. Estimated construction time(in months) N/A
40. Dollar amount of construction loan \$ 0
41. Construction loan interest rate 0 %
42. Estimated construction loan interest costs \$ 0
43. Term of financing (in years) N/A
44. Interest rate on permanent loan 0 %
45. FHA mortgage insurance premium \$ 0
46. FHA mortgage fees \$ 0
47. Financing fees \$ 0
48. Placement fees \$ 0
49. AMPO (non-profit only) \$ 0
50. Title and recording fees \$ 0
51. Legal fees \$ 0
52. Total interest expense on permanent mortgage loan \$ 0
53. Sub-total Part IX-A HUD Section 232 Financing (add lines 42, 45, 46, 47, 48, 49, 50 and 51) \$ 0

Part IX-B – Industrial Development Authority Revenue and General

Obligation Bond Financing

(Circle selected method of financing)

54. Method of construction financing (construction loan, proceeds of bond sales, if other, specify) N/A
If construction is to be financed from any source other than bond sale proceeds, answer question 56 through 58. Otherwise, proceed to question 59.
55. Estimated construction time (in months) N/A
56. Dollar amount of construction loan \$ 0
57. Construction loan interest rate 0 %
58. Estimated construction loan interest cost \$ 0
59. Nature of bond placement (direct, underwriter, if other, specify) N/A
60. Will bonds be issued prior to the beginning of construction? _____ Yes _____ No N/A
61. If the answer to question 60 is yes, how long before (in months)? N/A
62. Dollar amount of bonds expected to be sold prior to the beginning of construction \$ 0
63. Will principal and interest be paid during construction or only interest? N/A
64. Bond interest expense prior to the beginning of construction(in dollars) \$ 0
65. How many months after construction begins will last bond be sold? N/A
66. Bond interest expense during construction \$ 0
67. What percent of total construction will be financed from bond issue? \$ 0
68. Expected bond interest rate 0 %

- | | | |
|-----|---|-------------|
| 69. | Anticipated term of bond issued (in years) | <u>N/A</u> |
| 70. | Anticipated bond discount (in dollars) | <u>N/A</u> |
| 71. | Legal costs | \$ <u>0</u> |
| 72. | Printing costs | \$ <u>0</u> |
| 73. | Placement fee | \$ <u>0</u> |
| 74. | Feasibility study | \$ <u>0</u> |
| 75. | Insurance | \$ <u>0</u> |
| 76. | Title and recording fees | \$ <u>0</u> |
| 77. | Other fees (list each separately) | |
| | a. _____ | \$ <u>0</u> |
| | b. _____ | \$ <u>0</u> |
| | c. _____ | \$ <u>0</u> |
| 78. | Sinking fund reserve account
(Debt Service Reserve) | \$ <u>0</u> |
| 79. | Total bond interest expenses (in dollars) | \$ <u>0</u> |
| 80. | Sub-total Part IX_B (add lines 58, 64, 66,
71, 72, 73, 74, 75, 76, 77a, b, c and 78) | \$ <u>0</u> |

Part IX C – Conventional Mortgage Loan Financing

- | | | |
|-----|---|------|
| 81. | Estimated construction time (in months) | N/A |
| 82. | Dollar amount of construction loan | \$ 0 |
| 83. | Construction loan interest rate | 0 % |
| 84. | Estimated construction loan interest cost
(in dollars) | \$ 0 |
| 85. | Term of long term financing (in years) | N/A |

86. Interest rate on long term loan 0 %
87. Anticipated mortgage discount (in dollars) \$ 0
88. Feasibility study \$ 0
89. Finder's fee \$ 0
90. Legal fees \$ 0
91. Insurance \$ 0
92. Other fees (list each separately)
- _____ \$ 0
93. _____ \$ 0
94. Total permanent mortgage loan interest expense (in dollars) \$ 0
95. Sub-total Part IX_C (add lines 84 & 88 thru 93) \$ 0

Financial Data Summary Sheet

96. Sub-total Part I Direct Construction Cost (line 7) \$ 250,000
97. Sub-total Part II Equipment not included in construction contract (line 9) \$ 850,000
98. Sub-total Part III Site Acquisition Costs (line 15) \$ 0
99. Sub-total Part IV Site Preparation Cost (line 23) \$ 0
100. Sub-total Part V Off-Site Costs (line 28) \$ 0
101. Sub-total Part VI Architectural and Engineering fees (line 33) \$ 22,150
102. Sub-total Part VII Other Consultant fees (line 35) \$ 15,000
103. Sub-total Part VIII Taxes During Construction (line 38) \$ 0
104. Sub-total Part IX-A HUD-232 Financing (line 53) \$ 0

105. Sub-total Part IX-B Industrial Development Authority Revenue & General Revenue Bond Financing (line 80) \$ 0
106. Sub-total Part IX-C Conventional Loan Financing (line 95) \$ 0
107. **TOTAL CAPITAL COST** (lines 96 thru 106) \$ 1,137,150
108. Percent of total capital costs to be financed 0 %
109. Dollar amount of long term mortgage (line 107 x 108) \$ 0
110. Total Interest Cost on Long Term Financing \$ 0
- a. HUD-232 Financing (line 53) \$ 0
- b. Industrial Development Authority Revenue & General Revenue Bond Financing (line 79) \$ 0
- c. Conventional Loan Financing (line 94) \$ 0
111. Anticipated Bond discount
- a. HUD-232 Financing (line 53) \$ 0
- b. Industrial Development Authority Revenue & General Revenue Bond Financing (line 70) \$ 0
- c. Conventional Loan Financing (line 87) \$ 0
112. **TOTAL CAPITAL AND FINANCING COST**
(ADD LINES 107, 110a, b or c AND 111a, b or c) \$ 1,137,150
- D. 1. Estimated costs for new construction (excluding site acquisition costs) \$ 250,000
2. Estimated costs of modernization and renovation (excluding site acquisition costs) \$ 0
- E. Anticipated Sources of Funds for Proposed Project Amount
1. Public Campaign \$ 0
2. Bond Issue (Specify Type) _____ \$ 0

- | | | |
|-----|---------------------------------------|-------------------|
| 3. | Commercial Loans | \$ <u>0</u> |
| 4. | Government Loans (Specify Type) _____ | \$ <u>0</u> |
| 5. | Grants (Specify Type) _____ | \$ <u>0</u> |
| 6. | Bequests | \$ <u>0</u> |
| 7. | Private Foundations | \$ <u>0</u> |
| 8. | Endowment Income | \$ <u>0</u> |
| 9. | Accumulated Reserves | \$ <u>850,000</u> |
| 10. | Other (Identify) _____ | \$ <u>0</u> |

- F. Describe in detail the proposed method of financing the proposed project, including the various alternatives considered. Attach any documents which indicate the financial feasibility of the project. *Refer to binder section 4, page 8*
- G. Describe the impact the proposed capital expenditure will have on the cost of providing care in the facility. Specify total debt service cost and estimated debt service cost per patient day for the first two (2) years of operation. (Total debt service cost is defined as total interest to be paid during the life of the loan (s). Estimate debt service cost per patient day by dividing estimated total patient days for year one into amount of debt service for that year. Repeat for year two.) Please attach an amortization schedule showing how the proposed debt will be repaid. *There will be no impact.*
- H. Attach a copy of the following information of documents.
1. The existing and/or proposed room rate schedule, by type of accommodation. *N/A*
 2. The audited annual financial statements for the past two (2) years of the existing facility or/if a new facility without operating experience, the financial state of the owner (s). Audited financial statements are required, if available. *Refer to binder section 15*
 3. Copy of the proposed facility's estimated income, expense and capital budget for the first two years of operation after the proposed project is completed. *Refer to binder section 16*

SECTION VI

ASSURANCES

I hereby assure and certify that:

- a. The work on the proposed project will be initiated within the period of time set forth in the Certificate of Public Need; and
- b. completion of the proposed project will be pursued with diligence; and
- c. the proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations and ordinances.

I hereby certify that the information included in this application and all attachments are correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.

<u>Eric H. Norby, MD</u>	<u>3289 Woodburn Rd #60</u>
Signature of Authorizing Officer	Address – Line 1
<u>Eric H. Norby, MD</u>	
Type/Print Name of Authorizing Officer	Address – Line 2
<u>President / Owner</u>	<u>Annandale, VA 22003</u>
Title of Authorizing Officer	City/State/Zip
<u>703-698-0666</u>	<u>3-11-2024</u>
Telephone	Date

Copies of this request should be sent to :

- A. Virginia Department of Health
Division of Certificate of Public Need
9960 Mayland Drive – Suite 401
Henrico, Virginia 23233
- B. The Regional Health Planning Agency if one is currently designated by the Board of Health to serve the area where the project would be located.

Revised 02/24/2015

Metro Region PET Center

Phone: (703) 698-5593 • Fax: (703) 698-5171
Backup Cell Phone: (703) 453-7346



Woodburn Nuclear Medicine

Phone: (703) 698-0666 • Fax (703) 573-6120
Backup Cell Phone: (703) 453-7347

Commonwealth of Virginia Application for A Medical Care Facility's Certificate of Public Need

APPLICATION ADDENDUMS & SUPPLEMENTAL INFORMATION

SECTION I FACILITY ORGANIZATION AND IDENTIFICATION

G. ATTACH A LIST OF NAMES AND ADDRESSES OF ALL OWNERS OR PERSONS HAVING A FINANCIAL INTEREST OF 5% OR MORE IN THE MEDICAL CARE FACILITY

Eric H. Norby, MD
3289 Woodburn Road, Suite 60
Annandale, VA 22003

(a) IN THE CASE OF A PROPRIETARY CORPORATION ALSO ATTACH:

(1) A LIST OF THE NAMES AND ADDRESSES OF THE BOARD OF DIRECTORS OF THE CORPORATION

Eric H. Norby, MD
3289 Woodburn Road, Suite 60
Annandale, VA 22003

Aaron L. Stack, MD
3289 Woodburn Road, Suite 60
Annandale, VA 22003

(2) A LIST OF THE OFFICERS OF THE CORPORATION

Eric H. Norby, MD
3289 Woodburn Road, Suite 60
Annandale, VA. 22003

(3) THE NAME AND ADDRESS OF THE REGISTERED AGENT FOR THE CORPORATION

The Corporation Service Company
11 South 12th Street
P.O. Box 1463 Richmond, VA. 23218



Your images and report are available on our secure viewing platform, 3C Care Systems, for a minimum of 12 months. For online access, please call Jim Marshall at 703-863-5069.

3289 Woodburn Road • Suite 060 • Annandale, Virginia 22003

SECTION II ARCHITECTURE AND DESIGN

C. DESIGN OF THE FACILITY

(1) DOES THE FACILITY HAVE A LONG-RANGE PLAN? IF YES, ATTACH A COPY.

Woodburn Nuclear Medicine/Metro Region PET Center does not have a formal long-range plan. The practice has been in existence for over 30 years while under the continued ownership of Dr. Eric H. Norby. Dr. Norby has no plans to retire at this time, close the practice or discontinue care to patients. Additionally, Woodburn Nuclear Medicine/Metro Region PET Center's facility lease has 11 years remaining.

(2) BRIEFLY DESCRIBE THE PROPOSED PROJECT WITH RESPECT TO LOCATION, STYLE AND MAJOR DESIGN FEATURES AND THE RELATIONSHIP OF THE CURRENT PROPOSAL TO THE LONG-RANGE PLAN.

This project will be located in one of our several suites at 3289 Woodburn Road in Annandale, Virginia. This ideal location in northern Virginia is very convenient for patients due to its proximity to the Capital Beltway and the Metro. In addition, Woodburn Nuclear Medicine/Metro Region PET Center is located close to several oncology offices and research facilities, all of which refer patients to our facility. At other facilities patients have to wait an inordinate length of time for their PET/CT scan. An adjacent hospital has a 3-week delay for patients to have their PET/CT scans scheduled. At Woodburn Nuclear Medicine/Metro Region PET Center, STAT scans can always be performed within 24-48 hours.

The project fits into Woodburn Nuclear Medicine/Metro Region PET Center's informal long range plan to continue servicing its current and new patient population for many years to come. The suite that will house the new PET/CT scanner has an 11-year lease.

(3) DESCRIBE THE RELATIONSHIP OF THE FACILITY TO PUBLIC TRANSPORTATION AND HIGHWAY ACCESS.

Woodburn Nuclear Medicine/Metro Region PET Center is conveniently located 1 mile from the Dunn Loring Metro station and ¼ mile from the Gallows Road exit on the Capital Beltway. In addition, Woodburn Nuclear Medicine/Metro Region PET Center offers free transportation to patients who do not have access to transportation to our facility. This service has been in effect for over 10 years.

(4) RELATE THE SIZE, SHAPE, CONTOUR AND LOCATION OF THE SITE TO SUCH PROBLEMS AS FUTURE EXPANSION, PARKING, ZONING AND THE PROVISION OF WATER, SEWER AND SOLID WASTE SERVICES.

Woodburn Nuclear Medicine/Metro Region PET Center's new PET/CT scanner will be placed in an already existing space at Woodburn Medical Park. Woodburn Medical Park is located in Annandale, Virginia and it was constructed over 30 years ago. Water, sewer and solid waste services are provided by the landlord. Please refer to page 9 of

this section of the binder for the March 28, 2022 letter from the landlord, Avison Young, which addresses these issues.

(6) DESCRIBE ANY DESIGN FEATURES WHICH WILL MAKE THE PROPOSED PROJECT MORE EFFICIENT IN TERMS OF CONSTRUCTION COSTS, OPERATING COSTS, OR ENERGY CONSERVATION

Woodburn Nuclear Medicine/Metro Region PET Center's new PET/CT scanner will be in a suite that has long been in use for imaging. This will lead to diminished costs because much of the site already has lead-lined walls and the control room is in place and operational. Minimal construction of the space will be needed and will be based on requirements provided by Siemens, the equipment manufacturer.

D. DESCRIBE AND DOCUMENT IN DETAIL HOW THE FACILITY WILL BE PROVIDED WITH WATER, SEWER AND SOLID WASTE SERVICES. ALSO DESCRIBE POWER SOURCE TO BE USED FOR HEATING AND COOLING PURPOSES.

The facility is located in a medical building that was completed in 1988 in which these services already exist. Please refer to the letter from Avison Young in the binder section 4, page 9.

E.

(3) SPECIFY DESIGN CRITERIA USED OR RATIONALE FOR DETERMINING THE SIZE OF THE TOTAL FACILITY AND EACH DEPARTMENT WITHIN THE FACILITY.

Design criteria are based on specifications from Siemens, the PET/CT scanner's manufacturer.

SECTION III SERVICE DATA

A. IN BRIEF NARATIVE FORM DESCRIBE THE KIND OF SERVICES NOW PROVIDED AND/OR THE KIND OF SERVICES TO BE AVAILABLE AFTER COMPLETION OF THE PROPOSED CONSTRUCTION OR EQUIPMENT INSTALLATION.

Woodburn Nuclear Medicine/Metro Region PET Center will continue to offer PET/CT imaging predominantly for cancer patients for diagnosis, staging and therapy assessment.

Note that Woodburn Nuclear Medicine/Metro Region PET Center is currently enrolled in seven clinical trials, most of which require serial PET/CT scans for their subjects. These studies are not performed by other area PET/CT facilities. Please refer to binder section 4 page 10 for a complete list of these research studies.

B. DESCRIBE MEASURES USED OR STEPS TAKEN TO ASSURE CONTINUITY OF CARE.

Continuity of care will not be impacted by this project as patient imaging will continue during the project's construction phase.

C. WHAT PROCEDURES ARE UTILIZED IN QUALITY CARE ASSESSMENT?

Woodburn Nuclear Medicine/Metro Region PET Center has a rigorous Quality Assurance program whereby all images and reports are routinely reviewed by the Medical Director and other staff physicians.

D. DESCRIBE THE PLAN FOR OBTAINING ADDITIONAL MEDICAL, NURSING AND PARAMEDICAL PERSONNEL REQUIRED TO STAFF THE PROJECT FOLLOWING COMPLETION AND IDENTIFY THE SOURCES FROM WHICH SUCH PERSONNEL ARE EXPECTED TO BE OBTAINED.

Woodburn Nuclear Medicine/Metro Region PET Center is already fully staffed to accommodate the needs of this PET/CT scanner.

F.

(3) IS (WILL) THERE BE AN ARRANGEMENT WHEREBY MEDICAL RECORDS CAN READILY BE TRANSFERRED BETWEEN THIS OUTPATIENT FACILITY AND AN INPATIENT FACILITY(IES)?

Images and reports can be electronically transferred to any facility via Woodburn Nuclear Medicine/Metro Region PET Center's cloud based PACS system.

SECTION IV PROJECT JUSTIFICATION AND IDENTIFICATION OF COMMUNITY NEED

A. PLEASE PROVIDE A COMPREHENSIVE NARRATIVE DESCRIPTION OF THE PROPOSED PROJECT.

Woodburn Nuclear Medicine/Metro Region PET Center's current PET/CT scanner is fully utilized and has a workload of what would typically be for two scanners. Continuing to operate with only one PET/CT scanner would eventually impact our ability to provide proper and timely care for our existing patients and referring physicians for several reasons:

- 1) Difficulty with timely scheduling of patients: To avoid patients waiting long periods to receive their PET/CT scan, we have extended our hours throughout the week and on weekends. This allows Woodburn Nuclear Medicine/Metro Region PET Center to continue to schedule all STAT and urgent studies within 24-48 hours.
- 2) This has led to a significant increase in payroll costs due to necessary overtime.

- 3) Continuity of care during mandatory camera maintenance and unexpected downtimes is not possible with one PET/CT scanner. With a second scanner, our patients would not be impacted by those events. As a matter of fact, last Fall our PET/CT scanner was down for three days and it took weeks to recover to accommodate the missed appointments.
- 4) Woodburn Nuclear Medicine/Metro Region PET Center is currently participating in 7 research studies, most of which require serial PET/CT scans. These studies require screenings done within a specified date range. This criteria is necessary to maintain the integrity of the research. Please refer to page 10 in this section for details about the specific studies.

Therefore, to provide the highest standard of care for our patients and to adhere to rigid timeframes of the research studies with which we participate, we have elected to apply for a COPN to purchase an additional PET/CT scanner. The PET/CT room will require minor upgrades to accommodate the new PET/CT scanner, as previously discussed in Section II, C6 above. Also, please refer to binder section 9 to view the construction plan.

B. IDENTIFICATION OF COMMUNITY NEED

1. DESCRIBE THE GEOGRAPHIC BOUNDARIES OF THE FACILITY'S PRIMARY SERVICE AREA.

Woodburn Nuclear Medicine/Metro Region PET Center is in Fairfax County Planning District 8. It is located in Woodburn Medical Park II at 3289 Woodburn Road, Annandale, VA. We are adjacent to the Capital Beltway approximately 0.5 miles from INOVA Fairfax Hospital and 10 miles from Washington, DC. Greater than 65% of our patients are from Fairfax County, including the cities of Alexandria, city of Annandale and Fairfax. An additional 25% of our patient population lives in Prince William County and 10% are from Loudoun County. The remainder of our patients originate from Fauquier County, Fredericksburg and Stafford County.

C.

1. IS SERVICE TO BE OFFERED PRESENTLY BEING OFFERED BY ANY OTHER EXISTING FACILITIES IN THE HEALTH PLANNING REGION?

Yes, PET/CT imaging is currently offered by other existing facilities in Planning District 8. However, other area facilities do not participate in the dementia and oncology research studies as does Woodburn Nuclear Medicine/Metro Region PET Center. Please refer to binder section 4, page 10 for a complete list of the research studies with which we participate.

2. IF YES,

a. IDENTIFY THE FACILITIES

- Fairfax PET/CT Imaging Center
- Kaiser Permanente Woodbridge Imaging Center
- PET/CT of Reston
- Sentara Northern Virginia Medical Center
- UVA Cancer Center
- Virginia Hospital Center

The following PET/CT facilities only perform myocardial imaging. This cardiac imaging is not performed at Woodburn Nuclear Medicine/Metro Region PET Center.

- Amelia Heart & Vascular Center – Alexandria
- Amelia Heart & Vascular Center – Arlington
- Amelia Heart & Vascular Center – Springfield
- Carient Heart & Vascular – Manassas
- Carient Heart & Vascular – Vienna
- Virginia Heart

b. DISCUSS THE EXTENT TO WHICH THE FACILITIES SATISFY THE CURRENT DEMAND FOR THE SERVICES.

As per item IV A above, an additional PET/CT scanner is critically needed to meet the demands of Woodburn Nuclear Medicine/Metro Region PET Center's current patient referral volume. This will not impact other facilities that perform PET/CT in PD8 because these patients are already being referred to Woodburn Nuclear Medicine/Metro Region PET Center. It will just allow Woodburn Nuclear Medicine/Metro Region PET Center to service its patients and referrers much more efficiently and with less scheduling delays for our patients. It will also ensure that Woodburn Nuclear Medicine/Metro Region PET Center is able to meet the stringent timeline requirements of the various research studies with which our facility participates. It is pertinent that Woodburn Nuclear Medicine/Metro Region PET Center be able to meet these research studies' requirements as it is the only facility in PD8 that fully participates in all of these studies.

c. DISCUSS THE EXTENT TO WHICH THE FACILITIES WILL SATISFY THE DEMAND FOR SERVICES IN FIVE YEARS.

Woodburn Nuclear Medicine/Metro Region PET Center has been in operation for 30 years and will continue to be for many years to come, having all leases extending 11 years to the year 2035.

There has been an ever-increasing demand for PET/CT services at Woodburn Nuclear Medicine/Metro Region PET Center. This is partly due to increasing insurance coverage for additional cancer diagnoses and to the many local research studies that utilize PET/CT. Woodburn Nuclear Medicine/Metro Region PET Center's growth can also be attributed to our specialized practice and recognition by area referring physicians of our highest quality and standards. It can be assumed that other imaging facilities are experiencing the same increase in PET/CT referrals. As this trend continues, PET/CT scan volume will increase for all PET/CT facilities in Planning District 8.

Woodburn Nuclear Medicine/Metro Region PET Center is currently enrolled in 7 research studies, most of which require serial PET/CT scans of their subjects. Please refer to binder section 4, page 10 for additional information about these important studies.

D. DISCUSS HOW PROJECT WILL FILL AN UNMET NEED IN THE DELIVERY OF HEALTHCARE IN THE SERVICE AREA INCLUDING, WHERE APPLICABLE, GEOGRAPHIC BARRIERS TO ACCESS.

We have received feedback from both referring physicians and patients that wait times for scheduling a PET/CT scan at other PD8 facilities have increased dramatically. Recently, a patient called our Center to schedule a PET/CT scan and informed our staff that her wait time at a nearby hospital would be three weeks. Since the beginning of 2023, there has been a continuing increase in the number of PET/CT referrals received at Woodburn Nuclear Medicine/Metro Region PET Center. Despite that, STAT and urgent referrals are always accommodated within 24-48 hours. PET/CT imaging is critical in the management of cancer patients. An additional PET/CT scanner at Woodburn Nuclear Medicine/Metro Region PET Center will allow our facility to better service our patients and referrers by offering more timely scheduling so that patients do not need to wait an inordinate length of time to obtain their scan. As many of our patients are fighting cancer, avoiding delays in receiving our services is paramount. An additional PET/CT scanner will enable Woodburn Nuclear Medicine/Metro Region PET Center to not only accommodate our routine cancer patients and referring physicians as well but also those enrolled in research studies.

Due to Woodburn Nuclear Medicine/Metro Region PET Center's ideal location within the Washington, DC metropolitan area, there are no geographic barriers to patient access to our services. The facility is conveniently located 1 mile from a Metro station and ¼ mile from the Gallows Road exit on the Capital Beltway. Additionally, Woodburn Nuclear Medicine/Metro Region PET Center offers free transportation to patients who are very ill or do not have access or transportation to our facility.

E. DISCUSS THE CONSISTENCY OF THE PROPOSED PROJECT WITH THE APPLICABLE REGIONAL HEALTH PLAN, STATE HEALTH PLAN, STATE OR OTHER PLANS PROMULGATED BY STATE AGENCIES.

12VAC5-230-200 - TRAVEL TIME

Woodburn Nuclear Medicine/Metro Region PET Center is located within 30 minutes driving time one way under normal conditions for 95% of the PD8 population. We are conveniently located 1 mile from a Metro station and ¼ mile from the Gallows Road exit on the Capital Beltway. Additionally, Woodburn Nuclear Medicine/Metro Region PET Center offers free transportation to patients who are very ill or do not have access or transportation to our facility.

12VAC5-230-210 - NEED FOR NEW FIXED SITE SERVICE

12 VAC5-230-220 – EXPANSION OF FIXED SITE SERVICE

As is evident on the Revenue and Expense Schedule in binder section 16, Woodburn Nuclear Medicine/Metro Region PET Center has been performing over 6000 scans annually on its fixed PET/CT scanner since prior to 2020. The proposed additional PET/CT scanner would not "...significantly reduce the utilization of existing fixed site PET/CT providers in the health planning district" because it would only be used for patients that are already being referred to Woodburn Nuclear Medicine/Metro Region PET Center.

12VAC5-230-240 – STAFFING

All services at Woodburn Nuclear Medicine/Metro Region PET Center are performed under the direct and strict supervision of our four board certified physicians. Also, Woodburn Nuclear Medicine/Metro Region PET Center is already fully staffed for this project.

SECTION V FINANCIAL DATA

F. DESCRIBE IN DETAIL THE PROPOSED METHOD OF FINANCING THE PROPOSED PROJECT, INCLUDING THE VARIOUS ALTERNATIVES CONSIDERED. ATTACH ANY DOCUMENTS WHICH INDICATE THE FINANCIAL FEASIBILITY OF THE PROJECT.

The construction costs of this project will be paid with the landlord's Tenant Improvement allowance and with Woodburn Nuclear Medicine/Metro Region PET Center's cash reserves. The PET/CT scanner will be paid with accumulated reserves.



Research Studies

Oncology:

- NEXT Oncology –Phase 1 cancer research through clinical trials of anticancer agents with the goal of providing innovative developments in cancer treatment.

Dementia:

- IXICO Study VX15/2503-11 – Investigating the safety, tolerability and effects on cognition and brain metabolism of Pepinemab, in early Alzheimer's Disease (AD) dementia (early AD) subjects.
- Lucidity Study TRs 237-039 – Investigating the cognitive benefits of Hydromethylthionine Mesylate (HMTM).
- Together – UCB-AH0003 - To test the efficacy, safety and tolerability of Bephanemab in patients with mild cognitive impairment or mild Alzheimer's disease.
- Evoke - This study is done to find out whether the medicine, Semaglutide, has a positive effect on early Alzheimer's disease.
- Sana Research – EIP21-NFD-5014 – Clinical study of the P38 Alpha Kinase Inhibitor Neflamapimod effect on patients with Lewy Body Dementia (DLB).

Parkinson's Disease:

- Orchestra Study – UCB PD0053 - to evaluate an investigational compound, UCB0599, help in slowing the progress of Parkinson's disease



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