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HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

ST. HEALTH PLAN & DEV. AGENCY

ADMINISTRATIVE APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number #22-06A **Date of Receipt:**

To be assigned by Agency

Applicant: Ohana Endoscopy Clinic, L.L.C.

Phone: 808-762-2311

Project Title: Establishment of Outpatient Surgery Center Limited to Endoscopic Procedures

Project Address:
590 Farrington Highway, Space 170
Kapolei, HI 96707

Applicant Facility/Organization: Ohana Endoscopy Clinic, L.L.C.
Name of CEO or equivalent: Mel A. Ona, M.D., M.S., M.P.H., M.A.
Title: Managing Member/President
Address: 590 Farrington Highway, Unit 526A, Kapolei, HI 96707
Phone Number: 808-762-2311 **Fax Number:** 808-427-6051
Contact Person for this Application: Mel A. Ona, M.D., M.S., M.P.H., M.A.
Title: Managing Member/President
Address: 590 Farrington Highway, Unit 526A, Kapolei, HI 96707
Phone Number: 808-762-2311 **Fax Number:** 808-427-6051

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 Date

Mel A. Ona, MD
Name (please type or print)

Managing Member/President
Title (please type or print)

1. TYPE OF 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
Maui 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). See attached Exhibit 3.A.

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.). Office of Healthcare assurance Ambulatory Surgery Center license.

C. Your governing body: list by names, titles and address/phone numbers.
Mel A. Ona, M.D. is the managing member of Ohana Endoscopy Clinic, LLC.
590 Farrington Highway, Unit 526A, Kapolei, HI 96707. 808-762-2311.

D. If you have filed a Certificate of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following (See attached Exhibit 3.D.):

- Articles of Incorporation
- By-Laws

- Partnership Agreements
- Tax Key Number (project's location)

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 Service	Change in Beds
Inpatient Facility					
Outpatient Facility				X	
Private Practice					

5. 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.

Not applicable. Application for new Outpatient Ambulatory Surgery Center CON.

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

6. PROJECT COSTS AND SOURCES OF FUNDS

A. List All Project Costs:		AMOUNT:
1. Land Acquisition		See building lease and Exhibit 3.A
2. Construction Contract		
3. Fixed Equipment	$	20,833
4. Movable Equipment	$	471,171
5. Financing Costs		
6. Fair Market Value of assets acquired by lease, rent, donation, etc.		
7. Other: _Fair market value of leased premises	$	2,000,000
TOTAL PROJECT COST:	**$**	**2,492,004**

B. Source of Funds		
1. Cash	$	133,389
2. State Appropriations		NA
3. Other Grants		NA
4. Fund Drive		NA
5. Debt		
6. Other: Equipment Lease	$	358,615
7. Fair market value of leased premises to be paid by monthly rent: Same # as 7 above	$	2,000,000
TOTAL SOURCE OF FUNDS:	**$**	**2,492,004**

7. CHANGE OF 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 reference the 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.

This is an Application for a new outpatient surgery (surgicenter) CON, service category Certificate of Need Rules Section 11-186-5(3)(B).

8. 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:
NOTE: Project originally constructed for the benefit of the Mel A. Ona, M.D., Inc. professional medical practice (the "Practice") as a CON exempt physician office endoscopy surgical suite utilized exclusively to treat the patients of the physicians

employed by that Practice. By this Application the Practice seeks to obtain a new outpatient surgery (surgicenter) CON for its existing practice-based endoscopy surgical suite.

a) Date of site control for the proposed project, Building lease finalized: 3/9/2020. See Exhibit 3.A.
b) Dates by which other government approvals/permits will be applied for and received: December 2022
c) Dates by which financing is assured for the project: N/A
d) Date construction will commence: N/A
e) Length of construction period: N/A
f) Date of completion of the project: N/A
g) Date of commencement of operation: Upon OHCA licensure approval.

9. 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.

a) Relationship to the State of Hawai`i Health Services and Facilities Plan.
b) Need and Accessibility
c) Quality of Service/Care
d) Cost and Finances (include revenue/cost projections for the first and third year of operation)
e) Relationship to the existing health care system
f) Availability of Resources.
g) Date of commencement of operation

Introduction

Mel A. Ona, M.D., Inc. is a professional gastroenterology specialty medical practice located in Kapolei, Hawaii (the "Practice"), and is wholly owned by Mel A. Ona, M.D. The Practice employs three full-time gastroenterologists, Dr. Mel Ona, his father Dr. Fernando Ona, and Dr. Jorge Guzman. Dr. Guzman only began working for the Practice in March of this year. As outlined in Paragraph 8 above, in June 2020 the Practice began the build-out of a CON exempt office-based endoscopy center, and the center began operations on October 30, 2020. The center exclusively performs endoscopic procedures for the Practice patients of Dr. Mel Ona, Dr. Fernando Ona, and Dr. Jorge Guzman, and all services at the endoscopy center are billed under the Practice provider number. All

endoscopy center staff employees are presently directly employed by the Practice, including Maryson Cabudoy, RN, who serves as the Practice endoscopy center manager.

By this Application, the Practice seeks to obtain a surgery center CON to enable it to operate the endoscopy center as a licensed surgery center, which under the Medicare billing rules would require the center to be operated separate and apart from a physician practice. To facilitate the future transition of the Practice office-based endoscopy center operations to licensed endoscopy surgery center operations, the initial lease of the endoscopy center space, as well as certain equipment lease financing, was established through the Ohana Endoscopy Clinic, LLC ("OEC"). OEC currently is a shell entity with no operations, and all expenses and responsibilities of operating the endoscopy center are incurred exclusively by the Practice, and billed through the Practice. If this CON application is granted and a surgery center license is issued, all responsibility for endoscopy center personnel, and all endoscopy center operations, will be transferred to OEC, which would be the entity that holds the CON and surgery center license. OEC is presently owned equally by Dr. Mel Ona and Dr. Fernando Ona.

This CON Application follows existing precedent established by the State Health Planning and Development Agency ("SHPDA"). See attached **Exhibit 9.1** - March 6, 2017 SHPDA Letter approving an administrative review imaging center CON for PET and CT technology historically operated through a CON exempt private physician practice. This administrative review CON Application relies upon facts very similar to those presented in the attached March 6, 2017 SHPDA administrative review CON approval letter. Both projects rely upon administrative review eligibility criteria found in Subsection 11-186-99.1(b)(6), i.e.: "Any proposal which is determined by the agency not to have a significant impact on the healthcare system." This CON Application involves converting existing CON exempt physician office endoscopy center operations to CON approved endoscopy surgery center operations, so existing historical Practice endoscopy procedure volume establishes the requisite need for the service. Since the Practice endoscopy procedure volume is only generated by the father and son physician members of the Practice, and by Dr. Guzman since March of this year, the procedure volume does not have a significant impact upon other area healthcare providers. There is no compelling public interest which would be served by requiring this Application to go through the standard review process. Other support for satisfying the administrative review CON criteria is discussed further herein.

The Practice's current office endoscopy operations are operating at a material loss, and must convert to licensed surgery center operations to be financially viable. If a surgery center CON and license cannot be timely obtained, the Practice endoscopy center will be forced to close, and important quality healthcare services will be lost to the community.

See the "Cost and Finances" subparagraph under this Paragraph 9 for a discussion of the financial performance of the Practice endoscopy operations to date, as well as the projected improved financial performance assuming a surgery center CON is obtained, and operations continue into the future as a licensed endoscopy surgery center.

The existing Practice office-based endoscopy center is a 2,100 sq ft. facility that consists of two clinical encounter/procedure rooms, four pre-/post-operative bays, one endoscope processing room, one administrative office, a staff bathroom with shower, one patient bathroom, a staff lounge/break room, a utility room, waiting room, and an enclosed front desk/registration area. A copy of the Practice endoscopy center floor plan is attached hereto as **Exhibit 9.2**.

The Practice endoscopy center provides a variety of endoscopic procedures, including upper endoscopy, flexible sigmoidoscopy, and colonoscopy for screening for colorectal cancer.

As of March 31, 2022, the Practice endoscopy center has performed 2,262 endoscopic procedures since beginning operations in October 2020. Indeed, whereas this procedure volume establishes need for the endoscopy services, it is not material to other outpatient providers in the area as the demand for high-quality endoscopy has increased significantly since the beginning of the COVID-19 pandemic. Screening procedures are performed at the Practice endoscopy center because of the lack of conveniently located outpatient ambulatory endoscopy providers in West Oahu, thus it should not be counted as lost volume to other centers.

A. Relationship to the State of Hawai'i Health Services and Facilities Plan.

The State of Hawaii Health Services and Facilities Plan contains specific goals related to Hawaii's health care environment, which include: increasing cost-effective access to necessary health services, promoting the financial viability of the health care delivery system, encouraging optimization of services and expensive technology to meet health care needs at reasonable costs, and promoting regionalization of services where appropriate.

Based upon recent ASC Certificate of Need application precedent, our licensed ASC would satisfy important requirements under the Hawaii Health Services and Facilities Plan per Chapter 2 (Thresholds and Suboptimization Clause). Specifically, our ASC would have a collaborative arrangement with an existing acute care hospital in the same county.

The proposed endoscopy center will establish an affiliation agreement (see Exhibit 9.3) with Pali Momi Medical Center (PMMC) that will:

(i) include a standard transfer agreement to direct patients requiring emergency services to PMMC emergency department

(ii) support appropriate training and recruitment of health care personnel to provide outpatient endoscopic services that will benefit the service area (west Oahu)

(iii) enhance the emergency medical system and trauma care systems of the service area; the proposed endoscopy center, when necessary, will provide assistance in the emergency management and care of patients during situations such as natural disaster and pandemic; and

(iv) have the proposed endoscopy center accept patients irrespective of type of payor.

We are also negotiating a collaborative arrangement with The Queen's Medical Center (West Oahu), Ewa Beach, HI.

The Practice endoscopy center provides patients convenient access to colorectal cancer screening, which is critical for early diagnosis and effective treatment. From October 30, 2020 through March 31, 2022, our Practice center has diagnosed 27 colorectal cancers, one duodenal cancer, one gastric cancer, and one esophageal cancer. Because of these early diagnoses, many of these patients have been effectively treated with chemotherapy and curative surgical resections. Clearly, endoscopic procedures identify elements of high risk and diagnose and/or remove pre-cancerous lesions associated with esophageal, gastric, and colon cancer.

The Practice endoscopy center advances the several statewide and regional priorities of the Statewide Health Coordinating Council (SHCC).

One of the General Principles of the SHCC is to "ensure that any proposed service will at least maintain overall access to quality health care at a reasonable cost." The Practice endoscopy center improves the cost-effectiveness of Hawaii's health care system by promoting early detection of cancer through the use of screening procedures, thereby eliminating the need for more costly, and often less effective treatment of late-stage colon and rectal cancer. Based upon public program and private insurance rate schedules, the cost of cancer screening at surgery centers is also over 50% less than the cost at hospitals. Dr. Mel Ona, Dr. Fernando Ona, and Dr. Jorge Guzman all receive referrals from local primary health providers.

Another one of the SHCC priorities is to strive for equitable access to health care services (i.e., remove financial barriers). Based upon the historical experience of the Practice

endoscopy center, the OEC surgery center would continue to fulfill the healthcare needs of underserved patients living in Kapolei and in areas west of Kapolei. The COVID-19 pandemic has made patients hesitant about travel and more cautious concerning greater personal contact risks presented at larger healthcare institutions. Our conveniently located center addresses these patient concerns. We continue to serve all Hawaii residents including the elderly, racial/ethnic minorities, low-income persons, and persons with disabilities.

Moreover, the Practice endoscopy center would encourage and support prevention initiatives (Ref: Chapter 3: Statewide and Regional Priorities, General Principles, page 33) through early detection and diagnosis of treatable diseases and reducing morbidity and pain. It will advance the general principle of promoting and supporting the long-term viability of the health care delivery system in that it will reduce the effects of chronic disease and prolong health related quality of life by providing accurate and timely diagnosis and treatment of conditions such as gastroesophageal reflux disease, peptic ulcer disease, and inflammatory bowel diseases (such as ulcerative colitis and Crohn disease).

To be financially viable, the Practice endoscopy center must obtain a surgery center CON in order to bill an associated ASC facility reimbursement to Medicare, Medicaid and private insurers so that the center can continue to provide quality healthcare services to its community.

The endoscopy center will address subarea health planning council (SAC) priorities through reducing health disparities among Hawaii's residents by making these services available to the population of West Oahu where endoscopy services outside a hospital system are currently non-existent. Other than Dr. Mel Ona, Dr. Fernando Ona, and Dr. Jorge Guzman (gastroenterologist recently hired by the Practice on 3/7/22) there are no other gastroenterology providers established in Kapolei and locations westward (e.g. Waianae, Makaha, Nanakuli). The West Oahu SAC priorities list "services for uninsured and underinsured, telemedicine, and specialty care" among the areas to "IMPROVE AND INCREASE ACCESS."
(page 35, https://health.hawaii.gov/shpda/files/2013/07/shhsfp09.pdf).

By facilitating early detection and treatment of gastroenterological diseases, the center will support secondary and tertiary care and will respond to the community's need for additional specialty care/colorectal cancer screening. Colorectal cancer is the third most frequently diagnosed cancer in Hawaii with over 700 new cases diagnosed annually. Approximately 220 deaths occur annually in Hawaii due to colorectal cancer and it is the second leading cause of cancer death in men and the 3rd leading cause of death in

women. Between 2009 and 2013, colorectal cancer incidence was highest among the population between the ages 55 to 74. [Ref. Hawaii Cancer at a Glance, 2009-2013, Hawaii Tumor Registry, University of Hawaii Cancer Center].

The Practice addresses the West Oahu SAC priority of "INCREASING COMMUNITY ENGAGEMENT" (page 35, https://health.hawaii.gov/shpda/files/2013/07/shhsfp09.pdf) by improving patient healthcare education and increasing preventive medicine such as Dr. Ona's health education article [Ref. https://thefilipinochronicle.com/2020/04/17/colon-health/] and local news coverage featuring Dr. Mel Ona and Dr. Fernando Ona at Ohana Endoscopy [Ref. https://www.khon2.com/news/business-matters/business-matters-new-kapolei-facility-makes-colonoscopy-procedures-easy-safe/]. Dr. Ona has also conducted several health-related lectures including Grand Rounds at the hospital, lectures for a family medicine residency program, and presentations for primary care physicians, which also fulfills community engagement with providers.

The Practice endoscopy center fulfills the West Oahu SAC priority to "IMPROVE EDUCATION AND INCREASE PREVENTIVE MEDICINE" (page 35, https://health.hawaii.gov/shpda/files/2013/07/shhsfp09.pdf) by conducting endoscopic screening at guideline-recommended frequency intervals that increase the chance that colorectal cancers will be detected at an earlier stage. This is the preferred clinical outcome because a precancerous lesion can be removed before it transforms into colorectal cancer. If a cancerous tumor is detected early, then the cancer is more likely to be cured by surgery alone, the surgery may be less extensive, and recovery from surgery is faster and less complicated. About 80 percent of the Hawaii residents who develop colorectal cancer are age 55 or older.

The Practice endoscopy center has been operating at a material loss since its inception because Medicare and Medicaid only reimburse a professional fee for office-based endoscopy procedures, and provide for no facility fee to cover the substantial office endoscopy surgical costs. Generally, private insurance companies follow Medicare reimbursement policies, and do not provide any facility reimbursement for endoscopy procedures performed in a physician office. The Practice has had limited success in obtaining modest office-based endoscopy facility reimbursement from private insurers. In contrast, licensed surgery centers receive a material facility reimbursement from both public and private insurers. OEC must expeditiously obtain a surgery center CON and license so that it can obtain a facility fee reimbursement to ensure the viability of continued endoscopy operations. If OEC cannot timely obtain a surgery center CON and license, the Practice endoscopy center cannot continue to sustain mounting operating losses, and will be forced to close, thereby depriving the community of important quality healthcare services. See subparagraph D. Cost and Finances in this Paragraph 9 for further

discussion of the finances of the Practice endoscopy center, as well as the projected improved finances of OEC operations if a surgery center CON and license can be obtained.

B. Need and Accessibility.

The greatest percentage of patients served by the Practice endoscopy center are between the ages of 40 and 79 (see Figure 1 below).

Figure 1: Ohana Endoscopy patients stratified by age

Row Labels	Count of Charge Id
0-19	0.47%
20-39	14.53%
40-59	52.23%
60-79	31.15%
80-99	1.63%
Grand Total	**100.00%**

According to the House Concurrent Resolution 129 Working Group (HCR 129), 3/10/17, one of the healthcare criteria under evaluation was to "identify barriers to colorectal cancer screening among underserved, hard-to-reach population groups, and develop effective strategies to overcome those barriers." [Ref. https://health.hawaii.gov/opppd/files/2017/12/HCR-129-LegReport-2017_Colorectal-Cancer-1.pdf]

In 2015, colorectal cancer screening prevalence was 70.5% in Hawaii. However, the Centers of Disease Control highlighted the need to target communities experiencing disparities with "enhanced resource allocation and intervention." [Ref. https://www.cdc.gov/dhdsp/maps/gisx/mapgallery/HI-colorectal-cancer.html]

The OEC surgery center would clearly satisfy this need.

Our center is located nearly 10 miles away from the closest competing outpatient/ambulatory surgery center providers, which underscores the importance of the location of our center in providing convenient patient care to our market population (Kapolei and points westward) and emphasizes the fact that our center will have no negative impact on other GI endoscopy service providers.

Medicare and Medicaid endoscopy facility fees are more than 50% less than that charged by hospital outpatient departments, which materially increases the access to care for low

income and elderly patients. These lower costs create significant savings for Medicare and Medicaid, as well as lower patient co-payments.

The Practice endoscopy center service area includes Kapolei and areas to the west. The facility is located within the Kapolei Shopping Center at 590 Farrington Highway, Unit 170, Kapolei, HI 96707, and is easily accessible via public transportation with a plethora of handicap-accessible parking.

The center services particularly target persons over the age of 45 for which colorectal cancer screening is recommended. The percentage of west Oahu residents within this age group has increased during the past several years and is expected to rise in the future.

In 2001, Medicare began coverage of colorectal screening colonoscopies and legislation requires Hawaii health insurers to provide coverage for persons beginning at age 50. The American College of Gastroenterology now recommends colonoscopy every ten years for persons over age 45 as the preferred method for early detection of colorectal cancer. As more insurers provide coverage for the procedure, particularly for persons between ages 45 and 50, the need will increase significantly.

While the area availability of endoscopy is currently limited to The Queen's Medical Center (West Oahu), which is 5.7 miles from the Practice endoscopy center, more facilities, particularly lower cost ASC facilities, are needed to care for underserved populations in the area. Lack of conveniently located area endoscopy facilities, especially in west Oahu, have led to patients failing to obtain important colorectal screening procedures. It has also resulted in endoscopy service referrals to hospitals located in central Oahu and Honolulu, which results in patient inconvenience, greater travel times, and increased costs at these hospital-based facilities.

The Chief of the Gastroenterology Department at The Queen's Medical Center recently shared with the Practice that in order to meet growing demand for gastroenterology services in the area, the hospital hired two additional G.I. physicians who are expected to begin providing services in West Oahu in the summer 2022. That hospital department head also disclosed that by this summer the hospital's endoscopy center may have to run seven days a week to keep up with endoscopy demand generated by the hospital's employed G.I. physicians. Consequently, The Queen's Medical Center does not have the capacity to perform the endoscopy procedures currently performed by the Practice physicians. If the Practice endoscopy center must close because it cannot obtain a surgery center CON and license to remain financially viable, there is no other area

endoscopy center with capacity to treat the endoscopy procedure volume generated by the Practice.

The Table at Figure 2 below highlights that almost all of the patients cared for by Dr. Mel Ona, Dr. Fernando Ona, and Dr. Jorge Guzman are from west Oahu, with only 4.35% of patients from Honolulu. Clearly, patients in west Oahu are responding positively to the opening of the Practice endoscopy center, and would continue to be served by the OEC endoscopy surgery center.

Figure 2: Percentage Patient Count by City

Row Labels	Count of Charge Id
Waianae	21.08%
Kapolei	20.92%
Ewa Beach	20.50%
Waipahu	14.68%
Mililani	5.82%
Honolulu	4.35%
Wahiawa	3.25%
Pearl City	3.25%
Aiea	2.73%
Waialua	0.89%
Haleiwa	0.63%
Kaneohe	0.47%
Lanai City	0.31%
Waimanalo	0.16%
Kailua	0.16%
Harbor City	0.10%
Makawao	0.10%
Kahuku	0.05%
Bellevue	0.05%
Kamuela	0.05%
Austin	0.05%
Kualapuu	0.05%
Pago Pago	0.05%
Wailuku	0.05%
Kenosha	0.05%
Colorado Springs	0.05%
SCHOFIELD BARRACKS	0.05%
Keaau	0.05%
Grand Total	**100.00%**

The table at Figure 3 below further highlights the ethnic and racial makeup of the patients served by the Practice endoscopy center since October of 2020. 63% of the Practice endoscopy patients are of Asian, Native Hawaiian, or African American ethnicity, and would continue to be served by the OEC endoscopy surgery center.

Figure 3. Ohana Endoscopy patients stratified by race.

Row Labels	Count of Charge Id
Asian	38.79%
Native Hawaiian or Ot	22.70%
White	18.68%
Unknown/Refused	18.10%
Black or African Amer	1.58%
American Indian or Al	0.14%
Grand Total	**100.00%**

The Practice endoscopy center focuses heavily on providing diagnostic screening services for older and lower income patients. As reflected in Figure 4 below, Medicare and Medicaid patients make up 41% of the Practice endoscopy patients, and the service will be lost to those patients if OEC cannot obtain a surgery center CON and license.

Figure 4: Primary Insurance for Ohana Endoscopy patients.

Row Labels	Count of Charge Id
HMSA	40.69%
Medicare / Medicare Advantage	19.72%
Medicaid	19.35%
UHA	5.77%
Govt. / Military	5.30%
HMAA	5.19%
Other	2.62%
HILB	1.36%
Grand Total	**100.00%**

Patient Vignettes

A 26-year-old Asian female from Ewa Beach presented to Dr. Fernando Ona with chronic anemia and rectal bleeding. Previously, she had been misdiagnosed by an Emergency Room physician as having hemorrhoids. Her issues with bleeding and constipation had been ongoing for two years and had never been accurately diagnosed or adequately treated. After a consultation and subsequent colonoscopy by Dr. Fernando Ona, we

determined that the patient had adenocarcinoma. She was on Medicaid coverage. She is undergoing chemotherapy and radiation treatment with a plan for surgical resection.

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A 46-year-old Asian male from Ewa Beach presented to Dr. Fernando Ona with episodes of diarrhea and blood in his stools. He had a prior colonoscopy and upper endoscopy in 2002 and was told that he had no colon problems. He is married and has a 3-year-old son. He had no family history of colon cancer. After a consultation by Dr. Fernando Ona and a colonoscopy, we determined that the patient had adenocarcinoma. Fortunately, he has coverage through HMSA for his care to date and his upcoming treatments.

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A 44-year-old Native Hawaiian female presented with a history of abdominal pain that she had for many years but her pain had increased significantly in the past two weeks. Painful episodes could last for days along with nausea and vomiting. After a consultation by the Nurse Practitioner and a colonoscopy by Dr. Mel Ona, we diagnosed the patient with adenocarcinoma. Fortunately, she has coverage through HMSA for her care to date and for her upcoming treatments.

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Dr. Mel Ona, Dr. Fernando Ona, and Dr. Jorge Guzman are committed to providing charity care to members of their community and anticipate that charity care cases will comprise up to 5% of their total patients. The doctors will allocate time each quarter for these procedures.

As stated above, we have performed over 2,200 high-quality, safe, endoscopic procedures since October 30, 2020. Indeed, this procedure volume is not material to other hospital outpatient providers in the area as the demand for high-quality endoscopy has increased significantly since the beginning of the COVID-19 pandemic. Screening procedures are performed at the Practice endoscopy center because of the lack of conveniently located outpatient ambulatory endoscopy centers in west Oahu, thus this nominal endoscopy procedure volume generated predominantly by the father and son physicians should not be counted as lost volume to other centers. This CON application should satisfy the Administrative review eligibility criteria of not having a significant impact on the area healthcare system.

C. Quality of Service/Care.

The Practice endoscopy center and future OEC surgery center will comply with State and Federal regulations for delivery of care, maintenance of equipment and maintenance of the clinical environment. It will be licensed by the Department of Health and certified by Medicare. The OEC endoscopy surgery center will seek accreditation through the Accreditation Association for Ambulatory Health Care (AAAHC)

The Practice endoscopy center patient care is currently being provided by Dr. Mel Ona, his father Dr. Fernando Ona, and Dr. Jorge Guzman. These doctors would continue to provide care at the future OEC endoscopy surgery center if a CON is obtained. All doctors hold Hawaii medical licenses, and are Board Certified in gastroenterology. All doctors are on the staff of at least one of the Hawaii Pacific Health hospitals and Dr. Mel Ona is an active staff member at The Queen's Medical Center. A more detailed description of the qualifications, background and experience of the endoscopy center physicians and other healthcare providers is provided below:

Mel A. Ona, M.D., M.S., M.P.H, M.A. earned his medical degree from St. George's University School of Medicine and completed his Internal Medicine residency at NYU Langone Brooklyn (formerly Lutheran Medical Center) where he served as a PGY-3 Chief Resident. He completed his gastroenterology fellowship at The Brooklyn Hospital Center (affiliate: Mount Sinai Hospital) where he also served as Chief GI Fellow. He received advanced endoscopy training at the renowned Cedars-Sinai Medical Center. He has three Masters degrees, authored several books, published over 40 articles in peer-reviewed journals, and is an Assistant Clinical Professor of Medicine at the University of Hawaii John A. Burns School of Medicine. Dr. Mel Ona was married in Hawaii in August 2008, and frequently visited the state until finally moving to Hawaii in 2017 to establish his private G.I. practice.

Fernando V. Ona, M.D., F.A.C.G., F.A.C.P. completed his Internal Medicine residency at Boston VA Medical Center and Gastroenterology Fellowship at both the Boston VAMC and the Mallory Institute-Thorndike Laboratory/Harvard Medical Services of Boston City Hospital. He completed a Hepatology Fellowship at the Tufts-New England Medical Center under Dr. Marshall Kaplan. After GI training, he was Chief of Gastroenterology and Director of GI Fellowship Training Program at St. Mary's Hospital in NY. He was also a full-time faculty member of the University of Rochester School of Medicine and served as Associate Professor of Medicine. After 25 years of service, he transferred to Hawaii and served as Chief of GI at the VA Pacific Island Health Care System. He also served as Clinical Associate Professor of Medicine at the University of Hawaii John A. Burns School of Medicine. In 1999, Dr. Fernando Ona moved to Hawaii and began his medical

practice. This move was motivated in part to be closer to the Philippines where he had established a health center in 1997 that provides free medical care to patients living in the area of his home village. Dr. Fernando Ona formerly served as Chief of the G.I. Department at the Spark M. Matsunaga Department of Veterans Affairs Medical Center in Honolulu, Hawaii, and would travel several times a year to the Philippines to care for patients.

Jorge E. Guzman, M.D., Ph.D. earned his medical degree, post-doctoral fellowship and Ph.D. all from The Ohio State University College of Medicine in Columbus, OH. He also completed various post graduate fellowship training in a variety of areas including EUS and ERCP. Dr. Guzman is board-certified by the American Board of Gastroenterology, American Board of Internal Medicine. He has authored numerous publications regarding gastroenterology, biochemical pharmacology, inflammatory bowel disease, neurogastroenterology, motility, cell biology, and more. Dr. Guzman began working with the Practice on March 7, 2022.

Clinical Director and Nursing Staff:

Maryson Cabudoy, R.N. Maryson graduated with her BSN from Biola University in Southern California and has nearly 30 years of nursing experience in GI, Recovery, and Intensive Care. She also successfully managed an outpatient endoscopy center in Oahu for over a decade. Maryson is a strong advocate for colon cancer prevention. Her brother was diagnosed with colon cancer at age 40 and is a cancer survivor because of Maryson's knowledge and expertise. She plans to implement a colonoscopy screening program for patients who lack insurance/access to health care.

Cristy Cabico, R.N. Cristy graduated with a BS in nursing from University of Baguio, Philippines in 2008. She has worked as a certified nurse assistant/home health aide until 2014 and more recently as a nurse in an ambulatory surgery center setting. She has also worked as a GI endoscopy technician and is the primary intake nurse at Ohana Endoscopy since November 2020.

The endoscopy center contracts for anesthesiology services with two independent Anesthesiologists and one independent nurse anesthetist as provided below:

Audie Asistin, M.D.
Alfie Riveral, M.D.
Melissa Alsbergas, C.R.N.A.

While it must be noted that as of 11/29/2019, The Centers for Medicare and Medicaid Services (CMS) no longer required ASCs to have a written transfer agreement [Ref. https://www.ascassociation.org/asca/federalregulations/overview/2019-burden-reduction-rule], the OEC surgery center nevertheless plans to have a transfer agreement with Pali Momi Medical Center, Aiea, HI and The Queen's Medical Center (West Oahu), Ewa Beach, HI in the event of a medical emergency. The Practice is committed to the safety and wellbeing of our patients.

Physicians will be assisted by registered nurses or licensed practical nurses. Staff competency will be maintained by regular in-service education.

If this Administrative CON application is approved, the center will work with the Accreditation Association for Ambulatory Health Care (AAAHC) to obtain endoscopy surgery center accreditation.

The future OEC surgery center would continue to benchmark quality and service standards by participating in a national gastroenterology registry created by the GI Quality Improvement Consortium (GIQuIC), [ref. https://giquic.gi.org/docs/15-GIQuIC-Brochure-Final.pdf] which tracks performance over time and compares these measures to peers on a national basis. Current colonoscopy GIQuIC measures include: history and physical documentation, informed consent documentation, adequacy of bowel preparation, written discharge instructions (outpatient), ASA category documentation, indication documentation, cecal intubation rate with photo documentation, adenoma detection rate (screening: female and male), withdrawal time, immediate adverse event, and appropriate surveillance interval measures. Current EGD GIQuIC measures include: appropriate specimen acquisition in Barrett's esophagus, appropriate anticoagulation management, Helicobacter pylori status, immediate adverse events, indication documentation, informed consent documentation, ASA category documentation, and history/physical documentation.

The practice endoscopy center (and future OEC surgery center) utilizes a state-of-the-art electronic medical record system that ensures medical record accuracy, improvements in patient outcomes, and reductions in wasteful resource consumption. The system provides healthcare providers with real-time access to reporting of healthcare services (e.g. labs, imaging, therapeutic and diagnostic procedures). The modern electronic health record also provides a patient portal that enables patients to access/review/update their medical records, review test results/notes/educational handouts, and communicate with our practice (thereby streamlining patient-provider communication), which enhances patient engagement to improve treatment adherence and retention.

D. Cost and Finances.

See Section 6 herein, PROJECT COSTS AND SOURCES OF FUNDS, for a breakdown of the $2,492,004 cost to build out the Practice office-based surgical suite, and the breakdown of the source of funds to cover such cost.

The Practice endoscopy center has been operating at a material loss since it began operations on October 30, 2020; i.e., $669,456 aggregate loss – see Financial Exhibit A below. The losses are attributable to the fact Medicare and Medicaid patients make up a material part of the Practice's endoscopy services, and those public programs only pay a professional physician fee for office-based endoscopy procedures, and pay no separate facility fee to cover the substantial office endoscopy surgical space, equipment and nonphysician personnel costs. Medicare and Medicaid do provide for a very modest site of service differential professional fee increase when endoscopy procedures are performed in a physician office, but that increase is very modest as will be addressed in more detail herein. Generally, private insurance companies follow Medicare reimbursement policies, and do not provide any facility reimbursement for endoscopy procedures performed in a physician office. Through the efforts of an outside consultant, the Practice had some success in obtaining additional office-based endoscopy facility reimbursement from private insurers. In contrast, licensed surgery centers receive a material separate facility reimbursement from both public and private insurers.

Financial Exhibit A below provides a broad financial overview of the Practice's office-based endoscopy financial operations.

Financial Exhibit A:

January 2021 through December 2021 (on a cash basis)		Q1 2022	Total	Jan-22	Feb-22	Mar-22
Facility Revenue from Office-Based Endoscopy Procedures	$842,594	$260,959	$1,103,553	$90,848	$92,152	$77,959
Facility Expenses for Office-Based Endoscopy Procedures	$1,535,578	$237,431	$1,773,009	$64,109	$74,140	$99,182
2021 net loss	($692,984)	$23,528	($669,456)	$26,739	$18,012	($21,223)

January 2021 through March 2022 (on a cash basis)
Facility Revenue from Office-Based Endoscopy Procedures: $1,103,553
Facility Expenses for Office-Based Endoscopy Procedures: $1,773,009
Net Endoscopy Facility Loss through March 2022: ($669,456)

The Practice office-based endoscopy facility revenues and expenses are complicated to calculate. In the above Financial Exhibit A, the $1,103,553 aggregate revenue figure represents the additional Practice endoscopy professional fee site of service differential

paid by the Medicare and Medicaid programs, as well as the limited circumstances where private insurers paid a separate office-based endoscopy facility fee. This revenue figure does not include payments received solely for physician professional endoscopy services. The expense figure reflected in Financial Exhibit A only consists of direct costs attributable to the operation of the endoscopy surgical suite facility. Such costs would include the rental of the endoscopy suite space, the rental of endoscopy equipment, space build out and equipment financing costs, endoscopy staff compensation, the cost of endoscopy utilities and supplies, and apportioned back-office staff costs associated with endoscopy billing, collections and medical records. Note also that Financial Exhibit A does not account for the $669,456 debt that Dr. Ona incurred to fund the operating deficits, and that will have to be repaid over time outside of the Practice and OEC (see paragraph immediately below).

The substantial $669,456 office-based endoscopy operating loss was funded by capital contributions made by Dr. Mel Ona to his Practice. Dr. Mel Ona funded these capital contributions from personal funds, and from funds borrowed from his wife and father. Dr. Mel Ona and the Practice cannot continue to sustain these material operating losses. To continue the important endoscopy services currently provided by the Practice, OEC must expeditiously obtain a surgery center CON and license, which would allow OEC to bill a surgery center facility component. Revenues generated by the endoscopy surgery center facility reimbursement would provide sufficient funds to ensure the future financial viability of endoscopy operations for the patients of the Practice.

As discussed above, Medicare and Medicaid do not pay a separate facility reimbursement when endoscopy procedures are performed in a physician office, and only pay a modest additional site of service professional fee reimbursement. Financial Exhibit B below illustrates the material difference in the Medicare endoscopy physician practice site of service payment differential, as compared to the substantial separate facility payment when endoscopy procedures are performed at a licensed ambulatory surgery center.

Financial Exhibit B: 2021 Medicare Payment Rates Endoscopy Services

2021 Medicare Payment Rates Endoscopy Services					
CPT Code	ASC Endo Professional Fee [1]	Practice Endo Professional Fee [2]	Site of Service Practice Payment Differential [3]	ASC Facility Fee [4]	Payment Difference Practice vs ASC [5]
43235	$124.57	$311.60	$187.03	$411.32	$224.29
43239	$140.27	$400.92	$260.65	$411.32	$150.67
45378	$188.42	$356.96	$168.54	$403.11	$234.57
45380	$204.13	$461.64	$257.51	$526.70	$269.19
45385	$265.20	$516.86	$251.66	$526.70	$275.04
45390 [6]	$337.07	$0.00	$0.00	$1,153.08	$1,153.08

[1] Represents the endoscopy procedure Medicare professional fee reimbursement at an ASC.
[2] Represents the endoscopy procedure Medicare professional fee reimbursement at a physician practice.
[3] Column 1 subtracted from column 2. Represents the Practice site of service additional endoscopy professional fee payment.
[4] Represents the Medicare endoscopy procedure facility fee.
[5] Column 3 subtracted from column 4. Represents the additional Medicare facility payment for endo procedures performed at ASCs.
[6] Endo CPT Code 45390 does not have a Practice Medicare reimbursement.

If an ambulatory surgery center CON is granted to OEC, the Practice will transition all endoscopy operations to OEC, and OEC will obtain the necessary surgery center licenses and permits to enable it to bill and collect a surgery center facility component from both public program payers and private insurers. OEC's ability to bill and collect a surgery center facility component will generate sufficient additional endoscopy revenues to overcome historical Practice endoscopy operating losses, and will allow the Practice physicians to continue to provide valuable endoscopy services for their patients. Financial Exhibit C below represents projected OEC endoscopy financial operations in the first year and third year after receiving a surgery center CON, and beginning operations as a licensed surgery center. The first year of projected ASC operations begins six months after OEC obtains its ASC CON and license, which is the first date OEC projects receiving Medicare/Medicaid facility fee revenues. This six-month delay in receipt of Medicare/Medicaid facility fee collections takes into account the time required to obtain CMS ASC certification, a Medicare provider number, credentialing with all insurers, and

the normal billing and collection delay for facility fees billed under the new ASC provider number.

Financial Exhibit C:

	Projected 1st Yr of Operations	Projected 3rd Yr of Operations
Total Operating Revenue	$ 1,406,019	$ 1,576,521
Operating Expenses		
Medical Supplies & Linens	$ 148,273	$ 163,100
Equipment Lease Costs (in place of Depreciation)	$ 116,199	$ 116,199
Employee Benefits	$ 31,097	$ 32,652
Insurance	$ 3,015	$ 3,166
Interest	$ 86,172	$ 86,172
Legal & Accounting	$ 68,737	$ 22,683
ASC License & Accreditation Fees	$ 10,465	$ -
Office Supplies	$ 6,643	$ 7,307
Other Expenses	$ 47,534	$ 52,288
IT Expenses	$ 61,225	$ 61,225
Rent	$ 274,083	$ 283,675
Repairs & Maintenance	$ 5,128	$ 6,153
Salaries	$ 325,979	$ 440,108
Telephone	$ 83,790	$ 85,466
Utilities	$ 32,704	$ 34,339
Hawaii General Excise Tax	$ 55,387	$ 70,132
Total Expenses	$ 1,356,430	$ 1,464,665
Net Income from Operations	**$ 49,589**	**$ 111,856**
Add Back: Depreciation less Principal Payments		
Cash Available for Distribution Before Taxes	**$ 49,589**	**$ 111,856**

E. Relationship to the existing Health care system.

The future OEC endoscopy surgery center would continue the quality healthcare services currently provided by the Practice endoscopy center. The center would provide much needed endoscopy screening services in west Oahu. The updated guideline that recommends colorectal cancer screening beginning at age 45 underscores the need for colorectal cancer screening. Other than Dr. Mel Ona, Dr. Fernando Ona, and Dr. Jorge

Guzman, there are no other gastroenterology providers established in Kapolei and locations westward (e.g. Waianae, Makaha, Nanakuli). The ability to recruit additional gastroenterology providers to the area is hindered by the lack of available facilities to perform endoscopic procedures. The closest endoscopy center is 8.7 miles away, and is operated by Queens Medical Center (West Oahu. As discussed above, that endoscopy center is fully utilized, and has no capacity to serve additional patients. If OEC does not obtain a surgery center CON, and the Practice endoscopy center is forced to close, there is no other area endoscopy facility available to treat the Practice's existing endoscopy patients.

As stated above, we have performed over 2,200 high-quality, safe, endoscopic procedures since October 30, 2020. Indeed, this procedure volume is not material to other hospital outpatient providers in the area as the demand for high-quality endoscopy has increased significantly since the beginning of the COVID-19 pandemic. Screening procedures are performed at the Practice endoscopy center because of the lack of conveniently located outpatient ambulatory endoscopy centers in west Oahu, thus this nominal endoscopy procedure volume generated predominantly by the father and son physicians should not be counted as lost volume to other centers. This CON application should satisfy the Administrative review eligibility criteria of not having a significant impact on the area healthcare system.

F. Availability of Resources.

Dr. Mel Ona, his father, Dr. Fernando Ona, and Dr. Jorge Guzman currently provide services at the Practice endoscopy center, and would continue to do so at the OEC endoscopy surgery center if a CON can be obtained. As discussed above, the center currently contracts with two independent anesthesiologists to provide sedation. Qualified personnel are recruited by invitation to apply through online resources. Other center staff resources are outlined in greater detail herein. See subparagraph 9.C. Quality of Service/Care.

Funding for the endoscopy center has been obtained from capital contributions obtained from the sole shareholder of the Practice (Dr. Mel Ona), an equipment lease from the manufacturer, and a conventional bank loan. If OEC is granted a CON, then its ability to obtain a surgery center facility reimbursement will represent the additional financial funding necessary to ensure financial viability.

All staff for the endoscopy center are currently in place already and no additional staff are anticipated upon establishment of the ambulatory surgery center.

10. ELIGIBILITY TO FILE FOR ADMINISTRATIVE REVIEW. This project is eligible to file for Administrative review because: (Check all applicable)

_____ It involves bed changes, which will have a capital expense of $1,000,000 or less, and which will have an increased annual operating expense of less than $500,000.

_____ It involves service changes which will have a capital expense of $1,000,000 or less, and which will have an increased annual operating expense of less than $500,000.

_____ It is an acquisition of a healthcare facility or service, which will result in lower annual operating expenses for that facility, or service.

_____ It is a change of ownership, where the change is from one entity to another substantially related entity.

_____ It is an additional location of an existing service or facility.

__x__ The applicant believes it will not have a significant impact on the health care system. See the detailed discussion in support of this application criteria outlined in paragraph 9 above (Executive Summary).