



HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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STANDARD APPLICATION - CERTIFICATE OF NEED PROGRAM

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Application Number: # 24-08 Date of Receipt:  
To be assigned by Agency

**APPLICANT PROFILE**

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

Project Address: 250 Kinoole Street, Hilo, HI 96720

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., Suite 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, Suite 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

June 28, 2024  
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: \_\_\_\_\_

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**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: \_\_\_\_\_
  - Maui County: \_\_\_\_\_
  - Kaua`i County: \_\_\_\_\_
  - Hawai`i County:   X

**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 19 June 2024.
- 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 - Hawai'i County  
Certificate of Occupancy - Hawai'i County  
Fire Marshal's Approval - Hawai'i County, 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) – 3-2-3-12-37 (250 Kinoole Street, Hilo, HI 96720)

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.

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	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
<b>TOTAL</b>			

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)**

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

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**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

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

**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 19 June 2024.
- 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 – 3 months after CON approval
- e) Length of construction period – 6 months
- f) Date of completion of the project - 12 months after CON approval
- g) Date of commencement of operation – 18 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 250 Kinoole Street, Hilo, HI 96720. 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 the Big Island with much-needed, on-island, state-of-the-art, PET-CT diagnostic imaging services. PPM seeks to reduce inequalities in healthcare on the Big Island by increasing the accessibility of vital medical imaging. Because these services are not available on the Big Island, this will minimize the physical, mental and financial strain that comes with having to travel to Oahu for these procedures. Additionally, PPM intends to produce and supply a broad-range of radiopharmaceuticals (Rp's), which will enable the delivery of innovative patient diagnostic and therapeutic care which is not available on the island. Examples of this includes 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, they will be accessible for the first time on the Big Island. This cutting-edge medical equipment will not only enhance services but also attract skilled and knowledgeable medical professionals to the Big Island. PPM's primary mission is to offer patients in Hawai'i advanced treatment and services currently not available.

- a) Relationship to the State of Hawai'i Health Services and Facilities Plan
- PPM's service area is Hawai'i County. This service will be accessible to the population residing on the Big Island as well as patients living on 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 on the Big Island.

○ **INEQUITY TO QUALITY HEALTHCARE**

PET scanning requires two components: the radioactive isotopes that illuminate (help to visualize) the cancer, and the PET-CT scanner, which 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. Neither the PET-CT scanner nor radioactive isotope is available on the Big Island, PPM's goal is to change this. FDG, like all radioactive isotopes, deteriorates over time (with the half-life of the radioisotope). Because of the quick decrease in radioactivity concentration, FDG must be produced in Hawai'i and cannot be bought from the US mainland. 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 26 years old.

- To address healthcare disparities in Hawai'i, hospitals on the island of Maui 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. This motivated PPM to develop a way to address fundamental imbalances in healthcare, in particular, the limited access of vital diagnostic technology (PET-CT scanners) that promote improvements in therapy and will facilitate clinical research trials in underserved populations throughout the state.
- PPM's mission is to install PET-CT scanners in these medically underserved areas. Patients living on Maui and the Big Island deserve the same quality of healthcare as patients living on Oahu.

o **ADDITIONAL PET-CT SCANNERS ARE GREATLY NEEDED**

- 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: <http://www.newscenter.lbl.gov/2017/07/07/new-chemistry-pet-scans-for-medical-imaging>, 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 important to note that since this information was published in 2017 there have been a wide range of medical advancements in the field of molecular diagnostic imaging. It is anticipated that the number of PET-CT scanners per person in the United States has increased significantly. There are currently just four operable PET-CTs 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 of diagnostic imaging units per population in the US. Nevertheless, when the diagnostic imaging center is fully operational, the Rp's PPM will produce will exceed the typical capacity of an average medical diagnostic facility in the US in terms of volume, Rp's type, and diagnostic modalities it supports. Consequently, even more PET-CT scanners will be required to satisfy the demand.
- 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. The most significant fact is that there are no PET-CT scanners on any other island besides Oahu.
- 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 may be available soon, but it will only be available on Oahu. These Rp's are novel and will be available at the new diagnostic imaging center. According to Alzheimer's Association's website, there are approximately 31,000 people living in Hawai'i aged 65 and older living with this disease. 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 are also affected by this disease. 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 improve the quality of life. PET-CT units are necessary to provide this medical service.

- Theranostic clinical research trials are expected to develop rapidly in the near future and will typically necessitate three to four PET-CT scans. As these clinical research trials and innovative medical services commence, the demand for PET-CT scanners will escalate.
- Significant growth in PET-CT imaging is predicted because of the notable advantages cardiac PET imaging offers in comparison to other diagnostic modalities currently available. Cardiac PET is the gold standard in nuclear cardiac imaging.
  - In an article provided by the National Library of Medicine, Nayfeh, Malek, et al. "The Role of Cardiac PET in Diagnosis and Prognosis of Ischemic Heart Disease: Optimal Modality Across Different Patient Populations." May 10, 2023. <http://www.ncbi.nlm.nih.gov>, it states, "Infact among non-invasive cardiac imaging modalities, PET has seen the largest increase in use among Medicare beneficiaries with an increase of 146% between 2010 and 2019, while SPECT has decreased by 36% in that same period." This shows a significant upward trend in the use of this optimal diagnostic image modality.
  - One financial factor to consider is that hospitals will receive the same revenue when cardiac PET services are provided at PPM's diagnostic imaging center as they would if SPECT were administered at their facility. Furthermore, since PPM's medical facility would handle the procedure, hospitals will not be required to perform any additional work.
  - In terms of sensitivity, specificity, and overall accuracy, cardiac PET is a precise diagnostic technique. This enables physicians to obtain detailed information about the flow of blood through the coronary arteries. In comparison to other forms of stress testing, the information is more dependable and precise. This enhanced imaging improves interpretative certainty, results in an accurate diagnosis, and increases the likelihood of prescribing the appropriate treatment, thereby reducing the risk of prescribing unnecessary, invasive operations.
  - Cardiac PET imaging enhances the clarity and resolution of images, enabling the precise quantification of calcium accumulation in the cardiac arteries, which may result in a reduction in myocardial blood flow. This provides clinicians with a potent instrument for determining whether a patient's symptoms are the result of heart artery issues (e.g., arteries that have narrowed to the extent that blood flow is impaired, flow abnormalities, the development of coronary artery calcification, etc.) or something else. To enhance the probability of a better quality of life, it is imperative to implement prompt and aggressive preventive measures during the initial stages of plaque development in the coronary arteries.



- Unlike other cardiac tests, PET allows patients with obesity (BMI > 35 kg/m<sup>2</sup>), large breasts, breast implants, excess wall tissue or pericardial (buildup of fluid in the space around the heart) or pleural effusions (buildup of fluid between the tissues that line the lungs and the chest) to receive high-quality images. These patients have attenuation artifacts (tissue attenuation), which reduces SPECT image quality and diagnostic accuracy; hence, PET is the preferred nuclear imaging approach for these patients.
- Cardiac PET procedure is more efficient than many diagnostic modalities, such as SPECT, and there is a rapid turnaround of the results. This facilitates a more expedited treatment process.
- Compared to current modes of nuclear stress testing of a similar nature (e.g., SPECT), Cardiac PET results in less radiation exposure.
- Cardiac PET is the only noninvasive imaging technique that can quantitatively assess myocardial blood flow and glucose utilization by detecting viable heart tissue (myocardial viability), a test that SPECT is unable to perform. Heart tissue that is viable and has the potential for recovery after injury or ischemia is referred to as myocardial viability. Revascularization may be advantageous for these patients.
- Cardiac PET has unique features that will assist in evaluating the severity and risk of heart disease, the planning of treatment using medications, other diagnostic tests, and the efficacy of the current treatment plan, as well as the patient's risk of developing cardiac complications in the future.
- Cardiac PET scans are more effective in diagnosing CAD and coronary microvascular dysfunction, as well as assessing tissue function levels.
- As CAD severity increases, various stress testing methods become less reliable. Cardiac PET is the best stress test for patients with severe CAD, allowing for better management of these complicated patients.
- 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 startling 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. Consequently, it is imperative that we remain resolute and unwavering in our efforts to bring cutting-edge cancer medical instruments and therapies to Hawai'i.

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

- The single supplier of Rp's has recently commenced production in support of 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) concerns 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 that delaying cancer treatment by even one month can increase the risk of death by 6-13%.
- 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. 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.

- The longer the period cancer patients must wait to be diagnosed can result in several negative consequences:
  - The likelihood and/or difficulty of combating cancer may be reduced because it is further advanced.
  - Poorer survival rates. Research shows that delaying cancer treatment by even one month can increase the risk of death by 6-13%.
  - 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.
  - Patients may be required to undergo more aggressive treatment and planning, which is likely to result in an increase in stress and anxiety.
  - Costly medical expenses because of the necessity for aggressive cancer treatment.
  - 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.
  - Healthcare costs following a cancer diagnosis can be substantially higher for patients who were diagnosed later than those who were diagnosed earlier.
  - Patients may find the lengthy waiting period to be both 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 the Big Island patients face will be remedied by having a PET-CT scanner and cyclotron accessible on the Big island.

c) Quality Criteria

- The proposed service will bring a state-of-the-art diagnostic imaging modality to the underserved population of the Big Island.
  - No longer will this population have to worry about the additional emotional, physical, and financial hardships flying to Oahu brings.
  - No longer will this population have to settle for less than optimal diagnostic modalities for cancer diagnosis when flying to Oahu is not an option. Currently, MRI is the substitute diagnostic modality for cancer diagnosis on the Big Island.
  - No longer will this population have to sit and wait for an unacceptably long period to obtain a PET-CT scan. Research findings have shown that when cancer is diagnosed and treated early, quality of life and survival rates are significantly improved. In addition, patients experience undue stress waiting for the day the scan will be done and what the results may show, which could include follow-up treatment and care.
  - No longer will this population have to wonder why they couldn't receive advanced medical treatments in regards to neurology (e.g., Alzheimer's therapies).

- No longer will this population have to wonder why they don't have access to cardiac PET (the gold standard in nuclear cardiac imaging) for their coronary heart disease medical concerns. This superior imaging capability increases interpretive certainty, leads to an accurate diagnosis, and increases the likelihood of prescribing the correct treatment, thereby reducing the likelihood of prescribing more invasive, unnecessary procedures.
- No longer will this population have to wonder why they couldn't participate in theranostic studies (a spectrum of research studies focused on patient's needs) which have encouraging outcomes that could allow patients more time with loved ones or cure cancer for good. PSMA PET is a theranostics procedure for prostate cancer diagnosis, staging, and treatment of prostate cancer that is now available, but only on Oahu.
- No longer will this population wonder why the same quality of health care and service with respect to diagnostic modalities available on Oahu is not accessible on their island.
- 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 inequity in the quality of healthcare that is accessible to patients living on islands other than Oahu. 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:
  - 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)
    - the patient's stage of cancer may not permit flying
    - patients may be unwilling to travel due to fear, anxiety, or other reasons.
    - patients may not have someone to accompany them, such as a relative, friend, or caretaker.

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

d) Cost and Finances

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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 underserved rural areas, in order to achieve equitable access (i.e., on-island) to quality healthcare throughout the state of Hawai'i at reasonable costs. PPM intends to begin its mission by offering on-island diagnostic services to the Big Island.

- 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 to Oahu. 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 offers cardiac PET procedures to diagnose heart disease. (Some Rp's have short half-lives (time required for a quantity of a radioisotope to decay by half), which makes it necessary to have the cyclotron near the PET-CT unit to support the diagnostic process.) PPM intends to install a PET-CT scanner and a cyclotron to support these advanced medical services. Cardiac PET will be available for the first time on the Big Island.
- In addition to the obstacles that cancer patients already face when traveling to Oahu for diagnosis and treatment, patients may also encounter a variety of financial hardships, such as the inability to afford travel expenditures due to living paycheck-to-paycheck and unpaid medical bills:
  - travel costs that may not be covered by insurance such as
    - airplane fares
    - rental car/taxi or ridesharing company fares
    - gas
    - parking fees
    - lodging
    - meals
  - the scheduling and coordination of appointments with doctors, healthcare professionals, or laboratories for tests can result in unanticipated tension and anxiety, as well as a significant out-of-pocket expense, which sometimes may be unaffordable

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- time off concerns (e.g., lack of medical or equivalent leave, need to work to make money, work obligations that do not permit time off, etc.)
  - family obligations (e.g., no one to care of kids, single parent, personal family issues, etc.) may result in additional out-of-pocket expense.
  - Many seniors have limited access to finances to cover unforeseen and costly expenses
  - Similar challenges may be pertinent to the individual who is accompanying the cancer patient.
  - Cancer patients may choose less effective treatment options due to financial constraints. This increases health risks and may result in further costs in the future.
- 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 \$1,974,773 above annual operating/internal costs of \$2,465,227 and net savings/excess funds from operations for Year 3 of the proposed project will be \$3,888,125 above annual operating/internal costs of \$3,311,875.

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 26 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, 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.
- 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 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 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.
- 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 with hospitals, but rather partnering with and providing hospitals (with focus on underserved populations/areas) with the best technology available so they can offer the finest-quality care and treatments for all patients. 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 the Big Island 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. 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.

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- PPM's partnership with the University of Missouri, the 5<sup>th</sup> 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 the Big Island. 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.