



TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

PH 30-2023

CHAPTER 333

OREGON HEALTH AUTHORITY

PUBLIC HEALTH DIVISION

FILED

05/17/2023 8:57 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Demonstration of Need for Acute Inpatient Beds and Facilities

EFFECTIVE DATE: 05/17/2023 THROUGH 11/12/2023

AGENCY APPROVED DATE: 05/17/2023

CONTACT: Matt Gilman

503-979-9628

publichealth.rules@odhsoha.oregon.gov

800 NE Oregon Street, Suite 465

Portland, OR 97232

Filed By:

Public Health Division

Rules Coordinator

NEED FOR THE RULE(S):

The Oregon Health Authority (OHA) is temporarily amending OAR 333-590-0010 through 0060 relating to the analysis of information an applicant must provide to OHA to demonstrate the need for a hospital. These amendments are necessary to be able to adequately evaluate a Certificate of Need application using relevant data, methods, and timelines. There are currently outdated data references in the rules that direct an applicant to review data outside the window of time relevant to current applicants. Additionally, there are assumptions built into the current rules that direct an applicant to assume a declining use rate for hospitals, and prescribes methodology built on this now inaccurate trend for Oregon's hospital use rates. Current rules reference studies that are no longer published or relevant to the grant of a Certificate of Need. The Certificate of Need program has received a letter of intent to apply for a Certificate of Need, and prior to the submission of the application, the updated rules need to be in place so current, relevant data, timelines, and methodology can be analyzed and used for purposes of reviewing the application.

JUSTIFICATION OF TEMPORARY FILING:

The Oregon Health Authority (OHA) finds that failure to act promptly will not serve the public interest, OHA, and Certificate of Need (CN) applicants. These rules need to be adopted promptly so that the rules reflect relevant methodology, data, trends, and timeframes which will allow OHA to adequately review and assess an application consistent with their rules as written. Without these amendments, the CN program would be required to use current rules, which cannot be applied as written and any decision will not accurately reflect the extent to which the proposal is needed and will be legally vulnerable to challenge. This creates the potential for delayed and inefficient consideration of whether the specific proposal is needed in Oregon.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

ORS chapter 413: https://www.oregonlegislature.gov/bills_laws/ors/ors413.html

ORS chapter 441: https://www.oregonlegislature.gov/bills_laws/ors/ors441.html

ORS chapter 442: https://www.oregonlegislature.gov/bills_laws/ors/ors442.html

RULES:

333-590-0010, 333-590-0030, 333-590-0040, 333-590-0050, 333-590-0060

AMEND: 333-590-0010

RULE TITLE: Definitions

RULE SUMMARY: Amend OAR 333-590-0010 – Redefining “Acute Inpatient Bed Capacity” to “Bed Capacity.” This rule is being amended to add specificity and remove the phrase “which could be made available” and add the phrase “space that is readily available.”

RULE TEXT:

As used in OAR chapter 333, division 590:

- (1) "Acute Inpatient Bed" means a space with physical facilities which is being used to provide inpatient care to a patient located in a hospital and is intended primarily for occupancy by a patient who will be fed, lodged, and treated on an overnight basis, except that newborn nursery bassinets, neonatal intensive care and labor room beds are not included.
- (2) "Acute Inpatient Care" means care provided in hospital beds, involving at least one overnight use of a bed. Acute inpatient care does not include skilled nursing facility, intermediate care facility, long-term care or supportive routine care for chronic disease or disability, convalescent care, or rest cures. Neither does acute inpatient care include outpatient or clinic care, emergency room care, outpatient laboratory tests, or ambulatory surgery. Acute inpatient care does include general medical/surgical care and short-stay specialty and sub-specialty acute care, including but not limited to gynecological, obstetrical, pediatric, ICU/CCU, psychiatric, alcoholism, chemical dependency, and rehabilitation care.
- (3) " Bed Capacity" means any space readily available for use as an acute inpatient bed, even if this space is not presently being used for this purpose.
- (4) "Population-Based Discharge and Use-Rates" means rates based on geographical area patient origins and population rather than on the statistics of utilization of a single facility.

STATUTORY/OTHER AUTHORITY: ORS 431.120, 442.315

STATUTES/OTHER IMPLEMENTED: ORS 431.120, 442.315

AMEND: 333-590-0030

RULE TITLE: Assumptions

RULE SUMMARY: Amend OAR 333-590-0030 – Removing assumption that hospital use rates have been, and will continue to, decline in the future. This rule is being amended because the reference to declining use rates is not accurate.

RULE TEXT:

The following general assumptions are made with respect to the balance between bed capacity and anticipated future utilization. In specific cases, certain assumptions may or may not apply:

- (1) The annual patient days needed by the population of a Health Service Area can be more confidently forecasted than the demand at a single hospital or local market area.
- (2) Hospital service area patient days can be more confidently forecasted by isolating the trends in the area's population from trends in the area's use-rate (annual patient days per 1,000 population). The two trends can then be recombined by multiplication.
- (3) Within the area to be served by the proposal, factors such as changing age structure of the population, transportation patterns, locations of physician specialists, changes in the intensity or types of services delivered, commitments to develop other procompetitive initiatives such as alternative delivery systems, selective contracting, successful competitive bidding, and other market-oriented changes must be taken into account.
- (4) The applicant's population base for purposes of calculating use-rate will take into account the number of persons from outside the area to be served by the facility who are projected to use the facility.
- (5) If the applicant facility proposes to provide all or some of its services to members, subscribers and enrollees of institutions, HMOs or health care plans, the population to be served by the facility will be considered to be the members, subscribers and enrollees of such institutions, HMOs or health care plans who reside in the facility's proposed service area. In cases where the applicant provides or proposes to provide only a portion of its services to such members, subscribers and enrollees, the population to be served by the proposal will be adjusted on a proportionate basis. Assumptions as to the use-rate of such members, subscribers or enrollees will be based either on past experience of the institution, HMO or health care plan or, in the case where no past experience exists, on past experience of similar institutions, HMOs or health care plans in the state.
- (6)(a) When calculating use rate, the applicant may take into consideration if the applicant facility involves:
 - (A) A medical or other health professions' school; or
 - (B) A multidisciplinary clinic; or
 - (C) A specialty center; or
 - (D) A facility established or operated by a religious body or denomination to meet the needs of members of such religious body or denomination for care and treatment in accordance with their religious or ethical convictions, when these religious and ethical convictions demonstrably preclude use of established health care facilities in the area, and particular health care facilities provided for the purpose of rendering health care to such members. Utilization and beds at such facilities shall not be counted when considering the need for services at other facilities in the hospital service area.
- (b) Modification of the calculated use-rate shall be based on documentation (which the Division can validate) by the applicant that a population different from or in addition to the proposed service area population (as defined in OAR 333-590-0050(1)) is served or will be served by the facility, and that this population has experienced trends in hospital use-rates which are different from those in the applicant's proposed service area.
- (7) The share of patient days captured by a hospital in a given service area will generally be stable for the next 10 years unless local factors change.
- (8) In estimating future market share, current hospital discharge data will be the basis against which the effects of factors such as population shifts; changes in future or past hospital location, service mix, age mix, or reimbursement mix; documented commitments to develop procompetitive initiatives such as alternative delivery systems, selective

contracting and successful competitive bidding; and other evidence which may indicate changes in market share, such as projected decreases in market shares of other facilities, will be evaluated. The burden of proof shall be on the applicant.

(9) The use-rate of persons, ages 0–14, 15–44, 45–64, or 65 plus, from counties of origin expected to contribute substantially to future utilization of the hospital should be taken into account in interpreting quantitative estimates of future general use-rates, patient days and bed need.

(10) The number of beds needed to provide an anticipated range of patient days in a given hospital should be calculated to include an allowance for enough excess capacity to meet statistically estimated peak demand, taking into account number of beds, proximity to other hospitals, and feasibility of improved utilization through effective scheduling and other management actions.

STATUTORY/OTHER AUTHORITY: ORS 431.120, 442.315

STATUTES/OTHER IMPLEMENTED: ORS 431.120, 442.315

AMEND: 333-590-0040

RULE TITLE: Determination of Service Area for Existing Hospitals

RULE SUMMARY: Amend OAR 333-590-0040 – Amends rule to require application to provide a comprehensive market share analysis for their proposed service area. Removes “should” language. This rule is being amended to remove vague, outdated rule language and add specificity to what the applicant is required to provide.

RULE TEXT:

For purposes of divisions 545 through 670 of OAR chapter 333, the service area for an existing general hospital will be defined as including those zip codes from which either 10 percent or more of the hospital's discharges originate, or in which the hospital has at least a 20 percent market share. Minor adjustments to the boundaries of the hospital service area may be made to create a contiguous service area or to conform more closely to the boundaries of demographic units for which census data are reported (county, county census division, enumeration district, or zip codes if conversion has been done).

(1) An applicant shall provide a comprehensive market share analysis for the proposed service area of the proposed facility using relevant and recent data. This market analysis shall describe the estimated geographic area the facility will draw patients from and assess the impact to patients and like facilities within that region. More recent patient origin data on a less than statewide basis may also be considered if a method of adjustment for balance-of-state origins and utilization acceptable to the Division and the applicant can be developed prior to filing the application.

(2) Federal (V.A.) hospitals may be excluded from the calculation of discharge and patient day market shares, and from other steps in this methodology, but if federal hospitals are excluded from any step, they must be excluded from all steps. For instance, market shares cannot be calculated using nonfederal patient days when the service area use-rate is calculated based on combined federal and nonfederal patient days.

(3) In the absence of evidence to the contrary, current market shares will be expected to be stable. Factors to which consideration may be given include population shifts; public health emergencies; different rates of population growth among subareas within the hospital service area; changes in hospital location service mix, age mix, reimbursement mix, transportation patterns, locations of physician specialists; projected changes in amount or types of utilization among other providers with market shares in the hospital service area; and documented commitments to develop procompetitive initiatives such as alternative delivery systems, selective contracting, successful competitive bidding, and other market oriented changes.

STATUTORY/OTHER AUTHORITY: ORS 431.120, 442.315

STATUTES/OTHER IMPLEMENTED: ORS 431.120, 442.315

AMEND: 333-590-0050

RULE TITLE: Bed Need Methodology for Proposed New Hospitals

RULE SUMMARY: Amend OAR 333-590-0050 – Removes references to population data from 1970 to 1995 and requires applicant to review population data for the prior 20 years in 10-year increments. Requires applicant to use Portland State University's Population Research Center for population data. Removes references to "Daily Census Standard Deviations" and requires applicant to provide a statistical methodology to the Public Health Division (Division) with sufficient information for the Division to be able to validate their statistical model. Removing language that states that specialty beds "will not" be issued "unless" and replaces with "may" be issued "where." This rule is being amended because it currently cites old and outdated resources. Additionally, specificity is being added to where the applicant will get census data from.

RULE TEXT:

The method for estimating bed need at a proposed new general hospital shall be consistent with the principles enumerated in OAR 333-590-0030, and the legislative findings and policy of ORS 442.025:

(1) Determine the service area of the applicant facility as those zip codes from which either 10 percent or more of the hospital's discharges are reasonably expected to originate, or in which the hospital would have at least a 20 percent market share. Minor adjustments to the boundaries of the service area may be made to create a contiguous service area or to conform more closely to the boundaries of demographic units for which census data are reported (county, county census division, enumeration district, or zip codes if conversion has been done). If a project proposes to serve a population group with special needs or beliefs, those factors must be taken into consideration consistent with OAR 333-590-0030.

(2) Determine the estimated population for the hospital service area identified in section (1) of this rule for the prior 20 years in 10-year increments, and five- and 10-year forecasts as a basis for estimating population for past years and forecasting future years. Applicants are directed to use Portland State University's Population Research Center (PRC) Intercensal Estimate reports, and when available, Revised Intercensal Population estimates. The applicant shall use the Population Forecasts for the five- and 10-year population forecast. An updated link to the data source can be found on the Certificate of Need Program's website. If the applicant uses an alternate data source, the applicant must provide justification for the alternate data source.

(a) For the five- and 10-year forecasts, official population forecasts developed by the PRC should be used. If previously prepared forecasts are not available from PRC for the service area, then the applicant should contact the Division to prepare a joint request for preparation of a service area forecast compatible with county and state forecast series. The applicant shall pay any associated costs. All reports prepared by PRC must be made available to the Division;

(b) Age-specific forecasts and changes over time in the age composition of the service area population should be examined, and their implications for use-rates taken into consideration.

(3) Determine current year proposed service area and historical Health Service Area population-based discharge and patient day use-rates utilizing relevant and recent data. More recent data on a less than statewide basis may also be considered if a method of adjustment for balance-of-state origins and utilization acceptable to the Division and applicant can be developed. Future use-rate may be modified if one or more of the conditions specified in OAR 333-590-0030(4) through (6) are met:

(a) Determine current year and historical utilization, by the service area population of existing facilities, using available recent relevant data for each of the prior 10 years, including use of Medicare Cost Reports. List, chronologically, factors which may have affected these trends, such as population shifts, public health emergencies, and changes in hospital location, service mix, age mix, reimbursement mix, transportation patterns, locations of physician specialists, and changes in the intensity or types of services delivered;

(b) Estimate future utilization rates by the hospital service area population, based on population forecasts for age/sex breakdowns, according to consideration of each of a range of age/sex adjusted use-rates for:

(A) The state as a whole;

- (B) The Health Service Area;
 - (C) The nearest facilities with service mixes most comparable to the proposed facility;
 - (D) The nearest facilities with comprehensive service mixes;
 - (E) Available HMO age/sex use-rate data for California, Oregon and Washington.
- (4) Develop a consistent and reasonable set of well-documented assumptions regarding the appropriate use-rates reviewed in section (3) of this rule, and regarding the extent to which utilization at the proposed hospital will be "new" utilization and the extent to which it will replace utilization at existing hospitals.
- (5) Analyze the advantages and disadvantages of both "new" and "replacement" components of utilization, with respect to both the population to be served and existing facilities, considering the legislative findings cited in ORS 442.025 with respect to reasonable access to quality health care at a reasonable cost.
- (6) Given all information from the preceding steps, and the five- and 10-year population estimates, compute the range of possible future patient days in five years and in 10 years at the proposed facility, allowing appropriate adjustments for out-of-area utilization and other special factors or considerations relevant to the proposal.
- (7) Convert each computed value of forecasted patient days based on preceding sections of this rule to average daily census (ADC).
- (8) For each of the values computed under section (7) of this rule, estimate the statistical variability, or standard deviation, of the daily census and provide the methodology used by the applicant and sufficient information to validate use of the statistical model.
- (9) Estimate the statistically expected peak daily census at the proposed facility by applying an appropriate statistical model and provide sufficient information to validate the use of the statistical model.
- (a) If the facility is more than 10 miles by road from the nearest alternative facility, use an appropriate multiplier in order to assure an available bed on all but one day out of each 500 days, a 99.8 percent probability;
 - (b) If the facility is 10 miles or less by road from the nearest alternative facility, use an appropriate multiplier to assure an available bed on all but four days out of each 365, a 99 percent probability.
- (10) Using a 10-year projection from the calendar year of submission of the application, and the analysis in sections (4) and (5) of this rule, select from the results of section (7) of this rule the most likely average daily census, noting the assumption in section (6) of this rule. Include consideration of the following factors:
- (a) Whether it is planned that new health services will be added, or existing ones expanded, decreased, or deleted; the best feasible mathematical estimates of appropriate utilization levels and patient days generated because of such changes; and the best available evidence of whether these will be "new" days areawide, or will shift present areawide utilization patterns for the service(s), or both;
 - (b) Whether any new or expanded services will involve:
 - (A) Adding physicians up to, but not beyond, established minimum physician-to-population ratios for applicable specialists; or
 - (B) Adding physicians beyond such ratios.
 - (c) Utilization generated as a result of addition of physician staff members, up to ratios specified in paragraph (10)(b)(A) of this rule may be considered in addition to utilization projected using the use-rate assumption in section (3) of this rule. In the event that the proposed situation is as in paragraph (10)(b)(B) of this rule, the estimated utilization so generated will not be counted as need. Physician-to-population ratios will not be used as a basis for reducing projected utilization derived from the basic use-rate assumptions in section (3) of this rule;
- (11) Select, from the results of section (9) of this rule, the peak daily census associated with the result of section (10) of this rule. If this number of beds exceeds the present number of acute inpatient beds within 50 miles by road of the population to be served, the applicant must evaluate the extent to which admissions scheduling by the applicant or by existing institutions could alleviate the need for new beds. The Division shall evaluate the extent to which procedures and treatments that could be accomplished on an outpatient basis are planned to be handled on an inpatient basis at the applicant facility and may make a compensatory adjustment in the bed need estimate. In performing this evaluation, the Division shall consult with professional review organizations, third-party payers, and professional and provider

organizations. One indication of need for compensatory adjustment may be a case mix adjusted Medicare diagnosis related group (DRG) length of stay or admission rate in excess of those at comparable facilities.

(12) If the result of section (11) of this rule indicates that added beds may be needed in the proposed hospital service area, an applicant for a new facility shall weight it against the availability of beds at other facilities within 50 miles by road of the proposed facility's location and against the feasibility of alternative health care services, under OAR 333-590-0060.

(13) A certificate of need will be issued to meet the indicated need based on sections (11) and (12) of this rule, if supported by provisions of OAR 333-590-0060 and the Division's findings on the criteria in division 580.

(14) If the number of beds proposed at the applicant facility cannot be justified under these general acute inpatient rules, a certificate of need for new specialty beds may be issued where an adjustment is indicated because conversion of other beds to sufficient specialty beds to meet calculated specialty bed need is not architecturally and economically feasible.

STATUTORY/OTHER AUTHORITY: ORS 431.120, 442.315

STATUTES/OTHER IMPLEMENTED: ORS 431.120, 442.315

AMEND: 333-590-0060

RULE TITLE: Relationship of Proposed New Hospitals to Existing Health Care System

RULE SUMMARY: Amend OAR 333-590-0060 – Removes specific statistical “multiplier” and requires applicant to provide relevant and recent data to support their project. This rule is being amended to allow the applicant to cite their own relevant data to support their proposal.

RULE TEXT:

An applicant proposing a new acute inpatient facility, rather than replacement or expansion of an existing facility, must weigh its plans against the availability of beds at existing, reasonably accessible facilities, especially those within the proposed service area of the applicant; and against the feasibility of development of alternative facilities and services. To develop a quantitative estimate of the situation, the following methodology will be used. Its results are to be evaluated against factors such as quality of care; types of services; levels of care available; anticipated changes in hospital locations, patient origins, service mix, age mix, reimbursement mix, transportation patterns, population shifts, and locations of physician specialists; and documented commitments to develop pro-competitive initiatives such as alternative delivery systems, selective contracting, successful competitive bidding, and other market-oriented changes:

- (1) Identify as other significant providers, those hospitals located within the proposed service area of the applicant facility.
- (2) For the applicant and for each other significant provider, estimate the anticipated commitment ratio, considering the ratio of each facility's patient days originating from the service area of the applicant facility to the total patient days originating from that service area, using relevant and recent data.
- (3) Calculate expected first year average daily census at the applicant facility, based on OAR 333-590-0050(7), and for each other significant provider for that year.
- (4) Calculate peak daily census for that year at each facility by applying the methodology in OAR 333-590-0050(6) through (9) to the service area and utilization statistics for these facilities, taking into consideration, utilizing a relevant verification model, the low probability that all facilities will be simultaneously full.
- (5) Estimate the commitment of beds by each facility to the hospital service area at peak occupancy as arrived at by the applicant in section (4) of this rule, by multiplying the results of section (4) of this rule by the commitment ratios calculated in section (2) of this rule.
- (6) To estimate available beds at each facility, subtract the peak occupancy of each, as defined in section (4) of this rule, from:
 - (a) The capacity defined in OAR 333-590-0010(3); and
 - (b) The measure in subsection (a) of this section, plus “shelled space,” that is, convertible space which requires construction rather than merely changing furniture.
- (7) Estimate the number of beds in excess of peak occupancy which could readily be committed to the service area of the applicant, by multiplying the results from section (6) of this rule by the commitment ratios developed in section (2) of this rule.
- (8) Taking into consideration the factors listed at the beginning of this rule, evaluate the feasibility and costs of meeting the estimated future need at the applicant facility, as determined under OAR 333-590-0050, from the inventory of available beds identified in section (6) of this rule. Consider the financial feasibility of utilizing “shelled space” rather than new construction. The impact of approval of the proposal on the financial viability of facilities which share the applicant's market area shall be evaluated by the Division using the financial ratios specified in OAR 333-580-0100(3) and (4).
- (9) If need for acute inpatient beds is not demonstrated under OAR 333-590-0050; or if need is demonstrated but, under this rule, it is found that the need can be met by utilization of available beds at existing facilities which are within 50 miles by road of the proposed facility's location; the applicant must consider the least costly way to solve the applicant's problem of meeting health care needs of the population involved. In addition, the applicant may prepare an

analysis related to:

(a) Whether one or more of the factors consistent with OAR 333-590-0030 is likely to generate at least 30 percent or more of reasonably estimated acute inpatient care utilization by the population proposed to be served, and if so;

(b) Whether the applicant can document unsuccessful good faith efforts, prior to submission of the letter of intent, to arrange for utilization of existing facilities and/or services (if any such facilities or services exist within 50 miles by road of the proposed facility's location), consistent with meeting the needs of the population to be served in the least costly, least duplicative manner; and, if OAR 333-590-0030(5) applies, consistent with the intended HMO service model and the provisions of section (10) of this rule.

(10) The Division shall take into account the acute inpatient care needs of members, subscribers and enrollees of institutions, HMOs or health care plans, as defined in OAR 333-545-0020(14), that operate or support particular health care facilities for the purpose of rendering health care to such members, subscribers and enrollees:

(a) An applicant to serve such groups shall:

(A) Identify the needs of their members, subscribers and enrollees for the proposed facility or service;

(B) Demonstrate that the identified needs are reasonable when related to the health care costs of present and future members, subscribers, and enrollees;

(C) Describe the proposal's potential for reducing the use of inpatient care in the community through an extension of preventive health services and provision of more systematic and comprehensive health services;

(D) Identify the availability, and estimate the cost, of obtaining proposed beds, services or equipment from existing providers in the proposed hospital service area, other than the applicant.

(b) A certificate of need shall be issued to meet the needs or reasonably anticipated needs of such group members when beds, services or equipment are not available from non-plan providers in the area to be served. Beds, services, or equipment are not available to an HMO from a non-HMO provider unless:

(A) They would be available through a long-term contract of sufficient duration and with sufficient provisions for notice of termination to enable the HMO to negotiate an alternative contract with another non-HMO provider, or to develop facilities and/or service capabilities and operate same after notice of contract termination from the non-HMO provider;

(B) They would be available and accessible to physicians associated with the HMO on a basis comparable to physicians not affiliated with the HMO;

(C) They could be provided by a non-HMO provider in a manner that can demonstrate to be as cost effective as if they were developed and operated by the HMO; and

(D) They would be available in a manner that is consistent with the HMO's basic method of operation.

(11) Based on subsections (9)(a) and (b), and (10)(a) and (b) of this rule, the Division may consider proposed findings of need and feasibility, taking into account such factors as:

(a) At least 70 percent of the population to be served is more than 50 miles by road from the nearest hospital with 45,000 patient days or more in the most recent year for which data are available;

(b) Population base sufficient to sustain the new facility or service;

(c) Community effectively isolated from reasonable access to acute care services, given road and weather conditions;

(d) Financial condition of applicant adequate to handle consequences of failure of facility or service to open or to stay open, without financial impact on proposed population to be served;

(e) Whether the proposed service(s) and bed capacity(ties) represent the least costly approach, in relation to capital and operating expenses, to meet acute inpatient care need;

(f) Whether the facility, sized as required under subsection (e) of this section, is designed so that future expansion would be architecturally feasible;

(g) Restrictive admissions policies;

(h) Access to care for public paid patients;

(i) Restrictive staff privileges and/or denial of privileges at existing and proposed facilities.

STATUTORY/OTHER AUTHORITY: ORS 431.120, 442.315

STATUTES/OTHER IMPLEMENTED: ORS 431.120, 442.315