

CHAPTER 33L**CERTIFICATE OF NEED: HOME HEALTH AGENCY POLICY MANUAL****Authority**

N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5 and 2H-7.

Source and Effective Date

R.1997 d.163, effective April 7, 1997.
See: 28 N.J.R. 3908(b), 29 N.J.R. 1309(a).

Executive Order No. 66(1978) Expiration Date

Chapter 33L, Certificate of Need: Home Health Agency Policy Manual, expires on December 31, 1997.

Chapter Historical Note

Chapter 33L, Certificate of Need: Home Health Agency Policy Manual, was adopted as R.1987 d.452, effective November 16, 1987. See: 19 N.J.R. 1483(c), 19 N.J.R. 2184(a). Amendments were adopted as R.1989 d.559, effective November 6, 1989; Emergency R.1991 d.22, effective December 13, 1990, and R.1991 d.159, effective March 18, 1991. See: 21 N.J.R. 2455(a), 21 N.J.R. 3506(a); 23 N.J.R. 124(a), 23 N.J.R. 905(a). Pursuant to Executive Order No. 66(1978), Chapter 33L, Certificate of Need: Home Health Agency Policy Manual, expired on November 16, 1992.

Chapter 33L, Certificate of Need: Home Health Agency Policy Manual, was adopted as R.1994 d.279, effective June 6, 1994. See: 26 N.J.R. 1065(a), 26 N.J.R. 2266(a). Pursuant to Executive Order 66(1978), Chapter 33L, expired on June 6, 1996.

Chapter 33L, Certificate of Need: Home Health Agency Policy Manual, was adopted as R.1997 d.163, effective April 7, 1997. See: Source and Effective Date.

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SUBCHAPTER 1. GENERAL PROVISIONS**8:33L-1.1 Purpose and scope**

(a) The Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.) establishes as a policy of the State of New Jersey that health care services "of the highest quality, of demonstrated need, efficiently provided and properly uti-

lized at a reasonable cost are of vital concern to the public health," N.J.S.A. 26:2H-1. This Act has given the State Department of Health the "central responsibility for the development and administration of the State's policy with respect to health planning, hospital and related health care services and health care facility cost containment and all public and private institutions, whether state, county, municipal, incorporated, not incorporated, serving principally as residential health care facilities, nursing or maternity homes or as facilities for the prevention, diagnosis, or treatment of human disease, pain, injury, deformity, or physical condition," N.J.S.A. 26:2H-1.

(b) The statute goes on to stipulate that "no health care facility shall be constructed or expanded, and no new health care services shall be instituted . . . except upon application for and receipt of a certificate of need" (N.J.S.A. 26:2H-7). Consequently, the rules which are detailed below specify the certificate of need requirements for all new or expanding home health agencies, or for home health agencies which are transferring ownership. These rules do not, however, apply to homemaker or temporary nursing agencies, which are not Medicare-certified and which do not propose to become Medicare-certified, or programs which are hospice only.

8:33L-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Charity care" means home visits that are provided by a home health agency to medically indigent patients either at no charge to the patient or at a reduced charge.

"Coordination and standardization of care" means the provision of home health services in accordance with patients' need and with protocols established by a home health agency, so that all patients of the agency receive the following aspects of service in a standardized, consistent manner: screening for agency admission and discharge, case management, follow-up of health-related problems, and referrals to other agencies and service providers for care that can not be offered by the home health agency.

"Department" means the New Jersey State Department of Health.

"Home health agency" or "agency" means a facility which is licensed by the New Jersey State Department of Health to provide preventive, rehabilitative, and therapeutic services primarily to patients in their homes. All home health agencies shall provide nursing, homemaker-home health aide, and physical therapy services in the patient's home or place of residence.

"Hospice" means a comprehensive program of palliative/supportive services for dying persons and their families, utilizing an interdisciplinary team of professionals and volunteers. The program provides components of physical, psychological, social, and spiritual care, including bereavement counseling, institutional respite, inpatient care, and home care.

"Hospital-related home health agency" means a home health agency for which the license is held by a hospital, or by a subsidiary corporation of a hospital, or an agency which is a member of a corporate system which includes a licensed hospital in the service area proposed in the agency's certificate of need application.

"Low income municipality" means any municipality with a population of 30,000 or more where 15 percent of families are living below the Federal poverty level, according to the most recent U.S. Census Bureau data.

"Medically indigent patient" means a person who requires nursing care or other home health agency services but who lacks sufficient resources to pay either the full amount of agency charges or any portion of those charges for the care (that is, income at or below 250 percent of the Federal poverty guidelines, as published annually in the Federal Register) and who also lacks third party payment coverage for the full cost of the needed services.

"Reimbursable cost center" means a service such as nursing, physical therapy, occupational therapy, speech therapy, social work, and home health aide service, for which Medicare reimburses home health agencies.

"Seven-day-a-week, 24 hour-a-day service" means continuous nursing staff coverage which is available to the home health agency's new referrals (that is, patients for whom the agency has received written physician's orders) and current patients during evenings, nights, weekends, and holidays.

"Skilled nursing visit" means personal contact between an individual patient and a registered nurse or licensed practical nurse who is sent from a home health agency. The visit takes place in the patient's place of residence and is conducted for the purpose of providing preventive, rehabilitative, or therapeutic nursing care, including, but not limited to, health assessment, monitoring, counseling, and complex therapies such as total parenteral nutrition (TPN), central line infusion and ventilator care.

"Special needs populations" means those patients with diagnoses which continuously require comprehensive skilled nursing care including treatment modalities such as TPN and chemotherapy. For example, these can include pediatric, HIV-infected or medically indigent patients.

SUBCHAPTER 2. REQUIREMENTS

8:33L-2.1 Service area

(a) The service area of a home health agency shall be the county within which the agency's office is located, or a specified sub-area of that county, or two or more counties or the sub-areas of two or more counties. Each office of an agency shall be staffed and equipped in accordance with the Department of Health Standards for Licensure, as required by N.J.A.C. 8:42.

(b) Any proposed establishment of a new service area as described in (a) above, or any proposed expansion of or other change in an existing agency's service area, shall require Certificate of Need approval through a full review process, pursuant to N.J.A.C. 8:33.

(c) Due to the complexity inherent in successfully establishing a new home health agency, the maximum number of counties that any applicant for a new home health agency shall propose to serve is one county or the sub-areas of two contiguous counties.

1. An exception to (c) above may be considered by the Department of Health in the case where an applicant for a new agency proposes to serve no more than two contiguous counties, each with a population density of less than 300 persons per square mile, according to the most recent available U.S. Census data. For the purpose of this chapter, these counties are Cumberland, Hunterdon, Salem, Sussex, and Warren. The request for an exception to (c) shall be granted, provided that the application complies with all other applicable requirements contained in this chapter.

(d) Certificate of need applicants proposing to serve an area that extends more than 25 miles from the agency's chief office shall identify those strategies that will be implemented to assure coordination and standardization of home health care throughout the service area, including whether the agency will maintain branch offices in specified locations.

8:33L-2.2 Home health service utilization rates

(a) An applicant for a certificate of need to provide home health services shall demonstrate the capability to provide a minimum of 5,000 skilled nursing visits per year within the first two years of operation in the proposed service area, as described in N.J.A.C. 8:33L-2.1(a). In addition, the agency shall provide all other services required to comply with applicable licensure requirements pursuant to N.J.A.C. 8:42. The volume of skilled nursing visits shall be increased to 10,000 visits per year within five years after the date of the agency's Certificate of Need approval and shall be maintained annually.

(b) The following are exceptions to (a) above:

1. Agencies serving counties with a population density of less than 300 persons per square mile, according to the most recent available U.S. Census data. For the purpose of this section these counties are Cumberland, Hunterdon, Salem, Sussex, and Warren. In these low population density counties, a home health agency must demonstrate the capacity to provide a minimum of 4,000 skilled nursing visits per year within the first two years, in addition to all other services provided to comply with the requirements for licensure pursuant to N.J.A.C. 8:42. The volume of skilled nursing visits shall be increased to 8,000 visits per year within five years after the date of the agency's Certificate of Need approval and shall be maintained annually;

2. Existing agencies which receive Certificate of Need approval to expand their service area, in which case the agency shall demonstrate the capability to provide a minimum of 2,000 skilled nursing visits per year in each newly approved service area, in addition to providing all other services necessary to comply with the requirements for licensure pursuant to N.J.A.C. 8:42. The volume of skilled nursing visits shall be achieved within two years after the date of the agency's Certificate of Need approval and shall be maintained annually; and

3. Agencies proposing to serve a low income municipality or a special needs population, as described in N.J.A.C. 8:33L-2.4(h) and (i). For these agencies, the applicant shall demonstrate the capability to provide a minimum of 2,500 skilled nursing visits per year, in addition to providing all other services required to comply with the requirements for licensure pursuant to N.J.A.C. 8:42. The volume of skilled nursing visits shall be achieved within two years after the date of the agency's Certificate of Need approval and shall be maintained annually.

(c) Certificate of need approval for the expansion of an existing home health agency into a new service area shall only be granted if the existing agency is providing at least 5,000 skilled nursing visits per year if the agency is located in a low population density county as described in (b)1 above. This minimum volume of visits shall be maintained annually in addition to the visits approved for the new service area, as described in (b)2 above.

(d) If an agency receives certificate of need approval to offer services in a specified area and, after five years from the date of certificate of need approval, is unable to demonstrate to the satisfaction of the Department of Health, the applicable volume of skilled nursing visits specified in (a) through (c) above, the Commissioner of Health may, in accordance with this chapter, revoke the agency's license or may institute other licensure penalties. Any licensure revo-

cation procedure shall be conducted in accordance with the Administrative Procedures Act (N.J.S.A. 52:14B-1 et seq.) and the Uniform Administrative Procedure rules (N.J.A.C. 1:1).

8:33L-2.3 Cost efficiency

(a) Applicants for certificate of need approval shall document that the least costly alternatives, either directly provided or subcontracted services, will be utilized, where the services meet applicable quality of care standards. However, because of the potential for problems with providing continuity of care, agencies proposing the full subcontracting of nursing services shall not receive certificate of need approval.

(b) Consistent with applicable licensure rules (N.J.A.C. 8:42), agencies shall be precluded from fully subcontracting for all nursing services. Violation of this condition at any time shall constitute a sufficient basis for the Commissioner of the Department, within his or her discretion, in accordance with this chapter, to revoke the agency's license or institute other licensure penalties. Any revocation procedure shall be conducted in accordance with the Administrative Procedures Act (N.J.S.A. 52:14B-1 et seq.) and the Uniform Administrative Procedure Rules (N.J.A.C. 1:1).

(c) To maximize productivity without compromising the quality of care, staffing should be adequate to meet the demands of patient volume in accordance with the provisions of N.J.A.C. 8:42.

8:33L-2.4 Certificate of need requirements

(a) In addition to all other applicable required items of documentation specified in this chapter, applicants proposing to expand an existing home health agency's service area or to institute a new agency shall submit all of the following with their application:

1. Documentation of proposed referral resources. Letters of support from community agencies and health care facilities shall be submitted indicating to the satisfaction of the Department of Health the number of referrals which can be expected annually and indicating a willingness to establish referral arrangements upon home health agency licensure;

2. Documentation of the financial feasibility of the project. Expense and revenue projections shall be submitted covering a period of at least two years beyond the point at which expenses are expected to no longer exceed revenues. Also required for submission is third party verification of the availability of sufficient capitalization to meet start-up costs for the period until revenues exceed expenses or for the first six months of operation, whichever is longer;

3. Documentation of home health care access problems in the service area. Certificate of need approval shall only be granted in those instances where there are one or more of the following documented access problems and where the applicant is able to provide compelling evidence, to the satisfaction of the Department of Health, that these specific problems will be substantially ameliorated by the new agency. Where data from annual surveys conducted by the Department of Health form the basis for identifying the service area's access problems enumerated in (a)3i through iv below, the most recent, annual home health agency survey data that are available at the time that the Certificate of Need applications are accepted for processing shall be utilized. Access problems to be considered include the following:

i. Absence of an existing home health agency providing care in the proposed service area which offers skilled nursing services on a seven-day-a-week, 24-hour-a-day basis, as defined at N.J.A.C. 8:33L-1.2 and as indicated by results from an annual survey conducted and reported by the Department of Health and by annual licensure inspection reports. For the purpose of this section, on-call staff are required to be responsive within one hour of attempted contact via an answering service or direct telephone contact. Tape answering machines are not considered sufficient for the provision of on-call coverage during evenings, nights, weekends, and holidays.

ii. Absence of existing home health agencies providing care in the proposed service area which, in addition to those forms of care required for agency licensure, offer speech pathology, occupational therapy, and social work services. These services may be made available either through direct provision or through sub-contracting by the home health agencies. Annual licensure inspection reports and results of an annual survey conducted and reported by the Department of Health shall be used to determine provision of the aforementioned services by home health agencies in service areas.

iii. Absence of existing home health agencies providing care in a proposed service area which offer complex treatment modalities. For the purpose of this rule, complex treatment modalities shall include mechanical ventilator care, intravenous and central line infusion therapies. These services shall be available to patients in the service area who require them, either through direct provision by one or more of the service area's home health agencies or through subcontracting by the home health agencies with another licensed home health agency that provides the service directly. Annual licensure inspection reports and results of an annual survey conducted and reported by the Department of Health shall be used to determine provision of the aforementioned services by home health agencies in service areas.

iv. Absence of a Medicare-certified hospice program providing care for the terminally ill in the proposed service area. Agencies receiving Certificate of Need approval to correct this access problem shall be required to obtain Medicare certification as a hospice program and to maintain this certification continuously. Documentation of areas served by Medicare-certified hospice programs shall be reported by the Department of Health based on information supplied by the Department's Division of Health Facilities Evaluation, supplemented by information from the New Jersey Hospice Organization;

4. Documentation of experience in the provision of preventive, rehabilitative and therapeutic services to patients;

5. Documentation on the volume of proposed visits by type and the number of staff who will be providing these visits; and

6. Documentation that the full range of services, for example, nursing, physical therapy, occupational therapy and speech therapy, will be provided in accordance with N.J.A.C. 8:42-3.1.

(b) Where there is more than one certificate of need application for a home health agency in a service area with documented access problems as identified in (a)3 above, priority shall be given to approving that application which proposed to correct all or the greatest number of identified access problems in the service area and which is in compliance with all other applicable criteria in this chapter. Additional prioritization criteria include the following:

1. The broadest range of services, including the provision of health promotion, chronic illness care, and illness prevention programs to the community;

2. The greatest amount of free (that is, no pay) care to medically indigent patients;

3. Patient volume of special needs populations;

4. The expansion of an existing agency, provided that the agency has been operational for a minimum of three years, has a track record of quality care as determined by the Department of Health's Division of Health Facilities Evaluation, and has a record of compliance with previous conditions of certificate of need approval;

5. The expansion of an existing agency with a documented history of a greater than average amount of care provided on a no pay basis to medically indigent patients; and

6. The ability to implement the project quickly.

(c) When a home health agency receives certificate of need approval to ameliorate a service area's access problems as specified in (a)3 above, that approved agency shall be given a two year period to correct the identified access problems. No additional agencies shall be approved in the service area for the purpose of addressing those same access problems during the two year period subsequent to the date of Certificate of Need issuance. The approval of an agency shall be conditioned such that the Commissioner of Health may revoke the agency's license if the applicant fails to demonstrate good faith efforts to ameliorate the access problems as specified in the certificate of need application. Any licensure revocation procedure shall be conducted in accordance with the Administrative Procedures Act (N.J.S.A. 52:14B-1 et seq.) and the Uniform Administrative Procedure Rules (N.J.A.C. 1:1).

(d) To insure consumer choice, every county or sub-area of a county shall be served by a minimum of three home health agencies. If an area is served by only two home health agencies, and it exhibits none of the access problems identified in (a)3 above, an additional agency may still receive Certificate of Need approval to serve that area, provided that it complies with all other applicable requirements in this chapter.

(e) Applicants shall submit a copy of proposed staff education materials, including documentation regarding how universal precautions shall be instituted by all agency staff who are involved in direct patient care. As a condition of certificate of need approval, agencies shall agree not to deny care on the basis of diagnosis.

(f) Agencies receiving certificate of need approval shall be required to complete and return the Department of Health's survey of home health agencies and to submit a complete cost report on an annual basis, or more frequently, if requested by the Department. Unless otherwise specified by the Department, a separate survey shall be completed for each county served by the agency. This survey shall include, but not be limited to, questions regarding the number of clients served according to age groupings, types (for example, skilled nursing, occupational therapy and social work) and numbers of visits provided, number of visits according to reimbursement source (including no-pay visits to medically indigent patients), and agency charges for services rendered.

(g) Applicants shall agree to enter into and maintain a formal affiliation with the Department of Health's AIDS Division to assure follow-up and case management of patients who are or may be HIV-infected.

(h) To promote access to care for medically indigent patients, the Commissioner of Health shall give consideration to approving a new or expanding home health agency proposing to serve any low income municipality with a population of at least 30,000 or group of contiguous low income municipalities with a population of at least 30,000.

Documentation shall be submitted by the applicant, to the satisfaction of the Department of Health, indicating that existing agencies serving the area are not offering adequate home health care access to the low income population. This criterion shall apply even if the proposed service area does not demonstrate an access problem in accordance with the criteria identified in (a)3 above.

1. Documentation to be submitted by the applicant shall include a local community health care needs assessment/survey and letters from at least three referral sources (that is, health care facilities or social service agencies that are 100 percent corporately independent from the applicant) citing specific instances during the prior 18 month period when patients were denied timely access to needed services by existing home health care agencies in the service area.

2. In addition to meeting other applicable requirements of this chapter, the applicant shall submit a plan documenting how charity care for medically indigent patients shall be provided and paid for, in an amount that exceeds the average amount being provided by all other home health agencies already serving the proposed service area.

(i) To promote the availability of care for special needs populations that may have difficulty accessing needed home health services, the Commissioner of Health shall give consideration to approving a new or expanding agency, even if the proposed service area does not demonstrate an access problem in accordance with the criteria identified in (a)3 above.

1. As a condition of certificate of need approval, home health agencies approved to serve a special needs population shall be permitted to provide home health services only to members of the identified population; all other patients shall be referred to other home health agencies in the service area.

2. In addition to complying with all other applicable requirements of this chapter, the applicant for a home health agency proposing to service a special needs population shall submit the following forms of documentation, to the satisfaction of the Department of Health:

- i. Evidence that none of the existing agencies serving the area is offering adequate home health care access to the identified special needs population;

- ii. Letters from at least three referral sources (that is, health care facilities or social service agencies that are 100 percent corporately independent from the applicant) citing specific instances during the prior 18 month period when patients within the special needs population were denied timely access to needed services by existing home health care agencies;

- iii. A detailed description of the unique programs and services that will be offered by the proposed agency to meet the special needs of the identified population

and of how these programs and services will be integrated within the area's existing health care system;

iv. Evidence that the health problems of the special needs population can be substantially ameliorated by the forms of care that are typically provided by a home health agency;

v. A description of staff qualifications and strategies that will be implemented by the agency to recruit and retain staff with expertise in the care of the special needs population; and

vi. Verification that the agency will be financially feasible and that reimbursement from third party payers will be available for the majority of services to be provided by the agency.

Case Notes

Denial of application for certificate of need to provide home health care services in two counties was justified where, although application proposed to offer full range of treatments, applicant specifically indicated in supplemental questionnaire that it was planning to provide much more limited range of therapies. Matter of Visiting Nurse Ass'n of Sussex County, Inc., 302 N.J.Super. 85, 694 A.2d 1038 (N.J.Super.A.D., 1997).

Transcripts of board meetings were not adequate written decision for denial of applications for certificate of need to provide home health care. In the Matter of Olsten Kimberly Quality Care, Passaic, 96 N.J.A.R.2d (HLT) 69.

Denial of certificate of need application was upheld where applicant failed to show unmet need for home health care services. In the Matter of Clara Maass Health Systems, Inc., 96 N.J.A.R.2d (HLT) 57.

Denial of certificate of need application upheld when applicant did not demonstrate unmet need or lack of access to home care services. In the Matter of Hudson Home Health Systems of New Jersey, Inc., 96 N.J.A.R.2d (HLT) 41.

Unacceptable data justifies state agency's denial of certificate of need. In the Matter of the Visiting Nurse Association of Sussex County, 96 N.J.A.R.2d (HLT) 36.

Application for certificate of need should not have been determined on basis of prioritization only. Holy Redeemer v. State Health Planning Board, 95 N.J.A.R.2d (HLT) 18.

8:33L-2.5 Special requirements for hospital-related home health agency applicants

(a) In addition to the applicable documentation required by N.J.S.A. 8:33L-2.4, home health agencies which are hospital-related shall submit all of the following with their certificate of need applications:

1. Documentation describing the related hospital's existing discharge planning system, identifying improvements which will be effected as a result of establishment of the proposed agency, and explaining why these improvements could not be effected by making use of existing home health providers in the proposed service area;

2. Documentation that consumer choice of home health service providers shall be promoted within the related hospital. Evidence that referral relationships with other licensed home health service providers in the service area will be established and maintained shall be provided in the application. Hospital-related home health agencies receiving certificate of need approval shall be required to allow for the distribution of brochures from all licensed home health agencies in the service area to all patients in the related hospital. Arrangements shall be required to insure that referrals will be made to home care intake coordinators from other home health agencies in the service area, if this is desired by the patient or the patient's family; and

3. Documentation regarding home follow-up for patients discharged early due to managed care payment plans, for example, post-partum follow-up.

Case Note

Hospital's application for expansion of home health agency service area failed to document either need for or potential adverse effects of expansion. In the Matter of the Application of Englewood Hospital & Medical Center for a Certificate of Need, 96 N.J.A.R.2d (HLT) 75.

8:33L-2.6 Transfer of ownership for home health agencies

The transfer of ownership of a home health agency shall require licensure approval in accordance with N.J.A.C. 8:42.

8:33L-2.7 Care for medically indigent patients

(a) As a condition of certificate of need approval, applicants proposing new agencies or expansion of existing agencies shall be required to provide a copy of a policy including marketing materials for the provision of services, regardless of ability to pay, and for the provision of charity care at a minimum of three percent of its total annual home health reimbursable cost centers.

(b) As a condition of certificate of need approval, applicants shall be required to maintain a sliding fee scale to be used for all proposed home health services. The sliding scale shall incorporate provisions for patients to receive care free of charge, if they meet the definition of "medically indigent," as stated in N.J.A.C. 8:33L-1.2. The proposed fee schedule shall allow for partial payment by patients who have incomes above 250 percent of the Federal poverty guidelines (see definition of "medically indigent") but below 300 percent of the Federal poverty guidelines. The sliding scale shall be submitted with the certificate of need application. Any changes in the schedule are subject to prior approval by the Department.

(c) Pursuant to the prioritization criteria identified in N.J.A.C. 8:33L-2.4(b)2, certificate of need applicants proposing to provide more than the required three percent charity care shall accept as a condition of approval that failure to provide the proposed percentage of charity care annually shall, at the discretion of the Commissioner of

Health, and based on the applicant's compliance with this chapter, result in revocation of the agency's license or other licensure penalties. Any licensure revocation procedure shall be conducted in accordance with the Administrative Procedure Act (N.J.S.A. 52:14B-1 et seq.) and the Uniform Administrative Procedure Rules (N.J.A.C. 1.1).