



**STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY**
DEPARTMENT OF HEALTH - KA 'OIHANA OLAKINO

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December 17, 2024

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

IN THE MATTER OF)	CERTIFICATE OF NEED
)	APPLICATION
)	NO. 24-08
Pacific Pearl Medical, LLC)	
)	
Applicant)	
)	DECISION ON THE MERITS
_____)	

DECISION ON THE MERITS

The State Health Planning and Development Agency (hereinafter "Agency"), having taken into consideration all of the records pertaining to Certificate of Need Application No. 24-08 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Certificate of Need Review Panel and Statewide Health Coordinating Council, the Agency hereby makes its Decision on the Merits, including findings of fact, conclusions of law, order, and written notice on Certificate of Need Application No. 24-08. Where appropriate, Findings of Fact shall operate as Conclusions of Law, and Conclusions of Law shall operate as Findings of Fact. As many of the criteria for Certificate of Need are interrelated, each of the criteria and subheadings within the Findings of Fact shall be deemed to incorporate and include all other Findings of Fact to the extent relevant.

I

FINDINGS OF FACT

1. This is an application for a Certificate of Need for the establishment of Positron Emission Tomography/Computed Tomography (PET/CT) scanner services at 250 Kinoole Street, Hilo, HI, at a capital cost of \$2,175,000.
2. The applicant, Pacific Pearl Medical, LLC, is a limited liability corporation.

3. The Agency administers the State of Hawaii's Certificate Program, pursuant to Chapter 323D, Hawaii Revised Statutes (HRS), and Title 11, Chapter 186, Hawaii Administrative Rules (HAR).

4. On July 1, 2024, the applicant filed with the Agency, a Certificate of Need application for the establishment of Positron Emission Tomography/Computed Tomography (PET/CT) scanner services at 250 Kinoole Street, Hilo, HI, at a capital cost of \$2,175,000 (the "Proposal"). On July 29, 2024, the Agency determined the application to be incomplete. On July 30, 2024, the applicant submitted revisions/additional information. On July 30, 2024, the application was determined to be complete. For administrative purposes, the Agency designated the application as No. 24-08.

5. The period for Agency review of the application commenced on September 4, 2024, the day notice was provided to the public pursuant to HAR 11-186-39.

6. The application was reviewed by the Certificate of Need Review Panel at a public meeting on October 30, 2024. The Panel voted 7 to 0, in favor of recommending approval of the application.

7. The application was reviewed by the Statewide Health Coordinating Council at a public meeting on December 9, 2024. The Council voted 7 to 0, in favor of recommending approval of the application.

8. This application was reviewed in accordance with Section 11-186-15(a), HAR.

9. Section 323D-43(b), HRS states:

"(b) No certificate of need shall be issued unless the state agency has determined that:

- (1) There is a public need for the facility or service; and
- (2) The cost of the facility or service will not be unreasonable in the light of the benefits it will provide and its impact on health care costs."

10. Burden of proof. Section 11-186-42, HAR, provides:

"The applicant for a certificate of need shall have the burden of proof, including the burden of producing evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence."

II

FINDINGS OF FACT
CERTIFICATE OF NEED CRITERIA

A. **REGARDING THE RELATION OF THE PROPOSAL TO THE STATE HEALTH SERVICES AND FACILITIES PLAN CRITERIA**

11. The applicant states¹ that “Currently, no PET-CT diagnostic service is offered on the Big Island. Patients must fly to Oahu to have a PET-CT diagnostic scan. This project aims to decrease the physical, mental, and financial hardship that patients on the Big Island endure when having to travel to Oahu for these services. PPM's mission is to alleviate healthcare inequalities by making this vital diagnostic imaging service accessible to the Big Island's patients including the elderly, low-income people, racial and ethnic minorities, women, people with disabilities, and other underserved populations.”

12. The applicant states that “The health care delivery system's long-term viability will be strengthened by the availability of an additional PET-CT scanner (and cyclotron) on the Big Island by addressing the rapidly expanding demand and disproportionate access to cancer-related quality diagnostic imaging services throughout the State. To ensure Big Island patients receive high-quality, equitable care that is timely, improves outcomes, and minimizes anguish for both patients and their loved ones, it is critical that they have access to this vital diagnostic imaging technology on their island.”

13. The applicant states that “The proposed service will enhance the State's diagnostic imaging capabilities, improve therapy planning and decision-making accuracy, and provide access to vital healthcare treatment options, including monitoring and research related studies on cancer and other diseases, which are currently not widely available in Hawai'i. Increasing the availability of this imaging equipment will benefit a larger population while also supporting the ever-increasing medical advances in determining cancer care planning and coordination and reducing the wait time for determining treatment plans.”

14. The applicant states that “Installation of 1 PET-CT in underserved locations supports the State-wide Health Coordination (sic) Council's priorities by... Striving for equitable access to health care services on the Big Island by making this vital

¹ For clarity, when the Agency quotes statements from the applicant in this section, it does so because the Agency finds such testimony to be persuasive and because the Agency has incorporated the referenced testimony as a finding of fact.

imaging service more affordable and available. Additionally, PPM intends to produce and supply a wide range of Rp's. This will facilitate the development of innovative patient services in the fields of neurology (Alzheimer's therapies), cardiology (cardiac PET) and theranostics (diagnostic and therapy clinical research trials for oncology) that are restricted to Oahu or not currently available in the State of Hawai'i."

15. The Agency finds that the Proposal meets the relationship to the state health services and facilities plan criteria.

B. REGARDING THE NEED AND ACCESSIBILITY CRITERIA

16. The applicant states that "Currently, no PET-CT diagnostic service is offered on the Big Island. Patients must fly to Oahu to have a PET-CT diagnostic scan. This project aims to decrease the physical, mental, and financial hardship that patients on the Big Island endure when having to travel to Oahu for these services. PPM's mission is to alleviate healthcare inequalities by making this vital diagnostic imaging service accessible to the Big Island's patients including the elderly, low-income people, racial and ethnic minorities, women, people with disabilities, and other underserved populations."

17. The applicant states that "Neither a PET-CT scanner nor Rp's are available on the Big Island. Patients who are diagnosed with cancer at an early stage have the best chance of surviving before it advances to a more serious form. Early detection is also advantageous for neurology and urology medical care."

18. The applicant states "Additionally, PPM intends to produce and supply a broad-range of radiopharmaceuticals (Rp's), which will enable the delivery of innovative patient services in the field of cutting-edge technology, including cardiac PET imaging (the gold standard in nuclear cardiac imaging) for cardiology, PET Amyloid and Tau imaging (early diagnosis of Alzheimer's disease leading to treatment before cognitive decline) for neurology, PSMA PET (theranostics for the diagnosis, staging, and treatment of prostate cancer) for urology, and a spectrum of clinical research studies focused on our citizen's needs for theranostic studies. These are advanced medical services that are either restricted to the island of Oahu or unavailable to patients in the state of Hawai'i. Nevertheless, PPM's mission is to make these advanced medical services accessible for the first time on the Big Island."

19. The applicant states that "Page 15 of CON #23-02A notes, the State of Hawai'i is currently underserved by PET- CT, with rates per 1,000, approximately half of the United States as a whole. The rate of 3.46 in 2019 and 3.56 in 2020 for the State of Hawai'i, as shown in the "PET-CT Rates per 1000 People" table on

page 15 of CON #23-02A..., is significantly lower than the national average of 6.7 for these years. It is evident from these statistics that the PET-CT scan capacity per population in Hawai'i is insufficient. The most significant fact is that there are no PET-CT scanners on any other island besides Oahu."

20. The applicant projects utilization of 1920 PET-CT scans in Year 1 of the Proposal, 2640 PET-CT scans in Year 2, and 3120 PET-CT scans in Year 3 of the Proposal.

21. The Agency finds that the need and accessibility criteria have been met.

C. REGARDING QUALITY AND LICENSURE CRITERIA

22. The applicant states that "PET-CT scans may detect cancer earlier than conventional imaging procedures due to their increased sensitivity. When cancer is discovered early, treatment can begin and the patient has a better chance of "fighting cancer"... PET-CT scans are highly accurate in distinguishing between benign and malignant tumors. This minimizes the need for unnecessary invasive treatments, reduces substantial medical costs, reduces false positives, improves patient target selection, and reduces treatment variability... PET-CT scans can assist in pinpointing the optimal location for a biopsy."

23. The applicant states that "A significant issue is that cancer patients on the Big Island are inclined to spend an estimated 12 hours to undergo a PET-CT scan on Oahu, which may result in additional challenges and hardships due to the procedure's inaccessibility. Having a PET-CT accessible on the Big Island would mitigate these potential problems:

(a) physical hardships

- senior patients experience significant challenges when traveling, including the complex and distressing coordination of appointments and physical limitations that limit their mobility
- patients frequently experience fatigue, nausea, and dizziness
- decline to travel as a result of humiliating medical conditions (e.g., incontinence, anal bleeding)

(b) the patient's stage of cancer may not permit flying

(c) patients may be unwilling to travel due to fear, anxiety, or other causes

(d) patients may not have someone to accompany them, such as a relative, friend, or caretaker

(e) despite the fact that cancer patients are informed that this diagnostic modality will give them the best opportunity to fight cancer, many agree to a less-than-optimal diagnostic modality or are unable to afford the additional financial expenses"

24. The applicant states that "PPM will operate in accordance with all applicable state and federal guidelines and the standards for the American College of Radiology (ACR), which require adherence to extensive policies and procedures to ensure the quality and safety of patient care. PPM will also obtain the American College of Radiology (ACR) PET-CT accreditation."

25. The applicant states that "PPM will have a Quality Assurance program headed by Dr. Twyla Bartel who is board-certified in both Nuclear Medicine and Diagnostic Radiology and has specialized PET-CT fellowship training. Dr. Bartel is also a PPM Board of Directors member. Dr. Bartel will have policy and procedures in place to monitor and evaluate the quality of diagnostic imaging procedures produced by the PET- CT scanners."

26. The applicant states that "The PET-CT program will adhere to the licensing standards and guidelines developed by the Society of Nuclear Medicine, Nuclear Regulatory Commission, Food and Drug Administration and American College of Radiology. PPM will be certified/recognized by the American Registry of Radiologic Technologists (ARRT) and Nuclear Medicine Technology Certification Board (NMTCB)."

27. The applicant states that "The Nuclear Medicine technologist will be licensed by the State of Hawaii. Also, the Nuclear Medicine Technologist will be registered with either the Nuclear Medicine Technology Certification Board (NMTCB) or American Registry of Radiological Technologists (ARRT) requiring minimum experience and ongoing continuing education. The Nuclear Medicine technologist assigned to operate the PET-CT scanner will be scheduled to receive additional training on this equipment."

28. The Agency finds that the quality and licensure criteria have been met.

D. REGARDING THE COST AND FINANCIAL CRITERIA

29. The applicant states that "PPM has obtained the financial resources to secure all equipment and staffing resources required for the proposed project... The total project cost is \$2,175,000, which includes \$1,025,000 for the purchase of 1 PET-CT scanner (\$995,000) and 1 Medrad CT injector (\$30,000), \$500,000 for the construction contract and \$650,000 for FMV of assets acquired by lease. PPM's total source of funds for this project is \$2,175,000, which includes "other" funds (FMV of leased space to be paid by monthly rent) totaling \$650,000. (See Attachment A-4, Letter of Credit)."

30. The applicant projects revenue of \$4,440,000 and expenses of \$2,465,227 for Year 1 of the Proposal and revenue of \$7,200,000 and expenses of \$3,311,875 for year 3 of the Proposal.

31. The applicant states that “The predominant patient population served by the medical community in the State of Hawai’i is the elderly population (persons 65 and older). This population is the most rapidly growing segment of our population that has an increasing incidence of cancer. The new cyclotron alongside the proposed new PET-CT scanner will fill a gap in services and expand the accessibility to quality images, treatment, and care to these patient populations... Senior patients experience significant challenges when traveling, including complex appointment coordination and physical constraints that limit their mobility. Having this diagnostic technique on-island will ensure that these elders receive equal healthcare as seniors living on Oahu... Seniors generally have limited financial means to cover unforeseen expenses. Seniors often have limited financial resources to meet unexpected bills. This project will eliminate the additional expenses associated with flying to Oahu.”

32. The Agency finds that the cost and financial criteria have been met.

E. REGARDING THE RELATIONSHIP OF THE PROPOSAL TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA CRITERIA

33. The applicant states that “The most significant advantages of PET-CT scanning are the ability to confirm cancer cases early (PET-CT can detect potential cancer sooner than other tests available in Hawai’i today), to determine exact and accurate details on the location of the cancer and the extent of its spread, to determine how well the cancer is responding to treatment, and to improve tumor staging. PET-CT scans produce optimal diagnostic images that enable the identification of effective treatment plans for patients and the monitoring of the patient’s response to such protocols. Due to these overall benefits, the quality of life for patients will be enhanced because of the obligation to prescribe PET-CT scans over less accurate diagnosis and treatment practices sometimes prescribed in the State of Hawai’i. The overall costs would be reduced because of the accurate diagnosis and treatment, which would eliminate unnecessary surgeries, misdiagnosis, and other expenses. This service will be accessible to cancer patients, including but not limited to low-income individuals, racial and ethnic minorities, women, persons with disabilities, the elderly, and other underserved groups. Most importantly, this service will be accessible on the Big Island, a medically underserved community.”

34. The applicant states that “Because there are no PET-CT services on the Big Island, plans to make this service available on the Big Island will eliminate the

need for patients to travel to Oahu, benefiting both patients and physicians on this island. Furthermore, this will increase the likelihood of cancer cures because patients will have access to this procedure in the early stages of cancer, enhancing their quality of life. It will also give Big Island patients access to other vital diagnostic imaging services in the fields of cardiology, urology, neurology, and theranostics all of which will be available on the island for the first time.”

35. The Agency finds that the relationship to the existing healthcare system of the area criteria have been met.

F. REGARDING THE AVAILABILITY OF RESOURCES CRITERIA

36. The applicant states that “PPM has obtained the financial resources to secure all equipment and staffing resources required for the proposed project... The total project cost is \$2,175,000, which includes \$1,025,000 for the purchase of 1 PET-CT scanner (\$995,000) and 1 Medrad CT injector (\$30,000), \$500,000 for the construction contract and \$650,000 for FMV of assets acquired by lease. PPM's total source of funds for this project is \$2,175,000, which includes "other" funds (FMV of leased space to be paid by monthly rent) totaling \$650,000. (See Attachment A-4, Letter of Credit).”

37. The applicant states that “PPM's partnership with the University of Missouri, the 5th largest nuclear medicine technologist training program in the United States, will enhance staffing prospects. PPM is in the planning stages of arranging for the transfer of nuclear medicine technologists from the University of Missouri to the diagnostic imaging center. During a six-month program in Hawai'i, the nuclear medicine technologists will have the opportunity to acquire knowledge and experience that will be beneficial to their accreditation, which will also serve as a gateway to employment... Transitional housing will be available to essential employees to ease the burden of relocating.”

38. The Agency finds that the availability of resources criteria have been met.

III

CONCLUSIONS OF LAW

Having taken into consideration all of the records pertaining to Certificate of Need Application No. 24-08 on file with the Agency, including the written and oral testimony and exhibits submitted by the applicant and other affected persons, the recommendations of the Certificate of Need Review Panel and Statewide Health Coordinating Council, and based upon the findings of fact contained herein, the Agency concludes as follows:

The applicant has met the requisite burden of proof and has shown by a preponderance of the evidence that the Proposal meets the criteria established in Section 11-186-15(a), HAR.

Accordingly, the Agency hereby determines that, pursuant to Chapter 323D-43(b), HRS:

- (1) There is a public need for this service; and
- (2) The cost of the service will not be unreasonable in light of the benefits it will provide and its impact on health care costs.

ORDER

Pursuant to the findings of fact and conclusions of law contained herein, IT IS HEREBY DECIDED AND ORDERED THAT:

The State Health Planning and Development Agency hereby APPROVES and ISSUES a Certificate of Need to Pacific Pearl Medical, LLC for the Proposal described in Certificate of Need application No. 24-08. The maximum capital expenditure allowed under this approval is \$2,175,000.

WRITTEN NOTICE

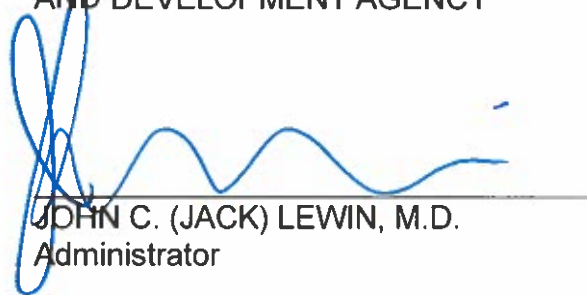
Please read carefully the written notice below. It contains material that may affect the Decision on the Merits. The written notice is required by Section 11-186-70 of the Agency's Certificate of Need Program rules.

The decision on the merits is not a final decision of the Agency when it is filed. Any person may request a public hearing for reconsideration of the decision pursuant to Section 11-186-82 HAR. The decision shall become final if no person makes a timely request for a public hearing for reconsideration of the decision. If there is a timely request for a public hearing for reconsideration of the decision and after the Agency's final action on the reconsideration, the decision shall become final.

(Note, pursuant to Chapter 323D-47, Hawaii Revised Statutes, a request for reconsideration shall be received by the Agency within ten working days of the state agency decision.)

DATED: December 17, 2024
Honolulu, Hawaii

HAWAII STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY



JOHN C. (JACK) LEWIN, M.D.
Administrator