STATE OF ALASKA

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

ALASKA CERTIFICATE OF NEED
REVIEW STANDARDS AND METHODOLOGIES

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December 9, 2005

Frank H. Murkowski
Governor

Karleen K. Jackson
Commissioner

The *Alaska Certificate of Need Review Standards and Methodologies* included in this document have been adopted by reference in regulations of the Alaska Department of Health and Social Services. To ensure that you have the correct version of this document, please check the current version of 7 AAC 07.025 or contact the Certificate of Need Coordinator.

Questions regarding this document may be referred to Certificate of Need Coordinator, Department of Health and Social Services, P.O. Box 110601, Juneau, AK 99811-0601; telephone: (907) 465-3001.

Additional information is available at the department's Internet web site: http://www.hss.state.ak.us/dph/chems/cert_of_need/.

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Introduction

Alaska law requires that a person who plans to undertake certain activities related to a health care facility, or to make a conversion to a nursing home, must first demonstrate a need for the proposed services and obtain a certificate of need from Alaska Department of Health and Social Services. This is required for nursing home conversions, regardless of cost. For other activities related to health care facilities, the requirement applies to a total expenditure for the activity that meets or exceeds the statutory minimum set by AS 18.07.031.

The purpose of this document is to set out the review standards and methodologies that will be used by the department to evaluate applications for certificates of need. The document has been adopted by reference in the department's regulations at 7 AAC 07.025. Please check that regulation to ensure that you have the most current version of this document.

Additional information regarding the history and current trends for certain types of health care services is available from the department to assist an applicant in the process. Contact the Certificate of Need Coordinator for more information about available resources.

Alaska geography, topography, and demography are unique. They significantly affect both need and demand for health care services. The development and operation of these services necessarily reflect Alaska's distinctive operational environment. To the extent possible, the planning and regulation of health care services should recognize and incorporate these local preferences and operational realities.

I. General Review Standards Applicable to all Certificate of Need Applications

Review Standards

The department will apply the following general review standards, the applicable service-specific review standards set out in this document, the standards set out in AS 18.07.043, and the requirements of 7 AAC 07 in its evaluation of each certificate of need application:

1. The applicant documents need for the project by the population served, or to be served, including, but not limited to, the needs of rural populations in areas having distinct or unique geographic, socioeconomic, cultural, transportation, and other barriers to care.

2. The applicant demonstrates that the project, including the applicant's long-range development plans, augments and integrates with relevant community, regional, state, and federal health planning, and incorporates or reflects evidence-based planning and service delivery. A demonstration under this standard should show that the applicant has checked with the department regarding any relevant state plan, with appropriate federal agencies for relevant federal plans, and with appropriate communities regarding community or regional plans.[1]

3. The applicant demonstrates evidence of stakeholder participation in planning for the project and in the design and execution of services.

4. The applicant demonstrates that they have assessed alternative methods of providing the proposed services and demonstrates that the proposed services are the most suitable approach.

5. The applicant briefly describes the anticipated impact on existing health care systems within the project's service area that serve the target population in the service area, and the anticipated impact on the statewide health care system.

6. The applicant demonstrates that the project's location is accessible to patients and clients, their immediate and extended families and community members, and to ancillary services. This includes the relocation of existing services or facilities.

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[1] *For state planning processes and materials, applicants should contact the Certificate of Need coordinator or check the department's Internet web site at http://www.hss.state.ak.us/dph/chems/cert_of_need/ for links to state planning documents. A summary of state plans through 2003 is available at the following Internet web site: http://www.hss.state.ak.us/dph/targets/ha2010/volume3/plans.htm. For federal health planning processes, a project may refer to documents such as the Healthy People planning documents (for example, Healthy People 2010) and other documents developed by the Centers for Disease Control (www.cdc.gov), Centers for Medicare and Medicaid (www.cms.gov), Agency for Health Care Research and Quality (www.ahrq.com), and other agencies.*

Additional Considerations for Concurrent Review of More than one Application

In completing a concurrent review of two or more applications under 7 AAC 07.060, in addition to applying the standards set out above, the department will compare the extent to which each applicant, including any parent organization of the applicant,

1. demonstrates a commitment to quality that is consistent with, or better than, that of existing services, if any;

2. demonstrates a pattern of licensure and accreditation surveys with few deficiencies and a consistent history of few verified complaints; and

3. demonstrates that the applicant has consistently provided, or has a policy to provide, high levels of care to low-income and uninsured persons.

Review Methodology

For each specific service for which a methodology for calculating a standard of need has been established, the methodology is outlined in this document.

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II. Acute Care Hospital Services: Review Standards and Methodology

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific standards in its evaluation of an application for a certificate of need that involves the addition, renovation, replacement, or relocation of acute care hospital beds:

1. Beds for acute care hospital services for the state or service area will be within the limits calculated using the methodology below. An application will not be approved if bed need standards are exceeded.

2. An applicant serving patients from a community with a population of 10,000 or less demonstrates that the transport of patients to or from those areas for medical care or services will be facilitated, directly or through coordinated efforts with other organizations.

Review Methodology

The department will use the following formula to determine the need for acute care hospital services:

►**STEP ONE:** Determine the projected inpatient caseload for the population to be served using the formula:

$$C = (P_s \text{ x } UR_s) \text{ x } SAS$$

C (caseload) = the number of inpatient days of hospital care required by the service area population in the fifth year from the project implementation date. Both total inpatient caseload and service specific caseload projections will be used if the application is for a specific service (e.g. general medical/surgical, intensive care, pediatrics, acute rehabilitation or obstetrical).
P$_s$ (projected state population) = the official state population cohort projection appropriate to the inpatient service proposed in the fifth year following implementation of the project.
UR (use rate) = the current utilization rate (the average annual number of inpatient days of hospital care used during the preceding three years divided by the population).
SAS (service area share) = the proposed service area's current share of the population to be served, as of the most recent geographic population estimates. If there is public information about service area population changes expected over the planning horizon, such as a military base closing, or a major economic project such as a new mine, the service area share estimate may be modified with explanation to reflect the expected change.

►**STEP TWO:** Determine the projected average daily inpatient census for the service using the formula:

$$ADC = C / SA$$

ADC (average daily census) = average number of inpatients in the proposed hospital service on any given day
C (caseload) = the number of inpatient days of hospital care for the service required by the population to be served in the fifth year from the project implementation date
SA (service availability) = defined as 365 days

►**STEP THREE:** Determine the projected number of hospital beds needed for the service by using the formula:

$$PBN = ADC / TO$$

The projected number of hospital beds needed (PBN) = Service average daily census (ADC) divided by the service target occupancy (TO) factor:

PBN (projected bed need) = Total number of hospital beds needed for service area
ADC (average daily census) = average number of inpatients in the proposed hospital service on any given day
TO (target occupancy**)** = Service target occupancy rate for hospital beds, defined as:

> ***General medical-surgical beds:***[2]
>> Hospitals with more than 100 licensed beds: 75%
>> Hospitals with 50 to 100 licensed beds: 65%
>> Hospitals with fewer than 50 licensed beds: 50%
>
> ***Intensive care beds:***
>> Hospitals with 100 or more licensed beds: 65%
>> Hospitals with fewer than 100 licensed beds: 50%
>
> ***Pediatric beds***:
>> Hospitals with 100 or more licensed beds: 65%
>> Hospitals with fewer than 100 licensed beds: 50%
>
> ***Acute rehab beds:***
>> Hospitals with 100 or more licensed beds: 80%
>> Hospitals with fewer than 100 licensed beds: 65%
>
> ***Obstetrical beds***: [3]
>> Hospitals with 100 or more licensed beds: 65%
>> Hospitals with fewer than 100 licensed beds: 50%

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[2] *For a small facility that does not have specialized units, the general medical-surgical occupancy rates apply.*
[3] *Includes birthing rooms, labor beds, delivery beds, and LDRP beds*

►**STEP FOUR:** Calculate the unmet bed need (UBN) by type of service by subtracting the existing inventory and CON-approved number of the proposed type of hospital beds (IHB) from the total hospital bed need (PBN) for the proposed service area:

$$UBN = PBN - IHB$$

PBN (projected bed need) = Total number of hospital beds by service category needed for service area
IHB (inventory hospital beds) = Number of existing beds and CON-approved hospital beds by service category in the proposed service area.

III. Hospital Laboratory and Emergency Department Services:
Review Standards and Methodology

A. Hospital Laboratory Department Services

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards, as applicable, in its evaluation of an application for a certificate of need that involves the addition, expansion, or relocation of a laboratory. A proposal to add, expand, or relocate a hospital laboratory will not be approved unless the applicant demonstrates that:

1. The population served by a laboratory to be moved will continue to have reasonable access to the service at the new site, or will have reasonable access to comparable laboratory services in the community;

2. For an offsite laboratory replacement project, implementation will result in a substantial cost savings, cost avoidance, consolidation of underutilized facilities, or in other ways improves operational efficiency;

3. Redundant equipment is justified based on demand analysis or limited access to other laboratory equipment and services within the community;

4. Accreditation reports and a visual inspection of the laboratory show a defined need to add space, redesign the laboratory to make it more efficient and safe, ensure higher quality services, and correct functional problems that affect quality and efficiency.

Review Methodology

The department will use a net square feet per patient bed method as follows: Laboratory size may not exceed 50 net square feet per patient bed based on the projected number of beds that would be served by the laboratory or are requested in the application and recommended for approval in the review document.

B. Hospital Emergency Department Services

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards, as applicable, in its evaluation of an application for a certificate of need that involves the expansion of an emergency department:

1. The applicant demonstrates that the project promotes, or otherwise helps ensure, the maintenance of a stable and efficient emergency medical system.

2. For the addition or expansion of general emergency services, a proposal will not be approved unless each emergency department treatment room will provide a minimum of 1,500 visits annually. The total number of emergency department treatment rooms (excluding specialized rooms such as cast/x-ray rooms, observation rooms, secure rooms and space for visiting physician clinics) approved will not exceed one room per 1,500 visits annually, based on utilization projections in the fifth year of operation. The department may approve additional space if the applicant documents use patterns, and submits data and analysis that show seasonal high peak use rates warranting additional treatment rooms.

3. For the addition or expansion of fast track emergency services within a facility, a proposal will not be approved unless the applicant demonstrates that:

    a. the fast track space will have at least one physician, advanced nurse practitioner, or physicians' assistant assigned full-time to the service; and

    b. a minimum of two fast track rooms are needed, each anticipated to accommodate at least 1,500 visits per room per year by the fifth year of operation; and

    c. remaining general emergency service rooms will continue to handle a minimum of 1500 visits annually.

4. For a proposal for additional space in the hospital emergency department, the applicant must perform a size-by-functional-need survey and analysis for additional space that demonstrates efficient use of the space.

Review Methodology

The department will use the following formula to determine the need for emergency department treatment room services:

$$\textbf{EDTR} = \textbf{C}_5\textbf{/1500}$$
$$\textbf{C}_5 = \textbf{P}_5 \textbf{ x SAS x UR}$$

EDTR = emergency department treatment rooms needed
C_5 = caseload (emergency department visits) projected for the fifth year after project completion
UR = current utilization rate   (average number of emergency department visits per year for the last three years, divided by population), to be determined on a service area basis
P_5 = projected population for the fifth year after project completion
SAS (service area share) = the proposed service area's current share of the population to be served, as of the most recent geographic population estimates. If there is public information about service area population changes expected over the planning horizon, such as a military base closing, or a major economic project such as a new mine, the service area share estimate may be modified with an explanation to reflect the expected change.

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IV. Behavioral Health Care Services: Review Standards and Methodology

A. *Acute Inpatient Psychiatric Treatment Services*

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need to establish, expand, or relocate acute inpatient psychiatric treatment services:

1. A new freestanding psychiatric hospital must have a minimum of 25 beds; new services located within existing acute care community hospitals must have a minimum of 12 beds. Any deviation must include a five-year projected cost benefit analysis that describes a sustainable "economy of scale."

2. To be considered for authorization to expand bed capacity, inpatient psychiatric treatment services must have an annual average occupancy of at least 80% during the preceding three years.

3. The applicant demonstrates that the project augments the existing community system of care and facilitates effective interface, transition and timely referral to lower levels of community-based settings.

Additional Considerations for Concurrent Review of More than one Application

In completing a concurrent review of two or more applications under 7 AAC 07.060, in addition to applying the standards set out above to each application, the department will

1. compare the extent to which each applicant demonstrates a willingness to accept persons under court detention orders, or have contractual agreements to serve such persons; and

2. approve an otherwise equivalent proposal that entails the conversion of excess acute care hospital capacity to inpatient psychiatric treatment services use over a proposal that entails the development of new facilities and the addition of beds to the licensed bed complement.

Review Methodology

The department will use the following formula to determine need for inpatient psychiatric treatment services and the number of dedicated hospital beds required:

►**STEP ONE:** Determine the potential inpatient psychiatric treatment services caseload using the formula:

$$C = P \times UR$$

C (caseload) = the number of days of inpatient psychiatric treatment care required five years from the project implementation date
P (projected population) = the official State population projected for the fifth year following implementation of the project
UR (use rate) = the current utilization rate (the average number of inpatient psychiatric treatment days of care used during the preceding three years, divided by population)

►**STEP TWO:** Determine the projected inpatient psychiatric treatment service average daily inpatient census using the formula:

$$PSAT \cdot ADC = C / SA$$

PSAT•ADC = inpatient psychiatric treatment service average daily census
SA (service availability) = defined as 365 days a year

►**STEP THREE:** Determine the number of inpatient psychiatric treatment service beds required using the formula:

$$PSATBN = PSAT \cdot ADC / TO$$

PSATBN = inpatient psychiatric treatment services bed need
PSAT•ADC = inpatient psychiatric treatment services average daily census
TO = target occupancy factor, defined as 80% for inpatient psychiatric treatment services

►**STEP FOUR:** Determine unmet inpatient psychiatric treatment services bed need, if any, by subtracting the number of licensed and CON-approved beds from the number projected to be needed.

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►**STEP FIVE:** Determine projected bed need for a proposed service area by multiplying the statewide projected bed need by the service area share of population to be served.

$$\mathbf{PBN_{sa} = PBN_t \ x \ SAS}$$

PBN$_{sa}$ = projected bed need for the service area
PBN$_t$ = total projected bed need for the state
SAS (service area share) = the proposed service area's current share of the population to be served, as of the most recent geographic population estimates. If there is public information about service area population changes expected over the planning horizon, such as a military base closing, or a major economic project such as a new mine, the service area share estimate may be modified with explanation to reflect the expected change.

B. Residential Psychiatric Treatment Centers (RPTC)

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for an RPTC:

1. The applicant identifies the probable impact on the cost to local consumers, and the cost to Medicaid and other medical assistance programs operated by the State of Alaska.

2. The applicant demonstrates the immediate and long-term financial feasibility of the project, based on availability of federal or other funding to construct and operate the project

3. An RPTC facility must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

4. Projects larger than 29 beds will not be recommended for approval unless

    a. services will be provided in a campus-like, cottage setting, with smaller home-like units with 15 beds per unit or less [see 7 AAC 43.560(b)(4)(A)];

    b. there are secure and nonsecure beds in the facility.

5. The applicant demonstrates that the project augments the existing community system of care and facilitates transition to lower levels of care, to community-based settings, or to an adult service system at maturity, providing an effective interface with lower levels of care in the same community. In applying this standard, the department will also consider

    a. whether the project includes a plan for connecting children and families to appropriate levels of care, to engage families in their children's treatment;

    b. the degree to which the proposed services assist in developing a Comprehensive, Continuous, Integrated System of Care (CCISC) for behavioral health as planned by the department.

Additional Considerations for Concurrent Review of More than one Application

In completing a concurrent review of two or more applications under 7 AAC 07.060, in addition to applying the standards set out above to each application, the department will approve an otherwise equivalent proposal if the applicant is a facility operated by a Native organization operating under a compact or contract with the federal government to provide health services to IHS beneficiaries under P.L. 93-638.

Review Methodology

 The department will use the following formula to determine need for RPTC beds. When appropriate, the department may consider historical regional differences in utilization rates and the fact that a program is providing services to a small-specialized population of adolescents or youth with special needs.

►**STEP ONE:** Calculate total projected RPTC caseload (TC$_p$)

The first calculation yields the expected number of patients/clients to be served in all settings, within and outside of Alaska in the target year (five years from the date the application is submitted). Multiply the projected population at risk by the projected use rate to obtain the projected total RPTC caseload:

$$TC_5 = P_5 \text{ x (UR)}$$

TC$_5$ (total projected caseload) = number of children and adolescents expected to need RPTC care in the target planning horizon of the project (five years from the date the application is submitted).
P$_5$ = projected population at risk is defined as the Department of Labor and Workforce Development's projected population ages 6-17 years of age at end of the five-year planning horizon.
UR (current use rate) = total cases/population, derived from historical admissions, and adjusted by the expected improvement over the planning horizon. For certificate of need program purposes, the current use rate is the average annual caseload for the most recent three years preceding the date the application is submitted, divided by the population of children aged 6 - 17 over the three-year period. The use rate is calculated by the department using Medicaid data to determine the number of children and adolescents served in-state and out-of-state. (Calendar year case data, and July 1 population estimates for each year, will be used for these calculations.)

►**STEP TWO:** Calculate projected in-state statewide RPTC caseload (ISC$_p$) and the adjusted projected in-state RPTC caseload (ISC$_{pa}$).

The projected in-state RPTC caseload (ISC$_p$) will be the projected total caseload minus the projected out-of-state caseload (OSC$_p$), reflecting the targeted reduction in children and adolescents placed in out-of-state settings:

$$ISC_p = TC_p - OSC_p$$

ISC$_p$ = projected in-state caseload
TC$_p$ = total projected caseload
OSC$_p$ = projected out-of-state caseload (to be forecast by the department)

Not all of the adolescents and children who return to Alaska will need to be served at the RPTC level of care. The development of lower levels of care will allow a reduction in projected in-state RPTC caseload (ISC$_p$). The department will estimate a caseload reduction factor (CRF) to reflect the percentage of children expected to be served in lower levels of care. The department will calculate the adjusted statewide adolescent and child in-state caseload that is expected to be served at the RPTC level of care (ISC$_{pa}$):

$$ISC_{pa} = ISC_p \text{ x } CRF$$

ISC$_p$ = in-state projected caseload
ISC$_{pa}$ = in-state projected caseload adjusted by the caseload reduction factor
CRF = caseload reduction factor set by the department to reflect expected reduction in RPTC admissions as lower levels of care are made available

►**STEP THREE:** The department projects the estimated in-state average length of stay (ISALOS$_p$) for the planning horizon.

The current ISALOS (ISALOS$_c$) is determined by the department based on an average of annual in-state Medicaid data for the most recent three-year period preceding the date the application is submitted, and includes all days of care regardless of whether they are associated with a single stay. The projected in-state average length of stay is calculated by multiplying the current in-state length of stay by a reduction adjustment factor (RAF):

$$ISALOS_p = ISALOS_c \text{ x } RAF$$

ISALOS $_p$ = in-state average length of stay, projected
ISALOS$_c$ = in-state average length of stay, actual current
RAF = reduction adjustment factor will be set by the department and posted annually on the department's website. This adjustment factor targets reductions in length of stay.

►**STEP FOUR:** The department calculates the projected number of RPTC days of care (DOC). Multiply the caseload (ISC) by the projected in-state average length of stay (ISALOS $_p$):

$$DOC = ISC \text{ x } ISALOS_p$$

DOC = days of care**:** the total number of in-state days of care expected in the target planning horizon year.

►**STEP FIVE:** Calculate projected RPTC average daily census (ADC)
Divide the projected days of care by 365 (days per year):

$$ADC = DOC/365$$

ADC (average daily census) = the average number of children and adolescents expected to be using the proposed RPTC facility at any given time during the target planning year.

►**STEP SIX:** Calculate the RPTC projected bed need (PBN):

The projected bed need (PBN) is calculated by dividing the expected RPTC average daily census (ADC) by the target occupancy (TO) factor of .85 (an 85 % occupancy rate).

$$PBN = ADC/ TO$$

ADC = average daily census
PBN = gross projected bed need
TO = target occupancy rate

Service area bed need is estimated by taking the statewide projected bed need times the service area share (SAS), which is the current proportion of the state's population at risk (youth 6-17) in the service area.

Areas with a population of 70,000 or more will have a target occupancy factor of .90 (90% occupancy rate). Areas with a population of less than 70,000 will have a target occupancy rate of 80% for the fifth year after implementation. The share of the statewide bed need allocated will thus be weighted toward proposals for smaller communities.

►**STEP SEVEN:** Calculate the RPTC net bed need (NBN) for the proposed service area.

The net bed need (NBN$_{sa}$)is calculated by subtracting the number of existing and approved beds within the service area from the projected bed need (PBN$_{sa}$) projected for the proposed service area:

$$\textbf{NBN}_{\textbf{sa}} = \textbf{PBN}_{\textbf{sa}} - \textbf{EB}_{\textbf{sa}}$$

NBNsa = the net RPTC bed need in the proposed service area in five years.
EB$_{sa}$ = number of existing beds and certificate-of-need-approved beds in the service area.

V. Long-Term Acute Care Hospital Services: Review Standards and Methodology

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for a long-term acute care hospital (LTACH) services:

1. The LTACH will be located in a community where cardiologists, pulmonologists, nephrologists, and infectious disease specialists maintain full-time practices.

2. A new freestanding LTACH must have a minimum of 25 beds; a new LTACH located within an existing short-term acute care hospital must have a minimum of 15 beds.

3. To be considered for approval to expand bed capacity, an LTACH must have an annual average occupancy of at least 85% during the preceding three years.

4. In service areas with more than one LTACH, all facilities together must have had an annual average occupancy of at least 85% during the preceding three years before additional licensed beds are authorized.

5. The applicant provides additional justification for an application that exceeds a rate of one bed per 10,000 persons for the proposed service area.

Review Methodology

The department will use the following formula to determine need for LTACH services:

►**STEP ONE:** Determine the potential LTACH caseload using the formula:

$$C = EP \text{ x } SCF \text{ x } LTACH \text{ } ALOS$$

C (caseload) = the number of long-term acute care hospital patient days three years from the project implementation date
EP (estimate of the long-term acute care hospital population candidates) = the average annual number of medical-surgical acute care hospital discharges with lengths of stay of 15 days or more over the preceding three years
SCF (service conversion factor) = the number of acute care hospital patients with lengths of stay of 15 days or more who would be likely to obtain LTACH services rather than alternative services (e.g., additional short term acute hospital care, nursing home care, or rehabilitation care), defined as 75% (0.75)

LTACH ALOS (long-term acute care hospital average length of stay) = defined as the three-year average historical length of stay of patients with lengths of stay of 15 days or more, as the best estimator available for potential LTACH candidates.

►**STEP TWO:** Determine the projected long-term acute care hospital average daily census using the formula:

$$\text{LTACH ADC} = C / SA$$

LTACH ADC = long-term acute care hospital average daily census
C (caseload) = projected number of long-term acute care hospital patient days of care required by the population to be served
SA (service availability) = defined as 365 days a year

►**STEP THREE:** Determine the projected number of long-term acute care hospital beds required to meet projected demand using the formula:

$$\text{PBN} = \text{LTACH ADC} / TO$$

PBN = long-term acute care hospital projected bed need
LTACH ADC = long-term acute care hospital average daily census
TO = long-term acute care hospital target occupancy, defined as 85% (0.85)

►**STEP FOUR:** Determine unmet long-term acute care hospital bed need, if any, by subtracting the number of existing licensed and CON-approved LTACH beds from the number of beds projected to be needed.

VI. Long-Term Nursing Care: Review Standards and Methodology

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for long-term nursing care services:

1. A new freestanding long-term nursing facility will not be approved unless the applicant has demonstrated a need for a minimum of 40 beds.

2. New long-term care nursing units co-located with hospitals will not be approved unless the applicant has demonstrated a need for a minimum of 15 beds. The department may approve a smaller number of beds if the applicant documents use patterns, and submits data and analysis that justify a smaller unit.

3. To be considered for approval to expand licensed capacity, a freestanding long-term nursing care facility must have an average annual occupancy of at least 90%, and co-located long-term nursing care units must have an average annual occupancy rate of at least 80%, during the preceding three years.

4. In a service area with more than one long-term nursing care facility, all facilities must have had an average annual occupancy of at least 90% during the preceding three years before additional beds are approved.

5. In the interest of serving individuals in the most cost-effective, least-restrictive setting possible, there must be a combination of at least one assisted living bed or adult day care slot for each existing and proposed new long-term nursing care bed. For a community with a population of 10,000 or less, the department may approve beds on a case-by-case basis.

Additional Considerations for Concurrent Review of More than one Application

In completing a concurrent review of two or more applications under 7 AAC 07.060, in addition to applying the standards set out above to each application, the department will approve an otherwise equivalent proposal if the applicant is a facility operated by a Native organization operating under a compact or contract with the federal government to provide health services to IHS beneficiaries under P.L. 93-638.

Review Methodology

The department will use the following formula to determine need for long-term nursing home beds:

►**STEP ONE:** Determine the projected long-term nursing care caseload using the formula:

$$\textbf{C} = \textbf{CASU}$$

C (caseload) = the average daily census of long-term nursing care patients five years from the project implementation date
Average Daily Census = patient days per year/365[4]
CASU (composite age specific use) = defined as the cumulative average daily census of long-term nursing care patients per 1,000 persons for the age groups: 0 – 64 years, 65 to 74 years, 75 to 84 years, and 85 years and over, five years from implementation of the project, calculated as follows:

CASU = (UR<65 x **PP<65) + (UR65•74** x **PP65•74) + (UR75•84** x **PP75•84) + (UR>85** x **PP>85**) where:

UR<65 = the average nursing home bed use rate of the service area population aged 0 to 64 years for the preceding three years
PP<65 = the projected population aged 0 to 64 years for the fifth year from the project implementation date
UR65•74 = the average nursing home bed use rate of the population aged 65 to 74 years for the preceding three years
PP65•74 = the projected population between 65 and 74 years of age for the fifth year from the project implementation date
UR75•84 = the average nursing home bed use rate of the population aged 75 to 84 years for the preceding three years
PP75•84 = the projected population between 75 and 84 years of age for the fifth year from the project implementation date
UR>85 = the average nursing home bed use rate of the population 85 years of age and older for the preceding three years
PP>85 = the projected population 85 years of age and older for the fifth year from the project implementation date

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[4] *Until data set is available to calculate age specific use rates, daily census on July 1 of each year, or an average of the daily census counts on the first day of every month, will be used to estimate age-specific average daily census counts.*

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►**STEP TWO:** Determine the projected number of nursing home beds required to meet projected demand using the formula:

$$PBN = C / NHTO$$

PBN = projected nursing home bed need
C (caseload) = the average daily census of long-term nursing care patients five years from the project completion date
TO = nursing home target occupancy, defined as 90% (0.90)

►**STEP THREE:** For service area bed need projections, multiply projected bed need by the current service area share of the population to be served aged 65 and over:

$$PBN_{sa} = PBN \text{ x } SAS$$

SAS (service area share) = the proposed service area's current share of the population to be served, as of the most recent geographic population estimates. If there is public information about service area population changes expected over the planning horizon, such as a military base closing, or a major economic project such as a new mine, the service area share estimate may be modified with explanation to reflect the expected change.

Determine unmet nursing home bed need, if any, by subtracting the number of existing licensed and CON-approved beds from the number of beds projected to be needed in the proposed service area.

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VII. Diagnostic Imaging Services: Review Standards and Methodology

The department will develop and maintain data sources for measuring utilization rates and will identify regional and national norms to use in assessing the reasonableness of applicant assertions about projected levels of service.

A. Magnetic Resonance Imaging

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards, as applicable, in its evaluation of an application for a certificate of need for magnetic resonance imaging:

1. Except as provided in Review Standard 2, an applicant who seeks to establish an MRI service demonstrates the ability to provide a minimum of 3,000 MRI scans per year by the end of the third operational year, dating from the initiation of the service.

2. An applicant who seeks to establish an MRI service in a community with a population of 10,000 or less demonstrates the ability to provide a minimum of 1,000 MRI scans per year by the end of the third year, dating from the initiation of the service. (Based on the estimate of a minimum of 2,500 scans/70,000 people, it is estimated that the minimum service area population for an MRI service to provide a minimum of 1,000 MRI scans per year would be 28,000 people.)

3. No MRI service will be approved at a location that is less than 30 minutes access time of an existing MRI service performing fewer than 3,000 scans per year, or of a CON-approved, but not yet operational, MRI service.

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B. Positron Emission Tomography (including PET/PET-CT)

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for Positron Emission Tomography:

1. An applicant who seeks to establish a new PET service demonstrates the ability to provide a minimum of 750 PET scans per year by the end of the third operational year, dating from the initiation of the service.

2. No new PET scanner will be approved at a location that is less than one hour travel time of an existing PET scanner performing fewer than 750 scans per year, or of a CON-approved, but not yet operational, PET scanner.

3. In a community that produces isotopes locally, no new PET scanner will be approved in the service area unless average use of each existing PET scanner exceeds 1,300 scans per year.

4. In a community that is dependent upon shipped isotopes, no new PET scanner will be approved in the service area unless average use of each existing PET scanner exceeds 1,000 scans per year.

5. An applicant who seeks to expand a PET service demonstrates an average service volume of at least 1,300 PET scans annually for each PET scanner at the service site.

6. PET services must be located in the same community as, or co-located with, facilities offering comprehensive oncology, cardiovascular, and neurology services.

C. Computed Tomography

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for computed tomography (CT) services:

1. An applicant who seeks to establish a new CT service in an urban area (population of 70,000 or more) demonstrates the ability to provide a minimum of 3,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

2. An applicant who seeks to establish a new CT service in a rural area demonstrates the ability to provide a minimum of 1,000 CT scans per year by the end of the third operational year, dating from the initiation of the service.

3. No new CT service will be approved in a service area or at a location that is less than 30 minutes travel time of an existing CT service performing fewer than 3,000 scans per year, or of a CON-approved but not yet operational, CT service.

4. An applicant who seeks to expand an existing CT service must demonstrate an average service volume of at least 4,000 CT scans annually for each existing CT scanner at the service site.

D. Cardiac Catheterization Services

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for cardiac catheterization services:

1. No new cardiac catheterization laboratories will be approved in a community with existing cardiac catheterization services unless all existing adult laboratories are operating at an average of at least 75% of capacity or an average of at least 750 procedures per year.

2. The applicant for a facility that will offer pediatric cardiac catheterization demonstrates that at least 250 procedures per year will be performed.

3. The applicant for a facility that will offer primary angioplasty without onsite cardiac surgery capability must have a proven and tested plan for rapid access (within 90 minutes from declaration of emergency to the patient being in a cardiac surgical operating room). Appropriate hemodynamic support capability for such a transfer must exist as well as a team of appropriately trained individuals. The ability to place an intraaortic balloon pump (IABP) and temporary transvenous pacemaker for stabilization before transport must also exist.

4. A facility requesting authorization to perform elective coronary interventions must be located within a hospital or in a laboratory attached to a hospital with onsite cardiac surgery capability. The department may approve a laboratory that is not located within a hospital or not attached to a hospital with onsite cardiac surgery capability, if the following conditions are met:

    a. Patients with acute coronary syndromes, severe congestive heart failure, pulmonary edema due to acute ischemia, severe multi-vessel or left main disease, and severe left ventricular dysfunction associated with valvular disease are excluded.

    b. Patients with complex (Type IIb and III) coronary lesions and other high-risk anatomic situations (only remaining coronary artery, vessel to be treated supplies more than 40% of remaining viable myocardium, etc.) are excluded. Facilities requesting approval for percutaneous coronary intervention (PCI) services in the absence of onsite cardiac surgery must develop criteria to screen for the types of clinical and anatomic situations appropriate and inappropriate for their facility based on published criteria in the literature.

c. A plan for proper oversight must be approved by the department before approval of a certificate of need. The plan must include

- accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO);

- membership in the American College of Cardiology – National Cardiovascular Data Registry (for benchmarking outcomes);

- an independent peer review of the program by the Society for Cardiovascular Angiography and Interventions or the American Medical Foundation for Peer Review, to be conducted once in the first six months and then annually thereafter for the first three years, to ensure that all issues related to quality assurance are monitored and addressed; and

- supplying the department with all reports and data developed within 10 working days after each is developed.

d. The laboratory director must have extensive experience performing coronary interventions (more than 500 procedures performed during their career and more than 75 procedures annually during the past two years), and must have and maintain a certificate of "Added Qualifications" in Interventional Cardiology from the American Board of Internal Medicine.

e. The laboratory must maintain a quality standard for diagnostic catheterization mortality of less than 3 per 1000 procedures and for PCI of less than 1 per 100 procedures.

5. An applicant who seeks to establish new cardiac catheterization services in a community without existing services demonstrates that the facility is likely to perform a minimum of 500 cardiac catheterizations per year by the third year after program implementation.

6. The applicant demonstrates that the facility has the capability of providing immediate transvenous pacemakers in case of cardiac arrest.

Review Methodology

Several calculations are used to determine the demand for cardiac catheterization services and the number of cardiac catheterization laboratories required to meet projected demand efficiently.

The department will use the following formula to determine need for cardiac catheterizations services:

►**STEP ONE:** Determine the projected cardiac catheterization caseload using the formula:

$$C = P \text{ x } UR$$

C (caseload) = the number of procedures in the third year following implementation of the project
P (projected population at risk) = the official state projection for the adult population (18 years of age and older) in the third year following implementation of the project
UR (use rate) = the average annual cardiac catheterization procedures for the preceding three years per 1,000 population.

►**STEP TWO:** Determine the number of cardiac catheterization laboratories required using the formula:
$$CCLR = (C / LC) / TO$$

C (caseload) = number of cardiac catheterization procedures
LC (laboratory capacity) = defined as 1,000 procedures per year
TO (target occupancy) = 75% (0.75)

►**STEP THREE:** Determine number of additional cardiac catheterization laboratories needed by subtracting number of currently existing and CON-approved laboratories from the number s found to be needed.

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►**STEP FOUR:** Determine projected cardiac catheterization laboratory need for a proposed service area by multiplying the statewide projected cardiac catheterization need by the service area share of population to be served.

$$\mathbf{PLN_{sa} = PLN_t \; x \; SAS}$$

$\mathbf{PLN_{sa}}$ = projected cardiac catheterization laboratory need for the service area
$\mathbf{PLN_t}$ = total projected cardiac catheterization laboratory need for the state

$\mathbf{SAS}$ (service area share) = the proposed service area's current share of the population to be served, as of the most recent geographic population estimates. If there is public information about service area population changes expected over the planning horizon, such as a military base closing, or a major economic project such as a new mine, the service area share estimate may be modified with explanation to reflect the expected change.

VIII. Surgical Care: Review Standards and Methodology

A. General Surgery Services

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standard in its evaluation of an application for a certificate of need for general surgery services: The applicant demonstrates need in accordance with the following review methodology.

These review standards for general surgery services do not apply to (1) open-heart surgery subject to the standards in B of this section; (2) surgery suites dedicated to C-sections and other birth-related surgeries; or (3) surgery suites dedicated to LASIK or other eye surgery.

Review Methodology

The department will use the following formula to determine need for general surgery capacity:

►**STEP ONE:** Determine the projected general surgery caseload using the formula:

$$C = P \times GSUR$$

C (caseload) = the number of general surgery cases projected for the fifth year from the project implementation date. Cases refer to patients who may have one or more surgical procedures during a particular visit to the operating room. If the patient returns at a later date for additional services, the next visit will count as an additional case.
P (projected population) = the official state projected population in the fifth year following implementation of the project
GSUR (general surgery use rate) = defined as the average number of general surgery cases provided over the preceding three years per 1,000 (persons)

►**STEP TWO:** Determine the projected number of operating rooms required to meet projected demand using the formula:

$$GORR = C / TU$$

GORR = general operating rooms required
C = projected general surgery cases
TU = target use rate for operating rooms, defined as 900 surgical cases per operating room for operating rooms serving both inpatients and outpatients and 1,200 surgical cases for operating rooms dedicated to outpatient surgery use

►**STEP THREE:** Determine unmet need for general purpose operating rooms, if any, by subtracting number of existing and CON-approved operating rooms from the number projected to be needed.

B. Open-Heart Surgery

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for open-heart surgery services:

1. An applicant who seeks to establish a new open-heart surgery program demonstrates that they are likely to perform a minimum of 100 surgery cases within the first year of operation and at least 250 cases annually within the fifth year after initiating the service.

2. An applicant who seeks to establish new open-heart surgery services demonstrates that the hospital provides at least 500 cardiac catheterizations annually.

3. An applicant who seeks to establish new open-heart surgery services demonstrates that each physician performing open-heart surgery performs a minimum of 50 open-heart surgeries per year, as the attending surgeon, in any hospital or combination of hospitals.

4. An applicant who seeks to provide pediatric open-heart surgery services demonstrates that the hospital maintains a pediatric intensive care unit and a Level III neonatal intensive care unit, and will perform a minimum of 100 pediatric open-heart surgical procedures annually within three years of initiating the service.

5. An applicant who seeks to expand open-heart surgery services demonstrates that each existing open-heart surgery operating room performed an average of at least 300 open-heart surgical procedures per year during the preceding three years.

Review Methodology

The department will use the following formula to determine need for open-heart surgery services:

►**STEP ONE:** Determine the projected open-heart surgery caseload for the population to be served using the formula:

$$C = P \times UR$$

C (caseload) = the number of persons expected to require open-heart surgery in the fifth year dating from the implementation date of the project
P (projected population at risk) = the official state projection for the adult population (18 years of age and older) in the fifth year following implementation of the project

UR (use rate) = the average number of open-heart surgery cases during the preceding three years per 1,000 persons (adult population)[5]

►**STEP TWO:** Determine the number of open-heart surgery programs required using the formula:

$$\textbf{OHSPR } = \textbf{C / TSPV}$$

OHSPR = open-heart surgery programs required
C (caseload) = number of persons expected to require open-heart surgery
TSPV (target average annual surgery program volume) = defined as 250 cases per year

►**STEP THREE:** Determine number of additional open-heart surgery programs required by subtracting the number currently existing and CON-approved programs from the number of programs determined to be needed.

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[5] *Target average surgery program volume for pediatric cases is 100 per year. No pediatric open heart surgery is currently available in Alaska. National rates will be used to calculate the expected pediatric caseload using the same approach as that described for adult open heart surgery. The department will seek regional (Pacific northwest) and/or national age specific use rates for adult open heart surgery in order to estimate more accurately the use rates for Alaskans some of whom currently go out of state for these services. Currently available is data on Alaska and Washington State procedures on Alaskan patients. These data will be compared with the expected rates based on national data.*

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IX. Therapeutic Care: Review Standards and Methodology

A. *Radiation Therapy*

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for radiation therapy:

1. Stereotactic Radiosurgery Services: An applicant who seeks to establish stereotactic radiosurgery services demonstrates a need for at least 250 stereotactic treatments annually without reducing demand at any existing service to less than 250 treatments per year.

2. Linear Accelerator Services:

   a. No new radiation therapy service will be approved unless existing radiation therapy services located in the service area in which the proposed new service is to be located have provided an average of at least 6,000 radiation therapy treatments per year over the last three years.

   b. No new radiation therapy service will be approved unless the applicant demonstrates that the new service will be used for at least 250 cancer patients and will perform at least 4,000 treatments by the third year of operation without reducing the average use of existing radiation therapy machines in the service area below 6,000 treatments per year.

   c. No proposal to expand an existing radiation service will be approved unless the linear accelerators operated by the applicant provided an average of at least 6,000 treatments per year over the preceding three years.

3. Radiation therapy services must be located in the same community as a facility providing comprehensive oncology and support services.

4. An applicant proposing to establish or expand radiation therapy services must agree to participate fully in the Alaska cancer registry program.

Additional Considerations for Concurrent Review of More than one Application

In completing a concurrent review of two or more applications under 7 AAC 07.060, in addition to applying the standards set out above to each application, the department will compare the extent to which each applicant demonstrates that the proposal upgrades existing radiation therapy services by incorporating intensity-modulated radiation therapy (IMRT) capability and computed tomography (CT) simulation in treatment planning.

Review Methodology

The department will use the following formula to determine need for radiation therapy services and equipment:

►**STEP ONE:** Determine the radiation therapy caseload using the formula:

$$C = P \times CIR \times 0.60$$

C (caseload) = the number of new cancer patients three years from the project implementation date expected to seek radiation therapy
P (projected population) = the official state population for the third year following implementation of the project
CIR (cancer incidence rate) = the average annual number of new cancer patients per 1,000 persons reported to the Alaska state cancer registry during the preceding three years

►**STEP TWO:** Determine the projected number of radiation therapy treatments required by the projected radiation therapy annual caseload using the formula:

$$RTR = C \times PPT$$

RTR (radiation therapy treatments required) = the number of radiation therapy treatments required to serve the projected radiation therapy caseload
C (caseload) = number of new radiation therapy patients per year
PPT (projected patient treatments) = defined as 30 treatments per new cancer patient receiving radiation therapy

►**STEP THREE:** Determine number of linear accelerators required (LAR) to meet projected demand using the formula:

$$LAR = RTR / TLAU$$

LAR (linaccs required) = number of linear accelerators required to meet total demand
RTR (radiation therapy treatments required) = the number of radiation therapy treatments required to serve the projected radiation therapy caseload
TLAU (target average linear accelerator use) = defined as 6,000 treatments per year

►**STEP FOUR:** Determine projected number of linear accelerators needed for a proposed service area by multiplying the statewide projected need by the service area share of the population to be served.

$$LAR_{sa} = LAR_t \text{ x } SAS$$

LAR$_{sa}$ = number of linear accelerators required to meet total demand in the service area

LAR$_t$ = total linear accelerators required statewide

 SAS (service area share) = the proposed service area's current share of the population to be served, as of the most recent geographic population estimates.

►**STEP FIVE:** Determine the number of additional linear accelerators needed by subtracting the number of existing and CON-approved accelerators from the total number determined to be needed in the service area.

►**STEP FIVE:** Determine the number of additional linear accelerators needed by subtracting the number of existing and CON-approved accelerators from the total number determined to be needed.

B. Renal Dialysis

Review Standards

After determining whether an applicant has met the general review standards in Section I of this document, the department will apply the following service-specific review standards in its evaluation of an application for a certificate of need for renal dialysis services:

1. Dialysis facilities must contain a minimum of six dialysis stations.

2. No new dialysis services will be approved unless existing services located in the service area in which the proposed new service is to be located operated at an average annual use rate of at least 80% of capacity over the last three years.

3. No proposal to expand an existing dialysis service will be approved unless each station operated by the applicant provided at least 12 treatments per week over the preceding year.

4. The applicant demonstrates that the dialysis center will provide education and services for home and peritoneal dialysis patients, as well as in-center patients.

Review Methodology

The department will use the following formula to determine need for ESRD services and equipment:

►**STEP ONE:** Determine the projected ESRD caseload using the formula:

$$C = P \times UR$$

C (caseload) = the number of ESRD patients three years from the project implementation date
P (projected population) = the official State population projected for the fifth year following implementation of the project
UR (end stage renal disease prevalence rate) = persons diagnosed with ESRD per 10,000 population

►**STEP TWO:** Determine the projected number of chronic renal dialysis treatments required to meet projected demand using the formula:

$$DTR = C \times PTR$$

DTR = Dialysis treatments required
C (caseload) = Projected ESRD caseload
PTR = Average ESRD patient treatment rate, defined as 3.0 treatments per patient per week or 156 treatments per patient annually

►**STEP THREE:** Determine the number of ESRD dialysis stations required to meet the projected number of treatments using the formula:

$$DSR = DTR / DSC / TSO$$

DSR = Dialysis stations required
DTR = Dialysis treatments required
DSC = Average dialysis station capacity, defined as 15.0 treatments per week or 780 treatments per year
TSO = Target ESRD station occupancy, defined at 80% (0.80)

►**STEP FOUR:** Determine unmet ESRD station need, if any, by subtracting number of existing and CON-approved ESRD stations from the number projected to be needed. Bed need estimates will be made for proposed service areas based on current share of the state's adult population by region or census area/borough included in the service area.

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