

CHAPTER 3**Health Care Certificates of Need****SECTIONS**

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§ 301. Short title.

This chapter may be cited as the “Federated States of Micronesia Health Care Certificate of Need Act of 1982.”

Source: PL 2-62 § 1.

§ 302. Purpose.

(1) The people of the Federated States of Micronesia are dependent upon the existence of an efficient, effective, and well-coordinated program of health care services and disease prevention activities. In order to achieve the necessary level of efficiency, effectiveness, and coordination, there is a continuous, compelling need for a rational program for the determination of allocations of scarce health resources.

(2) In addition, the impending termination of the Trusteeship Agreement and the probable change in

resources available for the delivery of health care and environmental protection requires a careful analysis of the proposed allocation of funds and resources to be used to provide health care, related services, and environmental health protection services to ensure that those funds and resources shall be utilized in accordance with the needs of the people of the Federated States of Micronesia.

(3) Therefore, it is declared to be the public policy of the Federated States of Micronesia and the purpose of this chapter to develop and operate a program which will identify the health needs of the residents of the Federated States of Micronesia and ensure that resources which are proposed for health programs or services meet those needs in the most efficient and effective manner possible.

(4) It is not the intent of this chapter to prohibit or any way curtail the development of private practice of medicine in the Federated States of Micronesia.

Source: PL 2-62 § 2.

FSM Const., art. IX, § 2(r), as amended, states as follows:

Section 2. The following powers are expressly delegated to Congress:

...

(r) to promote education and health by setting minimum standards, coordinating state activities relating to foreign assistance, providing training and assistance to the states and providing support for post-secondary educational programs and projects.

...

FSM Const., art. XIII, § 1 states as follows:

Section 1. The national government of the Federated States of Micronesia recognizes the right of the people to education, health care, and legal services and shall take every step reasonable and necessary to provide these services.

The provisions of the Constitution are found in Part I of this code.

Case annotations:

Professional Services Clause

The Constitution vests the nat'l gov't with power to act concerning health care and may place some affirmative health care obligations on it. [Manahane v. FSM, 1 FSM R. 161, 172 \(Pon. 1982\)](#).

Primary responsibility, perhaps even sole responsibility, for affirmative implementation of the Professional Services Clause, FSM Const. art. XIII, § 1, must lie with Congress. [Carlos v. FSM, 4 FSM R. 17, 29 \(App. 1989\)](#).

The Professional Services Clause of the Constitution demands that when any part of the nat'l gov't contemplates action that may be anticipated to affect the availability of education, health care or legal services, the nat'l officials involved must consider the right of the people to such services and make a reasonable effort to take "every step reasonable and necessary" to avoid unnecessarily reducing the availability of the services. [Carlos v. FSM, 4 FSM R. 17, 30 \(App. 1989\)](#).

Since the Constitution's Professional Services Clause is a promise that the nat'l gov't will take every step "reasonable and necessary" to provide health care to its citizens, a court should not lightly accept a contention that 6 FSMC 702(4), which creates a \$20,000 ceiling of governmental liability, shields the gov't against a claim that FSM gov't negligence prevented a person from receiving necessary health care. *Leeruw v. FSM*, 4 FSM R. 350, 362 (Yap 1990).

§ 303. Definitions.

As used in this chapter, unless the context otherwise requires:

(1) “Affected persons” includes the applicant, the Subarea Health Council, persons residing in the geographic area to be served by the applicant, any person who regularly uses health services or facilities within the area to be served by the proposed project, health care facilities and health maintenance organizations located in the service area which provide similar services to those under review, health care facilities and health maintenance organizations which have previously indicated their intention to provide similar services in the future, third-party payers who reimburse health care facilities in the service area, and rate review organizations in the service area.

(2) “Agency” means the Trust Territory Office of Health Services in its designated capacity as the Micronesia Health Planning and Development Agency which was created by designation agreement between the High Commissioner and the United States Secretary of Health, Education, and Welfare as the Trust Territory's designated agency to administer territorial health planning and development functions. The term “Micronesia Health Planning and Development Agency” is further defined to be synonymous with the terms “Territorial Health Planning and Development Agency,” “State Health Planning and Development Agency,” and “Office of Health Planning and Development.” These terms may be used interchangeably to mean the same in this chapter or in the regulations adopted under this chapter.

(3) “Certificate of need” means an authorization, when required under this chapter, to construct, expand, alter, or convert a health care facility or to initiate, expand, or modify a health care service, or to acquire major medical equipment.

(4) “Cost” for the purposes of determining whether a proposed project is subject to review under this chapter means the fair market value or the amount actually paid to acquire a facility or equipment or to initiate a service, whichever is higher.

(5) “Date activity undertaken” means the date on which institutional health services are actually started.

(6) “Director” means the Director of the Trust Territory Office of Health Services in his capacity as the Director of the Micronesia Health Planning and Development Agency.

(7) “Health care facilities” means hospitals, psychiatric hospitals, tuberculosis hospitals, skilled nursing facilities, kidney disease treatment centers including freestanding hemodialysis units, intermediate care facilities, ambulatory surgical facilities, and such other facilities as the agency by regulation shall so designate; provided, that “health care facilities” does not include recognized Christian Science sanitariums, or facilities owned and operated by the United States Federal Government.

(8) “Health maintenance organization” means a public or private organization which is qualified under section 1310 (d) of the United States Public Health Services Act or which:

(a) provides or otherwise makes available to enrolled participant health care services, including at least usual physician services, hospitalization, laboratory, x-ray, emergency and preventive services, and out-of-area coverage; and

(b) is compensated (except for copayments) for the provision of the above-listed services to enrolled

participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health services actually provided; and

(c) provides physician services through physicians who are employees or partners in the organization or through arrangements with individual physicians or groups of physicians.

(9) “Institutional health services” means health services provided in or through health care facilities or health maintenance organizations and includes the entities in or through which such services are provided.

(10) “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 care services and which costs more than \$50,000.

(11) “Micronesia Health Coordinating Council” means that Health Coordinating Council created by proclamation of the High Commissioner on October 6, 1976, and comprised of the Micronesia Regional Executive Committee and Subarea Councils for the Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau, as described in the Council's bylaws.

(12) “Obligation” means entry into a contract enforceable under the laws of this Government, taking of formal action to committee funds within applicant's own organization so as to serve as an in-house contractor, or, in the case of donated property, the date the gift transaction is completed.

(13) “Person” means an individual, a trust, or estate, a partnership, a corporation, a State, the National Government of the Federated States of Micronesia, a political subdivision, or any legal entity recognized by the Federated States of Micronesia Government.

(15) “Territorial health plan” is that comprehensive five-year health plan prepared and established by the Micronesia Health Coordinating Council which shall be based upon State health plans from the several States of the Federated States of Micronesia and shall include a medical facilities plan with appropriate consideration given to the development of facilities and services in the private sector and an environmental health section.

Source: PL 2-62 § 3.

Editor's note: Subsections rearranged in alphabetical order in the First Supplement of this code.

§ 304. Program established.

There is established the Federated States of Micronesia Certificate of Need Program which shall prescribe the means, procedures, and requirements for health care providers to apply for and obtain certificates of need prior to undertaking construction, expansion, alteration, or conversion of health care facilities or initiation, expansion, or modification of certain health care services including acquisition of equipment.

Source: PL 2-62 § 4.

§ 305. When required.

(1) Commencing on the effective date of the Act codified in this chapter, no person, whether public or private, shall make capital expenditures for activities enumerated in subsection (2) of this section without first obtaining a certificate of need or an exemption as required under this chapter.

(2) A certificate of need shall be required prior to:

(a) the development of all new institutional health services including, but not limited to, the construction, development, or other establishment of any new health facility;

(b) any obligation for a capital expenditure by or on behalf of a health care facility, other than to acquire an existing health care facility, in excess of \$50,000, including the costs of surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, expansion, replacement, or construction of any plant or equipment;

(c) the offering by a health care facility of health services which were not offered on a regular basis in or through such health care facility within the 12-month period preceding the time such services would be offered, if:

(i) the obligation of any capital expenditure is entailed by the addition of services, or

(ii) regardless of whether a capital expenditure is entitled, the annual operating costs for such services will exceed \$10,000;

(d) the termination of a health service which was offered in or through a health care facility if that termination is associated with obligation of any capital expenditures;

(e) the obligation of any capital expenditure by or on behalf of a health care facility which changes the bed capacity of a health care facility by increasing or decreasing the total number of beds (or distributing beds among various categories or relocating such beds from one physical facility or site to another) by ten beds or ten percent of total bed capacity, whichever is less, over a two-year period;

(f) the acquisition by any person of major medical equipment to be owned by or located in a health care facility or, regardless of ownership or location, if the equipment is to be used to provide patient care services, to inpatients or outpatients, unless such services are provided on an occasional basis in the event of natural disaster, major accident, or equipment failure;

(g) if any person acquires an existing health care facility, that person shall file a notice of intent with the Agency as prescribed under section 306 of this chapter. A certificate of need shall be required for such acquisition unless the Agency finds that the acquirer is a health maintenance organization, or that no changes will result in facilities or services rendered due to the acquisition;

(h) in the event that the Agency issues a certificate of need for a project and within one year of the date the project was undertaken there is a change in that project associated with a capital expenditure, regardless of the amount of the expenditure, that change will be subject to certificate of need review.

(3) A certificate of need which normally would be required under subsection (2) of this section will not be required if;

(a) a health care facility is being acquired by a health maintenance organization or if the acquisition will not result in a change of services or modification of the facility, including the organizational structure;

(b) the applicant is a health maintenance organization if:

(i) it has a current enrollment or reasonable anticipated future enrollment of at least 50,000

persons in the service area,

- (ii) the proposed facility or service will be reasonably accessible to the enrolled population,
- (iii) at least 75 percent of the persons to be served will be enrollees, and

(iv) an acquisition of a facility or equipment is by lease, the lease will be in effect for at least 15 years' duration after such acquisition;

(c) major medical equipment is acquired by or on behalf of a clinical laboratory to provide clinical laboratory services, if:

(i) the clinical laboratory is independent of a physician's office and a hospital, and

(ii) it is determined under title XVIII of the United States Social Security Act to meet the requirements of paragraphs (10) and (11) of 1861 (s) of that act.

(4) The Agency must issue a certificate of need for a capital expenditure necessary to:

(a) eliminate or prevent a safety hazard;

(b) comply with licensure standards; or

(c) comply with accreditation or certification standards required for the applicant to receive reimbursement under title XVIII or XIX of the United States Social Security Act; provided, that prior to issuance of such a certificate of need the Agency finds that:

(i) that facility or service for which the capital expenditure is proposed is needed, and

(ii) the obligation of the capital expenditure is consistent with the State health plan;

(5) For capital expenditures not meeting the criteria set forth in subsection (4) of this section, the Agency shall issue a certificate of need, if it is found that:

(a) the proposed facility, services, or equipment is needed by the population to be served;

(b) such facility, service, or equipment is consistent with the Trust Territory health plan; and

(c) the project complies with this chapter and regulations adopted under this chapter. The criteria to be used by the Agency in determining need for the facility, service, or equipment shall be as set forth in section 307 of this chapter.

Source: PL 2-62 § 5.

Cross-reference: The statutory provisions on the President and the Executive are found in title 2 of this code. The statutory provisions on the Legislature (the Congress of the Federated States of Micronesia) are found in title 3 of this code.

The website of the FSM National Government contains announcements, press releases, news, forms, and other information on the National Government at <http://fsmgov.org>.

The official website of the Congress of the Federated States of Micronesia contains the public laws enacted by the Congress, sessions, committee hearings, rules, and other Congressional information at <http://www.fsmcongress.fm/>.

§ 306. Applications.

(1) Applications of certificates of need and notices of intent shall be filed with the Agency on application forms provided by the Agency and shall contain such information and be in such form as the director may require.

(2) At least 30 days before any person acquires or enters into a contract to acquire an existing health care facility or major medical equipment which will not be located in or owned by a health care facility, the person shall notify the Agency of the intended acquisition period. Such notice of intent shall be in writing, containing such information as required by regulations as the Agency may promulgate.

(3) The Agency shall act upon any application submitted pursuant to this chapter within 90 days of receipt of such application; provided, that for reasonable cause and upon notice to the applicant, the Agency may extend its time for review for a specific period not to exceed 30 additional days. In cases where the Agency requests the applicant to provide additional information subsequent to submission of the application, the Agency must, at the request of the applicant, extend the review period for not less than an additional 15 days. Failure to act upon the application within the time period prescribed in this section is grounds for the applicant to seek judicial remedy but shall not be deemed an approval or denial of the certificate of need by the Agency.

(4) Prior to an exemption pursuant to subsection (3) of section 305 of this chapter, a notice of intent must be filed with the Agency and the Agency shall render a finding as to the applicability of the exemption within 30 days of receipt of such notice.

Source: PL 2-62 § 6.

§ 307. Review criteria.

The Agency shall adopt regulations under this chapter which shall prescribe specific criteria for the reviewing of certificate of need applications which criteria shall include at least the following general considerations; provided, that criteria adopted for review may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed; and provided further, that such regulations shall be adopted in accordance with section 313 of this chapter:

(1) the relationship of the health services reviewed to the territorial health plan and annual implementation plans;

(2) the relationship of services rendered to the long-range development plan, if any, of the person providing or proposing such services;

(3) the need that the population served or to be served by such services has for such services and the extent to which residents of the area, and in particular low-income persons, racial and ethnic minorities, women, handicapped, and other underserved groups, and the elderly, are likely to have access to those services. In the case of a reduction or elimination of service, including relocation of a facility or service, the extent to which the alternative arrangements, and the effect of the reduction, elimination, or relocation on the ability of low-income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly, to obtain the needed health care;

(4) the availability of less costly or more effective alternative methods of providing such services;

(5) the immediate and long-term financial feasibility of the proposal, as well as the probable impact of the proposal on the costs of and charges for providing health services by the person proposing the new institutional health

services;

(6) the relationship of the services proposed to be provided to the existing health care system of the area in which such services are propose to be provided and the probable impact of the proposal on the economic and social development of the Federated States of Micronesia;

(7) the contribution of the proposed service or facility to meeting the health needs of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services, particularly those needs identified in the Trust Territory health plan as priorities. For the purpose of determining the extent the proposed service or facility will be accessible, the Agency shall consider:

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

(b) the performance of the applicant in meeting its obligations, if any, under applicable Federal regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving Federal financial assistance, and

(c) 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, hospital privileges, etc.);

(8) 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 those resources as identified by the Trust Territory health plan;

(9) the relationship, including organizational relationship, of the health services proposed to be provided to ancillary or support services;

(10) the effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which services are to be provided;

(11) if proposed health services are to be available in a limited number of facilities, the extent to which the health profession schools in the area will have access to the services for training purposes;

(12) 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 areas in which the entities are located or in adjacent health service areas;

(13) the special needs and circumstances of biomedical or behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages;

(14) 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 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;

(15) the special circumstances of health care facilities with respect to the need for conserving energy;

(16) factors which affect the effect of competition on the supply of health services being reviewed;

(17) improvements and innovations in the financing and delivery of health services which foster competition

and serve to promote quality assurance and cost effectiveness;

(18) the efficiency and appropriateness of the use of existing services and facilities similar to those proposed;

(19) in the case of existing services or facilities, the quality of care provided by those facilities in the past;

(20) when an application is made by an osteopathic or allopathic facility to construct, expand, or modernize a health care facility or add services or acquire major medical equipment, the need will 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;

(21) in the case of applications by health maintenance organizations, the only criteria to be applied for determination of need shall be:

(a) the needs of enrolled members and reasonably anticipated new members of the health maintenance organization for the health services proposed to be provided, and

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

(i) would be available under a contract of at least five years' duration,

(ii) would be available and conveniently accessible through physicians and other health professionals associated with the health maintenance organization,

(iii) would cost no more than if the services were provided by the applicant health maintenance organization, and

(iv) would be available in a manner which is administratively feasible to the applicant health maintenance organization.

Source: PL 2-62 § 7.

Cross-reference: FSM Const., art. IX, § 2(r), as amended, states as follows:

Section 2. The following powers are expressly delegated to Congress:

...

(r) to promote education and health by setting minimum standards, coordinating state activities relating to foreign assistance, providing training and assistance to the states and providing support for post-secondary educational programs and projects.

...

FSM Const., art. XIII, § 1 states as follows:

Section 1. The national government of the Federated States of Micronesia recognizes the right of the people to education, health care, and legal services and shall take every step reasonable and necessary to provide these services.

The provisions of the Constitution are found in Part I of this code.

§ 308. Withdrawal.

The Agency may withdraw a certificate of need if:

- (1) The applications contain false or misleading information or intentionally omits material facts; or
- (2) Circumstances based upon which the certificates of need were issued have changed or new circumstances have developed which alter the need for the projects; provided, that the changed or new circumstances occur prior to the commencement of construction or substantial expenditure or obligation of funds.
- (3) All applications for a certificate of need shall include a timetable for implementing the project. The Agency shall periodically evaluate the progress of the applicant towards implementing the project according to the timetable submitted. Failure of the applicant to make a good faith effort toward implementation may constitute grounds for withdrawal of the certificate of need.
- (4) Any holder of a certificate of need shall be entitled to an administrative hearing prior to the suspension of its certificate of need.

Source: PL 2-62 § 8.

§ 309. Reconsideration of Agency action.

- (1) The Agency shall order a public hearing on an application upon written request by any person for the purposes of reconsidering an Agency decision, provided, that:
 - (a) the request is received within 30 days after the decision was rendered; and
 - (b) a good cause is shown. A request for public hearing shall be deemed to have shown good cause if it:
 - (i) presents significant relevant information not previously considered by the Agency,
 - (ii) demonstrates that there have been significant changes in factors or circumstances relied upon by the Agency in making its decision,
 - (iii) demonstrates that the Agency failed to follow appropriate procedures prescribed in these regulations, or
 - (iv) that the Agency acted without regard for a conflict of interest situation.
- (2) The Agency shall provide public notice of reconsideration hearings and adopt hearing procedures in accordance with this chapter and regulations adopted under the provisions of section 313 of this chapter.

Source: PL 2-62 § 9.

Cross-reference: The statutory provisions on Administrative Procedure are found in title 17 of this code.

§ 310. Judicial review.

(1) Any person adversely affected by a final decision of the Agency with respect to a certificate of need or an application for exemption may, within a reasonable time after the decision is made, obtain judicial review in accordance with title 17 of this code.

(2) The court shall affirm the decision of the Agency unless it finds it to be arbitrary or capricious or not made in compliance with applicable law.

(3) For the purposes of this section, “person adversely affected” includes the Agency, any person previously defined as “affected” in section 303 of this chapter, and any person who participated in the review proceeding before the Agency.

Source: PL 2-62 § 10.

Cross-reference: Title 17 of this code is Administrative Procedure. The statutory provisions on the FSM Supreme Court are found in title 4 of this code.

§ 311. Nontransferability.

A certificate of need issued under this chapter is not transferable without the prior written approval of the Agency.

Source: PL 2-62 § 11.

§ 312. Reporting.

The director shall submit an annual report to the Congress of the Federated States of Micronesia on or before January 10th of each year on all activities of the Agency and all funds received by the Agency pursuant to, or by virtue of this chapter.

Source: PL 2-62 § 13.

Cross-reference: The statutory provisions on the FSM Congress are found in title 3 of this code.

§ 313. Regulations.

(1) The Agency shall adopt and promulgate the regulations authorized in section 307 of this chapter in accordance with the procedures and requirements of the Federated States of Micronesia Administrative Procedure Act, title 17 of this code; except, that compliance by the Agency with the requirements of subsection (2) of this section shall constitute compliance with all the publication and notice requirements set forth in title 17 of this code; and further, that notwithstanding the provisions in sections 103 and 104 of title 17 of this code regarding the filing and effective date of regulations, regulations adopted and promulgated under this chapter shall be filed and become effective in accordance with subsection (3) of this section.

(2) In the adoption and promulgation of regulations pursuant to section 307 of this chapter, the Agency shall, prior to the adoption of regulations prescribing a review process or any revision thereof:

(a) give all interested parties a reasonable opportunity to offer written comments on the review procedures proposed for adoption;

(b) distribute copies of its proposed, adopted, and revised or amended review procedures to public and private health organizations, the Micronesia Health Coordinating Council, the Governors of the Federated States of Micronesia, the High Commissioner, the Secretary of Health, Education and Welfare, the President of the Federated States of Micronesia and such other interested persons as shall request them, including rate-setting agencies and health maintenance organizations should such be established within the Federated States of Micronesia; and

(c) the Agency shall notify the general public of its intent to adopt procedures and criteria, or revisions thereof, through publication in at least one newspaper of general circulation in the Federated States of Micronesia.

(3) The Agency shall file in the Office of the Registrar of Corporations of the National Government of the Federated States of Micronesia, the office of each State Governor, and with the Clerks of Court to both the State and National Courts and the Trust Territory High Court, a certified copy of the review procedure regulation adopted by it.

(4) Each regulation adopted is effective ten days after completion of the requirements of subsection (2) of this section.

(5) The regulations adopted and promulgated by the Agency in July 1979 in accordance with the act are confirmed and shall remain in effect until amended, repealed, or superseded by the Agency acting pursuant to and in accordance with this chapter.

Source: PL 2-62 § 14.

Cross-reference: Chapter 1 of title 17 of this code is on FSM Administrative Procedures. The statutory provisions on the FSM Supreme Court are found in title 4 of this code. The statutory provisions on the Registrar of Corporations are found in chapter 2 of title 36 (Corporations and Business Associations) of this code.

§ 314. Civil penalties.

Any person violating any of the provisions of section 305 of this chapter shall be subject to the imposition of a

civil fine in the amount of \$1,000 for each violation; provided, that for the purpose of determining the amount or fine to be imposed under this chapter, violations shall be deemed recurring, with each week or fractional part thereof that a violation continues being construed as a separate violation.

Source: PL 2-62 § 12.