H 3

CERTIFICATE

STATE OF WISCONSIN

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Donald E. Percy, Secretary of the Department of Health and Social Services and custodian of the official records of said department, do hereby certify that the annexed rules relating to the certificate of need provisions of Chapter 150, Wisconsin Statutes were duly approved and adopted by this department on May 15, 1978.

I further certify that said copy has been compared by me with the original on file in this department and that the same is a true copy thereof, and of the whole of such original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the department at the State Office Building in the city of Madison, this 15th day of May, A.D. 1978.

D.E.P.

Donald E. Percy, Secretary

ORDER OF THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES

ADOPTING RULES

Pursuant to authority vested in the Department of Health and Social Services by section 150.003, Wis. Stats., the Secretary hereby creates Chapter H3. of the WISCONSIN ADMINISTRATIVE CODE, and adopts as rules sections H3.00-H3.08, H3.10, H3.20, H3.23, H3.40, H3.42, H3.44, and H3.70. These sections read as per the following attached documents:

H 3.00 ADMINISTRATIVE RULES FOR SUBCHAPTER II, CHAPTER 150, WIS. STATS. The following rules shall be used in administering the certificate of need provisions of Chapter 150, Wis. Stats.

H 3.01 Definitions. For the purpose of this section the following definitions shall apply: (1) AFFECTED PERSONS. "Affected persons" means any or all of the following:

(a) The applicant.

(b) Those members of the public who are to be served by the proposed health service.

(c) Those persons who offer services in the same health service area which are similar to those proposed in the application or who have formally indicated an intention to provide such similar services in the future.

(d) Any agency which establishes rates for health care facilities or health maintenance organizations in the appropriate HSA.

(e) The HSA(s) in whose area the proposed health service will be offered and any HSAs serving contiguous areas.

(2) APPLICANT. An "applicant" is the person for whom a certificate of need is requested.

(3) CERTIFICATE OF NEED. A "certificate of need" is a written authorization by the department for a person to implement an approved proposal.

(4) DATE OF NOTIFICATION. The "date of notification" is the date on which the department publishes notice of the receipt of an application and the proposed period for the review in a newspaper of general circulation.

(5) DEPARTMENT. The "department" is the Department of Health and Social Services.

(6) HEALTH SYSTEMS AGENCY (HSA). A "health systems agency" is an agency designated under 42 USC 300 l. In these rules, where reference is made to a specific HSA (as in "the" HSA, or "appropriate" HSA), such reference applies to the HSA(s) within whose area the proposed health service will be offered.

(7) OBLIGATION. An "obligation" is an enforceable contract which is entered into for the construction, leasing, acquisition, or permanent financing of a capital asset.

(8) PERSON. A "person" is an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), a state or a political subdivision or instrumentality (including a municipal corporation) of a state.

H 3.02 Non-Substantive Reviews. (1) Applications for non-substantive reviews shall be submitted to the department and the HSA on forms printed by the department and may be supplemented by other material which the applicant wishes to include.

(2) All applications shall be reviewed for completeness upon receipt by the department and the HSA. An application shall be considered complete if all sections

(c) All applications shall be reviewed for completeness upon receipt by the department and the HSA. An application shall be considered complete if all sections of the application form which have been designated as relevant are answered and the estimated fee, if any, has been received. If the department determines that any of the designated items required to be answered by the applicant have not been answered, the application is incomplete. Whenever the department determines that an application is incomplete, notice shall be mailed to the applicant within five (5) working days of the receipt of the application. If the department fails to give such notice, the application shall be deemed to be complete upon receipt.

(2) Initiation of the review. (a) The review period for an application shall commence when both the department and the HSA have received a complete application, or when the department and the HSA receive additional materials making the application complete, whichever is later.

(b) The review period may be extended for up to 60 days if the department determines that it is not practicable to complete the review in the allotted time and any one of the following: the proposal has an estimated total cost in excess of $10 million, or will change the number of beds in a facility by ten percent or more, or establishes or replaces a health facility; or that an extension of the review period specified s. 150.06(1), Wis. Stats. is necessary to comply with H 3.04(5).

(3) Notification. (a) All persons affected by a proposal shall be notified of the proposed schedule for the review and of the opportunity for public meeting during the review period by the twentieth day of the month following the month in which the review period began.

(b) The applicant, HSA, and statewide health and health-related organizations shall receive the notification described in the preceding paragraph by mail.

(c) Notification to affected persons other than the general public shall be by mail and may be by newsletter.

(d) Notification of the public shall be through newspapers of general circulation.

(4) Review criteria. The proposal shall be reviewed on the basis of rules published by the department in accordance with s. 150.07(1), Wis. Stats.

(5) HSA review period. The HSA shall, except as otherwise provided by these rules, submit its findings and recommendations to the department within sixty (60) days of the date of notification to affected persons.

(6) Public meetings. (a) The HSA shall be responsible for holding public meetings related to the review of a proposal. Any affected person may request a public meeting by the department if the HSA has not provided for such. These meetings shall be held according to the procedures in this section.

(b) Procedures for conducting a public meeting. 1. A designated representative of the agency conducting the meeting shall serve as the presiding officer and be responsible for the conduct of the public meeting including the establishment of the order and length of presentation.

2. Requests to speak shall be made to the presiding officer at the beginning of the meeting, and if the officer permits, during the meeting.

3. All directly affected persons at the meeting shall have an opportunity to present oral or written testimony on the proposal.

the department and the HSA, and the department, after consultation with the HSA, concurs.

(b) Modification of a proposal. 1. An applicant wishing to modify a proposal must request an extension of the review period in order to allow time for the development of the modification, necessary amendments to the application, and consideration by the public, the HSA, and the department. If the modification and necessary amendments to the proposal are not submitted within the period of the extension designated for that purpose and no further extension is requested, the review shall continue based upon the original application.

2. A modification to a proposal which results in a change in the estimated total cost of more than $100,000 shall require an adjustment of the application fee.

(c) Withdrawal of a certificate of need application. 1. An applicant may withdraw an application for a certificate of need at any time without prejudice by notifying the HSA and the department in writing of the action.

2. If an application is withdrawn before the date of notification, the application fee will be returned. If the application is withdrawn on or after the date of notification, the fee will not be returned.

(9) Certificate of need. (a) If the department's decision to approve a proposal is consistent with the HSA's recommendation, the department shall issue a certificate of need on the day of the decision.

(b) If the decision of the department is to issue a certificate of need, but the terms of the same are not consistent with the recommendation of the HSA, the department shall issue the certificate of need thirty (30) days after the decision to approve the proposal unless an appeal is filed.

(c) If an appeal is filed, the department shall not issue a certificate of need until the hearing officer has issued a decision.

(d) A certificate of need shall be valid for one year from the date of issuance unless it is renewed.

(10) Amended certificate of need. If there is a change in a proposal which has previously received a certificate of need which in itself would be reviewable under a provision of Chapter 150, Wis. Stats., that change shall be reviewed under the procedures described in this section. Any approval of such change shall constitute an amendment to the certificate of need issued for the previously approved proposal.

(11) Renewed certificate of need. At the request of the applicant, a certificate of need may be renewed without any changes for any period up to one year if the department determines that substantial and continuing progress as defined in s. 150.01(6), Wis. Stats., has been made, or if the applicant demonstrates a commitment to obligate within the extension period.

H 3.05 Reconsideration Process. (1) Period for filing a petition for rehearing. A petition for rehearing shall not be a prerequisite for appeal. Any affected person may, within twenty (20) days after entry of the decision, file a written petition for rehearing with the department which shall specify in detail the grounds for the relief sought and supporting documentation. The department may order a rehearing on its own motion within twenty (20) days after a final decision.

(3) Whenever the applicant or the HSA requests an appeal, if the decision has not previously been served or made a part of the record, the department shall issue and serve a decision upon the applicant, the HSA and the hearing officer prior to the commencement of the appeal.

(4) Appointment of a hearing officer. The hearing officer shall be appointed by the governor under s. 252.075(3), Wis. Stats.

(5) The hearing officer shall commence proceedings within thirty (30) days after appointment by the governor.

(6) The appeal shall be conducted according to s. 227.20, Wis. Stats., and the functions of the court shall be performed by the hearing officer appointed by the governor. In addition:

(a) The hearing officer shall make a written statement of finding pursuant to s. 227.10, Wis. Stats. regarding the hearing within forty-five (45) days of the close of the hearing.

(b) The findings, conclusions and the decision resulting from the hearing shall, to the extent the decision of the department is reversed or modified, constitute the decision of the department.

(c) Written copies of the findings of the hearing officer shall be sent to the applicant, the HSA, the department and others upon request.

(7) The burden of proof shall be as follows:

(a) In an appeal of a decision to deny a certificate of need, the department shall bear the burden of showing that the proposal fails to meet the criteria and standards published by the department pursuant to s. 150.07, Wis. Stats.

(b) Except as set forth in subparagraph H 3.06(7)(c), in an appeal of a decision to grant a certificate of need, the appellant must show that the proposal fails to meet the criteria referred to in subparagraph (a) above.

(c) In an appeal by the applicant of a decision to grant a certificate of need on terms not proposed or agreed to by the applicant, the burden shall be on the department to show that the applicant's proposal would not have met the criteria referred to in subparagraph (a) above.

H 3.07 Annual Reports. The department shall make annual reports on its activities including, but not limited to, the status of projects currently under review, the number and types of reviews completed since the previous report, and a general statement of decisions and findings made since the previous report.

H 3.08 Public Access. The public shall, upon submission of a written request, have access to all application materials and all other materials pertinent to department review.

H 3.10 GENERAL STANDARDS. The following general standards shall be used in the review of all applications for certificates of need. More detailed service-specific standards as may be adopted shall also be applied when appropriate. New methods and techniques of providing health services are encouraged. These may include approaches which are not consistent with the rules contained in this chapter. When, in the judgment of the department, the interests of the public and the intent of the certificate of need program are best served by such action, the department may grant a variance from or waive application of these rules in regard to a specific application. The department may establish time limits or conditions for variances and waivers. A violation of the conditions of a variance or waiver is a violation of these rules.

(1) Definitions. (a) Health Service Area. The health systems agency's geographic area as designated under 42 USC 300 l.

(b) Health Systems Agency (HSA). A health systems agency is an agency designated under 42 USC 300 l-4. Where, in these rules, reference is made to a specific HSA (as in "the" HSA, or "appropriate" HSA), such reference applies to the HSA within whose area the proposed health service will be offered.

(c) Planning area. A planning area comprises the geographic unit of analysis for a determination of need.

(2) Relationship to Health Plans. Proposals shall not be inconsistent with federal, state, and local health plans. Consistency of the proposal with other special studies, surveys and information developed by various state and local agencies and relevant to the proposed project shall also be considered.

(3) Relationship to Health Facility Plans. Proposals from health facilities which have capital expenditure budgets or long-range plans shall not be inconsistent with the applicable sections of these budgets or plans.

NOTE: Long-range planning should be an ongoing function of every health care facility. The considered development of proposed projects needing certificate of need approval should be reflected in the facility's long-range capital expenditure budget or plan.

(4) Need For Services. The proposal must be needed. (a) Determination of the need for a proposal shall be based upon consideration of the availability, accessibility, and acceptability of similar services in the planning area.

(b) Consideration shall be given to the special needs and circumstances of:

1. 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.

2. Health maintenance organizations (HMO) for which assistance may be provided under Title XIII Public Health Services Act. Such needs and circumstances include the needs of and costs to members and projected members of the HMO in obtaining health services and the potential for a reduction in the use of inpatient care in the community through an extension of preventive health services and the provision of more systematic and comprehensive health services.

(8) Cost Containment. The proposal shall not result in unreasonable increases in patient charges.

(9) Relationship to Existing Health Care System. The proposal shall:

(a) Promote the continuity of care in the health care system.

(b) Facilitate the care of patients in the most appropriate setting.

(c) Not be an unnecessary duplication of resources.

(10) Resource Availability. Necessary resources, including qualified personnel shall be available to staff the proposed project, or a realistic plan for the acquisition of such resources shall be provided by the applicant.

(11) Relationship to Ancillary or Support Services. Ancillary or support services shall have capacity to accommodate the proposed project.

(12) Construction Considerations. In the case of new construction, renovation, or replacement, consideration shall be given to:

(a) The conformance of construction plans and methods with applicable federal, state, and local code.

(b) The costs and methods of the proposal's construction including, but not limited to, the costs and methods of energy provision and conservation.

(c) The probable impact of the construction project on the applicant's and other institution's costs of providing health services.

(d) The environmental impact of the construction.

(e) The effect of renovation activity on patient services.

ACUTE CARE SERVICES. The following standards shall be used by the department in the review of applications for certificates of need for the establishment or expansion of acute care facilities and services.

(1) Definition. (a) Acute care facilities. For purposes of this chapter, acute care facilities are those facilities defined in s. 50.33(1), Wis. Stats., but excluding those facilities exempted by s. 50.39(3), Wis. Stats. Facilities, or physically distinct units of facilities, which are dedicated to the diagnosis or treatment of mental illness, alcoholism or other drug abuse are excluded from the definition of acute care facilities.

(b) Basic Acute Care Services. For the purposes of the acute care standards, basic acute care services include medical/surgical, pediatric, and obstetric services.

(2) Accessibility. The location of acute care facilities shall allow reasonable access to basic acute care services. Reasonable access shall be defined as not more than 30 minutes driving time under normal conditions except in areas of low population density (less than 30 persons per square mile) which are currently in excess of 30 minutes travel time to acute care facilities, or where residents of an area have demonstrated a preference to utilize acute care facilities which are in excess of 30 minutes travel time.

(3) Need for Services. (a) For the purposes of the acute care standards, planning areas shall be developed to reflect changing medical trade patterns. The planning areas shall be revised in a manner consistent with the considerations enumerated below as data become available. The list of current planning areas shall be available, on request, at the health systems agencies and the department.

1. Planning areas shall be contiguous. With the exception of the southeastern Wisconsin health service area, minor civil division boundaries shall be utilized. Within the southeastern Wisconsin health service area a combination of postal zip code and minor civil division boundaries shall be utilized.

2. An analysis of existing utilization patterns, including, but not limited to, patient origin data shall substantiate that a plurality of the residents of the minor civil division or zip code areas in the planning area are treated by an acute care facility or facilities in that planning area.

3. The planning area configuration shall assure availability and reasonable accessibility to acute care facilities and basic acute care services as defined in the standards related to accessibility.

4. Except in areas of low population density (less than 30 persons per square mile) or where residents of an area travel in excess of 30 minutes to obtain acute care services, the geographic size of a planning area shall not exceed 50 miles between any two points in the planning area.

5. Where it can be established, based on analysis of patient origin data, that two or more acute care facilities serve the same geographical area, such facilities shall be included in the same planning area.

1. Distribute the projected average daily census among the services in the hospitals for which a need can be demonstrated. Such distribution shall be based upon an analysis of the current distribution of patient days among services in the planning area and historical trends in the distribution of these days.

2. For each service, apply the bed need formula: bed need = $ADC + (1.65\sqrt{ADC})$ where ADC = the projected average daily census for that service.

3. Sum the projected bed needs for the services in the planning area. The result shall be the projected bed need for the planning area.

(4) Relationship to Existing Health Care System. Acute care facilities proposing replacement or renovation shall provide written evidence of plans to achieve optimal efficiency through cooperative arrangements with other acute care facilities. These may include arrangements for shared services, for obtaining specialized services or consultation, and for transfer of patients, when necessary, to facilities providing specialized services.

(5) Maximum Space Limits. (a) The following maximum clear floor space limits for general medical/surgical, obstetric, and pediatric inpatient rooms shall be used in reviewing allocation of square footage in projects.

Number of Beds	Maximum Square Footage
1	150
2	225
3	300
4	375

(b) The above maximums may be exceeded in situations, such as special care CCU patient rooms, where additional space may be justified within a patient room or in a proposal to renovate a facility when such renovation will result in a reduction of bed capacity.

(6) Minimum Size/Patient Volume. (a) The following standards shall apply in determining the minimum size for acute care facilities: 1. The minimum size of an acute care facility in an SMSA shall be 200 beds.

2. The minimum size of an acute care facility in a non-SMSA area shall be 75 beds or the 5 year projected bed need for the planning area, whichever is less.

3. These standards shall not be applied to facilities where it can be demonstrated that reasonable access to an acute care facility (as defined in the standard relating to access) cannot be achieved in the absence of such a facility.

(b) The following standards shall apply in determining the minimum patient volume in obstetric services.

H 3.23

LONG TERM CARE FACILITIES. The following standards shall be used by the department in the review of applications for certificates of need for long-term care facilities in Wisconsin. For purposes of the review of applications for long-term care, standards defined in this section apply to all facilities subject to licensure under Chapter H 32, Wisconsin Administrative Code.

(1) Definitions. (a) Long-Term Care Facility. For purposes of this chapter, long-term care facilities are those which are licensed under the provisions of Chapter H 32, Wisconsin Administrative Code.

(b) Specialized Long-Term Care Facilities. For purposes of this chapter, specialized long-term care facilities include:

1. Facilities serving primarily a state or nationwide population and in which less than 50 percent of the residents have originated from any one non-specialized long-term care planning area.

2. Facilities in which: a. More than 50 percent of the residents are under age 65 and have a primary diagnosis of mental retardation or mental illness, and

b. A program oriented to the care and treatment of the mentally retarded or mentally ill is offered.

3. Facilities in which: a. More than 50 percent of the residents have a primary diagnosis of drug abuse or alcoholism, blindness, or severe physical handicap, and

b. A corresponding program of care and treatment is offered.

NOTE: The designation of specialized facilities for purposes of determination of need in no way implies that the populations served by those facilities cannot or should not be treated in long-term care facilities having adequate personnel or programs nor does it imply the appropriateness of any particular treatment modality in what has been described as either specialized or non-specialized long-term care facilities.

(2) Accessibility. The location of long-term care facilities should allow reasonable access to facilities by physicians, staff, relatives, and friends of the patient. Reasonable access shall be defined as not more than 30 minutes driving time under normal conditions.

(3) Need For Services. (a) For the purpose of the long-term care facilities standards, planning areas shall be counties except that the following areas within the southeastern Wisconsin health service area designated in the 1974-75 Hill-Burton State Plan shall constitute planning areas: Milwaukee northwest; Milwaukee south; Racine south central; Kenosha southeast; Washington/Ozaukee north; Walworth/Racine/ Kenosha southwest; Waukesha west.

(b) For the purposes of the specialized long-term care facilities standards, planning areas shall be coterminous with the health service areas except that for those facilities identified as serving a statewide population, the state shall constitute a single planning area.

2. The percentage of potential residents of the facility in the state and planning area who can be expected to require institutional services.

3. The availability of alternative non-institutional services in the planning area.

4. The comments and recommendations received by the department from, but not limited to, the following agencies:

a. Division of Community Services

b. 51.42/.437 Board

c. County social service department

d. Health Systems Agency

e. Mental health planning agency or body

f. Bureau of Protective Services

g. Other relevant agencies and organizations

5. The ability of long-term care facilities in the planning area to serve the specialized population.

(4) Relationship to Existing Health Care System. Applicants proposing to establish or expand long-term care facilities shall provide evidence of the accessibility of physicians and other health care personnel to residents of the facility.

(5) Minimum Facility Size. The minimum acceptable size for the establishment or replacement of a long-term care facility shall be 60 beds, except in those cases where proposed facilities are in areas where the 30-minute accessibility standard is not met.

3/15/78-rev.

BURN CENTERS. The following standards shall be used by the department in the review of applications for certificates of need for designated burn centers. The general criteria and standards shall be used in the review of all applications to establish other levels of burn services such as a burn program.

(1) Definitions. (a) Burn Center. A discrete, self-contained service that is equipped, staffed, and devoted exclusively to the provision of burn care. A burn center has its own nursing station; intensive care beds, rooms, and equipment are distinct from other units; and it is spatially separate from any other inpatient service. It has the capacity to provide: emergency care and stabilization of burn patients; evaluation of burn severity; acute, convalescent, and rehabilitative burn care; basic and clinical research; and education and training. All persons diagnosed as sustaining severe burn should be considered candidates for a burn center even though it may be geographically distant.

(b) Burn Program. A burn program is not a discrete, dedicated unit. A burn program may exist in any acute care facility which offers a consistent burn treatment plan and associated protocols directed by a qualified physician. It has the capability to provide: emergency care and stabilization of burn patients; evaluation of burn severity; referral of severe burns to burn centers for more intensive care; definitive care for low risk burn patients; and convalescent and rehabilitation burn care (optional).

(c) Severe Burn. Severe burns include all life-threatening burns, all burns to persons under two years of age or over 60 years of age that require hospitalization, and all second and third degree burns involving a significant area of the body. Significant area of the body is defined as 20 percent of the body surface for adults, ten percent of the body surface for children and persons aged 65 and over; and two percent of body surface for all electrical burns. These percentages may be reduced for burns involving multiple sites.

(d) Dedicated Burn Bed. A dedicated burn bed is one which is used solely for the case of the severely burned patient and for which specially trained staff are provided.

(2) Need for Services. (a) For purposes of reviewing proposals to establish or expand burn centers, the state of Wisconsin shall constitute a single planning area.

(b) The need for additional burn center beds shall be clearly demonstrated and documented. The demonstration of need shall include at least the following considerations:

1. A projection based on the current utilization in days of care/1,000 population which includes estimates of changes due to alterations in physician referral practices, patient migration, and the availability of alternate treatment resources.

2. The anticipated relationship with other burn centers and burn programs.

(5) Minimum Size. The minimum size of any new burn center shall be 4 acute and 2 intensive care beds. Where the need for additional burn center services is indicated, proposals to expand existing burn centers shall be given priority over proposals to establish new burn centers.

(6) Resource Availability. Facilities proposing to develop or expand a burn center shall provide documentation that the resources necessary for the projected number of severe burn patients are available. Such resources shall include those rated essential in criteria A.2., A.4., B., C., D., E., F., and G. of Specific Optimal Criteria for Hospital Resources for Care of Patients with Burn Injury, (April, 1976).

(7) Location of Standards. The above mentioned standards are available on file in the Department of Health and Social Services, Division of Health, in the Office of the Secretary of State, and the Revisor of Statutes Bureau.

4/13/78-rev.

PERINATAL SERVICES. The following standards shall be used in the review of proposals to establish or expand perinatal care centers, neonatal intensive care units including special care nurseries or high-risk obstetrics services.

(1) Definitions: (a) Delivery Base. The annual number of deliveries within a planning area from which the center expects to draw its high-risk patients.

(b) High-Risk Obstetric Service. An organized health care service combining specialized facilities and staff for the intensive care and management of high-risk maternal and fetal patients before and during birth, and to maternal patients following birth. A high-risk obstetrics service provides the most specialized level of care to maternal and fetal patients.

(c) Low Birth-Weight. Under 5 pounds, 8 ounces (under 2,500 grams).

(d) Neonatal. Pertaining to the first 28 days of life.

(e) Neonatal Intensive Care Unit. An organized health care service combining specialized facilities and staff for the intensive care and management of high-risk neonatal patients.

(f) Neonatal Intensive Care Bed. A bed in a neonatal intensive care unit or special care nursery capable of providing temperature support, oxygenation, ventilation, hydration, and monitoring heart rate, respiration, and direct and indirect blood pressure.

(g) Neonatal Intermediate Care Bed. A bed in a neonatal intensive care unit or special care nursery capable of providng temperature support, continuous cardiac monitoring, and indirect blood pressure determination.

(h) Perinatal. Pertaining to the mother, the fetus, or the neonatal infant.

(i) Perinatal Care Center. An organized health care service which includes a high-risk obstetrics service and a neonatal intensive care unit.

(j) Special Care Nursery. An organized health care service which provides care for a large number of newborns at some degree of risk.

(2) Need For Perinatal Services. (a) For purposes of planning for perinatal care centers in Wisconsin, planning areas shall be coterminous with health service areas. Patterns of patient migration between planning areas will be considered in applying this standard.

(b) The location of a perinatal care center shall allow reasonable access to the perinatal services by patients in the region served. Reasonable access shall be interpreted as a maximum of 2 hours of normal driving time one way.

(c) Determination of need for neonatal intensive and intermediate care beds shall be calculated in the following manner: 1. In a planning area, the projected need for neonatal intensive and intermediate care beds shall be computed as follows: a. Divide the annual number of low birth-weight deliveries in the planning area by the annual number of births.

b. Divide the result by 80.

(c) Applicants proposing to establish or expand a perinatal care center component shall provide documentation that they have established or have plans to establish a 24-hour telephone consultation service to physicians and other professionals and hospitals in the service area of the perinatal care center.

(4) Availability of Resources. Applicants proposing to establish or expand components of a perinatal care center shall document that they shall be able to meet the following minimum staffing requirements:

(a) Perinatal care centers. 1. Nursing care aspects of both the obstetric and neonatal components of the perinatal care center shall be coordinated by a registered professional nurse. This nurse shall have obtained specialized nursing knowledge and skills by successfully completing an organized educational program in maternal or neonatal intensive care, and shall have at least one year of experience in an obstetrics unit associated with a neonatal intensive care unit, or in a recognized perinatal care center.

2. A physician trained in anesthesiology shall be on call 24 hours per day.

(b) High-risk obstetrics component. 1. The high-risk maternal/fetal and intrapartum intensive care segment of a perinatal care center shall be under the direction of a physician trained in high-risk obstetrics. This obstetrician shall have at least one year of experience in high-risk intensive care in an organized high-risk program beyond the standard residency in obstetrics. Consultation from a physician trained in high-risk obstetrics shall be available for all high-risk patients.

2. A registered professional nurse shall be available to assist the antepartum, intrapartum, and postpartum care of each high-risk mother. These RNs shall have obtained specialized nursing knowledge and skills by successfully completing an organized educational program in maternal intensive care.

(c) Neonatal intensive care component. 1. The high-risk fetal/neonatal intensive care segment of the perinatal care center shall be under the direction of a physician who is board-eligible or board-certified in neonatology. Consultation from a physician trained in high-risk neonatology shall be available for all high-risk patients.

2. Registered professional nurses shall be on the nursing staff of the neonatal intensive care unit on each shift. At least one RN on each shift shall have obtained specialized nursing knowledge and skills by successfully completing an organized educational program in neonatal intensive care.

3. The neonatal intensive care unit shall maintain a minimum ratio of one RN for every two intensive care infants. The intermediate care unit shall be staffed with one RN for every four patients or one RN and additional nursing personnel at a minimum ratio of one RN or LPN for every four patients.

END-STAGE RENAL DISEASE SERVICES. The following standards shall be used by the department in the review of applications for certificates of need for the establishment or expansion of end-stage renal disease services.

(1) Definitions. (a) Chronic Maintenance Dialysis. A process by which waste products and excess fluid are removed from a patient's body by osmosis from one fluid compartment to another. The two types of dialysis which are currently in common clinical practice are hemodialysis and peritoneal dialysis.

(b) Chronic Maintenance Dialysis Station. The plumbing, electrical system, dialysis machine, and space which will accommodate a bed, chair, and other equipment used to perform chronic maintenance dialysis.

(c) Dialysis Machine. The device used to perform dialysis. Distinguished from the term "station" in that "machines" are not restricted for chronic maintenance dialysis and do not require approval; rather, they may be used for backup support for the stations, acute care of patients, or with patients who require isolation.

(d) End-Stage Renal Disease. That stage of renal impairment which is almost always irreversible and requires dialysis or kidney transplantation to maintain life.

(e) Free-Standing Renal Dialysis Facility. A non-hospital-based unit which is approved by the department and federal government to furnish chronic maintenance dialysis.

(f) Renal Dialysis Center. A hospital-based unit which is approved by the department and federal government to furnish the full spectrum of diagnostic, therapeutic (including inpatient dialysis furnished directly or under arrangement or agreement), and rehabilitative services, except renal transplantation, required for the care of ESRD dialysis patients.

(g) Renal Dialysis Facility. A hospital-based unit which is approved by the dpeartment and federal government to furnish chronic maintenance dialysis.

(h) Renal Transplantation Center. A hospital unit which is approved by the department and federal government to furnish transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement or agreement.

(i) Self-Care Dialysis. Chronic maintenance dialysis performed by a trained ESRD patient and patient helper at home or in approved self-care dialysis unit.

(j) Self-Care Dialysis Training Program. A program which formally trains ESRD patients and patient helpers to perform self-care dialysis.

(k) Self-Care Training Station. The plumbing, electrical system, and space which will accommodate a dialysis machine, bed, chair, and other equipment used to train ESRD patients, and patient helpers to perform self-care dialysis.

2. Utilization of Peritoneal Dialysis Stations. a. A facility or center proposing to establish a peritoneal dialysis station must demonstrate that at least one patient is in need of this type of treatment.

b. No additional peritoneal dialysis stations shall be established until each peritoneal dialysis station is actively treating at least two patients simultaneously.

c. Peritoneal dialysis stations used for the purpose of self-care training shall be excluded from consideration as active treatment stations at the rate of one exclusion for each six self-care patients trained per station within the preceding twelve months.

3. The availability of self-care dialysis training in the planning area.

4. The incidence and prevalence rates for ESRD within the planning area.

5. The availability of appropriate treatment for pediatric patients with end-stage renal disease.

6. Alternate methods of providing care and treatment for ESRD patients.

7. The existence of documented medical emergency situation, or seasonal influx of patients, for which a temporary station may be approved for up to six months operation. After that period, full approval must be sought by the facility or center.

(c) When the need for additional dialysis service capacity is demonstrated, existing facilities or centers shall increase the number of shifts operating daily, rather than institute additional stations.

(d) An additional self-care training station is justified only for those facilities or centers which have trained at least six persons per station within the previous year.

(4) Relationship to Existing Health Care System. Renal dialysis centers and facilities shall have referral agreements with renal transplantation centers.

COMPUTED TOMOGRAPHY SERVICES. The following standards shall be used by the department in the review of applications for the acquisition of computed tomography equipment.

(1) Definitions. (a) Computed Tomography Equipment. Diagnostic equipment which uses radiographic and computer techniques to produce cross-sectional images of the head and body. In this document all computed tomography equipment will be referred to as CT. When specifically a head or body scanner is under consideration, it will be so stated.

(b) Enhancement. Alteration of coefficients of absorption by administration of contrast media.

(c) Scan: The series of images (slices) necessary for CT diagnosis of one anatomical area. Tabulation of scans for CT utilization data:

1. An unenhanced scan shall count as one scan.

2. An enhanced scan shall count as one scan.

3. An unenhanced scan, followed by an enhanced scan, shall count as two scans.

(2) Need For Services. (a) For purposes of reviewing proposed applications for the acquisition of computed tomography equipment, planning areas shall be coterminous with health service areas.

(b) Utilization. 1. The quantitative demonstration of projected utilization shall include, but not be limited to, the following:

a. A description of the assumptions and methodology used to calculate the utilization projections.

b. Annual utilization projections based upon relevant historical data, physician referral and practice patterns (including the geographical origin of CT candidates by county or zip code), and the incidence of pathologic conditions or disease in the population for which CT is medically indicated.

c. The application shall contain a list of the active medical staff of the facility indicating medical specialty of each physician and other hospitals where the physician has staff privileges.

d. Documentation of where the CT patient population to be served received CT diagnostic services in the past or the modalities used to provide diagnostic services in lieu of CT.

e. A description of the proposed services' impact on the utilization of similar or alternate services in the planning area or adjacent planning areas.

2. Projected utilization volumes of the proposed CT scanner shall be evaluated by the department. Such evaluation shall include, but not be

4. A facility proposing to acquire a CT scanner shall provide evidence that it will perform 1,600 scans the first year of operation, 2,000 the second year and 2,500 every year thereafter.

(c) Additional technological enhancement, if reviewable, shall be approved only after demonstrating cost effectiveness or increased quality of care.

(3) Relationship To Existing Health Care System. To ensure a maximum potential for sharing of a CT scanner with other facilities within a health service area, a facility proposing to acquire a CT scanner shall provide evidence of cooperative agreements for utilization of the proposed equipment including, but not limited to:

(a) Multiple facility application.

(b) Letters of support from referring physicians, clinics, and other acute care facilities indicating a commitment to make referrals to the proposed CT scanner site.

(c) A detailed plan of the proposed methods by which these referrals are to be accommodated including at least:

1. Administrative procedures to ensure equitable access to non-facility patients.

2. Methods to be used in transportation of patients.

3. The prompt reporting of CT results to referring physicians according to standard medical practice.

4. A willingness and ability, when necessary to operate beyond a regularly scheduled day.

(4) Resource Availability. (a) Staffing Resources. A facility proposing to acquire a CT unit shall;

1. Provide full-time (24 hours/day, 7 days/week) coverage of the unit by physicians trained in the interpretation of CT images.

2. Have at least two physicians trained and certified in radiology, who are proficient in CT interpretation.

3. Provide adequate numbers of registered or licensed radiological technologists trained in CT operation who will be assigned full-time to the CT unit.

(b) Technical Resources. 1. An applicant proposing to acquire a CT scanner shall provide evidence that it is now providing in its facility or in a contiguous facility a broad spectrum of imaging modalities and special procedures which complement CT scanning, including but not limited to, angiography, lymphangiography, ultra-sound and nuclear medicine imaging, and 40,000 inpatient and outpatient (report separately) radiographic procedures (including fluoroscopy).

4. Indirect costs including those relating to space (physical plant), management support, and other relevant overhead costs.

5. Provision for the establishment of separate accounting of costs of the proposed CT scanning operation.

6. The projected non-professional and professional charges for:

a. An unenhanced scan.

b. An enhanced scan without an unehanced scan.

c. An unenhanced scan followed by an enhanced scan.

7. The projected number of scans to be performed annually.

(b) The proposed patient charges shall be based upon the projected annual utilization of the CT service. Direct costs, indirect costs, rates, etc., are to be annualized and provided in the application over a three-year projected utilization period. The amortization period for CT shall not be less than five years using a straight line method.

(c) The department's analysis of the financial feasibility of a proposal to acquire CT shall include consideration of at least the following:

1. Charges due to the direct costs associated with providing the service.

2. Charges due to the indirect costs associated with providing the service.

3. Debt capacity of the facility.

4. Economies of scale.

5. Current rate structure.

(7) Cost Containment. The applicant shall demonstrate that the proposed project fosters cost containment and improves the quality of care. The CT scanner shall be treated as a cost center in the facilities accounting system. The applicant shall provide a plan for amendment of the accounting system so that the CT services can be financially partialed out of the entire accounting system. The demonstration of cost containment shall address the following:

(a) Savings or losses for distance traveled, work time, convenience and other non-medical factors affecting patients.

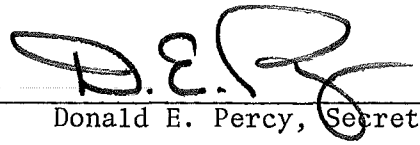
(b) Projected savings due to the elimination of other tests by the use of CT.

(c) The cost impact of utilization, geographic locations, and relationship of the proposed CT scanners on existing approved scanners in the service area and state.

The rules contained herein shall take effect on July 1, 1978.

May 15, 1978

Department of Health and Social Services



Donald E. Percy, Secretary