HAWAI'I STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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STANDARD APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: #25-10
To be assigned by Agency

Date of Receipt:

APPLICANT PROFILE

Project Title: Establishment of Positron Emission Tomography/Computer Tomography (PET-CT) Scanner Services

Project Address: Dream House Retail Center, Unit #6 and #7, 800 Kamaaha Avenue, Kapolei, HI 96707
Applicant Facility/Organization: Pacific Pearl Medical, LLC

Name of CEO or equivalent: Bruce Guier

Title: President of Pacific Pearl Medical (PPM)

Address: 1600 Ala Moana Blvd., #2302, Honolulu, HI 96815

Phone Number: (816)210-4172 Fax Number: _____

Contact Person for this Application: Bruce Guier

Title: CEO of Pacific Pearl Medical

Address: 1600 Ala Moana Boulevard, #2302, Honolulu, HI 96815

Phone Number: (816)210-4172 Fax Number: _____

CERTIFICATION BY APPLICANT

I hereby attest that I reviewed the application and have knowledge of the content and the information contained herein. I declare that the project described and each statement amount and supporting documentation included is true and correct to the best of my knowledge and belief.

Signature

7/8/25
Date

Bruce Guier
Name (please type or print)

CEO of PPM
Title (please type or print)

1. TYPE OR ORGANIZATION: (Please check all applicable)

Public	____
Private	X
Non-profit	____
For-profit	X
Individual	____
Corporation	____
Partnership	____
Limited Liability Corporation (LLC)	X
Limited Liability Partnership (LLP)	____
Other: _____	____

2. PROJECT LOCATION INFORMATION:

A. Primary Service Area(s) of Project: (Please check all applicable)

Statewide:	
O`ahu-wide:	____
Honolulu:	____
Windward O`ahu:	____
West O`ahu:	X
Oahu County:	____
Kaua`i County:	____
Hawai`i County:	____

3. DOCUMENTATION (Please attach the following to your application form):

A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)
Lease agreement is contingent upon approved CON. Final signatures will be obtained upon approval of this CON. See Attachment A-1, Letter of Intent dated.

B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.)
Building Permits – City & County of Honolulu
Certificate of Occupancy - City & County of Honolulu
Fire Marshal's Approval - City & County of Honolulu, Fire Prevention Bureau
Department of Health Licensure as a Radiation Facility providing Radiation Services - Indoor and Radiological Health Branch Radiation Section
Nuclear Regulatory Commission Licensure

C. Your governing body: list by names, titles, and address/phone numbers
See Attachment A-2, Pacific Pearl Medical Governing Body.

D. If you have filed a Certification of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:
Articles of Incorporation
- By-Laws – N/A
- Partnership Agreements – See Articles of Organization in Attachment A-3 (Articles of Incorporation).
- Tax Key Number (project's location) – 1-9-1-88-22-1 (800 Kamaaha Avenue, Kapolei, HI 96707)

4. **TYPE OF PROJECT.** This section helps our reviewers understand what type of project you are proposing. Please place an "x" in the appropriate box.

	Used Medical Equipment (over $400,000)	New/Upgraded Medical Equip. (over $1 million)	Other Capital Project (over $4 million)	Change in ownership	Change in service/ establish new service/facility	Change in Beds
Inpatient Facility						
Outpatient Facility		X			X	
Private Practice						

5. **TOTAL CAPITAL COST:** $2,175,000

6. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules. **N/A**

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
TOTAL			

7. **CHANGE IN SERVICE.** If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please consult Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

   New provider of PET-CT scanning services. Categories of services per Section 11-186-5, Non-Bed Services: Diagnostic Radiology, Computed Tomography Stationary and Nuclear Medicine.

8. PROJECT COSTS AND SOURCES OF FUNDS (For Capital Items Only)

A. List All Project Costs:

		AMOUNT:
1.	Land Acquisition	Lease
2.	Construction Contract	$500,000
3.	Fixed Equipment-General Electric (medical equipment supplier)	$995,000
4.	Movable Equipment	$30,000
5.	Financing Costs	$0
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	$650,000
7.	Other: _____	_____
	TOTAL PROJECT COST:	**$2,175,000**

B. Source and Method of Estimation

Describe how the cost estimates in Item "A" were made, including information and methods used:
Construction contract per Nelco Worldwide quote.
Fixed equipment estimate for PET-CT per GE quote.
Moveable equipment is per Soma Technology quote.
FMV-includes PET-CT area, wait room & control room.
$650 / sqft x 1,000 sqft = $650,000

C. Source of Funds

		AMOUNT:
1.	Cash (See Attachment A-4 for Letter of Credit)	$1,525,000
2.	State Appropriations	_____
3.	Other Grants	_____
4.	Fund Drive	_____
5.	Debt	_____
6.	Other: FMV of leased space to be paid by monthly rent	$650,000
	TOTAL SOURCE OF FUNDS:	**$2,175,000**

9. **IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:

a) Date of site control for the proposed project – Lease agreement is contingent upon approved CON. Final signatures will be obtained upon approval of this CON. See Attachment A-1, Letter of Intent dated .
b) Dates by which other government approvals/permits will be applied for and received – Upon approval of this CON, PPM will apply for other government approvals/permits, as required.
c) Dates by which financing is assured for the project – Financing is assured and immediately available.
d) Date construction will commence – 6 months after CON approval
e) Length of construction period – 12 months
f) Date of completion of the project - 18 months after CON approval
g) Date of commencement of operation – 24 months after CON approval (NRC approval will be obtained during this period)

Please remember that the Agency does monitor the implementation of Certificates approved. Non-implementation of a project as described in your application may result in a fine and/or withdrawal of the Certificate of Need.

10. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the Certificate of Need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site. See Attachment 5, project site map.

PACIFIC PEARL MEDICAL (herein referred to as "PPM"), seeks to provide Positron Emission Tomography/Computer Tomography (PET-CT) scanner services at 800 Kamaaha Avenue, Kapolei, HI 96707. PPM requests approval from the State Health Planning and Development Agency (SHPDA) to install 1 PET-CT scanner. This initiative will provide the medically underserved population of West Oahu with much-needed, state-of-the-art, PET-CT diagnostic imaging services. PPM seeks to reduce inequalities in healthcare in West Oahu by increasing the accessibility of vital medical imaging. This will lessen the physical and mental strain that may result from the necessity of traveling to Honolulu for these procedures, as these services are not available in West Oahu. Furthermore, PPM intends to produce and supply a broad-range of radiopharmaceuticals (Rp's) on Maui, allowing for the delivery of innovative patient diagnostic and therapeutic care that is either unavailable on Oahu or only available in limited circumstances. Examples of this include 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, Cardiac PET imaging (the gold standard in nuclear cardiac imaging) for cardiology, and a spectrum of clinical research studies focused on our citizen's needs for theranostic studies. This cutting-edge medical equipment will enhance healthcare services while also attracting skilled and knowledgeable medical professionals to Oahu. The availability of medical oncologists and other medical specialists is a growing concern in the State of Hawai'i, jeopardizing a patient's right to receive diagnostic results in an expeditious manner to support the shortest time frame from the need for diagnostic screening to the completion of therapy. Time is a cancer patient's worst enemy. It is critical that we offer patients with the best possible opportunities for success in the fight against cancer and other diseases. The ultimate goal of

PPM is to provide Hawai'i patients with improved access to advanced medical care and services that are not currently offered or available on a limited basis in the State of Hawai'i.

a) Relationship to the State of Hawai'i Health Services and Facilities Plan

- PPM's service area is West Oahu. This service will be accessible to the population residing on West Oahu as well as patients living on Oahu and other islands and will include the elderly, low-income people, racial and ethnic minorities, women, people with disabilities, and other underserved populations.
- PPM is an organization that aims to develop a diagnostic imaging center and ancillary services to provide equitable access to high-quality health care services. These services will offer innovative patient diagnostic and therapeutic care in oncology, cardiology, neurology, and urology at a reasonable cost.

b) Need and Accessibility

- PPM was formed to provide necessary and unavailable medical services to underserved populations in the State of Hawai'i.

  - **INEQUITY TO QUALITY HEALTHCARE**

    PET scanning requires two components: radioactive isotopes that illuminate (help visualize) the cancer, and a PET-CT scanner that detects the radiation from the cancer to ultimately create a three-dimensional image. FDG is a radiopharmaceutical drug that is widely used to perform PET-CT diagnostics for detection of cancer. A PET-CT scanner is not available in West Oahu. Prompt patient diagnostic imaging is inadequate in the State of Hawai'i to enable the earliest possible cancer/disease diagnosis. In addition, innovative therapeutic care is either unavailable on Oahu or only available in limited situations. PPM's goal is to change this. FDG, like all radioactive isotopes, undergoes a gradual degradation over time, which is correlated with the radioisotope's half-life. The rapid decrease in radioactivity concentration has rendered it impossible to purchase FDG from the US mainland, necessitating its production in Hawai'i. FDG is produced by the only cyclotron in the State of Hawai'i, which is operated and owned by Queen's Medical Center. This cyclotron is over 27 years old.
    - To address healthcare disparities in Hawai'i, hospitals on the island of Oahu and the Big Island (Hilo and Kona) were approached by PPM to inquire about on-island PET-CT services. All hospitals heartily welcomed the concept, pointing out that access to this cutting-edge diagnostic method has been long overdue.
    - The initial business plan of PPM was to purchase a PET-CT scanner for each of these islands and transport (fly) the FDG drugs to these outer islands from Oahu.
    - A proposal was made to Queen's Medical Center to purchase FDG drugs to provide PET-CT diagnostic imaging on other islands. Unfortunately, our desire to purchase this radiopharmaceutical drug was turned down by Queen's Medical Center. Because of this PPM came up with a plan to rectify the fundamental imbalances in the healthcare system, especially the limited

access of vital diagnostic tools (PET-CT scanners), which enable more appropriate and effective treatment selection and timely implementation of them. This plan will also facilitate clinical research trials in underserved populations such as West Oahu and throughout the state.

- PPM's mission is to install PET-CT scanners in these medically underserved areas. Patients living in West Oahu deserve access to the same quality of healthcare as patients living in Honolulu.

- **ADDITIONAL PET-CT SCANNERS ARE GREATLY NEEDED**
  a. According to information gathered from the Berkeley Lab News Room, Weiner, John. "Seeing More with PET Scans: Scientists Discover New Way to Label Chemical Compounds for medical Imaging." July 27, 2017: There were approximately 2,500 PET scanners in hospitals across the US in 2017. According to the 2017 US Census Bureau data, the US population was approximately 331.4 million. This is equivalent to approximately 133,600 individuals per PET-CT for this population.
     - It is crucial to highlight that since this information was published in 2017, there have been a wide range of medical advances (in oncology as well as other medical disciplines) that require cutting-edge diagnostic imaging. As a result, it is expected that the number of PET-CT scanners per person in the United States will have significantly increased and will continue to grow. There are currently just four operable PET-CT scanners in the State of Hawai'i. Given a population of 1.4 million, the State of Hawai'i would need at least ten (10) PET-CT scanners to satisfy similar rates (published in 2017) of diagnostic imaging units per population in the US.
     - In accordance with the newly published IMV 20245 PET Market Summary Report, Korstjens, Davin. "IMI: PET scan volumes continue to grow." March 7, 2024, "In 2023 compared to 2022, the total volume of positron emission tomography (PET) scans increased 10.2% year over year." Comparing this to the SHPDA Healthcare Utilization Report, Hawai'i 2023, Table 23 (Positron Emission Tomography-Computed Tomography (PET-CT) Utilization, 2023), the average utilization increase of the 4 PET-CT units in Hawai'i from 2022 to 2023 was 25.76%. This significant discrepancy in usage rate rise is most likely due to the low number of PET-CT units per population when compared to US PET sites. The significant rise in use from 2022 to 2023, as represented in the 25.76% increase, only serves to worsen the drawbacks of not having a sufficient number of PET-CT scanners:
       (1) Delays in diagnosing cancer. When cancer is detected late, it is usually in an advanced form (stage 3 or 4) and the cancer cells often have spread to other parts of the body (metastatic cancer). Furthermore, treatment options are limited and less effective, leading to dramatically lower survival rates. The most disheartening aspect is that advanced stage cancer patients typically experience significant pain, fatigue, and other symptoms, which severely impairs the patient's quality of life.

(2) Delays in treatment. A PET-CT scan is instrumental in determining the extent of cancer spread (staging) and guide treatment decisions. A delay in the scan could result in a delay in treatment, which would limit its effectiveness.

(3) Delays in Monitoring. PET-CT scans are used to monitor the effectiveness of cancer treatments and detect recurrences. If these follow-up scans are delayed, treatment efficacy may not be adequately monitored, and recurrence of the disease may not be promptly identified.

(4) Impact on treatment effectiveness. A delay in PET-CT scan can potentially lead to less effective treatment strategies or a delay in getting the best treatment options, which could impact survival rates.

(5) Impact on accurate staging. The potential for less accurate diagnosis and staging of diseases, particularly cancers, due to the use of suboptimal diagnostic modalities instead of PET-CT scans could result in the cancer not being accurately staged, and the treatment may not be the most effective or necessary.

- As reported by Health Care Business News, Iversen, Gus. "PET procedure volumes in US rose 12% in 2024." April 23, 2025, in 2024, the number of PET imaging procedures in the US increased by 12.2% year-over-year, according to the 2025 PET Market Summary Report released by the IMV Medical Information Division. The article emphasizes the ongoing surge in demand and the restricted expansion of imaging capacity. Instead of installing new systems, much of the increase in use was managed utilizing existing PET-CT equipment. As a result, schedule delays have continued. 40% of facilities reported outpatient wait times of eight or more days for routine (non-emergency) scans, which was consistent with the previous year, but up dramatically from 19% in 2019. Eight days is a long time to wait for a PET scan in the US. The longer treatment is delayed, the higher the risk, as cancer cells continue to grow and potentially spread, treatment options diminish, and survival rates fall dramatically. Research shows even a one-month delay in treatment could increases the risk of death by 6-13% for some cancers. In 2022, Kaiser Permanente patients waited an average 39.1 days for a PET-CT scan. This is a significant disparity in wait time when compared to the US (39.1 days versus 8 days). This emphasizes the extent to which Hawai'i is falling behind the rest of the US in terms of number of PET-CT units per population. Limiting the number of PET-CT units in Hawai'i restricts PPM's capability of bringing quality healthcare to Hawai'i. The State of Hawai'i should have at least 10 PET-CT units based on a population of 1.4 million. This number is based on PET-CT diagnostic centers (primarily servicing oncology patients) in the US. It does not consider centers that provide diagnostic services to facilitate medical advancements in cardiology, urology, neurology or theranostic clinical research trials.

- Once the diagnostic imaging center is completely operational, its capacity to produce the volume of Rp's, Rp's type, and diagnostic modalities supported by the Rp's will surpass that of an average medical diagnostic facility, which the aforementioned July 27, 2017 article is based on. As a result, the demand for PET-CT units will continue in order to accommodate the ever-evolving medical advancements that PET-CT scanners facilitate, which is a direct consequence of their role in medical innovation.

b. Page 15 of CON #23-02A states, "Moreover, based on national benchmarks, 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. Kaiser Permanente will increase the capacity of this service for the State of Hawai'i benefiting Kaiser Permanente members as well as the state as a whole. Given that Hawai'i PET-CT procedures per thousand is less than the national average is an indication that there is additional room for PET-CT growth with more that is potentially constrained by the lack of providers in the state." 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 and provided below, 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. Furthermore, there is still so much more we can do to improve the standard of healthcare for patients in not only cancer, but also in the medical specialties of cardiology, neurology, urology and theranostics clinical research trials.

c. Technological advancements in PET-CT use coupled with an increased demand for precision diagnostics are anticipated to drive the desire for PET-CT procedures.
   - Alzheimer's therapy is available on a limited basis on Oahu. These Rp's are novel and will be available at the new diagnostic imaging center. According to Alzheimer's Association, there are roughly 31,000 aged 65 and older suffering from Alzheimer's disease, with 11.5% of Hawaiian adults affected. The Alzheimer's Association states, "Alzheimer's disease is a growing public health crisis in Hawai'i" and projects this number to increase to 35,000 by 2025. It is estimated that an additional 60,000 family caregivers in Hawai'i carry the burden of this disease, spending 91 million hours of unpaid care equating to 1.9 billion dollars. $285 million is the cost of Alzheimer's to the state's Medicaid program. PET-CT procedures can help assess Alzheimer's disease in its early stages, which is critical for timely intervention and treatment before cognitive decline. Receiving a diagnosis of Alzheimer's disease is a life altering moment. However, there are advanced medical services available that can enhance the quality of life. Nevertheless, the new diagnostic center will offer these advanced medical services that can halt the progression of Alzheimer's disease in its early phases, thereby reducing the burden and improving the quality of life for patients and their caregivers. PET-CT units are necessary to provide this medical service.

- Theranostic clinical research trials are developing rapidly and will typically necessitate three to four PET-CT scans. New, advanced PET/CT units can significantly enhance theranostic studies. These units offer advantages in image quality, sensitivity, and the ability to perform quantitative assessments, which are crucial for guiding theranostic treatments and monitoring their effectiveness. PPM will be installing state-of-the-art PET-CTs. As these clinical research trials and innovative medical services commence, the demand for PET-CT scanners will escalate.

d. The risk of death from cancer in the United States has consistently decreased over the years, largely as a result of advancements in treatment and early cancer detection. However, the American Cancer Society's "Cancer Statistics, 2024" indicate that the incidence of cancer is increasing and is set to surpass two million for the first time. This starling quantity is equivalent to nearly 5,500 cancer diagnoses per day. What is even more concerning is that the United States is expected to experience over 611,000 cancer-related fatalities in 2024, which equates to over 1,600 deaths per day. Unfortunately, these statistics may be more pronounced in Hawai'i because the state lacks state-of-the-art medical technology and treatment in comparison to the diagnostic and treatment institutions in the rest of the United States. Consequently, many Hawai'i patients are either not aware of or are never presented with advanced treatment options. It is therefore imperative that we remain resolute and unwavering in our efforts to bring cutting-edge cancer medical instruments and therapies to Hawai'i.

- **UNACCEPTABLE WAIT TIMES TO SCHEDULE A PET-CT SCAN**

a. The single supplier of Rp's has recently commenced production in support of other advanced medical services such as PSMA PET and cardiac PET. The lengthy wait periods for PET-CT scans have likely been further exacerbated by these additional services. The number of operating cyclotrons and PET-CTs has remained constant at one and four, respectively. It is evident that Kaiser Permanente's (KP's) concerning wait-time metrics, discussed extensively in CON 23-02A, have not improved and are likely to have worsened. It is also likely that the unacceptably long wait times for a PET-CT scan have become even more burdensome.

Examples of the wait time issues discussed in CON 23-02A are:

- Page 6 of CON 23-02A states, "Currently, there are significant delays in receiving PET-CT for Kaiser Permanente members who are newly diagnosed with cancer. In 2022, only 17% of Kaiser Permanente members received a routine PET-CT within the target wait time of 14 days and only 26% of members received in urgent PET-CT within the target wait time of 7 days. Adding this service on site would expedite care for

Kaiser Permanente members newly diagnosed with cancer and lead to significantly improved cancer care coordination. In addition, there have been and will continue to be rapid innovations in the types of PET imaging agents that are targeted to detect specific types and severities of cancer. As the preeminent integrated care delivery organization in the State of Hawai'i, it is critical for Kaiser Permanente to have easy access to these new innovations to provide state-of-the-art care for its members."

- Page 14 of CON 23-02A states, "Currently wait times are approximately 1 month for PET-CT for KP members." In addition, the first table on page 14 showed a declining trend of target wait times year after year for emergency and urgent PET-CT scans (% performed in 7 days): 2017 (76%), 2018 (63%), 2019 (62%), 2020 (57%), 2021 (46%) and 2022 (26%). There was also a generally declining trend of target wait times for routine PET-CT scans (% performed in 14 days): 2017 (43%), 2018 (40%), 2019 (33%), 2020 (43%), 2021 (32%) and 2022 (17%). The average number of days KP patients had to wait for a routine PET-CT was well above the target of 14 days and has increased in the last 3 years of the reporting period (2020-2022): 2017 (32.3), 2018 (28.7), 2019 (35.8), 2020 (32.2), 2021 (34) and 2022 (39.1). It is notable that for the reporting year of 2022, patients waited an average 39.1 days for a PET-CT scan. Research shows even a one-month delay in treatment could increases the risk of death by 6-13% for some cancers. The longer treatment is delayed, the higher the risk, as cancer cells continue to grow and potentially spread.

b. PPM has engaged in many discussions with numerous medical centers in the State of Hawai'i and unacceptably long PET-CT scan wait times are a top concern. This is because the longer it takes to diagnose cancer, the more challenging it is to fight cancer. Many patients are symptomatic and thus by the time they are diagnosed they may have stage 3 or 4 cancer, which is frequently accompanied by metastatic cancer in other regions of the body. All medical centers have stated wait times of 4 weeks on average, which is in-line with the long wait times discussed in KP's CON 23-02A. Furthermore, medical technological advancements in new and more effective Rp's will only increase the volume of Rp's needed, resulting in a greater demand for PET-CT scanners. As stated previously, per the SHPDA Healthcare Utilization Report, Hawai'i 2023, Table 23 (Positron Emission Tomography-Computed Tomography (PET-CT) Utilization, 2023), there was an average utilization increase of the 4 PET-CT units in Hawai'i from 2022 to 2023 of 25.76%. The wait-time to schedule a PET-CT scan was undoubtedly exacerbated by this substantial increase in PET-CT utilization and/or may have led to the use of less-than-optimal diagnostic modalities due to the urgency of diagnosis to support immediate commencement of therapy. Bottom line, more PET-CTs are needed in Hawai'i to enhance the standard of medical care and, in particular, to give cancer patients a fighting chance at surviving the disease.

- The longer the period cancer patients must wait to be diagnosed can result in several negative consequences:
  (1) The likelihood and/or difficulty of combating cancer may be reduced because it is further advanced.
  (2) Poorer survival rates. Research shows even a one-month delay in treatment could increases the risk of death by 6-13% for some cancers.
  (3) Increased morbidity as a result of the spread of cancer, the impairment or prevention of vital organ function, and the scarcity of available options to combat the spread of cancer at the later stage.
  (4) Patients may be required to undergo more aggressive treatment and planning, which is likely to result in an increase in stress and anxiety.
  (5) Costly medical expenses because of the necessity for aggressive cancer treatment.
  (6) Patients may be required to take additional time off or may not be granted medical leave, which could lead to unforeseen financial expenses and other hardships.
  (7) Healthcare costs following a cancer diagnosis can be substantially higher for patients who were diagnosed later than those who were diagnosed earlier.
  (8) Patients may find the lengthy waiting period to be emotionally draining, aggravating and challenging to endure.
- Regardless of the reason for the unacceptable wait times, PPM seeks to help the State of Hawai'i stabilize the Rp's supply chain such that more medical centers and medical groups will have the quantities and types of Rp's to support their needs at their near target schedules. The State of Hawai'i will also have a much-needed backup supplier for Rp's when the State's only cyclotron is down. Most importantly, the PET-CT scan wait times and other issues and hardships Oahu patients face will be remedied by having an additional PET-CT scanner accessible on Oahu.

c) Quality Criteria
- The proposed service will bring a state-of-the-art diagnostic imaging modality to the underserved population of West Oahu. Patients residing in or near West Oahu will have easier access to PET-CT imaging services.
- PET-CT is an advanced nuclear imaging diagnostic modality.
  - PET-CTs, advanced 3-D imaging equipment, are used to support oncology services. PET-CT imaging allows doctors to study medical diseases and abnormalities related to the anatomy/structure (CT scan) and metabolic function (PET scan) of cells and tissues in the body. Without this cutting-edge diagnostic technology, it is difficult to accurately detect (i.e., know for certain that cancer exists), precisely locate the disease, and efficiently treat the cancer to ultimately defeat cancer.

- 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.

- There is a disparity in the quality of healthcare available to people who do not live in or around Honolulu, where the four PET-CT units are located. There may be additional challenges and hardships due to the lengthy traveling distance and potential for traffic congestion:
  - physical hardships
    a. senior patients experience significant challenges when traveling, including the complex and distressing coordination of appointments and physical limitations that limit their mobility.
    b. patients frequently experience fatigue, nausea, and dizziness.
    c. patients may not have someone to accompany and transport them to town, such as a relative, friend, or caretaker.

d) Cost and Finances

PPM's mission is to provide a comprehensive enterprise solution for molecular imaging and theranostics to Hawai'i clinicians and their patients, with a focus on underserviced rural areas, to achieve equitable access (i.e., on-island) to quality healthcare throughout the State of Hawai'i at reasonable costs. PPM intends to continue its mission by offering diagnostic services to patients residing in or near West Oahu.

- To ensure financial stability, PPM must be self-sustainable and profitable to accomplish our mission.
  - To guarantee sustainability, PPM must generate radiopharmaceutical drugs in sufficient quantities and types to support diagnostic imaging center services.
  - To be profitable, PPM must offer other PET-CT medical services that are not currently available in the State of Hawai'i or restricted. These services include: PET-CT scans to analyze neurological (brain) illnesses (e.g., Alzheimer's), carrying out theranostics studies (diagnostic and therapy clinical research trials for oncology) and cardiac PET imaging (the gold standard in nuclear cardiac imaging).
    - Cardiac PET is a rapidly growing advancement in premium molecular cardiology imaging. However, only Queen's Medical Center has the capability of offering cardiac PET procedures to diagnose heart disease. Ammonia (N-13), a radioisotope produced by a cyclotron and used for cardiac PET imaging, has a very short half-life. Thus, the radioisotope supply equipment (cyclotron) must be located near the PET/CT scanner. PPM intends to install a PET-CT scanner and a cyclotron to support these advanced medical services at the Maui diagnostic imaging center.

- Cardiac PET imaging is the gold standard in cardiology, and because it is regarded as a valuable tool in diagnosing and managing heart conditions, PPM's goal is to make this imaging service readily accessible to underserviced areas such as Maui (until the cyclotron is operational), Hilo and West Oahu by utilizing a rubidium generator. This generator is portable and can be relocated from one diagnostic center to another, enabling cardiac-PET imaging in Maui, Hilo, and West Oahu. In order to conduct cardiac PET diagnostic imaging, rubidium must be situated in close proximity to a PET/CT scanner, as it has an extremely short half-life of 68 seconds.

  - PPM has obtained the financial resources to secure all equipment and staffing resources required for the proposed project.
  - PPM projects that the net savings/excess funds from operations for Year 1 of the proposed project will be $1,446,774 above annual operating/internal costs of $2,153,226 and net savings/excess funds from operations for Year 3 of the proposed project will be $3,290,084 above annual operating/internal costs of $2,709,916.

e) Relationship to Existing Healthcare System

The State of Hawai'i has only one supplier of Rp's, the equipment used to produce the radioisotopes is over 27 years old. The possibility that the cyclotron may be unavailable for a lengthy period or will fail permanently is cause for grave concern. Additionally, this cyclotron is currently producing Rp's for other advanced medical services such as cardiac PET imaging and PSMA PET, which further constrains an already overwhelmed supply schedule. Patients will continue to endure unacceptably lengthy wait times and must juggle rescheduling appointments in the event the existing cyclotron goes down or fails permanently. Furthermore, having only one cyclotron operating at or near capacity restricts patient access to advances in healthcare treatments and therapies, as well as participation in theranostic clinical research trials. By installing a cyclotron in PPM's diagnostic imaging center on Maui, PPM intends to help the State of Hawai'i ensure redundancy in Rp's production, thereby reducing appointment delays for diagnostic imaging services. The additional cyclotron will not only address healthcare concerns but also ensure the financial stability of PPM.

- The additional cyclotron provides a greater assurance that Rp's will be available continuously in the State of Hawai'i and there is sufficient supply of Rp's to support the majority of PPM's diagnostic imaging center's needs and imaging appointment schedules. This will ensure PPM's sustainability.
- 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 proposed new PET-CT scanner will fill a gap in services and expand the accessibility to quality diagnostic imaging, 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 accessible to West Oahu seniors will ensure these elders receive equal healthcare as seniors living closer to town.

- The PET-CT scanner service will bolster research capabilities. Hawai'i is a melting pot of ethnicities, making it an optimal location for a spectrum of clinical research studies (theranostics).
- The cyclotron will be able to produce a broad spectrum of Rp's, thus the newest medical Rp's can be produced allowing patients another option to potentially improve their treatment outcomes and fight cancer for good.
- PPM aims to introduce new, unavailable medical technologies and improve existing systems. The objective is to provide the highest quality health care option possible, thereby enhancing the life expectancy of patients in Hawai'i.
- Building critical partnerships is a key aspect to the vision of the new diagnostic imaging center and involves having hospitals and medical groups in the State of Hawai'i (including the neighbor islands) own a part of our center. PPM's business plan is predicated upon not competing but rather partnering with and providing hospitals (with focus on underserved populations/areas) and medical groups with the best technology available so all patients can be offered the finest-quality care and treatments. Our center's purpose in forming this alliance is to be able to offer a broad range of radiopharmaceutical drugs and advanced medical services a lower cost, making healthcare more affordable for our Hawai'i residents.

f) Availability of Resources

Installation of 1 PET-CT supports the State-Wide Health Coordination Council's priorities by increasing and retaining the healthcare workforce to enable access to the appropriate level of care in a timely manner for underserved populations in the State of Hawai'i by improving the number of radiology professionals and support staff, and other resources.

- PPM's introduction of this vital medical technology to West Oahu will attract highly skilled and experienced individuals. The entire State of Hawai'i struggles with a shortage of doctors and nurses, and we are losing more each year. As reported by a Hawai'i News Now article, Kawano, Lynn. "Radiology workforce shortage hits Hawai'i hospitals with thousands of patient scans in the queue." April 17, 2025, discussed Queen's Medical Center's backlog of 8,000 images, which included PET scans, waiting to be reviewed by a radiologist. Some of these patients are "sickest patients in our community" who require a timely turnaround of their diagnostic images to support determining a therapy plan. Delays in this process for a cancer patient can have a significant impact on the fight against cancer. The earlier cancer is detected, the more favorable the survival rates and outcomes will be. Bringing medical advancement and limitless research opportunities to our islands will pique the interest of medical experts who would otherwise find Hawai'i lacking in medical equipment and care when compared to the rest of the United States. The establishment of cutting-edge medical technology to Hawai'i will serve to both attract and retain medical professionals in our state.

- 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. To offset Hawai'i's higher cost of living expense, PPM plans to pay essential employees sufficiently above the national average.
- PPM has identified key clinical team members for our diagnostic imaging center on Oahu. In addition, Mr. Guier (PPM CEO), a PPM principal resides in Hawai'i. He will oversee the construction, building's infrastructure / development, sales, etc. for this project.
- Radioisotope Life Sciences (RLS) Radiopharmacies will operate PPM's diagnostic imaging center's pharmacy. RLS is a company that owns and operates 31 radiopharmacies across 18 states, operating an extensive portfolio of molecular imaging products. RLS is the third-largest nuclear medicine pharmacy network in the country and the only one to receive The Joint Commission Gold Seal of Approval. By dispensing 100% of injectable unit dose products in clean chambers constructed to ISO1644-1 specifications, RLS provides the industry's highest quality radiopharmaceuticals.