

## DIVISION 580

### CERTIFICATE OF NEED APPLICATION INSTRUCTIONS AND FORMS

#### General Instructions

**333-580-0000** All applications must be completed in accordance with the instructions contained in this division. Only those parts which are pertinent and appropriate to the proposed project need be completed, but when a particular criterion or section is not applicable, the applicant must briefly explain why it does not apply. All documents submitted to the Health Division are public information. Assistance, or additional copies of the certificate of need rules, can be obtained upon request by contacting: Certificate of Need Review Coordinator, Health Division, 800 N.E. Oregon, #21, Portland, OR 97232. Phone: (503) 731-4320. Review of all applications not subject to abbreviated review under OAR 333-560-0010 will be governed by the following considerations:

- (1) The review process is governed by Divisions 545 through 670 of OAR Chapter 333.
- (2) An application must have been preceded by a letter of intent on which the division has ruled; and the waiting period defined in OAR 333-555-0010 must have been completed.
- (3) A single application should be filed for a project involving two or more project types when most aspects of the overall project are interdependent for purposes of making a decision.
- (4) All application contents must be typed or legibly printed.
- (5) To assist in achieving the equitable and objective review and determination, all replies required by this division should be as complete as possible. Incomplete applications will delay the review process.
- (6) Any schedules or continuation sheets called for must be attached to the applicable section.
- (7) External documents (e.g., an applicant's long-range plan, or consultant's study report, etc.) may be incorporated by reference as part of the application to avoid duplication of effort by the applicant. When this option is taken, the application *must* show the chapter, page or section reference number of the external document where the respective responses are contained, and the document referenced must be provided to the division.
- (8) Burden of proof for justifying need and viability of a proposal rests with the applicant.
- (9) Each certificate of need application must be accompanied by an application fee made payable to the Health Division, in the amount as shown in the Fee Schedule, OAR 333-565-0000(4).
- (10) The division must make a determination of completeness of all pertinent sections of the application with 15 days of receiving it, as provided in OAR 333-570-0020. The division will notify the applicant in writing of the determination of any additional information needed, or of completeness.
- (11) Any amendments to the application must be in writing, and will be considered in reference to OAR 333-570-0050. Amendments may cause the application to be treated as a new application if submitted more than 45 days following the division's written determination that the application is

complete, unless the division agrees to accept the amendment.

- (12) Applications may be withdrawn at any time without prejudice (OAR 333-570-0050(1)). Applicants shall notify the division in writing of any withdrawal. Application fee refunds may only be made if withdrawal is made in writing prior to the division's determination of completeness (OAR 333-565-0000(3) and (5)), or if the actual costs of a completed project are over ten percent less than the approved costs (OAR 333-565-0000(6)(b)).
- (13) Applicants must complete all appropriate sections of the application, and submit to the division the required number of copies of application forms (printed on white paper), and all attachments describing the project, or responding to the review criteria.
- (14) Upon request by the applicant, the division may waive the requirement for the completion of some parts of the application. This will provide an opportunity for the applicant and the division to eliminate unnecessary collection and submission of information.
- (15) Applicants for a certificate of need shall provide four copies of the *entire* application to: Health Division, 800 N.E. Oregon, #21, Portland, OR 97232. Four copies shall also be submitted to the division of any amendments to the application or supplementary materials.
- (16) Preapplication conferences are encouraged; and these application instructions are designed to make application for a certificate of need relatively simple. However, Health Division staff are available to further assist the applicant in this process.

Stat. Auth.: ORS 409.120, ORS 431.120(6) & ORS 442.315  
Stats. Implemented:  
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

### **Application Format**

**333-580-0010** The application should be presented in four sections:

- (1) Section A -- Introduction;
- (2) Section B -- Narrative discussion addressing the proposal's relationship to the statutory certificate of need review criteria as defined in OAR 333-580-0040 through 333-580-0060;
- (3) Section C -- Completed required forms; and
- (4) Section D -- Appendices.

Stat. Auth.: ORS 409.120, ORS 431.120(6) & ORS 442.315  
Stats. Implemented:  
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

### **Section A -- Introduction**

**333-580-0020** The applicant shall provide a short introductory narrative of the proposal outlining the major aspects of the proposal.

Stat. Auth.: ORS 409.120, ORS 431.120(6) & ORS 442.315  
Stats. Implemented:  
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

## Section B -- Review Criteria

**333-580-0030** (1) The applicant must demonstrate in narrative form that its proposal satisfies the criteria specified in OAR 333-580-0040 to 333-580-0060 and the applicable service-specific need methodologies and standards in Divisions 585 through 645. The application must have narrative sections corresponding to each section of OAR 333-580-0040 to 333-580-0060 [those statements labeled "(1)", "(2)" etc.]. In each section, the criterion to be addressed is shown in italics. An explanation of the way in which the criterion is to be addressed and specific issues to be discussed is then provided. The narrative should address each of these issues.

- (2) The division will make findings and base its decision on the extent to which the applicant demonstrates that the criteria and standards referenced in section (1) of this rule are met. Criteria will be considered to have been met if the applicant can demonstrate that the questions posed in the criteria can be answered in the affirmative. An application will be decided in accordance with the statutes and rules in effect at the time of filing of a completed letter of intent for that application. A completed letter of intent will be considered to have been filed only if the division finds that it includes all of the information required under OAR 333-555-0020(1).
- (3) Each relevant issue in the outline of criteria must have a written explanatory response which includes supporting evidence and identifies the source of evidence, assumptions, methodologies used in projections, estimates, etc.
- (4) Applicants are encouraged to include any additional information relevant to the review criteria which was not specifically requested by the state, but which would further support the proposal.

- (5) Applicants must demonstrate to the division that a proposal is approvable. All other application sections are supportive of this section.

Stat. Auth.: ORS 431.120(6) & ORS 442.315

Stats. Implemented: ORS 431.120(6) & ORS 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

### Need

**333-580-0040** Applicants must provide a narrative discussion of each of the following:

- (1) Criterion: Does the service area population need the proposed project?
- (a) The applicant must identify the service area's need for the proposal in the past, present and future;
- (b) In establishing the magnitude of present and future need for each service element, the applicant will:
- (A) Use appropriate indicators of a population's need (i.e., population-based use-rates, population-based "medical necessity" rates, or established productivity standards);
- (B) Use the standards and need methodologies specified in Divisions 585 through 645 of OAR Chapter 333 applicable to the services or facilities being proposed;
- (C) Consider industry standards and historical experience as appropriate comparisons where plans are silent;

(D) In the case of nursing home beds, determine whether the added beds are consistent with plans adopted by the relevant area agency on aging and the state Senior and Disabled Services Division.

(2) Criterion: If the project involves remodeling or replacement of an existing health facility structure, are there significant functional inefficiencies, obsolescence or structural problems which the facility has which seriously compromise the effective delivery of health care to patients, and which would be substantially corrected by the proposed project? The narrative should:

- (a) Identify and demonstrate all significant functional inefficiency (including physical access) problems;
- (b) Identify and demonstrate all significant obsolescence problems; and
- (c) Identify and demonstrate all significant structural problems.

(3) Criterion: Will the proposed project result in an improvement in patients' reasonable access to services? The applicant will identify any potential problems of accessibility including traffic patterns; restrictive admissions policies; access to care for public-paid patients; and restrictive staff privileges or denial of privileges.

(4) Criterion: If the project proposes to serve the needs of members of a health maintenance organization, do these members need the proposed project, considering the special needs and health care utilization rates of this population?

(a) HMOs shall:

(A) Identify the needs of their members, subscribers and enrollees for the proposal;

(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 a community through an extension of preventive health services and the 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 area, who are not HMOs.

(b) A certificate of need shall be issued to meet the needs or reasonably anticipated needs of 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 (e.g., HMO physicians have or will have staff privileges);
- (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 (e.g., acute care centralized at one non-HMO provider as opposed to contracts for care at multiple non-HMO providers).

Stat. Auth.: ORS 431.120(6), ORS 442.315 & ORS 442.325  
 Stats. Implemented: ORS 431.120(6), ORS 442.315 & ORS 442.325

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

### **Availability of Resources and Alternative Uses of Those Resources**

**333-580-0050** Applicants must provide a narrative discussion of each of the following:

- (1) Criterion: Does the proposed project represent the most effective and least costly alternative, considering all appropriate and adequate ways of meeting the identified needs?

- (a) The applicant must demonstrate that the best price for the proposal has been sought and selected;
- (b) The applicant must demonstrate that proposed solutions to identified needs represent the best solution from among reasonable alternatives:
  - (A) Internal alternatives:
    - (i) The applicant must list the major internal operational adjustments considered which could lower the cost and improve the efficiencies of offering the beds, equipment or service;
    - (ii) The applicant must demonstrate that the alternative considered represents the best solution for the patients, and discuss why other alternatives were rejected;
    - (iii) If the proposal is for an inpatient service, whether new or expanded, applicant must demonstrate this method of delivery is less costly than if done on an outpatient basis;
    - (iv) The applicant must demonstrate that the selected architectural solution represents the most cost effective and efficient alternative to solving the identified needs.

(B) External alternatives:

- (i) If the proposed beds, equipment or services are currently being offered in the service area, applicant must demonstrate:

- (I) Why approval of the application will not constitute unnecessary duplication of services;
- (II) Why the proposal is an efficient solution to identified needs;
- (III) Why the proposal represents the most effective method of providing the proposal; and
- (IV) That the applicant can provide this proposal at the same or lower cost to the patient than is currently available.

(ii) If paragraphs (A)(i) to (A)(iv) of this subsection cannot be demonstrated, the applicant must show that without the proposal, the health of the service area population will be seriously compromised.

(C) Less costly alternatives of adequate quality:

(i) If a less costly and adequately effective alternative for the proposal is currently available in the area, the applicant must demonstrate why its proposal is:

- (I) Not an unnecessary duplication; or
- (II) A more efficient solution to the identified needs.

(ii) Applicants must demonstrate that the identified needs of the population to be served cannot be reasonably served under current conditions, or by alternative types of service or equipment or equal quality to the proposal. "Alternatives of adequate

quality" does not imply that they need be exactly like those being proposed, but only that they meet identified needs at state approved levels.

(D) If there are competing applications for the proposal, each applicant must demonstrate why theirs is the best solution, and why a certificate of need should be granted them.

(2) Criterion: Will sufficient qualified personnel, adequate land, and adequate financing be available to develop and support the proposed project? The applicant must demonstrate that there are, or will be sufficient physicians in the area to support the proposal; sufficient nurses available to support the proposal; sufficient technicians available to support the proposal; adequate land available to develop the proposal and accommodate future expansion; and the source(s) and availability of funds for the project.

(3) Criterion: Will the proposed project have an appropriate relationship to its service area, including limiting any unnecessary duplication of services and any negative financial impact on other providers?

(a) The applicant must identify the extent to which the proposal and its alternatives are currently being offered to the identified service area population, or, in the case of acute inpatient beds, could be offered on the basis of an analysis under Division 590 of this Chapter;

(b) The applicant will discuss to the best of his or her knowledge, any negative impact the proposal will have on those presently offering or reimbursing for similar or alternative services. Areas to be discussed are utilization, quality of care, and cost of care;

- (c) The applicant must demonstrate that jointly operated or shared services between the applicant and other providers have been considered and the extent to which they are feasible or not;
  - (d) The applicant must demonstrate that all necessary support services and ancillary services for the proposal are available at acceptable levels to insure that patients will have the necessary continuity in their health care.
- (4) Criterion: Does the proposed project conform to relevant state physical plant standards, and will it represent any improvement in regard to conformity to such standards, compared to other similar services in the area?
- (a) The proposed project must comply with state licensing, architectural and fire code standards;
  - (b) If the proposal is already being offered in the defined service area, the applicant must describe, to the best of his or her knowledge, to what degree the existing service complies with state licensing, architectural and fire code standards.

Stat. Auth. : ORS 409.120, ORS 431.120(6) & ORS 442.315

Stats. Implemented:

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

### **Economic Evaluation**

**333-580-0060** Applicants must provide a narrative discussion of each of the items below. The entity actually proposing to implement a certificate of need must submit the required financial data. Additional financial data may be required to be presented by

the applicant or a related entity to isolate the financial activities of the proposal:

- (1) Criterion: Is the financial status of the applicant adequate to support the proposed project, and will it continue to be adequate following implementation of the project?
  - (a) Any financial forecasts which deviate significantly from the financial statements of the five-year historical period presented in the application must be fully explained and justified;
  - (b) An applicant must describe how it will cover expenses incurred by the proposal in the event the proposal fails to meet budgeted revenues in any forecasted year;
  - (c) Applicants must discuss the results of ratio analysis required by Form CN-9 and OAR 333-580-0100(4), explaining strengths and weaknesses. The discussion should refer to each ratio as detailed in **Table 1** of OAR 333-580-0100(4). Specifically:
    - (A) Applicants must describe their debt capability in terms of the required ratio analysis;
    - (B) The discussion of liquidity should include comments on the adequacy of cash, the collection period for patient accounts receivable, and the payment period for accounts payable;
    - (C) The profitability ratios required by OAR 333-580-0100(4) and Form CN-9 must be discussed.
- (d) Board designated assets: The intended uses of this fund are to be discussed in general terms. Alternative uses or contingent availability of these funds, such as to meet

cash requirement, also need to be addressed. Additionally, the proportion (percent) of depreciation that was or is to be funded is to be identified for each financial period presented;

- (e) The applicant must discuss the availability of other sources of funding, including, but not limited to, donor restricted assets, assets of parent or subsidiary corporations, or a related foundation which may be acquiring assets and/or producing income that is for the purpose of, or could be used for the purpose of, capital expenditure by the applicant;
- (f) Money market conditions must be discussed in terms of their impact on project financing, including interim financing, if applicable. Include the month and year in which financing is to be secured in this narrative:
  - (A) The estimated rate of interest must be justified by the applicant. If debt financing is secured before or during the review process, the actual rate of interest obtained should be reported within 30 days of securing financing;
  - (B) When a bond rating report is issued before or during the review period in conjunction with a proposed bond issue to fund a certificate of need proposal, the applicant must submit a copy of the report to the division within 30 days of its issuance;
  - (C) The financing term selected must be supported with evidence showing the benefits of its selection.
- (g) Patient days, admissions and other units of service used in forecasting projected expenses and revenues, both for the facility as a whole and for services affected by the

proposed project, must be consistent with projections used to determine area need. All assumptions must be discussed;

- (h) An applicant must identify and explain all inflation assumptions and rates used in projecting future expenses and in completing the forms described in OAR 333-580-0100. It is important that the assumptions used by the applicant in preparing financial forecasts be carefully considered. All relevant factors pertaining to historical experience of the applicant, together with upcoming changes affecting the future, should be considered in forecasting the financial condition of the entity. Specifically:
  - (A) Projected changes in wages and salaries should be based on historical increases or known contractual obligations and planned future personnel increases. Considerations should include expected full-time equivalent staffing levels, including increases resulting from the proposal;
  - (B) Projected deductions from revenues should be explained and justified;
  - (C) Expected changes in the intensity and/or complexity of services provided must be considered in addition to the rate of inflation in arriving at an overall rate of increase in revenues or expenses;
  - (D) Projected gross revenue must reflect:
    - (i) Patient day increases/decreases;
    - (ii) Outpatient activity increase/decrease;

- (iii) All debt service coverage requirements; and
  - (iv) Other significant impacts the proposal will make on revenue projections.
- (i) Each applicant must submit within 30 days, a copy of the financial feasibility report if the applicant arranges for such a report and it becomes available before or during the review period.
- (2) Criterion: Will the impact of the proposal on the cost of health care be acceptable?
- (a) The applicant must discuss the impact of the proposal both on overall patient charges at the institution and on charges for services affected by the project:
    - (A) An applicant must show what the proposal's impact will be on the gross revenues and expenses per inpatient day and per adjusted patient day;
    - (B) When a health service is affected by the proposal, an applicant must demonstrate what impact the proposal will have on related patient charges and operating expenses. Expenses and patient charges for individual health services will be compared to historical and forecasted rates of increase for the facility as a whole.
  - (b) The applicant must discuss both the proposed or actual charges for the proposed service and the profitability of the proposed service, compared to other similar services in the state (if any);
  - (c) The applicant must discuss the projected expenses for the proposed service, and demonstrate the reasonableness of these expense forecasts;
  - (d) If the proposed service is currently not being provided in the area, the applicant should identify potential travel cost savings by:
    - (A) Establishing what the existing travel costs are to patients;
    - (B) Establishing what the travel costs will be to patients after implementation of the proposal; and
    - (C) Showing what the difference is between the figures in paragraphs (A) and (B) of this subsection.
  - (e) The applicant must discuss the architectural costs of the proposal:
    - (A) An applicant must demonstrate that the existing structure will last long enough to derive full benefits from any new construction or remodeling;
    - (B) General construction costs must be within reasonable limits (within high/low range as described in the most current issue of the Dodge Research Report adjusted for location).

[ED. NOTE: The Table and Form(s) referenced in this rule is not printed in the OAR Compilation. Copies are available from the agency.]

Stat. Auth.: ORS 409.120, ORS 431.120(6) & ORS 442.315

Stats. Implemented:

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

## Special Requirements for Certain Types of Proposals

**333-580-0070** (1) As required by ORS 442.584, applications proposing any of the technologies or services selected for assessment by the Health Resources Commission must include the information specified in section (2) of this rule. This requirement shall not apply until such time as the Health Resources Commission has selected the technologies that it will assess under ORS 442.583.

- (2) Applications for projects involving any equipment or services selected for assessment by the Health Resources Commission must include the following information in a separately identified section or appendix to the application:
- (a) The estimated number of patients needing the service or procedure who are not currently being served and who cannot be served by existing programs in the service area;
  - (b) The anticipated number of procedures to be performed per year for a five-year period commencing on the date the service is started or the technology is acquired;
  - (c) The anticipated number of patients to be served by the applicant, based on the incidence in the population to be served or the conditions for which the technology or service will be used;
  - (d) Clinical indications for ordering use of the technology or service, with appropriate references to relevant literature;
  - (e) An estimate of the treatment decisions likely to result from the technology or service;

(f) A proposed method for collecting data on the patients served, costs engendered directly or indirectly and the health outcomes resulting from use of the technology or service.

- (3) The information required under this rule will not be used as a basis for any decision to approve or deny any application.

Stat. Auth.: ORS 431.120(6), ORS 442.315 & ORS 442.584

Stats. Implemented: ORS 431.120(6), ORS 442.315 & ORS 442.584

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

## General Instructions for Section C -- Completion of Forms

**333-580-0080** Applicants must complete Forms CN-1 through CN-12 and include these forms with the application, except that forms which are not relevant to the proposal need not be completed. Applicants should contact the Health Division to determine which forms are relevant to their proposal. Additional tables and graphs may be provided, and should appear as appendices in Section D and be referenced to the applicable discussion and criteria in Section B. Form CN-1 should be included as the first page of the application (after any cover pages and table of contents).

[ED. NOTE: The Form(s) referenced in this rule is not printed in the OAR Compilation. Copies are available from the agency.]

Stat. Auth.: ORS 409.120, ORS 431.120(6) & ORS 442.315

Stats. Implemented:

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

## Completion of Architectural Forms

**333-580-0090** In completing Form CN-3, "Capital Expenditure Estimate", all costs identified on this form, which will be incurred at a future date, must reflect the effects of inflation.

[ED. NOTE: The Form(s) referenced in this rule is not printed in the OAR Compilation. Copies are available from the agency.]

Stat. Auth.: ORS 409.120, ORS 431.120(6) & ORS 442.315

Stats. Implemented:

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

## Completion of Financial Forms

**333-580-0100** The applicant must submit financial information regarding the proposed service and the facility or organization as a whole on Forms CN-4 through CN-12. Projects with costs of under \$1,000,000 need only forecast three years financial information. Other projects should forecast five years. If there is more than one entity with a financial interest in a proposal, the entity actually proposing to implement the project must submit the required financial data. Additional financial data may be required to be presented regarding other entities with an involvement in the project. All forms should be filled out using the accrual basis of accounting, unless the division has specifically approved another method:

- (1) In completing Form CN-4, "Project Cost Estimate", the applicant should fill in all of the appropriate fund sources.
- (2) In completing Form CN-5, "Income Statement", Form CN-6, "Balance Sheet", and Form CN-7, "Statement of Changes in Financial Position", the applicant should provide all line items requested. The applicant may use its own facility

format if it includes all the line items requested, but in such cases the format used by the applicant should include a reference to the appropriate certificate of need form number.

- (3) In completing Form CN-8, "Debt Service Coverage", the applicant should forecast debt service coverage using the accrual basis of accounting. Debt service coverage is to be computed as follows:

$$\frac{\text{Net Income} + \text{Depreciation} + \text{Interest Expense}}{\text{Principal} + \text{Interest Expense}}$$

- (4) The applicant should complete Form CN-9, "Ratio Analyses", for the years requested. Financial performance of the applicant organization proposing the project will be evaluated by commonly accepted health care industry indicators related to financial soundness, plausibility of economic assumptions used, and overall effect on patient charges. These financial ratios are listed in **Table 1**. Applicants must use the formulas shown in **Table 1** in completing Form CN-9:
  - (a) If an applicant believes that some analysis, in addition to the Ratio Analysis, gives a more appropriate measure, the applicant may present such other analysis, together with an explanation of why it is more appropriate. The division will determine whether or not such alternative analysis is acceptable;
  - (b) As used in this rule:
    - (A) "Net Operating Income" means total operating revenue less total operating expenses;

- (B) Total operating revenue is exclusive of nonoperating revenue;
- (C) "Fund Balance" means the unrestricted fund balance at the end of the period;
- (D) Average annual outpatient revenue and inpatient days should be taken from the applicant's audited financial data.
- (5) In completing Form CN-10, "Volume-Adjusted Expenses and Revenues", the number of patient days used must be consistent with those cited elsewhere in the application. Unless otherwise approved by the division, historical figures will be derived from the Annual Reports of health facility utilization required by ORS 442.463.
- (6) In completing Form CN-11, "Financial Analysis for Individual Services", all new or proposed revenue-producing clinical or nonclinical services which, by themselves, qualify for certificate of need review whether alone or a subpart of a project, must each have a financial analysis separate from the institution as a whole, and a separately-completed Form CN-11.
- (7) In completing Form CN-12, "Sources and Uses of Funds for the Proposed Project", the applicant must provide all items requested.
- (8) In providing all of the financial forecasts required by this rule, the applicant must base its forecast on estimates of the most probable financial position, results of operations, and changes in financial position for future periods. "Most probable" means that the assumptions have been evaluated by management and that the forecast is based on management's

judgment of the most likely set of conditions and its most likely course of action.

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