



MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

**INSTRUCTIONS FOR
APPLICATION FOR CERTIFICATE OF NEED
HOSPITAL PROJECTS**

ALL APPLICATIONS MUST FOLLOW THE FORMATTING REQUIREMENTS DESCRIBED IMMEDIATELY BELOW. NOT FOLLOWING THESE FORMATTING INSTRUCTIONS WILL RESULT IN THE APPLICATION BEING RETURNED.

REQUIRED FORMAT:

Table of Contents. The application must include a Table of Contents referencing the location of application materials. Each section in the hard copy submission should be separated with tabbed dividers. Any exhibits, attachments, etc. should be similarly tabbed, and pages within each should be numbered independently and consecutively. **The Table of Contents must include:**

- **Responses to PARTS I, II, and III of this application form**
- **Responses to PART IV**
COMAR 10.24.10: Acute Care Hospital Services
Other applicable facility-specific State Health Plan chapters
Review Criteria listed at 10.24.01.08G(3)(b) through(f)
- **Attachments, Exhibits, or Supplements**
Identification of each attachment, exhibit, and supplement

Application pages must be consecutively numbered at the bottom of each page. Exhibits attached to subsequent correspondence during the completeness review process shall use a consecutive numbering scheme, continuing the sequencing from the original application. (For example, if the last exhibit in the application is Exhibit 5, any exhibits used in subsequent responses should begin with Exhibit 6. However, a replacement exhibit that merely replaces an exhibit to the application should have the same number as the exhibit it is replacing, noted as a replacement.

SUBMISSION FORMATS:

We require submission of application materials in three forms: hard copy; searchable PDF; and in Microsoft Word.

- **Hard copy:** Applicants must submit six (6) hard copies of the application to:
Ruby Potter
Health Facilities Coordinator
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215
- **PDF:** Applicants must also submit *searchable* PDF files of the application, supplements, attachments, and exhibits.¹ All subsequent correspondence should also be submitted both by paper copy and as *searchable PDFs*.
- **Microsoft Word:** Responses to the questions in the application and the applicant's responses to completeness questions should also be electronically submitted in Word. Applicants are strongly encouraged to submit any spreadsheets or other files used to create the original tables (the native format). This will expedite the review process.

PDFs and spreadsheets should be submitted to ruby.potter@maryland.gov and kevin.mcdonald@maryland.gov.

Note that there are certain actions that may be taken regarding either a health care facility or an entity that does not meet the definition of a health care facility where CON review and approval are not required. Most such instances are found in the Commission's procedural regulations at COMAR 10.24.01.03, .04, and .05. Instances listed in those regulations require the submission of specified information to the Commission and may require approval by the full Commission. Contact CON staff at (410) 764-3276 for more information.

¹ PDFs may be created by saving the original document directly to PDF on a computer or by using advanced scanning technology

For internal staff use

**MARYLAND
HEALTH
CARE
COMMISSION**

MATTER/DOCKET NO.

DATE DOCKETED

**HOSPITAL
APPLICATION FOR CERTIFICATE OF NEED**

PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: _____

Address:

Street City Zip County

Name of Owner (if differs from applicant):

2. OWNER

Name of owner: _____

3. APPLICANT. *If the application has co-applicants, provide the detail regarding each co-applicant in sections 3, 4, and 5 as an attachment.*

Legal Name of Project Applicant

Address:

Street City Zip State County

Telephone: _____

Name of Owner/Chief Executive: _____

4. NAME OF LICENSEE OR PROPOSED LICENSEE, if different from applicant:

5. LEGAL STRUCTURE OF APPLICANT (and LICENSEE, if different from applicant).

Check or fill in applicable information below and attach an organizational chart showing the owners of applicant (and licensee, if different).

- A. Governmental
 - B. Corporation
 - (1) Non-profit
 - (2) For-profit
 - (3) Close State & date of incorporation
 - C. Partnership
 - General
 - Limited
 - Limited liability partnership
 - Limited liability limited partnership
 - Other (Specify): _____
 - D. Limited Liability Company
 - E. Other (Specify): _____
- To be formed:
- Existing:

6. PERSON(S) TO WHOM QUESTIONS REGARDING THIS APPLICATION SHOULD BE DIRECTED

A. Lead or primary contact:

Name and Title: _____
Mailing Address: _____

Street City Zip State
Telephone: _____
E-mail Address (required): _____
Fax: _____

B. Additional or alternate contact:

Name and Title: _____
Mailing Address: _____

Street City Zip State
Telephone: _____
E-mail Address (required): _____
Fax: _____

7. TYPE OF PROJECT

The following list includes all project categories that require a CON under Maryland law. Please mark all that apply.

If approved, this CON would result in:

- (1) A new health care facility built, developed, or established
- (2) An existing health care facility moved to another site
- (3) A change in the bed capacity of a health care facility
- (4) A change in the type or scope of any health care service offered by a health care facility
- (5) A health care facility making a capital expenditure that exceeds the current threshold for capital expenditures found at:
http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/con_capital_threshold_20140301.pdf

8. PROJECT DESCRIPTION

A. Executive Summary of the Project: The purpose of this BRIEF executive summary is to convey to the reader a holistic understanding of the proposed project: what it is; why you need/want to do it; and what it will cost. A one-page response will suffice. Please include:

- (1) Brief description of the project – what the applicant proposes to do;
- (2) Rationale for the project – the need and/or business case for the proposed project;
- (3) Cost – the total cost of implementing the proposed project; and
- (4) Master Facility Plans – how the proposed project fits in long term plans.

B. Comprehensive Project Description: The description must include details, as applicable, regarding:

- (1) Construction, renovation, and demolition plans;
- (2) Changes in square footage of departments and units;
- (3) Physical plant or location changes;
- (4) Changes to affected services following completion of the project; and
- (5) If the project is a multi-phase project, describe the work that will be done in each phase. If the phases will be constructed under more than one construction contract, describe the phases and work that will be done under each contract.

Complete the DEPARTMENTAL GROSS SQUARE FEET WORKSHEET (Table B) in the CON TABLE PACKAGE for the departments and functional areas to be affected.

9. CURRENT PHYSICAL CAPACITY AND PROPOSED CHANGES

Complete the Bed Capacity (Table A) worksheet in the CON Table Package if the proposed project impacts any nursing units.

10. REQUIRED APPROVALS AND SITE CONTROL

- A. Site size: _____ acres
- B. Have all necessary State and local land use approvals, including zoning, for the project as proposed been obtained? YES _____ NO _____ (If NO, describe below the current status and timetable for receiving necessary approvals.)

- C. Form of Site Control (Respond to the one that applies. If more than one, explain.):

(1) Owned by: _____
Please provide a copy of the deed.

(2) Options to purchase held by: _____
Please provide a copy of the purchase option as an attachment.

(3) Land Lease held by: _____
Please provide a copy of the land lease as an attachment.

(4) Option to lease held by: _____
Please provide a copy of the option to lease as an attachment.

(5) Other: _____
Explain and provide legal documents as an attachment.

11. PROJECT SCHEDULE

In completing this section, please note applicable performance requirement time frames set forth at COMAR 10.24.01.12B & C. Ensure that the information presented in the following table reflects information presented in Application Item 7 (Project Description).

| | Proposed Project Timeline | |
|---|----------------------------------|--------|
| Single Phase Project | | |
| Obligation of 51% of capital expenditure from CON approval date | | months |
| Initiation of Construction within 4 months of the effective date of a binding construction contract, if construction project | | months |
| Completion of project from capital obligation or purchase order, as applicable | | months |
| Multi-Phase Project for an existing health care facility (Add rows as needed under this section) | | |
| One Construction Contract | | |
| Obligation of not less than 51% of capital expenditure up to 12 months from CON approval, as documented by a binding construction contract. | | months |
| Initiation of Construction within 4 months of the effective date of the binding construction contract. | | months |
| Completion of 1 st Phase of Construction within 24 months of the effective date of the binding construction contract | | months |
| Fill out the following section for each phase. (Add rows as needed) | | |
| Completion of each subsequent phase within 24 months of completion of each previous phase | | months |
| Multiple Construction Contracts for an existing health care facility (Add rows as needed under this section) | | |
| Obligation of not less than 51% of capital expenditure for the 1 st Phase within 12 months of the CON approval date | | months |
| Initiation of Construction on Phase 1 within 4 months of the effective date of the binding construction contract for Phase 1 | | months |
| Completion of Phase 1 within 24 months of the effective date of the binding construction contract. | | months |
| To Be Completed for each subsequent Phase of Construction | | |
| Obligation of not less than 51% of each subsequent phase of construction within 12 months after completion of immediately preceding phase | | months |
| Initiation of Construction on each phase within 4 months of the effective date of binding construction contract for that phase | | months |
| Completion of each phase within 24 months of the effective date of binding construction contract for that phase | | months |

12. PROJECT DRAWINGS

A project involving new construction and/or renovations must include scalable schematic drawings of the facility at least a 1/16" scale. Drawings should be completely legible and include dates.

Project drawings must include the following before (existing) and after (proposed) components, as applicable:

- A. Floor plans for each floor affected with all rooms labeled by purpose or function, room sizes, number of beds, location of bathrooms, nursing stations, and any proposed space for future expansion to be constructed, but not finished at the completion of the project, labeled as "shell space".
- B. For a project involving new construction and/or site work a Plot Plan, showing the "footprint" and location of the facility before and after the project.
- C. For a project involving site work schematic drawings showing entrances, roads, parking, sidewalks and other significant site structures before and after the proposed project.
- D. Exterior elevation drawings and stacking diagrams that show the location and relationship of functions for each floor affected.

13. FEATURES OF PROJECT CONSTRUCTION

- A. If the project involves new construction or renovation, complete the Construction Characteristics (Table C) and Onsite and Offsite Costs (Table D) worksheets in the CON Table Package.
- B. Discuss the availability and adequacy of utilities (water, electricity, sewage, natural gas, etc.) for the proposed project, and the steps necessary to obtain utilities. Please either provide documentation that adequate utilities are available or explain the plan(s) and anticipated timeframe(s) to obtain them.

| |
|--|
| |
|--|

PART II - PROJECT BUDGET

Complete the Project Budget (Table E) worksheet in the CON Table Package.

Note: Applicant must include a list of all assumptions and specify what is included in all costs, as well the source of cost estimates and the manner in which all cost estimates are derived.

PART III - APPLICANT HISTORY, STATEMENT OF RESPONSIBILITY, AUTHORIZATION AND RELEASE OF INFORMATION, AND SIGNATURE

1. List names and addresses of all owners and individuals responsible for the proposed project.
-

2. Is any applicant, owner, or responsible person listed above now involved, or has any such person ever been involved, in the ownership, development, or management of another health care facility? If yes, provide a listing of each such facility, including facility name, address, the relationship(s), and dates of involvement.
-

3. In the last 5 years, has the Maryland license or certification of the applicant facility, or the license or certification from any state or the District of Columbia of any of the facilities listed in response to Question 2, above, ever been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) ? If yes, provide a written explanation of the circumstances, including the date(s) of the actions and the disposition. If the applicant(s), owners, or individuals responsible for implementation of the Project were not involved with the facility at the time a suspension, revocation, or disciplinary action took place, indicate in the explanation.
-

4. Other than the licensure or certification actions described in the response to Question 3, above, has any facility with which any applicant is involved, or has any facility with which any applicant has in the past been involved (listed in response to Question 2, above) ever received inquiries from a federal or any state authority, the Joint Commission, or other regulatory body regarding possible non-compliance with Maryland, another state, federal, or Joint Commission requirements for the provision of, the quality of, or the payment for health care services that have resulted in actions leading to the possibility of penalties, admission bans, probationary status, or other sanctions at the applicant facility or at any facility listed in response to Question 2? If yes, provide, for each such instance, copies of any settlement reached, proposed findings or final findings of non-compliance and related documentation including reports of non-compliance, responses of the facility, and any final disposition or conclusions reached by the applicable authority.
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5. Has any applicant, owner, or responsible individual listed in response to Question 1, above, ever pled guilty to, received any type of diversionary disposition, or been convicted of a criminal offense in any way connected with the ownership, development, or management of the applicant facility or any of the health care facilities listed in response to Question 2, above? If yes, provide a written explanation of the circumstances, including as applicable the court, the date(s) of conviction(s), diversionary disposition(s) of any type, or guilty plea(s).
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One or more persons shall be officially authorized in writing by the applicant to sign for and act for the applicant for the project which is the subject of this application. Copies of this authorization shall be attached to the application. The undersigned is the owner(s), or Board-designated official of the applicant regarding the project proposed in the application.

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

Date

Signature of Owner or Board-designated Official

Position/Title

Printed Name

PART IV - CONSISTENCY WITH GENERAL REVIEW CRITERIA AT COMAR

10.24.01.08G(3):

INSTRUCTION: Each applicant must respond to all criteria included in COMAR 0.24.01.08G(3), listed below.

An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards and other review criteria.

If a particular standard or criteria is covered in the response to a previous standard or criteria, the applicant may cite the specific location of those discussions in order to avoid duplication. When doing so, the applicant should ensure that the previous material directly pertains to the requirement and the directions included in this application form. Incomplete responses to any requirement will result in an information request from Commission Staff to ensure adequacy of the response, which will prolong the application's review period.

10.24.01.08G(3)(a). The State Health Plan.

To respond adequately to this criterion, the applicant must address each applicable standard from each chapter of the State Health Plan that governs the services being proposed or affected, and provide a direct, concise response explaining the project's consistency with each standard. In cases where demonstrating compliance with a standard requires the provision of specific documentation, documentation must be included as a part of the application.

Every acute care hospital applicant must address the standards in **COMAR 10.24.10: Acute Care Hospital Services**. A Microsoft Word version is available for the applicant's convenience on the Commission's website. Use of the *CON Project Review Checklist for Acute Care Hospitals General Standards* is encouraged. This document can be provided by staff.

Other State Health Plan chapters that may apply to a project proposed by an acute care hospital are listed in the table below. A pre-application conference will be scheduled by Commission Staff to cover this and other topics. It is highly advisable to discuss with Staff which State Health Plan chapters and standards will apply to a proposed project before application submission. Applicants are encouraged to contact Staff with any questions regarding an application.

Copies of all applicable State Health Plan chapters are available from the Commission and are available on the Commission's web site here:

http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp

| | |
|--|---|
| 10.24. 07 | State Health Plan: an overview <ul style="list-style-type: none"> ○ Psychiatric services ○ EMS |
| 10.24. 09 | Specialized Health Care Services - Acute Inpatient Rehab Services |
| 10.24. 11 | General Surgical Services |
| 10.24. 12 | Inpatient Obstetrical Services |
| 10.24. 14 | Alcoholism and Drug Abuse Intermediate Care Facility Treatment Services |
| 10.24. 15 | Organ Transplant Services |
| 10.24. 17 | Cardiac Surgery and Percutaneous Coronary Artery Intervention Services |
| 10.24. 18 | Neonatal Intensive Care Services |
| Capital Projects Exceeding the CON Threshold for Capital Expenditures | Hospital Capital Projects Exceeding the CON Threshold for Capital Expenditures Hospital projects that require CON review because the capital expenditure exceeds the CON threshold for capital expenditures but do not involve changes in bed capacity, the addition of new services, and otherwise have no elements that are categorically regulated should address all applicable standards in COMAR 10.24.10: Acute Care Hospital Services in their CON application. Applicants should consult with staff in a pre-application conference about any other SHP chapters containing standards that should be addressed, based on the nature of the project. |

10.24.01.08G(3)(b). Need.

The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.

INSTRUCTIONS: Please identify the need that will be addressed by the proposed project, quantifying the need, to the extent possible, for each facility and service capacity proposed for development, relocation, or renovation in the project. The analysis of need for the project should be population-based, applying utilization rates based on historic trends and expected future changes to those trends. This need analysis should be aimed at demonstrating needs of the population served or to be served by the hospital. The existing and/or intended service area population of the applicant should be clearly defined.

Fully address the way in which the proposed project is consistent with each applicable need standard or need projection methodology in the State Health Plan.

If the project involves modernization of an existing facility through renovation and/or expansion, provide a detailed explanation of why such modernization is needed by the service area population of the hospital. Identify and discuss relevant building or life safety code issues, age of physical plant issues, or standard of care issues that support the need for the proposed modernization.

Please assure that all sources of information used in the need analysis are identified. Fully explain all assumptions made in the need analysis with respect to demand for services, the projected utilization rate(s), the relevant population considered in the analysis, and the service capacity of buildings and equipment included in the project, with information that supports the validity of these assumptions.

Explain how the applicant considered the unmet needs of the population to be served in arriving at a determination that the proposed project is needed. Detail the applicant's consideration of the provision of services in non-hospital settings and/or through population-based health activities in determining the need for the project.

Complete the Statistical Projections (Tables F and I, as applicable) worksheets in the CON Table Package, as required. Instructions are provided in the cover sheet of the CON package.

10.24.01.08G(3)(c). Availability of More Cost-Effective Alternatives.

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

INSTRUCTIONS: Please describe the planning process that was used to develop the proposed project. This should include a full explanation of the primary goals or objectives of the project or the problem(s) being addressed by the proposed project. The applicant should identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process, including:

- a) the alternative of the services being provided through existing facilities;

- b) or through population-health initiatives that would avoid or lessen hospital admissions.

Describe the hospital's population health initiatives and explain how the projections and proposed capacities take these initiatives into account.

For all alternative approaches, provide information on the level of effectiveness in goal or objective achievement or problem resolution that each alternative would be likely to achieve and the costs of each alternative. The cost analysis should go beyond development costs to consider life cycle costs of project alternatives. This narrative should clearly convey the analytical findings and reasoning that supported the project choices made. It should demonstrate why the proposed project provides the most effective method to reach stated goal(s) and objective(s) or the most effective solution to the identified problem(s) for the level of costs required to implement the project, when compared to the effectiveness and costs of alternatives, including the alternative of providing the service through existing facilities, including outpatient facilities or population-based planning activities or resources that may lessen hospital admissions, or through an alternative facility that has submitted a competitive application as part of a comparative review.

10.24.01.08G(3)(d). Viability of the Proposal.

The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

INSTRUCTIONS: Please provide a complete description of the funding plan for the project, documenting the availability of equity, grant(s), or philanthropic sources of funds and demonstrating, to the extent possible, the ability of the applicant to obtain the debt financing proposed. Describe the alternative financing mechanisms considered in project planning and provide an explanation of why the proposed mix of funding sources was chosen.

- Complete applicable Revenues & Expenses (Tables G, H, J and K as applicable), and the Work Force information (Table L) worksheets in the CON Table Package, as required. Instructions are provided in the cover sheet of the CON package. Explain how these tables demonstrate that the proposed project is sustainable and provide a description of the sources and methods for recruitment of needed staff resources for the proposed project, if applicable.
- Describe and document relevant community support for the proposed project.
- Identify the performance requirements applicable to the proposed project and explain how the applicant will be able to implement the project in compliance with those performance requirements. Explain the process for completing the project design, contracting and obtaining and obligating the funds within the prescribed time frame. Describe the construction process or refer to a description elsewhere in the application that demonstrates that the project can be completed within the applicable time frame.
- Audited financial statements for the past two years should be provided by all applicant entities and parent companies.

10.24.01.08G(3)(e). Compliance with Conditions of Previous Certificates of Need.

An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

INSTRUCTIONS: List all of the Certificates of Need that have been issued to the applicant or related entities, affiliates, or subsidiaries since 2000, including their terms and conditions, and any changes to approved CONs that were approved. Document that these projects were or are being implemented in compliance with all of their terms and conditions or explain why this was not the case.

10.24.01.08G(3)(f). Impact on Existing Providers and the Health Care Delivery System.

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

INSTRUCTIONS: Please provide an analysis of the impact of the proposed project:

- a) On the volume of service provided by all other existing health care providers that are likely to experience some impact as a result of this project²;
- b) On access to health care services for the service area population that will be served by the project. (state and support the assumptions used in this analysis of the impact on access);
- c) On costs to the health care delivery system.

If the applicant is an existing hospital, provide a summary description of the impact of the proposed project on costs and charges of the applicant hospital, consistent with the information provided in the Project Budget, the projections of revenues and expenses, and the work force information.

² Please assure that all sources of information used in the impact analysis are identified and identify all the assumptions made in the impact analysis with respect to demand for services, the relevant populations considered in the analysis, and changes in market share, with information that supports the validity of these assumptions.