



GENERIC APPLICATION

MARYLAND HEALTH CARE COMMISSION

INSTRUCTIONS: GENERIC APPLICATION FOR CERTIFICATE OF NEED (CON)

Note: Specific CON application forms exist for hospital, comprehensive care facility, home health, ICF and hospice projects. This form is to be used for any other services requiring a CON.

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, III, and IV of the application form**
- **Responses to PART IV must include responses to the standards in the State Health Plan chapter that apply to the project being proposed.**
 - All Applicants must respond to the Review Criteria listed at 10.24.01.08G(3)(b) through 10.24.01.08G(3)(h) as detailed in the application form.
- **Identification of each Attachment, Exhibit, or 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 and the applicant's responses to completeness questions in three forms: hard copy; searchable PDF; and in Microsoft Word.

- **Hard copy:** Applicants must submit six (6) hard copies of the application to:
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. 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.

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PDFs and spreadsheets should be submitted to: mhcc.cofilings@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.

A pre-application conference will be scheduled by Commission Staff to cover this and other topics. Applicants are encouraged to contact Staff with any questions regarding an application.

PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: _____

Address

Street City Zip County

2. Name of Owner

If Owner is a Corporation, Partnership, or Limited Liability Company, attach a description of the ownership structure identifying all individuals that have or will have at least a 5% ownership share in the applicant and any related parent entities. Attach a chart that completely delineates this ownership structure.

3. APPLICANT. *If the application has a co-applicant, provide the following information in an attachment.*

Legal Name of Project Applicant (Licensee or Proposed Licensee): _____

Address:

Street				
	City	Zip	State	County
Telephone:				

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

Company Name _____

Mailing Address:

Street _____ City _____ Zip _____ State _____

Telephone:

E-mail Address (required):

Fax::

If company name is different than applicant briefly describe the relationship

B. Additional or alternate contact:

Name and Title: _____

Company Name _____

Mailing Address: _____

Street

City

Zip

State

Telephone:

E-mail Address (required):

Fax:

**If company name
is different than
applicant briefly
describe the
relationship**

7. NAME OF THE OWNER OF THE REAL PROPERTY and
Improvements (if different from the licensee or proposed
licensee)

Legal Name of the Owner of the Real Property

Address:

Street

City

Zip

State

County

Telephone: _____

8. NAME OF THE OWNER OF THE BED RIGHTS (i.e., the person/entity that could
sell the beds included in this application to a 3rd party):

Legal Name of the Owner of the Rights to Sell the CCF Beds

If the legal entity that has or will have the right to sell the CCF beds is other than
the licensee or the owner of the real property identified above provide the
following information.

Address:

Street

City

Zip

State

County

Telephone: _____

9. If a management company or companies is or will be involved in the clinical or financial
management of the facility or will provide oversight of any construction or renovations proposed as
part of this APPLICATION, identify each company or individual that will provide the services and
describe the services that will be provided. Identify any ownership relationship between the
management company and the owner of the facility, bed rights, and/or the real property or any related
entity.

Name of Management Company

Address:

Street City Zip State County

Telephone: _____

***Please provide a chart showing the breakdown of ownership that includes the owners of the real property, bed rights and operations. Please include the management company if applicable.**

10. TYPE OF PROJECT

The following list includes all project categories that require a CON pursuant to COMAR 10.24.01.02(A). Please mark all that apply in the list below.

If approved, this CON would result in (check as many as apply):

- (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

11. 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 to do it, and what it will cost. A one-page response will suffice. Please include:

- i. Brief Description of the project – what the applicant proposes to do
- ii. Rationale for the project – the need and/or business case for the proposed project
- iii. Cost – the total cost of implementing the proposed project

b. Comprehensive Project Description: The description should include details regarding:

- i. Construction, renovation, and demolition plans
- ii. Changes in square footage of departments and units
- iii. Physical plant or location changes
- iv. Changes to affected services following completion of the project
- v. Outline the project schedule.

12. Complete Table A of the CON Table Package

13. Identify any community-based services that are or will be offered at the facility and explain how each one will be affected by the project.

14. REQUIRED APPROVALS AND SITE CONTROL

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

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

i. Owned by: _____

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

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

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

v. Other: _____
Explain and provide legal documents as an attachment.

15. PROJECT SCHEDULE

(INSTRUCTION: IN COMPLETING THE APPLICABLE OF ITEMS 10, 11 or 12, PLEASE CONSULT THE PERFORMANCE REQUIREMENT TARGET DATES SET FORTH IN COMMISSION REGULATIONS, COMAR 10.24.01.12)

For new construction or renovation projects.

Project Implementation Target Dates

An application for a CON or other Commission approval has the option to propose a schedule for implementation of the project that specifies the estimated time for, at a minimum, the following project implementation steps: Obligation of Capital Expenditure, Beginning Construction, Complete Construction and Full Operation.

If a schedule is not proposed as provided above, a holder shall obligate at least 51 percent of the approved capital expenditure for a project involving building construction, renovation, or both, as documented by a binding construction contract or equipment purchase order, within the following specified time periods:

- (a) An approved new hospital has up to 36 months
- (b) A project involving an approved new non-hospital health care facility or involving a building addition or replacement of building space of a health care facility has up to 24 months
- (c) A project limited to renovation of existing building space of a health care facility has up to 18 months
- (d) A project that does not involve construction or renovation shall document that the approved project is complete and operational within 18 months

In a multiphase plan of construction with more than one construction contract approved for an existing health care facility, a holder has:

- (e) Up to 12 months after approval to obligate 51 percent of the capital expenditure for the first phase of construction
- (f) Up to 12 months after completion of the immediately preceding phase of construction to obligate 51 percent of the capital expenditure for any subsequent approved phase

For projects not involving construction or renovations.
Project Implementation Target Dates, see #10 above

For projects not involving capital expenditures. Project Implementation Target Dates, see #10 above

16. PROJECT DRAWINGS

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

These drawings should include the following before (existing) and after (proposed), as applicable:

- a. Floor plans for each floor affected with all rooms labeled by purpose or function, number of beds, location of bath rooms, 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 projects involving new construction and/or site work a Plot Plan, showing the "footprint" and location of the facility before and after the project.
- c. Specify dimensions and square footage of patient rooms.

17. FEATURES OF PROJECT CONSTRUCTION

- a. If the project involves new construction or renovation, complete **Tables C and D of the Hospital CON Application Package**
- b. Discuss the availability and adequacy of utilities (water, electricity, sewage, natural gas, etc.) for the proposed project and identify the provider of each utility. Specify the steps that will be necessary to obtain utilities.

PART II - PROJECT BUDGET

Complete Table E of the Hospital CON Application Package

Note: Applicant should include a list of all assumptions and specify what is included in each budget line, as well as the source of cost estimates and the manner in which all cost estimates are derived. Explain how the budgeted amount for contingencies was determined and why the amount budgeted is adequate for the project given the nature of the project and the current stage of design (i.e., schematic, working drawings, etc.).

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 and its implementation.

2. Are the applicant, owners, or the responsible persons listed in response to Part 1, questions 2, 3, 4, 7, and 9 above now involved, or have they ever been involved, in the ownership, development, or management of another health care facility? If yes, provide a listing of these facilities, including facility name, address, and dates of involvement.

3. Has the Maryland license or certification of the applicant facility, or any of the facilities listed in response to Question 2, above, been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) in the last 5 years? If yes, provide a written explanation of the circumstances, including the date(s) of the actions and the disposition. If the applicant, 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) received inquiries in last from 10 years from any federal or state authority, the Joint Commission, or other regulatory body regarding possible non-compliance with any 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.

5. Have the applicant, owners or responsible individuals listed in response to Part 1, questions 2, 3, 4, 7, and 9, above, ever pled guilty to 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 to the court, the date(s) of conviction(s), diversionary disposition(s) of any type, or guilty plea(s).

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 proposed or existing facility.

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 to 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.

Every applicant must address each applicable standard in the chapter of the State Health Plan for Facilities and Services². Commission staff can help guide applicants to the chapter(s) that applies to a particular proposal.

Please provide a direct, concise response explaining the project's consistency with each standard. Some standards require specific documentation (e.g., policies, certifications) which should be included within the application as an exhibit.

Other Criteria:

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 a need for the proposed project.

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

If the current bed need projection published by the MHCC based on the need formula in the State Health Plan does not project a need for all of the beds proposed, the applicant should identify the need that will be addressed by the proposed project by quantifying the need for all facility and service capacity proposed for development, relocation, or renovation in the project.

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. 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 and identify all the assumptions made in the need analysis with respect to demand for services, the projected utilization rate(s), and the relevant population considered in the analysis with information that supports the validity of these assumptions. The existing and/or intended service area population of the applicant should be clearly defined.

Complete the Statistical Projection (Tables D and E, as applicable) worksheets in the CON Table Package, as required. Instructions are provided in the cover sheet of the CON package. Table D must be completed if the applicant is an existing facility. Table E must be completed if the application is for a new facility or service or if it is requested by MHCC staff.

10.24.01.08G(3)(c). Alternatives to the Project. The Commission shall consider the alternative approaches to meeting the need identified for the project that were considered by the applicant in planning the project and the basis for the applicant's choice of the project among considered alternatives. In a comparative review of applications within the same review cycle, the Commission shall compare the costs and the likely effectiveness of alternative projects in meeting identified needs, improving the availability and accessibility of care, and improving the quality of care.

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 project. It should also identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process, including the alternative of the services being provided by existing facilities.

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 cost 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 goal and objective achievement or the most effective solution to the identified problem(s) for the level of cost required to implement the project, when compared to the effectiveness and cost of alternatives including the alternative 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.

10.24.01.08G(3)(d). Project Financial Feasibility and Facility or Program Viability. The Commission shall consider the availability of resources necessary to implement the project and the availability of revenue sources and demand for the proposed services adequate to ensure ongoing viability and sustainability of the facility to be established or modified or the service to be introduced or expanded.

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 Revenue & Expense Tables and the Workforce and Bedside Care Staffing worksheets in the CON Table Package, as required (Tables H and I for all applicants). Attach additional pages as necessary detailing assumptions with respect to each revenue and expense line item. Instructions are provided in the cover sheet of the CON package and on each worksheet. 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. If the projections are based on Medicare percentages above the median for the jurisdiction in which the facility exists or is proposed, explain why the projected Medicare percentages are reasonable.
- Audited financial statements for the past two years should be provided by all applicant entities and parent companies to demonstrate the financial condition of the entities involved and the availability of the equity contribution. If audited financial statements are not available for the entity or individuals that will provide the equity contribution, submit documentation of the financial condition of the entities and/or individuals providing the funds and the availability of such funds. Acceptable documentation is a letter signed by an independent Certified Public Accountant. Such a letter shall detail the financial information considered by the CPA in reaching the conclusion that adequate funds are available.
- If debt financing is required and/or grants or fund raising is proposed, detail the experience of the entities and/or individuals involved in obtaining such financing and grants and in raising funds for similar projects. If grant funding is proposed, identify the grant that has been or will be pursued and document the eligibility of the proposed project for the grant.
- Describe and document relevant community support for the proposed project.
- Explain how the applicant will be able to implement the project in compliance with its implementation schedule (Part 1 question 15). Explain the process for completing the project design, obtaining State and local land use, environmental, and design approvals, contracting and obligating the funds within the estimated 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(s).

10.24.01.08G(3)(e). Compliance with Terms and Conditions of Previous Certificates of Need. An applicant shall demonstrate compliance with all terms and conditions of each previous CON granted to the applicant.

INSTRUCTIONS: List all of the Maryland Certificates of Need that have been issued to the project applicant, its parent, or its affiliates or subsidiaries over the prior 15 years, including their terms and conditions, and any changes to approved Certificates that needed to be obtained. 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). Project Impact. The Commission shall consider the impact of the proposed project on the costs and charges of existing providers of the facilities and services included in the project and on access to those facilities and services in the service area of the project.

INSTRUCTIONS: Please provide an analysis of the impact of the proposed project. 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, payer mix, access to service, with information that supports the validity of these assumptions. Provide an analysis of the following impacts:

- 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 project;
- b) On the payer mix of all other existing health care providers that are likely to experience some impact on payer mix as a result of this project. If an applicant for a new facility/service claims no impact on payer mix, the applicant must identify the likely source of any expected increase in patients by payer.
- c) 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);

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

10.24.01.08G(3)(g) Health Equity. The Commission shall consider how a proposed project will address health care disparities in availability, accessibility, and quality of care among different populations within the service area. The Commission shall consider how social determinants of health within the service area of the proposed project create disparities in the delivery of health care.

INSTRUCTIONS: In evaluating proposed projects for health equity, the Commission will scrutinize the project's impact on health care disparities and social determinants within the service area. Health equity involves the fair distribution of resources and opportunities, ensuring individuals, regardless of background, have the chance to achieve their highest level of health. It further encompasses addressing disparities and systemic barriers that affect different populations.

With health equity in mind, the applicant shall identify the specific medically underserved area(s)/group(s)¹ within the designated service area and outline how the proposed project will address the unique health needs and quality of care for each identified group.

Applicants are expected to furnish a detailed overview of their organization's expertise and experience in health care access and service delivery. Emphasis should be placed on highlighting any relevant background that underscores the organization's commitment to equitable health care. This encompasses efforts to integrate implicit bias and cultural competency training within the health facility and among current staff members.

Please provide a comprehensive account of how the applicant planned with the community during the preparations for this project and how it will continue to engage with the community. Include a description of any specific initiatives and programs aimed at improving community well-being that are relevant to the proposed project. If applicable, the applicant should acknowledge any unintended barriers caused by the project that may have been identified through community discourse and propose proactive solutions to mitigate and rectify potential issues.

10.24.01.08G(3)(h) Character and Competence.

¹ According to HRSA, medically underserved populations and areas are identified as those which lack access to primary care services. These groups may face economic, cultural, or language barriers to health care. Some examples include People experiencing homelessness, people who are low-income, people who are eligible for Medicaid, Native Americans and other historically disadvantaged populations of color, migrant farm workers, etc.
(<https://bhwh.hrsa.gov/workforce-shortage-areas/shortage-designation#mups>)

INSTRUCTIONS: In evaluating proposed projects for Character/Competence, the Commission will review the information provided in response to Part III of the application and look for a detailed narrative response highlighting any past issues and how any issues have now been corrected or addressed. If there have not been any past issues please include in your narrative any history that has been a positive reflection of character/competence. The response should include, at minimum:

- names/addresses of all owners and individuals responsible for the proposed project and its implementation. This includes any person with 5% or more ownership interest in the real property, bed rights or operations of the facility
- for each individual identified disclose any involvement in the ownership, development, or management of another health care facility
- for each individual and facility identified disclose if any license has been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) in the last 5 years
- for each individual and facility identified disclose inquiries in the last 10 years from any federal (CMS) or state authority (OHCQ), or other regulatory body regarding possible non-compliance with any state, or federal 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
- disclose if any owners and individuals responsible for the project have identified above have ever pled guilty to 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

REMEMBER TO SUBMIT THE COMPANION TABLE SET FEATURING THE PROJECT BUDGET, STATISTICAL PROJECTIONS, REVENUE AND EXPENSE PROJECTIONS, AND WORKFORCE INFORMATION