

UPDATED July 2024

ACUTE CARE

APPLICATION FOR CERTIFICATE OF NEED

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 Review Criteria listed at COMAR 10.24.01.08G. The first Review Criteria requires the Applicant to respond to all applicable standards in the State Health Plan chapter.

• 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 Microsoft Word.

- Hard copy: Applicants must submit four (4) 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 in their native format. This will expedite the review process.

Electronic files should be submitted to mhcc.confilings@maryland.gov

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

Note that there are certain actions that may be taken without CON review and approval. 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 facility owner 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 applicant:

5.	LEGAL ST	RUCTURE OF APPLICANT (and	I LICENSEE,	if different fro	m applicant).	
		⟨ ☑ or fill in applicable information rs of applicant (and licensee, if dif or fill in applicable information or fill i		d attach an d	organizational chart sho	owing the
	A. B.	Governmental 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):				_
0.		S) TO WHOM QUESTIONS REG	ANDING ITII	3 AFFLICATI	ON SHOOLD BE DIKE	CIED
	Name and	d Title:				
	Company Name	y 				
	Mailing Ad	ddress:				
	Street			City	Zip	State
	Telephone	e:				
	E-mail Ad	dress (required):				
	Fax:					
	If compa name is different applicant describe relationsl	than t briefly the				
	B. Additio	onal or alternate contact:				
	Name and	d Title:				

Company Name Mailing Address:			_		_	
Street			City		Zip	State
Telephone: E-mail Address (red	quired):					
7. NAME OF THE OW the licensee or property		ROPERTY and Im	provements (if	different from		
Legal Name of the Owr	ner of the Real Propert	у				
Address:						
Street		City	Zi	p	State	County
Telephone:						_
 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 Beds 						
If the legal entity that ha			other than the	licensee or the	owner of	the
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 app	roved, thi	s CON would result in (check as many as apply):			
	2. 4. 4.	An existir A change	alth care facility built, developed, or established ag health care facility moved to another site in the bed capacity of a health care facility in the type or scope of any health care service offered by a re facility			
11.	PROJEC	CT DESC	RIPTION			
	ho	olistic und	summary of the Project: The purpose of this BRIEF executive summary is to convey to the reader lerstanding of the proposed project: what it is, why you need to do it, and what it will cost. A one onse will suffice. Please include:			
		(1) (2) (3)	Brief Description of the project – what the applicant proposes Rationale for the project – the need and/or business case for the proposed project Cost – the total cost of implementing the proposed project			
	B. C	ompreher (1) (2) (3) (4)	nsive Project Description: The description should include details regarding: Construction, renovation, and demolition plans Changes in square footage of departments and units Physical plant or location changes Changes to affected services following completion of the project			
12.	Complete	e 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.	REQUIR	ED APPF	ROVALS AND SITE CONTROL			
	A. B.	Have a for the	te: acres Ill necessary State and local land use and environmental approvals, including zoning and site plar project as proposed been obtained? YES NO (If NO, describe below the current statu netable for receiving each of the necessary approvals.)			
	C.	Form o	f Site Control (Respond to the one that applies. If more than one, explain.):			
		(1)	Owned by:			
		(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.
<i>(E</i>)	Othory
(5)	Other:
	Explain and provide legal documents as an attachment.

15. PROJECT IMPLEMENTATION SCHEDULE (COMAR 10.24.01.12A) In completing this section, please note applicable obligation deadlines set forth in Commission regulations, COMAR 10.24.01.12. Ensure that the information presented reflects information presented in Application Item 11 (Project Description).

Project Implementation Schedule

An application for a CON or other Commission approval shall propose a schedule for implementation of the project in accordance with COMAR 10.24.01.12A(1) 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.

In developing the schedule, please note that COMAR 10.24.01.12C requires a holder to 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:

- (a) Up to 12 months after approval to obligate 51 percent of the capital expenditure for the first phase of construction
- (b) 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

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 the Construction and Renovation Square Footage worksheet in the CON Table Package (Table B)

В.	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 the Project Budget worksheet in the CON Table Package (Table C).

Note: Applicant should include a list of all assumptions and specify what is included in each budget line, as well 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 all persons listed in response to Part 1, questions 2, 3, 4, 7, 8, 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, 8, 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).
pro	e or more persons shall be officially authorized in writing by the applicant to sign for and act for the applicant for the ject which is the subject of this application. Copies of this authorization shall be attached to the application. The dersigned is the owner(s), or Board-designated official of the proposed or existing facility.
	ereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are e 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 10.24.01.08G(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.

Every applicant must address each applicable standard from COMAR 10.24.10.

Please 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, please include the documentation as a part of the application.

A. General Standards.

The following general standards encompass Commission expectations for the delivery of acute care services by all hospitals in Maryland. Each hospital that seeks a CON for a project covered by this Chapter of the State Health Plan shall address and document its compliance with each of the following general standards that is applicable to its project as part of its CON application. Each hospital that seeks an exemption from CON review for a project covered by this Chapter of the State Health Plan shall address and demonstrate consistency with each of the following general standards as part of its exemption request unless a standard is not applicable.

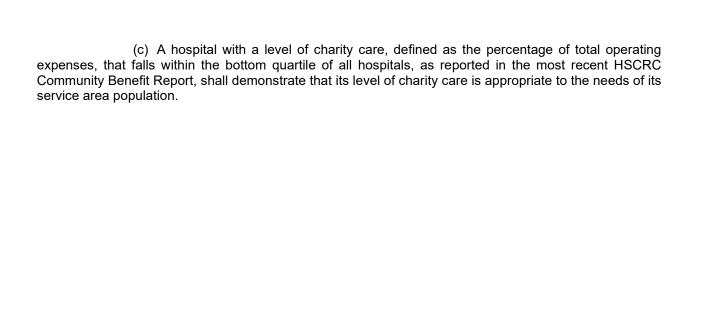
(1) Information Regarding Charges.

Information regarding hospital charges shall be available to the public.

- (a) At a minimum, a hospital shall:
- (i) Comply with requirements of the HSCRC regarding posting or providing charge information; and
- (ii) Comply with requirements of CMS for surprise billing and price transparency, including Code of Federal Regulations, Title 45, Parts 149 and 180.
- (b) A hospital shall demonstrate compliance with price transparency laws and regulations. Commission staff may request information about the hospital's compliance with price transparency laws and regulations from the applicant hospital, HSCRC, the Consumer Protection Division of the Attorney General's office, and other entities as appropriate.
 - (2) Charity Care and Financial Assistance Policy.

Each hospital shall have a written policy for the provision of charity care and reduced- cost care to patients who lack health care coverage or whose health care coverage is insufficient.

- (a) The hospital's policy shall comply with Health-General §19-214.1.
- (b) The policy shall provide that the hospital makes a determination of eligibility within 14 days following a patient's completion of an application for charity care services, application for medical assistance, or both.



(d) A hospital shall demonstrate compliance with laws and regulations for financial assistance. Commission staff may request information about the hospital's compliance with laws and regulations for financial assistance from the applicant hospital, HSCRC, the Consumer Protection Division of the Attorney General's office, and other entities as appropriate.

(3) Quality of Care.

An acute care general hospital shall provide high quality care.

- (a) Each hospital shall document that it is:
 - (i) Licensed, and in good standing, by the Maryland Department of Health;
- (ii) Accredited by the Joint Commission, or other accreditation organization recognized by CMS, as acceptable for obtaining Medicare certification and approved by the State of Maryland; and
- (iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.
- (b) Each hospital shall explain how the hospital is taking steps to improve its performance for each Quality Measure on which the hospital performed below the statewide average, as reported on the Commission's Maryland Quality Reporting website with respect to measures for patient satisfaction, patient safety, infections, and any other quality measures the Commission deems relevant to a hospital's proposed project.
 - (c) Each hospital shall:
 - (i) Explain its efforts to address measures of quality tracked by the HSCRC;
- (ii) Demonstrate that it has implemented a credible plan for achieving progress towards benchmarks for quality established by HSCRC.

B. Project Review Standards.

and

The standards in this section are intended to guide reviews of CON applications and requests for exemption from CON review involving acute care general hospital facilities and services. An applicant for a CON shall address, and its proposed project shall be evaluated for compliance with, all applicable review standards. An applicant for an exemption from CON review shall address, and its proposed project shall be evaluated for consistency with, all applicable review standards.

(1) Geographic Accessibility.

A new acute care general hospital or an acute care general hospital being replaced on a new site shall be located to optimize accessibility for the population in the likely service area. Optimal travel time for general medical, surgical, intensive care, critical care, and pediatric services shall be within 30 minutes under normal driving conditions. The geographic accessibility standard is met if 90 percent of the population in the health planning region in which the new hospital is located, or in which the existing hospital will be relocated, is within 30 minutes under normal driving conditions of acute care general hospital services, or if the Commission determines that access will be substantially improved for the population in the applicant's service area, through a reduction in travel time.

(2) Non-Geographic Barriers to Access.

Hospital services shall be accessible to all Maryland residents and the type, amount, or quality of hospital care provided may not be affected by the patient's gender, race, ethnicity, or ability to pay.

- (a) An acute care general hospital shall only deny admission if it is unable to provide the appropriate level of care for a patient or if a psychiatric patient's admission is involuntary and the hospital or hospital unit has been issued an exemption by the Commission that permits it to serve only voluntary psychiatric patients in accordance with COMAR 10.24.21.
- (b) An acute care general hospital shall identify and explain its efforts to address non-geographic access barriers, including but not limited to barriers that stem from a patient's race, gender, ethnicity, or ability to pay. A hospital shall also present how progress has been measured and shall be measured for any access barrier identified.
 - (3) Identification of Bed Need and Addition of Beds.

An applicant shall demonstrate, in a service-area level needs assessment, that changes in its MSGA bed capacity and pediatric bed capacity resulting from a proposed project are needed.

- (a) The applicant's service area-level needs assessment shall include the following information, separately for MSGA and pediatric bed capacity:
- (i) A forecast of demand for at least five years following operation of the bed capacity by the population in its likely service area;
- (ii) Market share analysis at the zip code area-level for the projected service area;
- (iii) The assumptions used to define the service area of the proposed project, including the projected discharge rates;
- (iv) The assumptions used to project the hospital's market share of discharges within the service area for the proposed project; and

- (v) The assumptions used to project the average length of stay for discharges following development of the proposed project.
- (b) An applicant shall demonstrate the reasonableness of all assumptions used in its needs assessment.
- (c) An applicant proposing changes in MSGA bed capacity shall address the most recently published MSGA bed need projections developed by Commission staff under Regulation .02 of this Chapter. The applicant shall justify differences in its service area-level needs assessment compared to the published MSGA projections for the jurisdiction where the hospital is located, and any jurisdiction that comprises a quarter or more of the hospital's projected MSGA discharges.
 - (4) Minimum Average Daily Census for Establishment of a Pediatric Unit.

An acute care general hospital may establish a new pediatric service unit or, in the case of a hospital relocation, retain a distinct pediatric unit only if the projected ADC of pediatric patients to be served by the hospital is at least five patients, unless:

- (a) The hospital is located more than 30 minutes travel time under normal driving conditions from a hospital with a pediatric unit; or
- (b) The hospital is the sole provider of acute care general hospital services in its jurisdiction.

(5) Adverse Impact.

A capital project undertaken by a hospital may not have an unwarranted adverse impact on hospital charges, availability of services, or access to services. The Commission will grant a CON only if the hospital documents the following:

- (a) A hospital that has permanent revenue of \$300,000,000 or greater seeking an adjustment in revenue for capital projects that exceeds a 25 percent threshold of its permanent revenue and a smaller hospital with permanent revenue less than \$300,000,000 that exceeds a 50 percent threshold of its permanent revenue base, shall document that its capital to operating costs ratio is below the average ratio of its peer group, per HSCRC standards. For a project that involves the replacement of physical plant assets, the hospital shall document that the average age of the physical plant assets to be replaced exceeds the average age of plant assets for its peer group, or otherwise demonstrate why the physical plant assets require replacement to achieve the primary objectives of the project; and
- (b) If the project reduces the potential availability or accessibility of a facility or service by eliminating, downsizing, adding, or otherwise modifying a facility or service, the applicant shall document that each proposed change will not inappropriately diminish, for the population in the primary service area, the availability or accessibility to care, including access for the indigent or uninsured.

(6) Cost-Effectiveness.

A proposed hospital capital project shall represent the most cost-effective approach to meeting the needs that the project seeks to address.

- (a) To demonstrate cost-effectiveness, an applicant shall identify each primary objective of its proposed project and at least two alternative approaches that it considered for achieving these primary objectives. For each approach, the hospital shall:
- (i) To the extent possible, quantify the level of effectiveness of each alternative in achieving each primary objective;
- (ii) Detail the capital and operational cost estimates and projections developed by the hospital for each alternative; and
- (iii) Explain the basis for choosing the proposed project and rejecting alternative approaches to achieving the project's objectives.
- (b) An applicant proposing a project involving limited objectives including, but not limited to, the introduction of a new single service, the expansion of capacity for a single service, or a project limited to renovation of an existing facility for purposes of modernization, may address the cost-effectiveness of the project without undertaking the analysis outlined in §B(6)(a) of this Regulation, by demonstrating that there is only one practical approach to achieving the project's objectives.
- (c) An applicant proposing establishment of a new hospital, or relocation of an existing hospital to a new site that is not within a Priority Funding Area as defined under State Finance and Procurement Article, Title 5, Subtitle 7B, Annotated Code of Maryland, shall demonstrate:
- (i) That it has considered, at a minimum, two alternative project sites located within a Priority Funding Area that provide the most optimal geographic accessibility to the population in its likely service area, as defined in §B (1) of this Regulation;
- (ii) That it has quantified, to the extent possible, the level of effectiveness, in terms of achieving primary project objectives, of implementing the proposed project at each alternative project site and at the proposed project site;
- (iii) That it has detailed the capital and operational costs associated with implementing the project at each alternative project site and at the proposed project site, with a full accounting of the cost associated with transportation system and other public utility infrastructure costs; and
- (iv) That the proposed project site is superior, in terms of cost-effectiveness, to the alternative project sites located within a Priority Funding Area.

(7) Construction Cost of Hospital Space.

The proposed cost of a hospital construction project shall be reasonable and consistent with current industry cost experience in Maryland. The projected cost per square foot of a hospital construction project or renovation project shall be compared to the benchmark cost of good quality Class A hospital construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors. If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any adjustment in global budget revenue proposed by the hospital related to the capital cost of the project may not include the amount of the projected construction cost that exceeds the Marshall Valuation Service® benchmark and those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.

(8) Construction Cost of Non-Hospital Space.

The proposed construction costs of non-hospital space shall be reasonable and consistent with current industry cost experience. The projected cost per square foot of non-hospital space shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide for the appropriate structure. If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any adjustment in global budget revenue proposed by the hospital related to the capital cost of the non-hospital space may not include the amount of the projected construction cost that exceeds the Marshall Valuation Service® benchmark and those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost. In general, rate increases authorized for hospitals may not recognize the costs associated with construction of non- hospital space.

(9) Inpatient Nursing Unit Space.

The expenditure for space built or renovated for inpatient nursing units that exceeds reasonable space standards per bed for the type of unit being developed may not be recognized in any adjustment in global budget revenue. If the inpatient unit program space per bed of a new or modified inpatient nursing unit exceeds 500 square feet per bed, any adjustment of global budget revenue proposed by the hospital related to the capital cost of the project may not include the construction cost for the space that exceeds the per bed square footage limitation in this standard or those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess space, unless the applicant demonstrates that the additional square feet per bed is necessary to meet licensure and reasonable design standards.

(10) Efficiency.

A hospital shall be designed to operate efficiently. Hospitals proposing to replace or expand diagnostic, or treatment facilities and services shall:

- (a) Provide an analysis of each change in operational efficiency projected for each diagnostic or treatment facility and service being replaced or expanded, and document the manner in which the planning and design of the project took efficiency improvements into account; and
- (b) Demonstrate that the proposed project will improve operational efficiency when the proposed replacement or expanded diagnostic or treatment facilities and services are projected to experience increases in the volume of services delivered; or
 - (c) Demonstrate why improvements in operational efficiency cannot be achieved.

(11) Patient Safety.

The design of a hospital project shall take patient safety into consideration and shall include design features that enhance and improve patient safety. A hospital proposing to replace or expand its physical plant shall provide an analysis of patient safety features included for each facility or service being replaced or expanded and document the manner in which the planning and design of the project took patient safety into account.

(12) Financial Feasibility.

A hospital capital project shall be financially feasible and may not jeopardize the long- term financial viability of the hospital.

- (a) Financial projections filed as part of a hospital CON application shall be accompanied by a statement containing each assumption used to develop the projections.
 - (b) Each applicant shall document that:
- (i) Utilization projections are consistent with observed historic trends in use of the applicable service(s) by the service area population of the hospital or State Health Plan need projections, if relevant:
- (ii) Revenue estimates are consistent with utilization projections and are based on current rates of reimbursement, or for a new hospital the anticipated rates of reimbursement, as determined through consultation with the HSCRC;
- (iii) Revenue estimates account for current contractual adjustments, discounts, bad debt, and charity care provision, as experienced by the applicant hospital or, if a new hospital, the recent experience of other similar hospitals;
- (iv) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant hospital, or, if a new hospital, the recent experience of other similar hospitals; and

- (v) The hospital will generate excess revenues over total expenses including debt service expenses and plant and equipment depreciation, if utilization forecasts are achieved for the specific services affected by the project within five years or less of initiating operations, with the exception that a hospital may receive a CON for a project that does not generate excess revenues over total expenses, when the hospital can demonstrate that the hospital's overall financial performance will be positive and that the services will benefit the hospital's primary service area population.
- (c) A hospital proposing an increase in its global budget revenue to account, in whole or in part, for depreciation or long-term interest expenses resulting from a proposed capital project shall timely file a partial rate application for review by HSCRC in conjunction with its CON application to allow an informed opinion on the financial feasibility of the proposed project and the long-term viability of the proposed or existing hospital.
 - (13) Emergency Department Treatment Capacity and Space.
- (a) An applicant proposing a new or expanded emergency department shall classify the emergency department service as low-range or high-range based on the parameters in the most recent edition of *Emergency Department Design: A Practical Guide to Planning for the Future* from the American College of Emergency Physicians. The number of emergency department treatment spaces and the departmental space proposed by the applicant shall be consistent with the range set forth in the most recent edition of the American College of Emergency Physicians *Emergency Department Design: A Practical Guide to Planning for the Future*, given the classification of the emergency department as low-range or high-range and the projected emergency department visit volume, unless the applicant can demonstrate a need for additional treatment space even with efficient operation of the emergency department.
- (b) In developing projections of emergency department visit volume, the applicant shall consider, at a minimum:
- (i) The existing and projected primary service areas of the hospital, historic trends in emergency department utilization at the hospital, and the number of hospital emergency department service providers in the applicant hospital's primary service areas;
- (ii) The number of uninsured, underinsured, indigent, and otherwise underserved patients in the applicant's primary service area and the impact of these patient groups on emergency department use;
- (iii) Any demographic, health service utilization data, and/or analyses that support the need for the proposed project;
- (iv) The impact of efforts the applicant has made or will make to divert non- emergency cases from its emergency department to more appropriate primary care or urgent care settings; and

 $\left(v\right)$ Any other relevant information on the unmet need for emergency department or urgent care services in the service area.

(14) Emergency Department Expansion.

A hospital proposing expansion of emergency department treatment capacity shall demonstrate that it has made appropriate efforts consistent with federal and State law, to maximize effective use of existing capacity for emergent medical needs and has appropriately integrated emergency department planning with planning for bed capacity, and diagnostic and treatment service capacity. At a minimum, the applicant hospital shall demonstrate that:

- (a) In cooperation with its medical staff, it has attempted to reduce use of its emergency department for non-emergency medical care. This demonstration shall, at a minimum, address the feasibility of reducing or redirecting patients with non-emergent illnesses, injuries, and conditions, to lower cost alternative facilities or programs;
- (b) It has effectively managed its existing emergency department treatment capacity to maximize use; and
- (c) It has considered the need for bed and other facility and system capacity that will be affected by greater volumes of emergency department patients.

(15) Shell Space.

- (a) Unfinished hospital shell space for which there is no immediate need or use may not be built unless the applicant can demonstrate that construction of the shell space is cost- effective.
- (b) If the proposed shell space is not supporting finished building space being constructed above the shell space, the applicant shall provide an analysis demonstrating that constructing the space in the proposed time frame is more cost-effective than not including the shell space based on the following:
 - (i) The most likely use identified by the hospital for the unfinished space;
 - (ii) The time frame projected for finishing the space; and
- (iii) A demonstration that the hospital is likely to need the space for the most likely identified use, in the projected time frame.
- (c) For shell space to be constructed on lower floors of a building addition that supports finished building space on upper floors, an applicant shall provide information on the cost, the most likely uses, and the likely time frame for using the shell space.
- (d) The cost of shell space included in an approved project and those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure



that are based on the construction cost of the shell space will be excluded from consideration in any revenue adjustment for capital costs by the HSCRC.

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 of the facility. 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 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, 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)² 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.

INSTRUCTIONS: In evaluating proposed projects for Character/Competence, the Commission will review the information provided in response to Part IIII 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 from 10 years from any federal (CMS) or state authority (OHCQ), or other regulatory body regarding possible noncompliance 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

(https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation#mups)



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² 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.

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