

Craig P. Tanio, M.D.
CHAIR



Ben Steffen
EXECUTIVE DIRECTOR

**MARYLAND
HEALTH
CARE
COMMISSION**

MATTER/DOCKET NO.

DATE DOCKETED

**INSTRUCTIONS FOR APPLICATION FOR CERTIFICATE OF NEED:
ALCOHOLISM AND DRUG ABUSE INTERMEDIATE CARE
FACILITY TREATMENT SERVICES**

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 this 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 10.24.14.05(A) through 10.24.14.05(F) 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:
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.

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.

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.

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

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) _____

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. 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

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 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

B. Comprehensive Project Description: The description should include details 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
- (5) Outline the project schedule.

9. CURRENT CAPACITY AND PROPOSED CHANGES: Complete Table A (Physical Bed Capacity Before and After Project) from the CON Application Table package

10. 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.)

C. Form of 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.

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

11. PROJECT SCHEDULE

(Instructions: In completing this section, please note applicable performance requirement time frames set forth in Commission Regulations, COMAR 10.24.01.12)

For new construction or renovation projects.

Project Implementation Target Dates

- A. Obligation of Capital Expenditure _____ months from approval date.
- B. Beginning Construction _____ months from capital obligation.
- C. Pre-Licensure/First Use _____ months from capital obligation.
- D. Full Utilization _____ months from first use.

For projects not involving construction or renovations.

Project Implementation Target Dates

- A. Obligation or expenditure of 51% of Capital Expenditure _____ months from CON approval date.
- B. Pre-Licensure/First Use _____ months from capital obligation.
- C. Full Utilization _____ months from first use.

For projects not involving capital expenditures.

Project Implementation Target Dates

- A. Obligation or expenditure of 51% Project Budget _____ months from CON approval date.
- B. Pre-Licensure/First Use _____ months from CON approval.
- C. Full Utilization _____ months from first use.

12. 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.

13. AVAILABILITY AND ADEQUACY OF UTILITIES

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 B (Project Budget) of the CON Application Table 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.

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 applicable criteria included in COMAR 10.24.01.08G. These criteria follow, 10.24.01.08G(3)(a) through 10.24.01.08G(3)(f).

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.

10.24.14.05 Certificate of Need Approval Rules and Review Standards for New Substance Abuse Treatment Facilities and for Expansions of Existing Facilities.

.05A. Approval Rules Related To Facility Size. Unless the applicant demonstrates why a relevant standard should not apply, the following standards apply to applicants seeking to establish or to expand either a Track One or a Track Two intermediate care facility.

- (1) The Commission will approve a Certificate of Need application for an intermediate care facility having less than 15 beds only if the applicant dedicates a special population as defined in Regulation .08.**
- (2) The Commission will approve a Certificate of Need application for a new intermediate care facility only if the facility will have no more than 40**

² [1] 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

adolescent or 50 adult intermediate care facility beds, or a total of 90 beds, if the applicant is applying to serve both age groups.

- (3) The Commission will not approve a Certificate of Need application for expansion of an existing alcohol and drug abuse intermediate care facility if its approval would result in the facility exceeding a total of 40 adolescent or 100 adult intermediate care facility beds, or a total of 140 beds, if the applicant is applying to serve both age groups.

.05B. Identification of Intermediate Care Facility Alcohol and Drug Abuse Bed Need.

- (1) An applicant seeking Certificate of Need approval to establish or expand an intermediate care facility for substance abuse treatment services must apply under one of the two categories of bed need under this Chapter:

(a) For Track One, the Commission projects maximum need for alcohol and drug abuse intermediate care beds in a region using the need projection methodology in Regulation .07 of this Chapter and updates published in the *Maryland Register*.

(b) For Track Two, as defined at Regulation .08, an applicant who proposes to provide 50 percent or more of its patient days annually to indigent and gray area patients may apply for:

(i) Publicly-funded beds, as defined in Regulation .08 of this Chapter, consistent with the level of funding provided by the Maryland Medical Assistance Programs (MMAP), Alcohol and Drug Abuse Administration, or a local jurisdiction or jurisdictions; and

(ii) A number of beds to be used for private-pay patients in accordance with Regulation .08, in addition to the number of beds projected to be needed in Regulation .07 of this Chapter.

- (2) To establish or to expand a Track Two intermediate care facility, an applicant must:

(a) Document the need for the number and types of beds being applied for;

(b) Agree to co-mingle publicly-funded and private-pay patients within the facility;

(c) Assure that indigents, including court-referrals, will receive preference for admission, and

- (d) Agree that, if either the Alcohol and Drug Abuse Administration, or a local jurisdiction terminates the contractual agreement and funding for the facility's clients, the facility will notify the Commission and the Office of Health Care Quality within 15 days that that the facility is relinquishing its certification to operate, and will not use either its publicly- or privately-funded intermediate care facility beds for private-pay patients without obtaining a new Certificate of Need.**

.05C. Sliding Fee Scale. An applicant must establish a sliding fee scale for gray area patients consistent with the client's ability to pay.

.05D. Provision of Service to Indigent and Gray Area Patients.

(1) Unless an applicant demonstrates why one or more of the following standards should not apply or should be modified, an applicant seeking to establish or to expand a Track One intermediate care facility must:

- (a) Establish a sliding fee scale for gray area patients consistent with a client's ability to pay;**
- (b) Commit that it will provide 30 percent or more of its proposed annual adolescent intermediate care facility bed days to indigent and gray area patients; and**
- (c) Commit that it will provide 15 percent or more of its proposed annual adult intermediate care facility bed days to indigent or gray area patients.**

(2) A existing Track One intermediate care facility may propose an alternative to the standards in Regulation D(1) that would increase the availability of alcoholism and drug abuse treatment to indigent or gray area patients in its health planning region.

(3) In evaluating an existing Track One intermediate care facility's proposal to provide a lower required minimum percentage of bed days committed to indigent or gray area patients in Regulation D(1) or an alternative proposal under Regulation D(2), the Commission shall consider:

- (a) The needs of the population in the health planning region; and**
- (b) The financial feasibility of the applicant's meeting the requirements of Regulation D(1).**

(4) An existing Track One intermediate care facility that seeks to increase beds shall provide information regarding the percentage of its annual patient days in the preceding 12 months that were generated by charity care, indigent, or gray area patients, including publicly-funded patients.

.05E. Information Regarding Charges. An applicant must agree to post information concerning charges for services, and the range and types of services provided, in a conspicuous place, and must document that this information is available to the public upon request.

.05F. Location. An applicant seeking to establish a new intermediate care facility must propose a location within a 30-minute one-way travel time by automobile to an acute care hospital.

.05G. Age Groups.

- (1) An applicant must identify the number of adolescent and adult beds for which it is applying, and document age-specific treatment protocols for adolescents ages 12-17 and adults ages 18 and older.**
- (2) If the applicant is proposing both adolescent and adult beds, it must document that it will provide a separate physical, therapeutic, and educational environment consistent with the treatment needs of each age group including, for adolescents, providing for continuation of formal education.**
- (3) A facility proposing to convert existing adolescent intermediate care substance abuse treatment beds to adult beds, or to convert existing adult beds to adolescent beds, must obtain a Certificate of Need.**

.05H. Quality Assurance.

- (1) An applicant must seek accreditation by an appropriate entity, either the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), in accordance with CFR, Title 42, Part 440, Section 160, the CARF...The Rehabilitation Accreditation Commission, or any other accrediting body approved by the Department of Health and Mental Hygiene. The appropriate accreditation must be obtained before a Certificate of Need-approved ICF begins operation, and must be maintained as a condition of continuing authority to operate an ICF for substance abuse treatment in Maryland.**
 - (a) An applicant seeking to expand an existing ICF must document that its accreditation continues in good standing, and an applicant seeking to establish an ICF must agree to apply for, and obtain, accreditation prior to the first use review required under COMAR 10.24.01.18; and**
 - (b) An ICF that loses its accreditation must notify the Commission and the Office of Health Care Quality in writing within fifteen days after it receives notice that its accreditation has been revoked or suspended.**

- (c) An ICF that loses its accreditation may be permitted to continue operation on a provisional basis, pending remediation of any deficiency that caused its accreditation to be revoked, if the Office of Health Care Quality advises the Commission that its continued operation is in the public interest.
- (2) A Certificate of Need-approved ICF must be certified by the Office of Health Care Quality before it begins operation, and must maintain that certification as a condition of continuing authority to operate an ICF for substance abuse treatment in Maryland.
 - (a) An applicant seeking to expand an existing ICF must document that its certification continues in good standing, and an applicant seeking to establish an ICF must agree to apply for certification by the time it requests that Commission staff perform the first use review required under COMAR 10.24.01.18.
 - (b) An ICF that loses its State certification must notify the Commission in writing within fifteen days after it receives notice that its accreditation has been revoked or suspended, and must cease operation until the Office of Health Care Quality notifies the Commission that deficiencies have been corrected.
 - (c) Effective on the date that the Office of Health Care Quality revokes State certification from an ICF, the regulations at COMAR 10.24.01.03C governing temporary delicensure of a health care facility apply to the affected ICF bed capacity.

.05I. Utilization Review and Control Programs.

- (1) An applicant must document the commitment to participate in utilization review and control programs, and have treatment protocols, including written policies governing admission, length of stay, discharge planning, and referral.
- (2) An applicant must document that each patient's treatment plan includes, or will include, at least one year of aftercare following discharge from the facility.

.05J. Transfer and Referral Agreements.

- (1) An applicant must have written transfer and referral agreements with facilities capable of managing cases which exceed, extend, or complement its own capabilities, including facilities which provide inpatient, intensive and general outpatient programs, halfway house

placement, long-term care, aftercare, and other types of appropriate follow-up treatment.

- (2) The applicant must provide documentation of its transfer and referral agreements, in the form of letters of agreement or acknowledgement from the following types of facilities:
 - (a) Acute care hospitals;
 - (b) Halfway houses, therapeutic communities, long-term care facilities, and local alcohol and drug abuse intensive and other outpatient programs;
 - (c) Local community mental health center or center(s);
 - (d) The jurisdiction's mental health and alcohol and drug abuse authorities;
 - (e) The Alcohol and Drug Abuse Administration and the Mental Hygiene Administration;
 - (f) The jurisdiction's agencies that provide prevention, education, driving-while-intoxicated programs, family counseling, and other services; and,
 - (g) The Department of Juvenile Justice and local juvenile justice authorities, if applying for beds to serve adolescents.

.05K. Sources of Referral.

- (1) An applicant proposing to establish a new Track Two facility must document to demonstrate that 50 percent of the facility's annual patient days, consistent with Regulation .08 of this Chapter, will be generated by the indigent or gray area population, including days paid under a contract with the Alcohol and Drug Abuse Administration or a jurisdictional alcohol or drug abuse authority.
- (2) An applicant proposing to establish a new Track One facility must document referral agreements to demonstrate that 15 percent of the facility's annual patient days required by Regulation .08 of this Chapter will be incurred by the indigent or gray area populations, including days paid under a contract with the Alcohol or Drug Abuse Administration or a jurisdictional alcohol or drug abuse authority, or the Medical Assistance program.

.05L. In-Service Education. An applicant must document that it will institute or, if an existing facility, maintain a standardized in-service orientation and continuing education program for all categories of direct service personnel, whether paid or volunteer.

.05M. Sub-Acute Detoxification. An applicant must demonstrate its capacity to admit and treat alcohol or drug abusers requiring sub-acute detoxification by documenting appropriate admission standards, treatment protocols, staffing standards, and physical plant configuration.

.05N. Voluntary Counseling, Testing, and Treatment Protocols for Human Immunodeficiency Virus (HIV). An applicant must demonstrate that it has procedures to train staff in appropriate methods of infection control and specialized counseling for HIV-positive persons and active AIDS patients.

.05O. Outpatient Alcohol & Drug Abuse Programs.

- (1) An applicant must develop and document an outpatient program to provide, at a minimum: individual needs assessment and evaluation; individual, family, and group counseling; aftercare; and information and referral for at least one year after each patient's discharge from the intermediate care facility.**
- (2) An applicant must document continuity of care and appropriate staffing at off-site outpatient programs.**
- (3) Outpatient programs must identify special populations as defined in Regulation .08, in their service areas and provide outreach and outpatient services to meet their needs.**
- (4) Outpatient programs must demonstrate the ability to provide services in the evening and on weekends.**
- (5) An applicant may demonstrate that outpatient programs are available to its patients, or proposed patient population, through written referral agreements that meet the requirements of (1) through (4) of this standard with existing outpatient programs.**

.05P. Program Reporting. Applicants must agree to report, on a monthly basis, utilization data and other required information to the Alcohol and Drug Abuse Administration's Substance Abuse Management Information System (SAMIS) program, and participate in any comparable data collection program specified by the Department of Health and Mental Hygiene.

.06 Preferences for Certificate of Need approval.

A. In a comparative review of applicants for private bed capacity in Track One, the Commission will give preference expand an intermediate care facility if the project's sponsor will commit to:

- (1) Increase access to care for indigent and gray area patients by reserving more bed capacity than required in Regulation .08 of this Chapter;**
- (3) Treat special populations as defined in Regulation .08 of this Chapter or, if an existing alcohol or drug abuse treatment facility, treat special populations it has historically not treated;**
- (4) Include in its range of services alternative treatment settings such as intensive outpatient programs, halfway houses, therapeutic foster care, and long-term residential or shelter care;**
- (5) Provide specialized programs to treat an addicted person with co-existing mental illness, including appropriate consultation with a psychiatrist; or,**
- (6) In a proposed intermediate care facility that will provide a treatment program for women, offer child care and other related services for the dependent children of these patients.**

B. If a proposed project has received a preference in a Certificate of Need review pursuant to this regulation, but the project sponsor subsequently determines that providing the identified type or scope of service is beyond the facility's clinical or financial resources:

- (1) The project sponsor must notify the Commission in writing before beginning to operate the facility, and seek Commission approval for any change in its array of services pursuant to COMAR 10.24.01.17.**
- (2) The project sponsor must show good cause why it will not provide the identified service, and why the effectiveness of its treatment program will not be compromised in the absence of the service for which a preference was awarded; and**
- (3) The Commission, in its sole discretion, may determine that the change constitutes an impermissible modification, pursuant to COMAR 10.24.01.17C(1).**

B. NEED

COMAR 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 discuss the need of the population served or to be served by the Project.

Responses should include a quantitative analysis that, at a minimum, describes the Project's expected service area, population size, characteristics, and projected growth. If the relevant chapter of the State Health Plan includes a need standard or need projection methodology, please reference/address it in your response. For applications proposing to address the need of special population groups, please specifically identify those populations that are underserved and describe how this Project will address their needs.

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. List all assumptions made in the need analysis regarding demand for services, utilization rate(s), and the relevant population, and provide information supporting the validity of the assumptions.

Complete Table C (Statistical Projections – Entire Facility) from the CON Application Table Package.

C. AVAILABILITY OF MORE COST-EFFECTIVE ALTERNATIVES

COMAR 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 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.

D. VIABILITY OF THE PROPOSAL

COMAR 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 Tables D (Revenues & Expenses, Uninflated – Entire Facility) and F (Revenues & Expenses, Uninflated – New Facility or Service) from the CON Application Table Package.
- Complete Table G (Work Force Information) from the CON Application Table Package.
- 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 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.
- Identify the performance requirements applicable to the proposed project (see question 12, “Project Schedule”) 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, obtaining State and local land use, environmental, and design

approvals, contracting 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(s).

E. COMPLIANCE WITH CONDITIONS OF PREVIOUS CERTIFICATES OF NEED

COMAR 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 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.

F. IMPACT ON EXISTING PROVIDERS AND THE HEALTH CARE DELIVERY SYSTEM

COMAR 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. 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 and cost to the health care delivery system including relevant populations considered in the analysis, and changes in market share, 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 nursing home 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);

d) On costs to the health care delivery system.

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

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

Created March 24, 2017