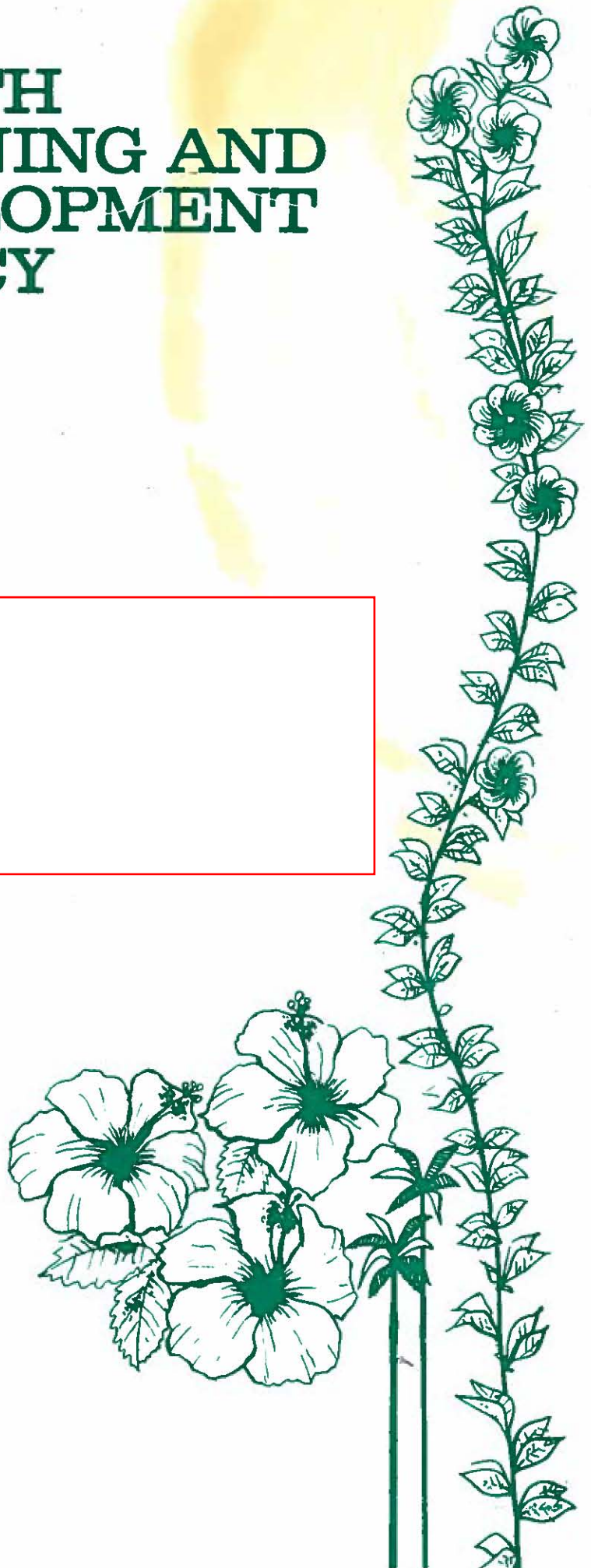


GUAM HEALTH PLANNING AND DEVELOPMENT AGENCY



**TERRITORY OF GUAM
CERTIFICATE OF NEED REGULATIONS
AND REVIEW PROCEDURES**

EFFECTIVE DATE: Nov. 3, 1984

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I. Certificate of Need Regulations

A. Purpose, Authority, and Scope of the Certificate of Need Review Program

In response to the perceived rapid increase of health care costs in the United States, Congress developed the Certificate of Need program as a means of controlling health care costs through the elimination of health care system inefficiencies, excess capacity, duplication and the maldistribution of services, and the unnecessary use of health technology and equipment. The aim of the Certificate of Need program is to allow for the development of accessible, cost-effective health care systems which provide quality services.

As a means of achieving Congress' intent, the Guam Health Planning and Development Agency, designated as the health planning and development agency for Guam, was authorized to administer the Guam Certificate of Need program in accordance with the Federal regulations established by U.S. P.L. 93-641, 96-79, 96-538, and 97-35, as well as the local regulations established by Guam P.L. 14-150 and 16-120.

The Guam Certificate of Need program applies to the obligation of capital expenditures, the offering of new and institutional health services, changes in bed capacity, the acquisition and development of health care facilities, and the acquisition of major medical equipment within the Territory of Guam.

Only the Guam Health Planning and Development Agency (or the appropriate judicial review body) is empowered to issue, deny, or withdraw certificates of need, grant exemptions from Certificate of Need reviews, or determine that certificate of need reviews are not required.

GHPDA shall issue a Certificate of Need only for those obligations of capital expenditures, offerings of new and institutional health services, and acquisitions of major medical equipment which are determined to be needed.

Persons shall obligate capital expenditures, offer new and institutional health services, or acquire major medical equipment only after a Certificate of Need is issued or an exemption under section C(2) and (3) is obtained.

Persons shall not obligate capital expenditures, offer institutional health services or acquire major medical equipment if a Certificate of Need authorizing that obligation, offering, or acquisition has been withdrawn or denied by GHPDA.

Any person who violates any provision of these rules and regulations shall be subject to the enforcement provisions established under Section F of these regulations.

B. General Provisions

(1) Definitions

Whenever used in this program and in proceedings brought under this chapter, unless the context requires otherwise:

Abortion means the termination of a human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.

Acquisition means any purchase, lease, donation, or other transaction involving major medical equipment, health care services, or health care facilities.

Acute Bed Services refer to those inpatient services provided to patients whose average length of stay is usually less than thirty days.

Acute Psychiatric Services means twenty-four hour inpatient acute care services for mentally ill patients whose length of stay is usually less than thirty days.

Affected Persons include the applicant; the Agency; any person residing within the geographic area served or to be served by the applicant; any persons who regularly use health care facilities within the geographic area; health care facilities and health maintenance organizations which provide services similar to the services of the facility under review; health care facilities and health maintenance organizations which, prior to receipt by the Agency of the proposal being reviewed, have formally indicated an intention to provide similar services in the future; third party payers who reimburse health care facilities for services in the Territory; and any agency which establishes rates for health care facilities or health maintenance organizations located in the Territory.

Agency means the Guam Health Planning and Development Agency, authorized by Public Laws 14-150 and 16-120 to conduct the Territory's health planning and development programs in accordance with U.S. Public Law 93-641 as amended by 96-79, 96-538, and 97-35.

Alcohol Rehabilitation Services mean services to a person who has been an alcohol abuser, to restore the person to the fullest physical, mental, social, vocational, and economic usefulness of which the person is capable.

Allopathic Physician means a physician practicing a philosophy of medicine which views the role of the physician as an active interventionist who attempts to counteract the effect of a disease by using treatments, surgical or medical, which produce effects opposite to those of the disease.

Ambulatory Surgical Facility means a facility, not a part of a hospital, which provides surgical treatment to patients not requiring hospitalization. The term does not include the offices of private physicians or dentists, whether for individual or group practice.

Applicant means any person who applies to the Agency for a Certificate of Need or for an exemption from Certificate of Need requirements.

Bed means a bed in a hospital or other inpatient health care facility which is maintained for continuous (24-hour) use by inpatients.

Capital Expenditure means an expenditure made by or on behalf of a health care facility which under generally accepted accounting principles is not properly chargeable as an expense of operations and maintenance. Capital Expenditures include: the site acquisition cost of land and buildings; or fair market value of land and buildings if leased; the total cost of construction including all site improvements; the cost of all major medical equipment; or fair market of major medical equipment value if leased; the cost of all professional fees associated with the development of the project, including fees for architectural

engineering, legal, accounting, feasibility, planning and financial services; the cost of all fees associated with financing, including any bond discount; and the cost of all interest to be incurred on funds borrowed during construction, (but not including the accrued interest expense of permanent financing).

Cardiac Catheterization means a special diagnostic procedure that is used to examine and evaluate the heart and the blood vessels which function to bring blood to, or away from, the heart. Cardiac catheterization includes left or right heart catheterization, angiography, and coronary arteriography.

Certificate of Need means a written authorization for the acquisition of major medical equipment, the offering of a new health service by or on behalf of a health care facility, or the obligation of certain capital expenditures by or on behalf of a health care facility for which a need is recognized. Certificate of Need are issued by the Agency or the appropriate judicial review body as specified in U.S. P.L. 93-641, 96-79, 96-538, and 97-35; and local P.L. 14-150 and 16-120.

Child Orthopedic Services mean long-term therapeutic and restorative services to children with orthopedic problems.

Chronic Renal Dialysis Services mean services for the treatment of irreversible kidney failure involving the removal of waste substances from a patient's blood by hemodialysis or peritoneal analysis.

Clinic means a health care facility, not a part of a hospital, which provides services relating to the diagnosis and treatment of patients on an outpatient or ambulatory basis, which is owned and operated by an individual, partnership, or group of physicians by formal arrangement, in which diagnostic resources are combined and shared, and, which has through formal contractual arrangement enlisted the services of other health care professionals to provide clinical laboratory, diagnostic radiology, and pharmacy services, such services which are provided within the same building or complex of buildings.

Clinical Laboratory Services mean services for the testing of specimens from the human body to aid in the diagnosis and treatment of diseases and in the maintenance of health.

Computed Tomography Services include diagnostic procedures involving computer analysis of a series of x-rays of the head or body resulting in the construction of an image.

Consumer of Health Care means any person whose occupation is other than the administrator of health activities or the provider of health services, who has no fiduciary obligation to a health care facility or other health agency, and who has no material or financial interest in the rendering of health service

Critical Care Services mean those services which provide maximum observation and support of vital functions and definitive therapy for patients with acute but reversible life-threatening impairments of single or multiple vital organ systems.

Day means a calendar day unless otherwise specified.

Dental Health Services refer to the range of services related to the prevention, diagnosis, and treatment of diseases of the teeth and related structures and maintenance of oral health.

Diagnostic Radiology Services mean services for the detection of physical disease and other ill-health conditions through the use of radiant energy including x-rays, cine fluorography, ventriculography and angiocardiology.

Drug Rehabilitation Services mean services to a person who has been dependent on licit or illicit drugs, to restore the person to the fullest physical, mental, social, vocational, and economic usefulness of which the person is capable.

Emergency Room Services mean services provided in a designated unit within a hospital for the immediate treatment of injury and other types of health emergencies.

Expenditure Minimum for Capital Expenditures means \$600,000.

Expenditure Minimum for Annual Operating Costs means \$250,000.

Family Planning refers to services which help families limit the family size and the spacing of years between children as well as the services which help couples with problems related to the bearing of children.

Fiduciary Position or Interest as applied to an entity means a position or interest characterized by a relationship of trust with respect to such entity, including the entity's members of boards of directors and officers, majority shareholders, agents, and attorneys.

Free-Standing Birthing Center means a public or private facility that is not a hospital nor administered by a hospital, which receives maternity patients and provides care during pregnancy, delivery, and the immediate post-partum period, and which limits such services to the low risk maternity mother and her newborn.

Guam Health Coordinating Council or GHCC means the body established pursuant to section 1524 of the U.S. Public Health Service Act to advise the Guam Health Planning and Development Agency.

Health includes physical and mental health.

Health Care Facility means all building units in which health care services are provided and includes the following: hospital, skilled nursing facilities, kidney disease treatment centers (including freestanding hemodialysis units),

intermediate care facilities, rehabilitation facilities, ambulatory surgical facilities, clinics, free-standing birthing centers, but does not include Christian Science sanatoriums operated or listed and certified by the First Church of Christ, Scientist, Boston, Massachusetts, and physician offices whether for individual, solo, or group practice.

Health Maintenance Organization or HMO means a public or private organization established under the laws of any State or Territory:

- (1) Which is a qualified health maintenance organization under section 1310(d) of the Public Health Service Act; or
- (2) Which:
 - (a) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, x-ray, emergency and preventive services, and out of area coverage; and
 - (b) Is compensated (except for co-payments) for the provision of the basic health care services listed in paragraph 2.(a) of this definition to enrolled participants by a payment which is paid on a periodic basis without regard to the date health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and
 - (c) Provides physicians' services primarily:
 - (i) Directly through physicians who are either employees or partners of the organization, or
 - (ii) Through arrangements with individual physicians or one or more groups of physicians, (organized on a group

practice or individual practice basis).

Health Services means clinically-related (i.e., diagnostic, treatment, or rehabilitative) services, and includes alcohol, drug abuse, and mental health services.

Hospital means an institution which primarily provides to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for the medical diagnosis, treatment and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. This term also includes psychiatric and tuberculosis hospitals.

Intermediate Care Facility (ICF) means an institution which provides, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility provides, but who because of their mental or physical condition require health-related care and services above the level of room and board.

Immediate Family means parents, spouse, children, brothers, and sisters who reside in the same household.

Long-Term Bed Care Services refer to those inpatient services provided to patients who are chronically ill, aged, disabled, or retarded and whose average length of stay is usually thirty days or more.

Major Medical Equipment means a single unit of medical equipment or a single system of components with related functions which is used to provide medical and other health services and which costs more than \$400,000. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services, if the clinical laboratory

is independent of a physician's office and a hospital and has been determined under Title XVIII of the Social Security Act to meet the requirements of paragraphs (10) and (11) of section 1861(s) of that Act. In determining whether medical equipment costs more than \$400,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to acquiring the equipment shall be included. If the equipment is acquired for less than fair market value, the term 'cost' means the fair market value.

Medical/Surgical Services include those inpatient diagnostic and treatment services utilizing medical or operative procedures.

Mental Health Services mean the diagnosis and treatment of emotional and mental diseases and conditions or their symptoms through the administration of medication and specialized therapy.

Mental Retardation Services mean services for the diagnosis and treatment of persons who have a significant sub-average general intellectual functioning and deficits in adaptive behavior which one manifested during the developmental period of life.

Monitored Care Services mean progressive care services involving a system of cardiac monitoring provided by staff who are qualified to handle cardiac irregularities but where the level of surveillance is below that found in critical care services.

Neonatal Intensive Care Services refer to the provision of care for newborns who require prolonged respiratory support, continuous cardiopulmonary support, intravenous therapy, major surgery, or treatment for infections.

Neurosurgery means surgery of any part of the nervous system.

Nuclear Medicine Services mean the services of a medical specialty that

uses radionuclides (elements which give off an emanation which is detectable by various instruments) for diagnosis and treatment.

Obligation means the incurrence of a capital expenditure by or on behalf of a health care facility:

- (1) When a contract, enforceable under Guam law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset; or
- (2) When the governing board of the health care facility takes formal action to commit the facility's funds for a construction project undertaken by the health care facility as its own contractor; or
- (3) In the case of donated property, on the date on which the gift is completed under applicable Guam law.

Obstetric Services mean those services for the care of women during pregnancy, childbirth, and after delivery, including prenatal care, labor, delivery, and postpartum care.

Open Heart Surgery means a surgical procedure requiring the circulation of the blood by a heart-lung machine while the heart or surrounding blood vessels are repaired.

Osteopathic Physician means a physician practicing a philosophy of medicine based on the theory that the normal body, when in correct adjustment, is a vital mechanical organism naturally capable of making its own responses to and defense against diseases, infections and other toxic conditions. The physician may use physical, hygienic, medicinal, and surgical measures to search for, and, if possible, correct any peculiar position of the joints or tissues, or peculiarity of diet or environment which is a factor in destroying the natural resistance.

Outpatient Clinic Services mean organized non-emergency services for the diagnosis and treatment of patients who are ambulatory and do not require hospitalization.

Outpatient Surgical Services mean services provided to treat a medical condition by surgery in an outpatient or ambulatory surgical center where the patient is not kept overnight. This term is synonymous with Ambulatory Surgical Services.

Pediatric Services mean those inpatient services for the diagnosis and treatment of diseases and conditions of children.

Person means an individual, a trust or estate, a partnership, a corporation (including association, joint stock companies, and insurance companies), a Territory, a political subdivision or an instrumentality (including a municipal corporation) of a Territory, or any legal entity recognized by the Territory.

Pharmacy means a location where drugs are dispensed in a health care facility.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the Territory.

Physician Office means the place designated for the provision of diagnostic, treatment and consultation services between physician and patient. The term does not include clinics, hospitals or other places of medical care.

Prenatal Services mean services provided to pregnant women.

Prevention and Detection Services mean services delivered to individuals in order to promote optimum physical and mental well-being, including protection from the development of disease and illness, or identification of disease and illness at the presymptomatic or unrecognized symptomatic stage to permit early intervention.

Provider of Health Care means an individual:

- (1) Who is a direct provider of health care (including, but not limited to, a physician, dentist, nurse, podiatrist, optometrist, or physician assistant,) in that the individual's primary current activity is the provision of health care to individuals or the administration of facilities or institutions (including, but not limited to, hospitals, long-term care facilities, substance abuse treatment facilities, outpatient facilities, and health maintenance organizations,) in which such care is provided and, when required by Territorial law, the individual has received professional training in the provision of such care or in such administration and is licensed or certified for such provision or administration; or
- (2) Who holds a fiduciary position with, or has a fiduciary interest in, any entity described in clause (b) or (c) of subparagraph (3) below; or
- (3) Who receives, either directly or through the individual's spouse, more than one-tenth of his gross income from any one or combination of the following:
 - (a) fees or other compensation for research into or instruction in the provision of health care; or
 - (b) entities or associations or organizations composed of entities or individuals engaged in the provision of health care or in such research or instruction; or

- (c) producing or supplying drugs or other articles for individuals or entities for use in the provision of, or in research into, or instruction in the provision of health care; or
- (d) entities or associations or organizations composed of such entities or individuals engaged in producing drugs or such other articles; or
- (4) Who is a member of the immediate family of an individual described in subparagraph (1), (2), or (3) above; or
- (5) Who is engaged in issuing any policy or contract of individual or group health insurance for hospital or medical service benefits.

Psychiatric Hospital means an institution which primarily provides to inpatients, by or under the supervision of a physician, specialized services for the diagnosis, treatment and rehabilitation of mentally ill and emotionally disturbed persons.

Psychiatric Services mean specialized services for the diagnosis, treatment or rehabilitation of mental illnesses or mental disorders in persons.

Radiation Therapy Services include services for the treatment of physical conditions or illnesses, primarily cancer, through the use of external ionizing radiation.

Recompression Center Services mean services at any location for the artificial restoration of pressure, especially the return to conditions of normal pressure after exposure to greatly diminished atmospheric pressure, and for the treatment of "bends" and related disorders.

Rehabilitation Services mean inpatient services to restore the ill or disabled person so as to achieve the fullest physical, mental, social, vocational, and economic usefulness of which the person is capable.

Skilled Nursing Facility (SNF) means an institution or a distinct part of an institution which primarily provides skilled nursing care and related services for inpatients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

Social Services mean programs provided by trained personnel to enable a patient, family members, or others to deal with the problems affecting the patient's social functions and well-being.

Territory means the Island of Guam.

Transplant Surgery Services include services for the transplant of an organ from one person to another person.

Tuberculosis Hospital means an institution which primarily provides to inpatients, by or under the supervision of a physician, medical services for the diagnosis and treatment of tuberculosis.

Tuberculosis Services mean therapeutic and supportive services for patients with tuberculosis who require long-term inpatient care.

Ultrasound Services mean services involving equipment using ultrasound (an acoustical frequency approximately 20,000 cycles per second) for medical therapy and diagnosis.

(2) Adoption and Public Notice of Regulations, Review Procedures, and Criteria

- (a) The Guam Health Planning and Development Agency shall adopt, review, and revise as necessary the local Certificate of Need regulations, review procedures, and criteria prior to conducting reviews.
- (b) The Guam Health Planning and Development Agency and the Guam Health Coordinating Council shall cooperate in the development of the local regulations, procedures, and criteria in order to achieve efficient reviews and consistent criteria for reviews.
- (c) Prior to the adoption of review procedures and criteria, or any revisions of the procedures and criteria, the Agency shall give interested persons an opportunity to offer written comments on the local regulations, procedures, criteria, and any revisions thereof, which it proposes to adopt.
- (d) The Agency shall distribute copies of its proposed local regulations, review procedures, criteria, and proposed revisions thereof, to Territory-wide health agencies and organizations, the Guam Health Coordinating Council, and any agency which establishes rates for health care facilities or HMOs in Guam.
- (e) The Agency shall publish in one or more newspapers of general circulation on Guam, a notice stating that local regulations, review procedures, criteria, and any revisions thereof, have been proposed for adoption and

are available at the Agency's address for inspection and copying.

- (f) In adopting the Certificate of Need regulations, review procedures, criteria, and any revisions thereof, the Agency shall follow the rule-making procedures in Chapter III of Title XXV of the Government Code of Guam.
- (g) The Agency shall distribute copies of its adopted local regulations, review procedures, criteria, and any revisions thereof, to Territorywide health agencies and organizations, the Guam Health Coordinating Council, any agency which establishes rates for health care facilities or HMOs in Guam, the Secretary of Health and Human Services and other persons upon request.
- (h) The Agency may request from the Secretary of HHS an exception to the requirement of paragraph (2)(c) above. The request must be in writing and must contain a detailed explanation of the reasons for the request, and of the substitute publication procedures that the Agency intends to follow, if the exception is approved. The Secretary may grant an exception if he determines that the proposed substitute procedures do not adversely affect the rights of affected persons.

(3) Revision and Dissemination of Scope of Coverage

- (a) The Guam Health Planning and Development Agency may revise as necessary the Scope of Guam's Certificate of Need Program. In developing such revisions the Agency shall follow the procedures for adoption and public notice of regulations, review procedures and criteria established by section (2) above.
- (b) The Agency shall disseminate a description of the new scope of coverage prior to reviewing any project not previously within the scope of Guam's CON program coverage.
- (c) The new scope of coverage shall be disseminated to all health care facilities and HMO's on Guam. The Agency shall provide public notice of the new scope of coverage through the publishing of the new scope of coverage in one or more newspapers of general circulation.
- (d) Whenever the Scope of Coverage of the Guam CON program is revised, the Agency shall disseminate and publish a description of the revised scope as outlined above.

(4) Exceptions to the Use of Adopted Procedures

- (a) As necessary, the Agency may request for an exception to the use of any of the required review procedures from the Secretary of Health and Human Services. The request for the exception must be submitted in writing to the Secretary. Prior to the submission of such a request, the Agency shall give interested persons an opportunity to offer written comments on the exception. Copies of these comments are submitted along with the official request for an exception.**
- (b) In approving the request for an exception, the Secretary may establish substitute procedures to be implemented in lieu of the adopted procedures. These substitute procedures will be consistent with the purposes of the U.S. Public Health Service Act and will not adversely and substantially affect the rights of affected persons.**
- (c) Once the request for exception is approved, the Agency will distribute copies of the approved exception along with any substitute procedures to Territory-wide health agencies and organizations, the GHCC, agencies which establish rates for health care facilities or HMOs in the Territory, and others upon request.**

(5) Severability

If any provision of this chapter, or the application thereof, to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.

C. Scope of Coverage of the Certificate of Need Review Program

The Guam Certificate of Need program applies to the obligation of capital expenditures, the offering of new institutional health services, the establishment of new services, and the acquisition of major medical equipment.

(1) No person shall incur an obligation for a capital expenditure that is subject to review under paragraphs (2)(a), (b), (c)(i), or (2)(e) of this section without obtaining a Certificate of Need for the expenditure. An obligation for a capital expenditure shall be considered to be incurred by or on behalf of a health care facility:

(a) When a contract, enforceable under Guam law is entered into by or on behalf of the health care facility for the construction, lease or financing of a capital asset; or

(b) When the government board of a health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or

(c) In the case of donated property, on the date on which the gift is completed under applicable Guam laws.

(2) For the purposes of this program, "the obligation of capital expenditures, the offering of new institutional health services, and the acquisition of major medical equipment" mean the following:

(a) Capital Expenditures.

Capital expenditures that exceed the \$600,000 expenditure minimum. The obligation by or on behalf of a health care facility of any capital expenditure (other than to acquire an existing health care facility) that exceeds the \$600,000 expenditure minimum for capital expenditures shall be subject to a review.

In determining whether or not an expenditure exceeds the expenditure minimum, the costs of any studies, surveys, designs, plans, working drawings, specifications, and other activities (including staff effort and consulting and other services) essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included.

(b) Bed Capacity.

The obligation of any capital expenditure by or on behalf of a health care facility which is associated with any of the following changes in bed capacity within any two-year period shall be subject to a review:

- (i) An increase or decrease in the total number of beds, by ten beds or ten percent, whichever is less; or

- (ii) A redistribution of ten beds or ten percent of the beds, whichever is less, among various categories; or
- (iii) A relocation of ten beds or ten percent of the beds, whichever is less, from one physical facility or site to another.

(c) Health Services.

The obligation of any capital expenditure by or on behalf of a health care facility which is associated with any of the following ⁿcharges in health services shall be subject to a review:

- (i) The addition of a health service which was not offered by or on behalf of the facility within the previous twelve (12) months; or
- (ii) The termination of a health service which was offered in or through the facility; or
- (iii) The addition of a health service which is offered by or on behalf of a health care facility which was not offered by or on behalf of the facility within the twelve (12)-month period before the month in which the service would be offered and which entails annual operating costs of at least the expenditure minimum of \$250,000 for annual operating costs.

(d) Major Medical Equipment.

- (i) The acquisition by any person of major medical equipment that exceeds the \$400,000 expenditure minimum for major medical equipment which will be owned by or located in a health care facility shall be subject to review;
- (ii) The acquisition by any person of major medical equipment not owned by or located in a health care facility shall be subject to a review if:
 - (A) the notice of intent required by section II (2)(b)(i) is not filed in accordance with that section; or
 - (B) the Agency finds within thirty (30) days after the date it receive notice of intent, that the equipment will be used to provide services for inpatients of a hospital.

(e) Acquisitions of Health Care Facilities.

Except as provided in Section I(D) regarding HMOs, the obligation of a capital expenditure by any person to acquire an existing health care facility shall be subject to a review if:

- (i) the notice of intent required under Section II(2)(b)(i) is not filed in accordance with that section; or
- (ii) if the Agency finds within thirty (30) days after the date it receives the notice of intent, that the services or bed capacity of the facility will be changed in being acquired.

For the purposes of (2)(e)(ii) above, the following shall constitute a change in services:

- (A) a change in bed capacity as described in paragraph (2)(b) of this section; or
- (B) the addition of a health service which was not offered by or on behalf of the facility within the previous twelve (12) months, or;
- (C) the termination of a health service which was offered by or on behalf of the facility.

(f) Leases, Donations, and Transfers.

An acquisition by lease, donation, transfer or comparable arrangement shall be reviewed if the acquisition would be subject to review under paragraphs (2)(a) through (2)(e) of this section if made by purchase. An acquisition for less than fair market value shall be reviewed if the acquisition at fair market value would be subject to review under paragraphs (2)(a) through (2)(e) of this section.

(g) HMOs.

With respect to an HMO, or a health care facility controlled directly or indirectly by an HMO or a combination of HMOs, any activity specified in paragraphs (2)(a) through (2)(e) above which is undertaken by or on behalf of an inpatient care facility and the acquisition of major medical equipment by an ambulatory care facility of an HMO to the extent required by paragraph (2)(d) above, shall be subject to a review unless these

activities or the acquisition are exempt under Section I(D) pertaining to the special considerations afforded to HMOs.

D. Special Considerations Regarding HMOs.

HMOs are afforded special considerations with regards to the Certificate of Need program. These considerations are described below and constitute the applicability of the CON review program to HMOs.

(1) Coverage.

With respect to an HMO, or a health care facility controlled directly or indirectly by an HMO, or a combination of HMOs, any activity specified in paragraphs (2)(a) through (2)(e) of Section C, Scope of Coverage of the Certificate of Need Review Program, which is undertaken by or on behalf of an inpatient health care facility, and any acquisition of major medical equipment by an ambulatory care facility of an HMO to the extent required by paragraph C(2)(d) of Section C shall be reviewed unless these activities or the acquisition are exempt under paragraph D(2) of this section.

For the purposes of review as required above, the method of payment for services (i.e., prepaid or fee-for-service) is not relevant in determining whether an activity is subject to review.

Applications for a Certificate of Need by an HMO or a health care facility which is controlled, directly or indirectly, by an HMO, shall not be disapproved by GHPDA solely because the proposal is not discussed in the Guam Health Plan or Annual Implementation Plan.

(2) Exemptions from review for HMOs.

Any activity described in paragraph D(1) above shall be exempt from review if the applicant meets the requirements of paragraph D(2)(b) below, and if the activity is proposed to be undertaken by:

(a) An HMO or a combination of HMOs if:

- (i) the HMO or combination of HMOs has, in the service area of the HMO or the service areas of the HMOs in combination, an enrollment of at least 50,000 individuals; and
- (ii) the facility in which the service will be provided is or will be geographically located so that the service will be reasonably accessible to the enrolled individuals; and
- (iii) at least 75 percent of the patients who can reasonably be expected to receive the health service will be individuals enrolled with the HMO or HMOs in the combination; or

(b) A health care facility if:

- (i) the facility primarily provides or will provide inpatient services; and
- (ii) the facility is or will be controlled, directly or indirectly, by an HMO or a combination of HMOs which has, in the service area of the HMO or service areas of the HMOs in the combination, an enrollment of at least 50,000 individuals; and

- (iii) the facility is or will be located geographically so that the service will be reasonably accessible to the enrolled individuals; and
 - (iv) at least 75 percent of the patients who can reasonably be expected to receive the health service will be individuals enrolled with the HMO or HMOs in the combination; or
- (c) A health care facility (or portion thereof) if:
- (i) the facility is or will be leased by an HMO or combination of HMOs which has, in the service area or the service areas of the HMOs in the combination, an enrollment of at least 50,000 individuals, and on the date the application is submitted under paragraph (3) below of this section, at least fifteen (15) years remain in the term of the lease; and
 - (ii) the facility is or will be geographically located so that the service will be reasonably accessible to the enrolled individuals; and
 - (iii) at least 75 percent of the patients who can be reasonably expected to receive the health service will be individuals enrolled with the HMO.

(3) Application for Exemption of an HMO.

- { (a) Any activity of an HMO, or a health care facility controlled directly or indirectly by an HMO, or a combination of HMOs shall not be exempt under paragraph D(2) of this section unless:

- (i) the applicant has submitted at the time and in the form and manner prescribed by the Agency, an application for an exemption; and
 - (ii) the application contains the information respecting the HMO, or health care facility controlled directly or indirectly by an HMO, or a combination of HMOs, and the proposed offering, acquisition, or obligation that the Agency may require to determine if the HMO or combination of HMOs meets the requirements of paragraph D(2) above of this section, or if the facility controlled directly or indirectly by an HMO meets or will meet those requirements; and
 - (iii) the Agency approves the application.
- (b) The Agency will approve an application submitted under this paragraph if the applicable requirements of paragraph D(2) above of this section have been met or will be met on the date the proposed activity, for which an exemption was requested, will be undertaken.
- (4) Sale, Lease, Acquisition or Use of HMO Exempt Facilities or Equipment.

A health care facility (or portion thereof) or medical equipment for which an exemption was granted under paragraph D(2) above of this section shall not be sold or leased. A controlling interest in the facility or equipment or in a lease of the facility or equipment shall not be acquired,

and a health care facility described in paragraph D(2)(c) above of this section shall not be used by any person other than the lessee described in paragraph D(2)(c) unless:

- (a) The Agency issues a Certificate of Need for the sale, lease, acquisition, or use; or
- (b) The Agency determines upon application that:
 - (i) the entity which intends to buy or lease the facility or equipment, or to acquire the controlling interest in the facility or equipment which intends to use the facility or equipment is an HMO or a combination of HMOs which meets the requirements of paragraph D(2)(a)(i) above of this section; and
 - (ii) with respect to the facility or equipment, the entity meets the requirements of paragraph D(2)(a)(ii) and (iii) above of this section, or paragraph D(2)(b)(i) and (ii) of this section.

(5) Required Approvals for HMOs.

Notwithstanding general review criteria established in accordance with section I H., the Agency shall approve the application for a Certificate of Need by an HMO or a health care facility which is controlled, directly or indirectly, by an HMO if it finds in accordance with criterion 20 that:

- (a) Approval of the application is required to meet the needs of the members of the HMO and of the new members which the HMO can reasonably expect to enroll; and

- (b) The HMO is unable to provide, through services or facilities which can reasonably be expected to be available to the HMO, its health services in a reasonable and cost-effective manner which is consistent with the basic method of operations of the HMO and which makes these services available on a long-term basis through physicians and other health professionals associated with it.

E. Required Approvals.

- (1) Except as provided in paragraph E(1)(b) below of this section, the Agency shall issue a Certificate of Need for a proposed capital expenditure if:
 - (a) The capital expenditure is required to:
 - (i) eliminate or prevent imminent safety hazards as defined by federal, or local; fire, building, or life safety codes or regulations; or
 - (ii) to comply with local licensure standards; or
 - (iii) to comply with accreditation or certification standards which must be met to receive reimbursement under Title XVIII of the Social Security Act or payments under a State plan for medical assistance approved under Title XIX of that Act; and
 - (b) The Agency has determined that:
 - (i) the facility or service for which the capital expenditure is proposed is needed; and
 - (ii) the obligation of the capital expenditure is consistent with the Guam Health Plan.
- (2) Those portions of a proposed project which are not required to eliminate or prevent safety hazards or to comply with certain licensure, certification, or accreditation standards are subject to review using the criteria developed under Section I.H.



F. Required Finding of Access.

- (1) For each project it approves, the Agency shall make written findings (which shall take into account the current accessibility of the facility as a whole) on the extent to which the project will meet the considerations in criterion 5, relating to the need of the population to be served for the proposed project and the extent to which the residents of the area will have access to the project, except in the following cases:
 - (a) The project is one described in Section I.E. (projects to eliminate or prevent certain imminent safety hazards or to comply with certain licensure or accreditation standards); or
 - (b) Where the project is a proposed capital expenditure not directly related to the provision of health services, or to beds, or to major medical equipment; or
 - (c) Where the project is proposed by or on behalf of an HMO or a health care facility which is controlled, directly or indirectly, by an HMO.
- (2) In any case where the Agency finds that an approved project does not satisfy the considerations of criterion 5, the Agency may, if it approves the application, impose the condition that the applicant take affirmative steps to meet this criterion.

- (3) When this written finding is required, the Agency, in evaluating the accessibility of the project, shall take into account the current accessibility of the facility as a whole. If the Agency disapproves a project, for failure to meet the need and access considerations of criterion 5, the Agency must so state in its written findings on the application.
- (4) In any case where the Agency finds that a project does not satisfy criterion 5, it shall so notify, in writing, the applicant, and the Region IX Office of the Department of Health and Human Services.

G. Enforcement Authority.

- (1) The Agency shall issue a Certificate of Need only for those obligations of capital expenditures, offerings of new and institutional health services, and acquisitions of major medical equipment which are determined to be needed.
- (2) Persons shall obligate capital expenditures, offer new and institutional health services, or acquire major medical equipment only after a Certificate of Need is issued or an exemption under sections I.D.(2) and (3) is obtained.
- (3) Persons shall not obligate capital expenditures, offer new and institutional health services, or acquire major medical equipment if a Certificate of Need authorizing that obligation, offering, or acquisition has been withdrawn or denied by the Agency.
- (4) No permit or license shall be issued by any Territorial Officer or government agency for the development, construction, expansion, alteration, conversion, institution or modification of a health care facility or health care service or for the operation of a new health care facility or health care service, unless there is submitted, in connection with the application for such a permit or license, a current Certificate of Need issued by the Agency or a statement issued by the Agency that the health care facility or health care service is not required to hold a Certificate of Need as established by these regulations.

- (5) Any person who violates any provision of this Subchapter or rules and regulations thereunder, with respect to the requirements for a Certificate of Need and Section 5103(g) of Article 1 of P.L. 14-150, as amended by P.L. 16-120, shall be guilty of a misdemeanor for each seven-day period, or fraction thereof, that the violation continues. Each subsequent seven-day period shall constitute a separate offense.
- (6) The Agency shall, in the name of the people of the Territory, through the Attorney General of the Territory, apply for an injunction in any court of competent jurisdiction to enjoin any person that has not received a Certificate of Need; and upon the filing of a verified petition in the court, the court, or any judge thereof, (if satisfied by affidavit or otherwise, that the person is or has been proceeding with an action covered under Subchapter I.C. of these regulations without notice or bond), will enjoin the defendant from further action. A copy of the verified complaint shall be served upon the defendant and the proceedings shall be thereafter conducted as in other civil cases. If it is established that the defendant has been or is proceeding with an action covered under Section I.C. without a Certificate of Need, the court, or any judge thereof, may enter a decree enjoining the defendant from further action. In case of violation of any injunction issued under this Section, the court may summarily try and punish the offender for contempt of court. The injunction proceedings shall be in addition to, and not in lieu of, all penalties and other remedies provided for in this Article.

H. Criteria and Standards for a Certificate of Need.

To the extent applicable, each application for a Certificate of Need shall be reviewed for consistency and compliance with the criteria and standards listed below. Those project proposals comparing favorably with all the established (and applicable) criteria and standards against which they are compared should receive favorable findings towards the issuance of a Certificate of Need. Those project proposals which do not compare favorably with the established (and applicable) criteria and standards against which they are compared should receive unfavorable findings leading towards the denial of a Certificate of Need.

Each criterion indicates the general considerations to be addressed by the proposal; while the standards represent the qualitative and quantitative existence or non-existence of the desired qualities addressed by the criterion. Thus, failure to favorably comply with the standard will result in the determination that the project proposal fails to adequately address the concerns of the stated criterion and will likely result in the denial of a Certificate of Need. Note that not all criterion and standards are applicable to every proposal, thus, based upon the filing of a notice of intent, the Agency will distribute the appropriate application forms indicating which criteria and standards the proposal should address in order to obtain a Certificate of Need.

Criterion 1: The relationship of the health services being reviewed to the Guam Health Plan, Annual Implementation Plan and other applicable health systems plans.

Standard:

The proposed project is supportive of and contributes to the health care objectives for Guam as prescribed by the Guam Health Plan and the Annual Implementation Plan.

Criterion 2: The relationship of services reviewed to the long-range development plan (if any) of the person providing or proposing the services.

Standards:

The project or proposal is consistent with or is identified as an element of the applicant's long-range plans and aspirations for the future indicating the applicant's commitment to achieve their stated plans or objectives.

Criterion 3: The availability of less costly or more effective alternative methods of providing the services to be offered, expanded, reduced, relocated or eliminated.

Standard:

The services to be offered, expanded, reduced, relocated or eliminated are the most desirable of available alternatives with respect to less costly or more effective methods of service provision.

Criterion 4: The immediate and long-term financial feasibility of the proposal, as well as the probable effect of the proposal on the costs of and charges for providing health services by the persons proposing the service.

Standards:

(a) The project is financially feasible with respect to the immediate and long-term financial obligations of the applicant.

(b) The project will not adversely affect the applicant's cost of, or charges for, providing health services.

Criterion 5: (a) The need that the population served or to be served has for the services proposed to be offered or expanded, and the extent to which all residents of the areas, and in particular, low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, are likely to have access to those services.

(b) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the need that the population presently served has for the service, the extent to which that need will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, to obtain needed health care.

(c) The contribution of the proposed service in meeting the health-related needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (for example low income persons, racial and ethnic, minorities, women, and handicapped persons) particularly those identified in the applicable Annual Implementation Plan, and Guam

Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, GHPDA shall consider:

(i) The extent to which medically underserved populations currently use the applicant's services in comparison to the percentage of the population in Guam which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved;

(ii) The performance of the applicant in meeting its obligations, if any, under any applicable Federal regulations requiring the provision of Uncompensated Care, Community Service, or Access by minorities and handicapped persons to programs receiving Federal financial assistance (including the existence of any civil rights access complaints against the applicant);

(iii) The extent to which Medicare, Medicaid and medically indigent patients are served by the applicant; and

(d) The extent to which the applicant offers a range of means by which a person will have access to its services (e.g., outpatient services, admission by house staff, admission by personal physician, etc.).

Standards:

(a) The proposed project fills an unmet community need identified in the Guam Health Plan and Annual Implementation Plan, if the type of project is addressed in the plan.

(b) The project will enhance the accessibility of health services to all island residents.

(c) The project will contribute to meeting the health related needs of members of medically underserved groups through the provision of equal access to health services particularly those identified in the Guam Health Plan as deserving of priority, as demonstrated by the following information:

(i) The applicant shall provide a comparison of the portion of the medically underserved population currently using the applicant's services with the total medically underserved population of Guam.

(ii) The applicant shall describe the portion of the medically underserved population expected to use the proposed services, if approved.

(iii) The applicant shall describe the extent to which Medicare, Medicaid, and the Medically Indigent are served by the applicant.

(iv) The applicant shall, if applicable, provide a history of its or organization's past performance in meeting obligations regarding Federal Regulations requiring the provision of: Uncompensated Care, Community Service, and Access by minorities or handicapped persons to programs receiving federal financial assistance.

(v) The applicant shall describe the extent to which a range of means by which a person will have access to its services (e.g., outpatient, admission by house staff, admission by personal physician, etc.), are offered by the proposed project.

(d) In the event that the project entails a reduction, elimination or relocation of existing health care services, the proposal will address alternative options for the population currently being served to obtain necessary services. The applicant must illustrate how the need for such services or facilities will be adequately met by the proposed relocation, reduction or elimination or by alternative arrangement.

Criterion 6: The relationship of the services proposed to be provided to the existing health care system of the area in which the services are proposed to be provided.

Standards:

(a) The project will not adversely affect the utilization of other facilities offering the same or similar services on the island.

(b) The project emphasizes comprehensive and continuous services, and has coordinated cost-effective linkages with facilities providing health services within the immediate community and with facilities providing special services in adjacent service areas.

Criterion 7: The availability of resources (including health personnel, management personnel, and funds for capital and operating needs) for the provision of the services proposed to be provided and the need for alternative uses of these resources as identified by the Annual Implementation Plan or Guam Health Plan.

Standards:

(a) The applicant has the financial resources to successfully complete and implement the proposed project.

(b) The applicant possesses competent management and organizational skills both responsive to community needs and capable of completing and operating the project.

(c) The project will be optimally utilized in a financially feasible manner within a reasonable project time.

(d) The applicant possesses the necessary operational, personnel, and management resources required to develop, maintain, and operate the proposed services.

(e) The project program will be adequately staffed by qualified personnel.

Criterion 8: The relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services.

Standards:

(a) The applicant has established cooperative agreements with ancillary or support service providers to ensure the maximum utilization of facility and service resources.

(b) The project proposal promotes fiscal economics through measures that assure efficiency and effectiveness which may include operation of joint, cooperative, or shared facility care resources and maximum utilization of facilities.

(c) The applicant has developed community support to ensure the services proposed to be provided are adequate.

Criterion 9: The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in Guam.

Standard:

The means proposed for the delivery of health services will not adversely affect the clinical needs of health professional training programs on Guam.

Criterion 10: If the proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools in the area will have access to the services for training purposes.

Standard:

The project encourages health professional training by providing access to proposed services or facilities for training purposes.

Criterion 11: Special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service area in which the entities are located or in adjacent health service areas. These entities may include medical and other health professionals schools, multidisciplinary clinics and specialty centers.

Standard:

The project addresses the special needs and circumstances of those providers availing their services and resources to individuals residing in adjacent health service areas (off-island).

Criterion 12: The special circumstances of health care facilities with respect to the need for conserving energy.

Standards:

(a) The project will promote effective energy conservation and fuel efficiency programs in the development and delivery of health care services.

(b) The proposed project addresses the special circumstances of health care facilities with respect to the need for conserving energy.

Criterion 13: The factors which affect of competition on the supply of health services being reviewed in accordance with the need to avoid duplications in services and alleviate excess services, facilities, and supplies.

Standard:

The project will strengthen competition in such a way as to provide quality assurance, cost-effectiveness, increased accessibility and the availability of services avoiding unnecessary duplications.

Criterion 14: Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost-effectiveness, while avoiding the duplication of services and contributing to the alleviation of excess services, facilities, and supplies.

Standard:

The project promotes competition through the use of improvements or innovations in the financing and delivery of health services.

Criterion 15: In the case of existing services or facilities, the quality of care provided by those facilities in the past.

Standard:

The project will maintain high standards with respect to the quality of care to be provided.

Criterion 16: In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed.

Standard:

The proposed project fosters cooperative agreements to ensure the efficient utilization of resources and avoids a duplication of existing services and facilities similar to those proposed:

- (a) The applicant provides a listing of similar facilities and service programs on Guam by size and level of service provided;
- (b) The applicant indicates that the proposed project will provide a level of services appropriately matched to the level of care afforded by the project's scope of coverage;
- (c) The applicant indicates the degree to which duplication, or conflict, or potential duplication, or potential conflict with existing services or facilities are avoided.

Criterion 17: In the case of a construction project:

(a) The costs and methods of the proposed construction, including the costs and methods of energy provision; and

(b) The probable impact of the construction project being reviewed on the costs of providing health services by the person proposing the construction project, and on the costs and charges to the public of providing health services by other persons.

Standards:

(a) The costs and methods of the proposed construction provided by the applicant include costs and methods of energy provision.

(b) The construction of the proposed project will not adversely impact on the costs and provision of health services by the applicant and the costs and charges to the public of the provision of health services by others.

Criterion 18: The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need, and for which local conditions offer special advantages.

Standard:

The project will address a national biomedical or behavioral research concern's needs and circumstances to which local conditions offer special advantages.

Criterion 19: When an application is made by an Osteopathic or Allopathic facility for a Certificate of Need to construct, expand, or modernize a health care facility, acquire major medical equipment, or add services, the need for that construction, expansion, modernization, acquisition

of equipment, or addition of services shall be considered on the basis of the need for and the availability, in the community, of services and facilities for Osteopathic and Allopathic physicians and their patients. The Agency shall consider the application in terms of the proposed projects impact on existing and proposed institutional training programs for doctors of Osteopathy and medicine at the student, internship, and residency training levels.

Standard:

For application made by an Osteopathic or Allopathic facility proposing to construct, expand, modernize, acquire equipment or add services the following standards will apply:

- (a) The project addresses a community need for Osteopathic and Allopathic services and facilities by physicians and their patients.
- (b) The project enhances the availability of Osteopathic and Allopathic services and facilities in the community.
- (c) The project shall not impact adversely on existing and proposed institutional training programs for doctors of Osteopathy and medicine at the student, internship, and residency training levels.

Criterion 20: The special needs and circumstances of HMOs. These needs and circumstances shall be limited to:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health services proposed to be provided by the organization; and

(b) The availability of the new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the Agency shall consider only whether the services from these providers:

(i) Would be available under a contract of at least five (5) years duration; and

(ii) Would be available and conveniently accessible through physicians and other health professionals associated with the HMO. (For example - whether physicians associated with the HMO have or will have full staff privileges at a non-HMO hospital); and

(iii) Would cost no more than if the services were provided by the HMO; and

(iv) Would be available in a manner which is administratively feasible to the HMO.

Standards:

(a) The project meets the health service needs of enrolled members and reasonably anticipated new members of the HMO.

(b) The availability of new health services from non-HMO providers or other HMOs shall be in a reasonable and cost-effective manner consistent with the basic method of operation of the HMO. If the services proposed by the project are available through coordination or contract with non-HMO providers the Agency shall consider only whether:

(i) The project contract for such services is for a duration of at least (5) years; and

(ii) Services provided to the project will be available and conveniently accessible through the physicians and other health professionals associated with the HMO; and

(iii) Services to be provided to the project would cost no more than if the services were provided by the applicant HMO; and

(iv) The services provided will be available in a manner administratively feasible to the applicant.

II. Certificate of Need Review Procedures.

Each applicant proposing an obligation of capital expenditures, the addition of a new health service, the offering of new institutional health services, a change in bed capacity, the acquisition of a new health care facility, or the acquisition of major medical equipment shall obtain a Certificate of Need or an exemption in accordance with the following review procedures.

A. General Provisions.

(I) Provision Applying to the Applicant.

(a) Information Requirements.

The Agency may require no information of a person subject to review which is not prescribed and published as being required. Agency requests for information shall be limited to information necessary for the Agency to perform the review.

(b) Burden of Proof.

The applicant for a Certificate of Need or for an exemption from the Certificate of Need requirements shall have the burden of proof, including the burden of producing evidence and the burden of persuasion. The degree or quantum of proof shall be a preponderance of the evidence.

(c) Prohibited Conduct.

(i) no person shall influence or attempt to influence action on any application for a Certificate of Need or an exemption by fraud, misrepresentation, or corruption.

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(ii) no person shall submit or cause to be submitted false statements or information in connection with any application for a Certificate of Need or an exemption.

(iii) no person shall disrupt or interfere with the fair and orderly review of any application for a Certificate of Need or an exemption.

(iv) if any person violates any subsection of this section, the Agency may take appropriate action to protect the public interest, including, but not limited to, issuing a verbal or written warning to the person, excluding the person from any public meeting or public hearing on the application, denying any request made by the person in connection with the application, or dismissing without prejudice any application of the person pursuant to section II E(1).

(d) Withdrawal of Application.

The applicant has the right to withdraw the application for a Certificate of Need or exemption at any time before the Agency files a written decision on the merits of the application or before the Agency dismisses the application without prejudice.

(2) Provisions Apply to the Agency.

(a) Public Access.

The general public shall have access to all applications for a Certificate of Need or an exemption that are reviewed by the Agency and to all other written materials essential to any Agency Certificate of Need review.

(b) Agency Reports of Reviews.

The Agency shall prepare and publish, at least annually, a report of the Certificate of Need reviews conducted by the Agency. The reports shall be published in the Agency's annual report to the Governor. Each report shall include a statement regarding the status of each review being conducted by the Agency, a statement about each review completed by the Agency since the publication of the Agency's last annual report, and a general statement of the findings and decisions made during the course of the reviews.

B. Pre-application Conference.

The pre-application conference is the initial step in the review process.

Upon receipt of an inquiry by a prospective applicant, as to the requirements of the Certificate of Need program, the Agency shall schedule a pre-application conference with the prospective applicant. The pre-application conference shall serve as a means of acquainting the prospective applicant with the Certificate of Need program and review procedures prior to the development and submission of an application.

Upon completing the pre-application conference the prospective applicant is expected to have obtained a more precise understanding of the rules and regulations concerning the Certificate of Need process, the review criteria, and standards upon which the merits of the application will be reviewed, and other pertinent planning information regarding the proposal.

C. Notice of Intent.

- (1) Any person proposing a project that requires a Certificate of Need or that may be eligible for an exemption from a Certificate of Need review shall file a letter of intent at the earliest possible opportunity, but at least thirty (30) days prior to submitting a formal Certificate of Need application.
- (2) A letter of intent must be filed with the Agency:
 - (a) At least thirty (30) days before any person acquires or enters into a contract to acquire major medical equipment which will not be owned or located in health care facility; or
 - (b) At least thirty (30) days before any person acquires or enters into a contract to acquire an existing health care facility; or
 - (c) As early as possible in the course of planning a construction project.
- (3) The letter of intent shall describe the proposed project in such detail as may be necessary to inform the Agency of the nature and scope of the proposed project. At a minimum, the letter of intent shall include: a description of the proposed project; its estimated costs; its location; and its estimated schedule, showing phases of the project development, expected starting dates, expected dates of obligation of funds for the different project phases, and expected dates of completion of the project.

- (4) Within fourteen (14) days of receipt of a letter of intent, the Agency will notify the person as to whether the (informational) content of the letter of intent is complete or incomplete.

(a) Complete Letters.

When the Agency determines that the (informational) content of a letter of intent is complete, the Agency shall notify the applicant as to whether or not the proposed project is subject to a CON review, the type of review (substantive or non-substantive) to be employed, and the necessary application forms to be filed by the applicant.

(i) Projects subject to a review.

After receiving a complete letter of intent the Agency shall determine if a proposed project is subject to a review as specified by the Scope of Coverage of the Certificate of Need Review Program.

(ii) Projects not subject to a review.

In the event that the Agency determines, according to a complete letter of intent, that a proposed project is not subject to a review, the Agency shall so notify the applicant.

The notice to the applicant shall state that the project, as described, is not subject to a review but that, a change in the nature and scope of the proposed or completed project may require a Certificate of Need review.

(b) Incomplete Letters.

When the Agency determines that the (informational) content of a letter of intent is incomplete, the Agency shall notify the applicant of the additional information required to complete the letter of intent.

The applicant shall have fourteen (14) days from the date of receipt of the Agency's notification of the incomplete status to submit the additional information required to complete the letter of intent.

Within fourteen (14) days of receipt of the additional information, the Agency will notify the applicant as to whether the (informational) content of the letter of intent is complete or incomplete.

The Agency may require the person proposing a project to file additional information regarding the project with the Agency as the information becomes available during the course of planning for the project.

No application for Certificate of Need or an exemption shall be accepted by the Agency until a complete letter of intent has been filed by the applicant and reviewed by the Agency.

The Agency may at the applicant's request, issue a preliminary finding of need, advising the applicant as to whether the project is needed or not. Such a preliminary finding of need by the Agency does

not guarantee or imply that the application will ultimately be approved, as circumstances of need may change, and the proposal may not adequately address the other criteria for a Certificate of Need.

D. Application Conference.

Once the Agency has determined that a project proposal is subject to a Certificate of Need review, the Agency will inform the applicant of the type of review required and supply the necessary application forms. Additionally, the Agency will schedule an application conference to assist in the development of a complete application prior to its submission for review.

The application conference is intended to serve as a technical assistance meeting between the Agency and the applicant prior to the submission of an application for a Certificate of Need. The meeting is intended to facilitate a greater understanding of the application form requirements and the information to be provided.

At this meeting, the Agency staff member assigned to coordinate the review of the project proposal will discuss with the applicant the types of information required to address the criteria and standards; potential resources of information; existing planning documents which address the proposed project; available support data; and any other technical assistance as may be necessary to complete the application forms.

B. Length and Types of Reviews.

In order to facilitate the review of applications for a Certificate of Need, the Agency has developed a classification scheme to distinguish between substantive and non-substantive project proposals requiring a Certificate of Need review. The classification of project proposals in this manner allows for the provision of two distinct timeframes of review, with the more substantive project proposals undergoing a ninety (90) day review process, and the non-substantive, HMO, or exempted project proposals undergoing a forty-five (45) day review process.

The classification of a project to determine whether it is eligible for a substantive or non-substantive review shall be determined by the Agency. The classification process will occur upon the acceptance of a complete notice of intent and the issuance of relevant application forms to the applicant.

Projects subject to review may be classified under one of the following review categories:

(1) Substantive Review Process.

A substantive review requires a formal ninety (90) day review of the application once the application has been determined to be complete.

All proposed projects which do not qualify for exemptions, are not proposed on behalf of or by HMOs, and those which do not meet the requirements for a non-substantive review below, shall be classified as subject to a substantive review.

For all substantive reviews, the Agency shall render a decision regarding the issuance, denial or withdrawal of a Certificate of Need, no later than the ninetieth (90) day following the formal notification of the start of a review as established below.

As the Agency may, from time to time, during the course of a review, require additional information from the applicant, the substantive review's ninety (90) day timeframe may be extended for an additional thirty (30) day period to provide for the incorporation of this additional information into the review process.

(2) Non-Substantive Review Process.

A non-substantive review involves a formal forty-five (45) day review of the application once the application has been deemed complete.

(a) To qualify for a substantive review, the proposed project must meet at least one of the following conditions:

(i) the capital expenditure is required to meet the mandatory federal and local, accreditation, certification, and licensure standards, or for the elimination or prevention of imminent safety hazards; or

(ii) the proposed construction or modification is not related to the rendering of direct patient care services such as parking facilities, sprinkler systems, heating or air conditioning equipment, fire doors, food services, equipment, building maintenance , business-related equipment (e.g.,

data processing and word processing equipment), telephone system, energy conservation measures, land acquisition, and other projects of a similar nature as determined by the Agency; or

(iii) the proposed capital expenditure is an acquisition of diagnostic or therapeutic equipment and is solely a replacement with approximate capabilities of the existing equipment. Furthermore, the applicant has demonstrated to the Agency's satisfaction that the replacement equipment will not expand or extend the scope or type of services currently rendered by the health care facility; or

(iv) the proposed project qualifies for a review or an exemption from review as provided for in Subchapter I Section D regarding special considerations regarding HMO's; or

(v) the project is proposed by or on behalf of an HMO or a combination of HMO's; or

(vi) any other project which the applicant proposes and the Agency determines is qualified for a non-substantive review.

(b) Upon completion of a non-substantive review the Agency may issue one of the following findings:

(i) the Agency may issue a Certificate of Need based upon the merits of the application; or

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(ii) the Agency may issue a determination that the decision to issue, deny or withdraw a Certificate of Need cannot be made except through a formal ninety (90) day substantive review as the scope of the proposed project may be more involved than initially perceived.

(A) in the event that a ninety (90) day formal review is required by the Agency, the applicant must submit the additional information required by the substantive review process application forms.

(B) the determination by the Agency that a formal ninety (90) day review is needed shall have no bearing or impact upon the final decision of the Agency regarding the Certificate of Need.

Any and all decisions made with regard to the non-substantive review process shall be subject to appeal as provided for in this manual.

(3) Comparative Reviews.

When two or more applications which pertain to similar types of services, facilities, or equipment are received to facilities or equipment, the applications may be considered together in a comparative review in order to assure fair and equitable treatment for all such proposals. Proposals which pertain to similar types of services, facilities, or equipment will be treated in the following manner:

- (a) The Agency shall be responsible for determining whether the proposals pertain to similar types of services, facilities or equipment.
- (b) This determination will be made after each of the two or more applications is deemed complete. The applications for similar types of services, facilities or equipment will be reviewed together provided that:
 - (i) each application is deemed complete within thirty (30) days of the initiation of the first review cycle; and
 - (ii) the date of obligation of the first application allows sufficient time for the extension of the review cycle to complete the comparative review.
- (c) Applications which pertain to similar types of services, facilities or equipment are:
 - (i) proposals which address the same or similar needs as defined in the Guam Health Plan. Evidence for this criteria would include the same, similar, or overlapping target populations or geographical services areas; or
 - (ii) proposals which involve the same service; or
 - (iii) proposals which involve the same site; or
 - (iv) proposals in which the economic feasibility of one excludes the other.

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(d) When two or more proposals are determined to pertain to similar types of services, facilities, and equipment, and the conditions outlined in paragraph (2), above, are met, the proposals will be reviewed together in a comparative review by the Agency. This review will include a joint hearing if requested by affected persons.

(e) Applications slated for comparative reviews shall subcategorized into the following health service categories to facilitate reviews.

- i) general medical-surgical
- ii) psychiatric
- (iii) obstetric
- iv) pediatric
- v) skilled nursing
- vi) intermediate care
- vii) critical care
- viii) other

The final decision regarding a Certificate of Need on each application pertaining to similar services, facilities, or equipment shall be based on the same criteria and standards used for all applications.

(4) Subsequent Review.

(a) Capital Expenditures.

A proposed change in any project associated with a capital expenditure for which the Guam Health Planning and Development Agency has previously issued a Certificate of Need shall require a subsequent review if the change is proposed within one (1) year after the date the activity for which the expenditure was approved is undertaken.

This subsequent review provision applies to all capital expenditures subject to a review under paragraphs (a), (b), or (c) (i) of the Certificate of Need Scope of Coverage.

A subsequent review is required whether or not a capital expenditure is associated with the proposed change.

(b) Major Medical Equipment.

If a person acquires major medical equipment not located in a health care facility without a Certificate of Need, and proposes at any time to use that equipment to serve inpatients of a hospital, the proposed new use shall be subject to a subsequent review unless it will be used to provide services to inpatients of a hospital only on a temporary basis as in the case of:

- i) a natural disaster; or,
- ii) a major accident; or,
- iii) equipment failure.

In accordance with the above provision "temporary basis" shall be defined as a period of time not to exceed 120 calendar days in length.

(c) Existing Facilities.

If a person acquires an existing health care facility without a Certificate of Need, and proposes to change within one (1) year after the acquisition, the services or bed capacity of the facility, the proposed change must be reviewed if it would have required review under paragraph (e) of the Certificate of Need Scope of Coverage.

F. Submission of Application Forms.

Formal application forms for all projects subject to a review are available from the Guam Health Planning and Development Agency.

A complete application form is required of all applicants prior to the start of a review. Incomplete application forms will not be accepted.

An applicant for a Certificate of Need shall specify the time the applicant will require to make the service or equipment available, or to complete the project.

Applications may be filed with the Agency at any time during the Agency's official hours of operation at either the Agency's location or by certified mail to the Agency's official address.

The Agency shall not charge a filing fee for the application, but may charge the applicant for reproduction and mailing costs.

The Agency shall, upon receipt of an application, determine whether the application is complete or incomplete with regard to the informational requirements for a review, in the following manner:

(1) Substantive Reviews.

Within fifteen (15) days of receipt of an application for a Certificate of Need, the Agency shall determine whether the application provides complete or incomplete information sufficient to address the concerns of the Certificate of Need criteria and standards for a review.

In the event that the Agency determines that the application is incomplete, the Agency shall notify the applicant, in writing, of the deficiencies and any additional information required to complete the application.

The applicant shall have thirty (30) days from the date of receipt of a written notice from the Agency to submit the additional information necessary to complete the application.

The Agency shall review all additional information submitted and present written findings as to whether the application is complete or incomplete within fifteen (15) days of receiving the additional information.

Failure by the applicant to submit the additional information required within the allotted thirty (30) day time frame shall constitute for the Agency to deem the application to have been withdrawn by the applicant.

Extensions to the thirty (30) day time frame for the submission of additional information must be approved in writing by the Agency.

(2) Non-Substantive Reviews.

Within ten (10) days of receipt of an application for a Certificate of Need, the Agency shall determine whether the application provides complete or incomplete information sufficient to address the criteria and standards of a review.

In the event that the Agency determines that the application is incomplete, the Agency shall notify the applicant in writing of the deficiencies and any additional information required to complete the application.

The applicant shall have twenty (20) days from the date of receipt of a written notice from the Agency to submit the additional information necessary to complete the application.

The Agency shall review all additional information submitted and present written findings as to whether the application is complete or incomplete within ten (10) days of receiving the additional information.

Failure by the applicant to submit the additional information required within the allotted twenty (20) day time frame shall result in the application's being deemed to have been withdrawn by the applicant.

Extensions to the twenty (20) day time frame for the submission of additional information must be approved, in writing, by the Agency.

G. Procedures During the Course of Review.

Once an application has been deemed complete, the formal review process begins.

(1) Notification of the Beginning of a Review.

The Agency, in determining that an application is complete and ready for review, shall provide written notice of the beginning of a review to the applicant, affected persons, and to any person who has requested the Agency to place his name on the mailing list maintained by the Agency.

The written notice shall contain the proposed schedule for the review, the period within which a public hearing may be requested by affected persons, and the manner in which notice of the time and place of any requested hearings will be provided.

The date of written notification of the start of a review shall constitute the first day on from which the ninety (90) or forty-five (45) day review timeframe is to commence.

The date of notification shall be the date on which the notice is sent to the applicant or the date on which the notice appears in a newspaper of general circulation, whichever is later.

Written notification to the general public and third party payers shall be provided by placing a notice in a newspaper of general circulation. All other affected persons shall be notified by mail.

(2) Review Period.

Agency review of the application shall encompass the time period from the date of notification to the date on which the Agency files an Agency decision on the merits of the application.

(a) In the case of substantive reviews, to the extent practicable, the timeframe shall not exceed ninety (90) days.

(b) In the case of non-substantive reviews, which include applications for exemptions and applications by or on behalf of an HMO or combinations of HMOs, to the extent practicable, the timeframe shall not exceed a period of forty-five (45) days.

(3) Notification of the Status of a Review.

(a) Upon request, the Agency shall provide information as to the status of the Agency's review of an application, to the applicant and members of the public.

Notification of the status of a review shall be in writing and shall provide the findings made in the course of review and other appropriate information.

(b) Upon completion of the staff review, the Agency shall provide the applicant with a copy of the staff report, a schedule of the Guam Health Coordinating Council project review committee meeting to discuss the application, and a schedule of the Guam Health Coordinating Council meeting to review the merits of the application.

The Agency may extend the period for Agency review of the application to a maximum of forty-five (45) days beyond the required timeframe period, if the Agency determines that it would not be practicable to complete the review during the normally stipulated review timeframe.

The Agency shall notify the applicant, in writing, of plans to extend the review beyond the original time period of review, within the initial timeframe.

The notice shall include the length of the extension and a statement of the reasons for such an extension.

(c) Failure by the Agency to Act Within the Required Time.

- (i) if the Agency fails to approve or disapprove an application within the applicable review period, the applicant may, within a reasonable period of time following the expiration of the applicable review period, bring an action in the Superior Court of Guam to require the Agency to approve or disapprove the application.
- (ii) A Certificate of Need or an exemption from Certificate of Need requirements shall not be issued or denied solely because the Agency failed to file a decision within the required time.

(d) Staff Review and Reports.

The Agency staff shall review each and every application filed with the Agency. The Agency staff may prepare one or more written staff reports on the application. A staff report may include an analysis of the application, identification of issues, and a discussion of the issues in relation to the applicable criteria for a Certificate of Need or an exemption. In the case of applications involving comparative reviews, the staff report may include a comparative analysis of the applications, the identification of issues, a discussion of the issues in relation to the applicable criteria, and staff recommendations regarding the applications. The staff report shall be made a part of the file of each application. The staff report shall be provided to the applicant, any other persons upon written request, and to the Guam Health Coordinating Council. The Agency staff may participate in any public meeting or public hearing held on any application.

(e) Public Hearing During the Course of Review.

Upon the request by any affected person or determination by the Agency, the Agency shall hold a public hearing, in conformity with the Open Government Laws of Guam, on any application other than an application for an exemption. The hearing will be held during the period the application is under Agency review, and shall be conducted by the Agency within thirty (30) days after the date of notification of the start of a review. The Agency shall disregard

any request for a public hearing under this section that is either filed in a untimely manner, or is considered to be of a frivolous nature. To the extent practicable, the public hearing may be held on a date that the Guam Health Coordinating Council meets to review the application. Prior to the hearing, the Agency shall provide written notice of the hearing to affected persons and to any other persons upon written request.

- (i) during a hearing, any person shall have the right to be represented by counsel, to present oral or written arguments and evidence relevant to the matter which is subject to the hearing, and to conduct reasonable questioning of persons who make relevant factual allegations (if the person is affected by the matter).
- (ii) the Agency shall maintain a verbatim record of any public hearing held under this subchapter.
- (iii) the agency will not impose any fees for the conduct of the hearing.
- (iv) the Agency may call upon technical advisory committees and individuals, who have special expertise, to provide technical assistance at the public hearing.
- (v) After the commencement of a hearing during the course of a review, and before a decision is made, there shall be no exparte contacts between any person acting on behalf of the applicant or holder of a Certificate of Need, or any person opposed to the Certificate of

Need, or in favor of withdrawal of a Certificate of Need, and any person in the Agency who exercises any responsibility respecting the application.

(4) Guam Health Coordinating Council Review of the Application.

(a) The Agency shall refer all completed applications, other than those considered emergency applications or applications for exemptions, to the Guam Health Coordinating Council (or GHCC) for review and recommendations.

(b) To the extent practicable, the application shall be reviewed in the following order:

(i) the appropriate GHCC review committee shall review the application at one or more public meetings called for the specific purpose of review, and shall submit any recommendations to the GHCC as a whole.

(ii) the GHCC shall review the application and recommendations of the review committee at one or more public meetings called for the specific purpose of review, and shall submit any recommendations to the Agency.

(c) Recommendation of the GHCC shall be submitted to the Agency at least seven (7) days before the period for the Agency's review of the application expires.

(d) Recommendations of the GHCC are not binding on the Agency.

- (e) Each meeting of the GHCC and the review committee, called for the purpose of reviewing an application, shall be open to the public, unless the meeting is closed to the public pursuant to the Open Government Laws of Guam. Any person shall have the right to attend a meeting open to the public, provided that any person who willfully disrupts a meeting to prevent and compromise the conduct of the meeting shall be removed from the meeting.
- (f) In any proceeding before the GHCC, or the GHCC review committee, or the Agency, any person may appear on his or her own behalf, by or with an attorney, or by another person designated as a representative. If a person is represented by an attorney, the attorney shall be authorized to practice law by the Superior Court of Guam. The GHCC or the Agency may, at any time, require any person, who is appearing in a representative capacity, to show his or her authority to act in that capacity.
- (g) No members of the GHCC shall vote on any matter respecting an applicant with which the member, the member's spouse, the member's child, the member's brother or sister or parent-in-law, the spouse of the member's child, the spouse of the member's brother or sister, or the member's parent has (or within the twelve months preceding the vote, had) any relationship of substantial ownership, directorship, officership, employment, prospective employment for which negotiations have begun, medical staff, fiduciary,

contractual, creditory, debtor, or consultation.

(i) if such a relationship exists or has existed, the member shall make a written disclosure of the relationship before any action, by the GHCC, is taken with respect to the applicant, and the member shall make the relationship public in any meeting in which action is to be taken with respect to the applicant.

(ii) Where any other conflict of interest exists, a member of the GHCC shall be disqualified from voting on any matter during the review of any application.

(5) Written Findings on the Merits of the Application.

Upon conclusion of the staff review, and receipt of the GHCC's recommendations, the Agency shall issue a decision on the merits of the application.

The decision on the merits of an application shall be in writing and shall include findings of fact and conclusions of law based upon the information provided in the application.

On the date the Agency issues a decision, the Agency shall deliver copies of the decision to the applicant, and mail copies to any parties to the public hearing held during the course of review. The Agency shall make copies of the decision available to major health care providers and any other persons upon request. In the case of a project proposed by an HMO, the Agency shall send a copy of these written findings to the Region IX Office of the Department of Health and Human Services.

The decision to issue, deny, or withdraw a Certificate of Need shall not prejudice any Agency action or decision on any future or other application for a Certificate of Need filed by the same applicant.

Written findings and the decision to issue a Certificate of Need shall take effect thirty (30) days following the date of issuance unless a request for a public hearing for the reconsideration of an Agency decision is filed with the Agency.

(a) Dismissal Without Prejudice.

(i) without reaching a decision on the merits of an application, the Agency may dismiss the application for either of the following reasons:

(A) failure of the applicant to respond to written Agency correspondence addressed to the applicant; or

(B) failure of the applicant to pursue the application.

(ii) before dismissing an application, the Agency shall provide the applicant with a written notice of the intent to dismiss the application and reasons for the dismissal. The Agency shall provide ten (10) days in which the applicant may respond to the notice of dismissal.

(iii) Should the Agency dismiss an application, the Agency shall explain in the record the reasons or reasons for the dismissal and shall furnish the applicant with a copy of the explanation.

(iv) dismissal of an application for any of the reasons in paragraph (5)(a)(i) of this section, shall be without prejudice to the applicant's right to refile the application.

(b) **Approved Certificates of Need.**

The Agency shall only issue a Certificate of Need for those obligations of capital expenditures, offerings of new and institutional health services, and acquisitions of major medical equipment which are found to be needed.

The written findings for each project approved shall include a written finding on the extent to which the project meets, or will meet, the CON criteria and standards regarding need, and a consideration of the current accessibility of the facility as a whole.

In issuing a certificate of need the Agency shall specify the maximum capital expenditure which may be obligated under the Certificate.

- (i) the approved maximum capital expenditure shall be equivalent to the value of the applicant's own estimate of total costs, plus a contingency amount not to exceed 15 percent of the estimated total costs.
- (ii) the Agency shall monitor capital expenditure obligated under Certificate of Need beginning three (3) months after the date the Certificate is issued and every three (3) months thereafter until the project is completed.

Any increase in the capital expenditures of an approved project which exceed the approved maximum capital expenditure by (5) percent or \$50,000, whichever is less shall require the review and written approval by the Agency.

(iii) Terms of Issuance.

When a Certificate of Need or an exemption from the Certificate of Need requirements is issued, the Certificate of Need or the exemption shall specify terms of issuance, including a description of the nature and the extent of the activity, or activities, authorized by the Certificate of Need or the exemption.

A Certificate of Need shall be valid for the period of one (1) year from the date of issuance.

No further action regarding the Certificate of Need program shall be required of an applicant after one (1) year, if the project for which the Certificate of Need was issued is completed.

(iv) Prohibition on Transfer.

A Certificate of Need or an exemption from the Certificate of Need requirements is issued only to the applicant named in the application. The Certificate of Need or the exemption shall not be sold, assigned, leased, donated, or otherwise transferred to any other person.

(c) Conditional Approval of Certificate of Need.

In any case where the Agency finds that an application would successfully meet the criteria for approval if the application were modified in some way, the Agency may issue approval of the application with imposed conditions requiring the applicant to take affirmative steps to meet those conditions.

Issuance of conditional approval by the Agency shall serve as a commitment by the Agency that a valid Certificate of Need will be issued when the application has been modified as required.

Issuance of conditional approval does not constitute the issuance of a Certificate of Need and does not allow the applicant to proceed with the project.

In issuing a conditional approval of a project the Agency shall specify a time period within which modifications are to be made. Upon the expiration of such a time period, the applicant certify that the required changes have been made.

Once the Agency ascertains that the changes have been made, the Agency shall issue the Certificate of Need for the project.

Failure on the part of the applicant to make, or to certify that the required modifications have been made, shall result in the denial of a Certificate of Need.

(d) Denial of a Certificate of Need.

- (i) the agency shall deny a Certificate of Need for any proposed project which does not satisfy the CON criteria and standards. The Agency shall state the project's failure to meet the need and access criteria in its written findings to the applicant, and shall send a copy of such findings to the Region IX Office of the Department of Health and Human Services.
- (ii) in the case of the Agency's issuance of conditional approval, failure by the applicant to make or to certify that required modifications have been made shall result in the denial of a Certificate of Need.

(e) Withdrawal of a Certificate of Need.

- (i) at any time after a Certificate of Need is issued, the Agency shall withdraw the Certificate of Need if the Agency determines that:
 - (A) the holder of the Certificate of Need is not meeting the timetable specified in the approved application, and is not making a good faith effort to meet it; or
 - (B) the project being implemented differs substantially from that which was authorized by the Certificate of Need.

(ii) the Agency shall withdraw, at any time, a Certificate of Need if the Agency determines that the applicant procured the Certificate of Need by fraud, misrepresentation, or corruption, or that the applicant submitted, or caused to be submitted, to the Agency false statements or information in connection with the application for the Certificate of Need.

(iii) in any proceeding brought by the Agency to withdraw a Certificate of Need, the Agency shall follow the required review procedures for:

- (A) notice of the beginning of a review;
- (B) public hearing during the course of review;
- (C) notification of the status of a review;
- (D) written findings on the merits of the application;
- (E) procedures during the course of review Section G(3)(e)(v) regarding exparte contracts;
- (F) request for reconsideration of the Agency's decision;
- (G) administrative review;
- (H) judicial review; and
- (I) agency reports of reviews.

(6) Post Decision Requirements of the Applicant.

The Agency shall periodically review the progress of the holder a Certificate of Need, in meeting the timetable specified in the approved application.

All persons receiving a Certificate of Need shall file, with the Agency, a written report on the development and progress of the project for which a Certificate was issued, beginning three (3) months after the date the Certificate is issued and every three (3) months thereafter.

(a) Projects Involving Construction.

The report shall contain the Certificate of Need identification number, the date of issuance, a summary of milestones and dates completed, (i.e., completion of financial arrangements, completion of design phase, beginning of construction, etc.), identification and explanation of project deficiencies and cost overruns, and revised estimates for the achievement of subsequent milestones.

(b) Projects not Involving Construction.

The report shall contain the Certificate of Need identification number, the date of issuance, a summary of project achievements to date, a detailed description of the nature and extent of operations (i.e., number and type of services provided, expenditures encumbered to date, etc.), identification and explanation of project deficiencies or problems encountered, and revised estimates for achievement of subsequent milestones, including projected cost overruns and anticipated delays in project implementation.

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Failure, on the part of the applicant, to provide the Agency with a written progress report, as specified above, may result in the Agency's determination that the applicant is not making a good faith effort to meet the timetable proposed for the project.

Determination by the Agency that the holder of a Certificate of Need is not meeting the timetable, or making a good faith effort to meet it, shall constitute grounds for the withdrawal of a Certificate of Need.

The Agency, or an authorized representative of the Agency, shall have the right to inspect any facility, site, location, book, document, paper, file, or other record of the holder of a Certificate of Need or an exemption, related to any project authorized by the Certificate of Need or the exemption, in order to monitor and evaluate the holder's compliance with the Certificate of Need's or the exemption's terms of issuance.

Within one (1) year after the Certificate of Need is issued, the holder of a Certificate of Need shall submit to the Agency trustworthy evidence that the project which is the subject of the Certificate of Need has been completed, or trustworthy evidence that obligations for capital expenditures for the project have been incurred.

Upon receipt of such trustworthy evidence, the Agency shall issue a statement that the applicant has met the full requirements of the Certificate of Need for the specified project. Any additions, alterations, or eliminations to the services, facilities, or equipment specified in the Certificate of Need may be subject to subsequent review by the Agency.

III. Post Decision Procedures.

A. Request for Reconsideration of the Agency's Decision.

Any person may, for good cause shown, request the Agency to hold a public hearing for reconsideration of the Agency's decision on the merits of an application regarding the issuance, denial or withdrawal of a Certificate of Need. The request shall be in writing and shall include a statement of the nature of the person's interest, as well as a statement of the reasons supporting the belief that good cause exists for a reconsideration of the Agency's decision. The request must be filed with the Agency no later than thirty (30) days following the issuance of an Agency decision on an application. The Agency shall deny any request for the reconsideration of an Agency decision which is not filed within the thirty (30) day timeframe, which fails to show that good cause exists, or which is frivolous in nature.

- (1) A request for a public hearing will be considered to show good cause of it:
 - (a) presents significant relevant information not previously considered by the Agency which, with reasonable diligence, could not have been presented before the Agency its decision; or
 - (b) demonstrates that there have been significant changes in factors or circumstances relied upon by the Agency in reaching its decision; or
 - (c) demonstrates that the Agency had materially failed to follow the Agency's adopted procedures in reaching its decision; or

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- (d) provides any other basis which the Agency determines constitutes good cause.

Upon receipt of a request for the reconsideration of the Agency's decision, the Agency shall notify the applicant, the GHCC, and affected persons of the request.

If good cause is determined to exist, the Agency shall schedule a public hearing for the reconsideration of the Agency's decision. The public hearing shall be held within thirty (30) days of receipt of the request for such reconsideration by the Agency. Notice of the time and place of the public hearing shall be sent to the person requesting the reconsideration, the applicant, the GHCC, affected persons, and others upon request. The public hearing shall serve as the forum in which the Agency's decision shall be reconsidered.

The Agency Administrator, or the designated Agency representative, shall preside as hearing officer during the course of the public hearing.

Written findings stating the Agency's decision, in the reconsideration of the initial decision, and the basis for the decision shall be issued to the person requesting the hearing, the applicant, the GHCC and interested persons upon request, within forty-five (45) days after the conclusion of the public hearing for the reconsideration.

The written findings shall state that the decision is the Agency's final action on the reconsideration.

(2) If the request for a public hearing for the reconsideration of an Agency decision is denied, the Agency shall file a written explanation of the reasons for the denial, and shall send it to the person requesting the reconsideration, the GHCC, the applicant, affected persons, and others upon request. The explanation shall include a written notice stating that:

- (a) the denial is the Agency's final action on the reconsideration; and
- (b) the decision which was to be reconsidered is the final decision of the Agency.

The Agency's denial of a request for reconsideration of the Agency's initial decision shall not preclude the interested person from seeking administrative or judicial review of the application and the Agency's final decision.

B. Administrative Review.

Upon the request of any affected person, the decision of the Agency to issue, deny, or withdraw a Certificate of Need, or to grant or deny an exemption, shall be administratively reviewed under the appeals mechanism afforded by the Guam Administrative Adjudication Law, Title XXV of the Government Code of Guam. With respect to section 24121 of this law, the Agency shall employ the use of a hearing officer whose duties shall be limited to: presiding over the hearing, ruling on the admission and exclusion of evidence, and advising the Agency on matters of law. All other powers relating to the conduct of the hearing shall remain with the Agency.

The written decision issued as a result of such a hearing shall be considered the final decision of the Agency.

C. Judicial Review.

Any person adversely affected by a final decision of the Agency with respect to a Certificate of Need or an application for an exemption, may, within thirty (30) days after the issuance of the decision and the completion of any administrative review of the decision, obtain judicial review of the decision in the District Court of Guam.

Procedures to be employed in the judicial review are to be as provided for in Title XXV, Chapter II, Section 24141 of the Government Code of Guam.

The written decision issued as a result of such a review shall be considered the final decision of the Agency.