Maryland
Hospital Association

September 25, 2018

Randolph Sergent
Chair, CON Modernization Task Force
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Chairman Sergent:

On behalf of Maryland's 63 hospital and health system members, we are pleased to submit recommendations from the hospital field to the Maryland Health Care Commission's (MHCC's) Certificate of Need (CON) Modernization Task Force. These recommendations are the culmination of more than ten meetings with a representative hospital work group and discussions with many hospital members.

Our general conclusions are:

- Certificate of Need (CON) is a necessary tool to ensure access to quality services and efficient care delivery
- CON should tightly align with the goals of the new Maryland Total Cost of Care Model

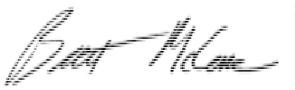
Specific recommendations include:

- Increasing the hospital capital threshold for projects that do not categorically require a CON
- Removing certain standards for hospital applications that are duplicated by, or could easily be shifted to, the Health Services Cost Review Commission
- Revising capital funding policies for hospitals
- Improving the application submission, review and approval process
- Adhering to timelines for approval and assuming auto approval for certain types of applications

We appreciate the Commission's time and attention to these important matters. I want to personally thank all of the representatives on the task force for their thoughtful input, and Commission staff for their tireless work throughout the process.

We look forward to discussing these recommendations on October 1. At the October 1 meeting, I plan to review only the summary slide deck, but am happy to discuss suggested statutory or regulatory changes.

Sincerely,



Brett McCone, Vice President

6820 Deerpath Road, Elkridge, MD 21075 ▪ 410-379-6200 ▪ www.mhaonline.org

# Maryland's Certificate of Need (CON) Program

## Summary of Hospital Recommendations to the Maryland Health Care Commission

**October 1, 2018**

Maryland Hospital Association

# Overview

- Background
- MHA work group process
- General conclusions
- Summary of recommendations
- Items for commission to clarify

# Background

- In 2018, legislative committees asked the Maryland Health Care Commission (MHCC) to study CON
  - MHCC work group, report due December 1, 2018
  - Multi-stakeholder process, including hospitals
  - Member desire to influence outcomes
- MHA's 2015 Capacity, CON and Capital Task Force recommended an MHA work group to propose specific changes affecting CON

# MHA Work Group Process

- MHA members from finance, planning, operations and government affairs
  - See appendix for members
- Ten meetings from November to August, parallel to MHCC work group
- Review and consideration by MHA's governing councils
- Recommending changes to statutes and regulations for MHCC's (and HSCRC's) consideration

# General Conclusions

- Certificate of Need (CON) is a necessary tool to ensure **access** to **quality** services and **efficient** care delivery
- CON should tightly align with the goals of the new Maryland Total Cost of Care Model
- CON and the State Health Plan (SHP) are policy levers to provide the appropriate supply of quality services needed, to support Model outcomes
- CON policies should support regulatory focus areas, including right sizing health care capacity
- The HSCRC should implement a capital funding policy that aligns with model goals

# General Conclusions

- CON recommendations intend to:
  - Eliminate agency duplication
  - Align services supply with new model
  - Avoid detailed CON reviews when not necessary (renovations, no interested parties)
  - Simplify CON application process
- Total Cost of Care Model and hospital global budgets enforce efficient and effective projects
  - No incentive to overbuild, or build inefficiently

# Key Recommendations

- Recommendations include changes to statutes and regulations (see chart on next page)
- Statutory: Change State Health Plan review requirements and CON services
  - Health General 19-118, 19-120, 19-214.1 (HSCRC charity care statute)
- Regulatory: Change State Health Plan general and hospital specific requirements
  - COMAR 10.24.01, 10.24.10
- Hospital CON application

# Key Recommendations

| Recommendation | Statute | Regulation | Policy / Application |
|---|---|---|---|
| Increase hospital capital threshold | X | X | |
| Implement capital funding policy | | X | X |
| Update Psychiatry SHP Chapter | | X | |
| Eliminate project alternatives | | X | X |
| Annual SHP Chapter Review | X | X | |
| TCOC Model Alignment language: SHP (and accompanying statute) | X | X | |
| Limit completeness questions; Enforce timelines | | X | X |
| Remove application requirements (some consolidated to HSCRC) | X | X | X |
| Repeal Limited Services Hospital; replace with Freestanding Med Facility | X | X | |
| Change hospital application document | | X | X |

# Capital Threshold

- Increase hospital exemption threshold from $10m (+inflation) to the lower of: **25%** of an individual hospital's **annual revenue**, or **$50 million**
  - $50m revenue base = $12.5m limit
  - $100m revenue base = $25m limit
  - $200m and higher = $50m limit
- CON continues to apply if project is under the threshold but required by statute – increasing beds, adding services, etc.

# Funding Capital in Hospital Rates

- HSCRC should **implement a** new, clear and transparent **capital funding policy**
  - Needed to establish rules and understand incentives
- CON approval still needed to request capital in rates
  - Hospital renovation projects below the proposed threshold could seek rate relief because CON is otherwise not needed
- Proactively declare intent to seek capital funding
  - If not seeking rates, assumes the “pledge” is automatic:
    - Cannot seek future rates for the project, and
    - CON would **not be** required, if no changes in services

# Updating the State Health Plan

- Require MHCC to:
  - Align SHP with Maryland's Total Cost of Care Model
    - Revise SHP preamble in each chapter to state that it was prepared to align with Maryland Model
  - Annually review of **each** SHP chapter to determine **if** updates needed
    - Report at a public meeting
  - Commission should
    - Prioritize chapter review
    - If updates are required, prioritize updates

# Psychiatric Services

- Immediately review the Psychiatric Services chapter of the state health plan
  - Most recent revision in **1997**
  - Updating the chapter will allow for a thorough and thoughtful approach, with appropriate stakeholder input, to address this critical need
  - Address the unmet need for behavioral health capacity across the continuum of services, including inpatient, outpatient and community based services
- **MHA's CON work group is continuing to process this important issue and may recommend other changes in both the short and long term**

# Updating CON Process and Requirements

- Adhere to timelines in CON review process
  - Non-comparative reviews with no interested parties should be auto approved at the 90th day if there is no action and agreement by the applicant
  - Other specific changes to regulations are proposed
- Eliminate alternative project requirements
  - Focus justification on submitted project efficiency and effectiveness
- Focus completeness questions to only those that add value and are needed for a decision on the application

# Updating CON Process and Requirements

- Remove limited services hospital references, replace with Freestanding Medical Facility (where needed)
- Update notification language (e.g., website)
- Language added to exemption criteria:
  - "Will result in more efficient and effective delivery of health care services, **aligning with Maryland's Total Cost of Care Model.**"
- Eliminate submission of previous CON terms and conditions compliance

# Updating CON Process and Requirements

- Replace Building Cost Index for inflation with standard 5 percent factor
  - Eliminates unnecessary review for simple cost inflation
- Change capital obligation definition in performance requirements to 51 percent of building cost + renovations cost (excluding equipment)

# Updating General Acute Care Services

- Update Section .03, Issues and Policies with new model information and new data
- Change policy language to align with model
- Remove requirements for charge information, charity care information, and quality of care documentation
  - Expand or reference HSCRC requirements of these items, particularly hospital quality requirements
  - **Extensive measurement, management and enforcement of hospital quality through HSCRC policies**

# Updating General Acute Care Services

- Remove requirement to identify two alternatives
- Eliminate cost per square foot guidelines
- Financial feasibility formally delegated to HSCRC, **with timeline requirements**
- Eliminate emergency department standards

# Revising Hospital CON Application

- Submit financials **including inflation/rate assumptions**; Already submitted to HSCRC
  - Little value to submit financials without inflation
- Eliminate documentation of compliance with previous CON terms and conditions
- Consolidate and simplify responses

# Right Sizing Service Capacity

- CON should not be a barrier to more efficient service delivery
  - Support policies and processes to allow transformation from more expensive services
- MHCC should take a leadership role to:
  - **Align** differing **agency requirements** when transformation occurs
  - **Support messaging** the benefits of right sizing

# Requesting Alignment and Clarification

- Two items for MHCC (and HSCRC) to consider
  - Align primary service area definition between HSCRC Global Budgeted Revenue (GBR) agreement and MHCC regulations
  - Remove definition of Physician Office Surgical Center (POSC)
    - Recent changes eliminate need?

# Appendix

# MHA Work Group Members

| | |
|---|---|
| **Tony Bladen**<br>*Chief Operations Officer*<br>CalvertHealth Medical Center | **Ryan O'Doherty**<br>*Vice President of External Affairs and Strategic Communications*<br>Mercy Medical Center |
| **Alison G. Brown**<br>*President, University of Maryland Medical Center Midtown Campus*<br>*Senior Vice President, Marketing, Communications & Community Health*<br>University of Maryland Medical System | **Amber Olig**<br>*Director of Corporate Strategy*<br>Greater Baltimore Medical Center |
| **Neil Carpenter**<br>*Vice President, Strategic Planning & Research*<br>LifeBridge Health | **Kim Repac**<br>*Senior Vice President & CFO*<br>Western Maryland Health System |
| **Kristin Feliciano**<br>*Chief Strategy Officer*<br>Holy Cross Health | **Bruce Ritchie**<br>*Vice President of Finance / CFO*<br>Peninsula Regional Medical Center |
| **Rob Jepson**<br>*Vice President, Business Development*<br>Adventist HealthCare Washington Adventist Hospital | **Pegeen Townsend**<br>*Vice President Governmental Affairs*<br>MedStar Health |
| **Bonnie B. Katz**<br>*Senior Vice President, Strategy and Business Development*<br>Sheppard Pratt Health System, Inc. | **Paula Widerlite**<br>*Chief Strategy Officer*<br>Anne Arundel Medical Center |
| **Anne Langley**<br>*Senior Director, Health Planning and Community Engagement*<br>The Johns Hopkins Health System | |

# MHA Work Group Members

| Standing Guests | MHA Staff |
|---|---|
| **Patricia Cameron**<br>*Senior Policy Analyst*<br>MedStar Health | **Erin Dorrien**<br>*Director, Policy & Data Analytics* |
| **Donna Jacobs**<br>*Senior Vice President, Government, Regulatory Affairs and Community Health*<br>University of Maryland Medical System | **Brett McCone**<br>*Vice President, Rate Setting* |
| **Robin Luxon**<br>*Senior Vice President of Corporate Planning, Marketing & Business Development*<br>University of Maryland Upper Chesapeake Health System | **Brian Sims**<br>*Senior Analyst, Rate Setting* |
| | **Jennifer Witten**<br>*Vice President, Government Affairs* |

Craig P. Tanio, M.D.
CHAIR

STATE OF MARYLAND

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

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

# INSTRUCTIONS FOR APPLICATION FOR CERTIFICATE OF NEED HOSPITAL PROJECTS

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

**REQUIRED FORMAT:**

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

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

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

**SUBMISSION FORMATS:**

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

- **Hard copy:** Applicants must submit six (6) hard copies of the application to:
  Ruby Potter
  Health Facilities Coordinator
  Maryland Health Care Commission
  4160 Patterson Avenue
  Baltimore, Maryland 21215

- **PDF:** Applicants must also submit *searchable* PDF files of the application, supplements, attachments, and exhibits.[1] All subsequent correspondence should also be submitted both by paper copy and as *searchable PDFs*.

- **Microsoft Word:** Responses to the questions in the application and the applicant's responses to completeness questions should also be electronically submitted in Word. Applicants are strongly encouraged to submit any spreadsheets or other files used to create the original tables (the native format). This will expedite the review process.

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

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

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

*For internal staff use*

**MARYLAND HEALTH CARE COMMISSION**

**MATTER/DOCKET NO.**

**DATE DOCKETED**

**HOSPITAL**
**APPLICATION FOR CERTIFICATE OF NEED**

**PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION**

**1. FACILITY**

**Name of Facility**: _____

**Address:**

_____
Street City Zip County

**Name of Owner (if differs from applicant):**

_____

**2. OWNER**

**Name of owner:** _____

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

**Legal Name of Project Applicant**

_____

**Address:**

_____
Street City Zip State County

**Telephone:** _____

**Name of Owner/Chief Executive:** _____

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

_____

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

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

A. Governmental ☐

B. Corporation

(1) Non-profit ☐

(2) For-profit ☐

(3) Close ☐ State & date of incorporation

C. Partnership

General ☐

Limited ☐

Limited liability partnership ☐

Limited liability limited partnership ☐

Other (Specify): _____

D. Limited Liability Company ☐

E. Other (Specify): _____

To be formed: ☐

Existing: ☐

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

**A. Lead or primary contact:**

**Name and Title:** _____

**Mailing Address:**

Street City Zip State

**Telephone:** _____

**E-mail Address (required):** _____

**Fax:**

**B. Additional or alternate contact:**

**Name and Title:** _____

**Mailing Address:**

Street City Zip State

**Telephone:** _____

**E-mail Address (required):** _____

**Fax:**

## 7. TYPE OF PROJECT

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

If approved, this CON would result in:

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

## 8. PROJECT DESCRIPTION

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

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

**Commented [MB1]:** This can be duplicative with project description. Suggest 1-2 sentence description only.

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

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

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

## 9. CURRENT PHYSICAL CAPACITY AND PROPOSED CHANGES

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

**10. REQUIRED APPROVALS AND SITE CONTROL**

A. Site size: _____ acres

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

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

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

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

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

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

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

## 11. PROJECT SCHEDULE

~~In completing this section, please note applicable performance requirement time frames set forth at COMAR 10.24.01.12B & C. Ensure that the information presented in the following table reflects information presented in Application Item 7 (Project Description)~~See COMAR 10.24.01.12B and C regarding time limits on your project based on the information provided below. .

Check one:

_____ Single Phase Project

_____ Multiple Phase Project with one construction contract

_____ Multiple Phase Project with multiple construction contracts.

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

| | | |
|---|---|---|
| ~~phase of construction within 12 months after completion of immediately preceding phase~~ | | |
| ~~Initiation of Construction on each phase within 4 months of the effective date of binding construction contract for that phase~~ | _____ | ~~months~~ |
| ~~Completion of each phase within 24 months of the effective date of binding construction contract for that phase~~ | _____ | ~~months~~ |

**12. PROJECT DRAWINGS**

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

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

A. Floor plans for each floor affected with all rooms labeled by purpose or function, room sizes, number of beds, location of bathrooms, nursing stations, and any proposed space for future expansion to be constructed, but not finished at the completion of the project, labeled as "shell space".

B. For a project involving new construction and/or site work a Plot Plan, showing the "footprint" and location of the facility before and after the project.

C. For a project involving site work schematic drawings showing entrances, roads, parking, sidewalks and other significant site structures before and after the proposed project.

D. Exterior elevation drawings and stacking diagrams that show the location and relationship of functions for each floor affected.

**13. FEATURES OF PROJECT CONSTRUCTION**

A. If the project involves new construction or renovation, complete the Construction Characteristics (Table C) and Onsite and Offsite Costs (Table D) worksheets in the CON Table Package.

~~B. Discuss the availability and adequacy of utilities (water, electricity, sewage, natural gas, etc.) for the proposed project, and the steps necessary to obtain utilities. Please either provide documentation that adequate utilities are available or explain the plan(s) and anticipated timeframe(s) to obtain them.~~

**PART II - PROJECT BUDGET**

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

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

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

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

---

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

---

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

---

4. Other than the licensure or certification actions described in the response to Question 3, above, has any facility with which any applicant is involved, or has any facility with which any applicant has in the past been involved (listed in response to Question 2, above) ever received inquiries from a federal or any state authority, the Joint Commission, or other regulatory body regarding possible non-compliance with Maryland, another state, federal, or Joint Commission requirements for the provision of, the quality of, or the payment for health care services that have resulted in actions leading to the possibility of penalties, admission bans, probationary status, or other sanctions at the applicant facility or at any facility listed in response to Question 2? If yes, provide, for each such instance, copies of any settlement reached, proposed findings or final findings of non-compliance and related documentation including reports of non-compliance, responses of the facility, and any final disposition or conclusions reached by the applicable authority.

---

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).

---

One or more persons shall be officially authorized in writing by the applicant to sign for and act for the applicant for the project which is the subject of this application. Copies of this authorization shall be attached to the application. The undersigned is the owner(s), or Board-designated official of the applicant regarding the project proposed in the application.

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

Date

Signature of Owner or Board-designated Official

Position/Title

Printed Name

**PART IV - CONSISTENCY WITH GENERAL REVIEW CRITERIA AT COMAR 10.24.01.08G(3)**:

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

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

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

**10.24.01.08G(3)(a). <u>The State Health Plan</u>.**

**<u>INSTRUCTION:</u>**

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

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

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

**Commented [MB2]:** Duplicative - this is understood.

**Commented [MB3]:** This attempts to avoid duplication, particularly in the completeness questions that request information already submitted to the state.

**Commented [MB4]:** This section should be a list rather than paragraphs.

**Copies of all applicable State Health Plan chapters are available from the Commission and are available on the Commission's web site here:**
**http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp**

| | |
|---|---|
| **10.24. 07** | **State Health Plan: an overview**<br>o **Psychiatric services**<br>o **EMS** |
| **10.24. 09** | **Specialized Health Care Services - Acute Inpatient Rehab Services** |
| **10.24. 11** | **General Surgical Services** |
| **10.24. 12** | **Inpatient Obstetrical Services** |
| **10.24. 14** | **Alcoholism and Drug Abuse Intermediate Care Facility Treatment Services** |
| **10.24. 15** | **Organ Transplant Services** |
| **10.24. 17** | **Cardiac Surgery and Percutaneous Coronary Artery Intervention Services** |
| **10.24. 18** | **Neonatal Intensive Care Services** |
| ~~**Capital Projects Exceeding the CON Threshold for Capital Expenditures**~~ | ~~**Hospital Capital Projects Exceeding the CON Threshold for Capital Expenditures**~~<br>~~Hospital projects that require CON review because the capital expenditure exceeds the CON threshold for capital expenditures but do not involve changes in bed capacity, the addition of new services, and otherwise have no elements that are categorically regulated should address all applicable standards in **COMAR 10.24.10: Acute Care Hospital Services** in their CON application. Applicants should consult with staff in a pre-application conference about any other SHP chapters containing standards that should be addressed, based on the nature of the project.~~ |

**Commented [MB5]:** Add 10.24.10

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

Commented [MB6]: Again, suggest lists rather than paragraphs.

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

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

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

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

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

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

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

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

**INSTRUCTIONS:** Please describe the planning process that was used to develop the proposed

Commented [MB7]: Lists rather than paragraphs.

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

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

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

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

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

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

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

**INSTRUCTIONS:** 1. Please provide a complete description of the funding plan for the project, documenting the availability of equity, grant(s), or philanthropic sources of funds and demonstrating, to the extent possible, the ability of the applicant to obtain the debt financing proposed. ~~Describe the alternative financing mechanisms considered in project planning and provide an explanation of why the proposed mix of funding sources was chosen.~~

- Complete applicable Revenues & Expenses (Tables G, H, J and K as applicable), and the Work Force information (Table L) worksheets in the CON Table Package, as required. Instructions are provided in the cover sheet of the CON package. Explain how these tables demonstrate that the proposed project is sustainable and 2. provide a description of the sources and methods for recruitment of needed staff resources for the proposed project, if applicable.

- 3. Describe and document relevant community support for the proposed project.

- 4. Identify the performance requirements applicable to the proposed project and explain how ~~the applicant will be able to implement the project in compliance with those performance requirements. Explain the process for completing the project design, contracting and obtaining and obligating the funds within the prescribed time frame. Describe the construction process or refer to a description elsewhere in the application that demonstrates that~~ the project can be completed within the applicable time frame.

**Commented [MB8]:** This is not necessary.

**Commented [MB9]:** Recommending tables reflect inflation since those are given to HSCRC anyway.

**Commented [MB10]:** No longer necessary

- 5. Audited financial statements for the past two years should be provided by all applicant entities and parent companies.

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

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

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

**Commented [MB11]:** This should be a condition of each approved CON, not the subsequent one. The commission already has this information.

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

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

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

a) On the volume of service provided by all other existing health care providers that are likely to experience some impact as a result of this project[2];

b) On access to health care services for the service area population that will be served by the project. (state and support the assumptions used in this analysis of the impact on access);

c) On costs to the health care delivery system.

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

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

**Title 10 MARYLAND DEPARTMENT OF HEALTH**
**Subtitle 24 MARYLAND HEALTH CARE COMMISSION**
**Chapter 01 Certificate of Need for Health Care Facilities**
**Authority: Health-General Article, §§19-109(a)(1) and 19-120, Annotated Code of Maryland**

**.01 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Acquisition" means:

(a) Any transfer of stock or assets that results in a change of the person or persons who control a health care facility; or

(b) The transfer of any stock or ownership interest in excess of 25 percent.

(2) "Adversely affected", for purposes of determining interested party status in a Certificate of Need review, as defined in §B(19) of this regulation, means that a person:

(a) Is authorized to provide the same service as the applicant, in the same planning region used for purposes of determining need under the State Health Plan or in a contiguous planning region if the proposed new facility or service could reasonably provide services to residents in the contiguous area;

(b) Can demonstrate that the approval of the application would materially affect the quality of care at a health care facility that the person operates, such as by causing a reduction in the volume of services when volume is linked to maintaining quality of care;

(c) Would suffer a substantial depletion of essential personnel or other resources by approval of the application by the Commission; or

(d) Can demonstrate to the reviewer that the person could suffer a potentially detrimental impact from the approval of a project before the Commission, in an issue area over which the Commission has jurisdiction, such that the reviewer, in the reviewer's sole discretion, determines that the person should be qualified as an interested party to the Certificate of Need review.

(3) "Aggrieved party" means:

(a) An interested party who:

(i) Presented written comments on an application to the Commission, both to the reviewer and in the form of exceptions to a proposed decision that is adverse to the position of that person, and

(ii) Would be adversely affected by the final decision of the Commission; or

(b) The Secretary.

(4) "Ambulatory surgical facility" means an entity or part of an entity with two or more operating rooms that:

(a) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and

(b) Seeks reimbursement from a third-party payor as an ambulatory surgical facility.

(5) "Approved bed" means a bed approved by the Commission in a Certificate of Need, but not yet licensed.

(6) "By or on behalf of" includes, but is not limited to, a capital expenditure which affects the physical plant, service volume, or service capacity of a health care facility or health maintenance organization regardless of the source of the funds.

(7) "Capital expenditure" means:

(a) An expenditure, including predevelopment costs, which:

(i) Is made by or on behalf of a health care facility, and which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance, or which is made to obtain by lease or comparable arrangement any physical plant for a facility;

(ii) Is made as part of an acquisition, improvement, or expansion, including redevelopment costs, and is more than the threshold for capital expenditures;

(iii) Is made as part of replacement of a physical plant of the health care facility and is more than the threshold for capital expenditures;

(iv) Results in a change in the bed capacity of a health care facility with respect to which the expenditure is made that meets the criteria of Regulation .02A(3) of this chapter;

(v) Results in a relocation of a health care facility that meets the criteria of Regulation .02A(2) of this chapter; or

(vi) Results in a change in the health care services to be offered by a health care facility that meets the criteria of Regulation .02A(4) of this chapter;

(b) A donation of a physical plant to a health care facility, if a Certificate of Need would be required for an expenditure by the health care facility to acquire the physical plant directly;

(c) A transfer of a physical plant to a facility for less than fair market value, which is considered a capital expenditure if the transfer of the physical plant at fair market value would be a capital expenditure.

(8) "Certificate of Need (CON)" means an approval issued by the Commission for a health care project under Health-General Article, Title 19, Annotated Code of Maryland.

(9) "Department" means the Maryland Department of Health.

(10) "Existing health care facility" means a health care facility, as described in §B(12) of this regulation, which is licensed by the Department.

(11) "General hospice care program" means a coordinated, interdisciplinary program of hospice care services for meeting the special physical, psychological, spiritual, and social needs of dying individuals and their families, by providing palliative and supportive medical, nursing, and other health services through home-based or inpatient care during illness and bereavement.

(12) Health Care Facility.

(a) "Health care facility" means:

(i) A hospital, as defined in Health-General Article, §19-301(g), Annotated Code of Maryland;

~~(ii) A limited service hospital, as defined in Health-General Article, §19-301(e), Annotated Code of Maryland;~~

(iii) A related institution, as defined in Health-General Article, §19-301(o), Annotated Code of Maryland;

(iv) An ambulatory surgical facility;

(v) A rehabilitation facility;

(vi) A home health agency, as defined in Health-General Article, §19-401(b), Annotated Code of Maryland;

(vii) A hospice, as defined in Health-General Article, §19-901, Annotated Code of Maryland;

(viii) Other health institutions, services, or programs that may be specified as requiring a Certificate of Need under State law.

(b) "Health care facility" does not mean:

**Commented [MB1]:** Removing because authority has not been used and Freestanding Medical Facilities are essentially the same vehicle. Corresponding statutory change proposed.

**Commented [MB2]:** Recommended MHCC evaluate if Physician Office Surgical Center (POSC) term is still needed.

(i) A hospital or related institution operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts;

(ii) For the purpose of providing an exclusion from a Certificate of Need under Health-General Article, §19-120, Annotated Code of Maryland, a facility to provide comprehensive care constructed by a provider of continuing care, as defined in Article 70B, Annotated Code of Maryland, if the facility is for the exclusive use of the provider's subscribers who have executed continuing care agreements except as provided by Regulation .03J of this chapter;

(iii) A kidney disease treatment facility, or the kidney disease treatment stations and services provided by or on behalf of a hospital, if the facility or the services do not include kidney transplant services or programs;

(iv) The office of one or more individuals licensed to practice dentistry under Health Occupations Article, Title 4, Annotated Code of Maryland, for the purposes of practicing dentistry.

(13) "Health care project" means a health care project requiring a Certificate of Need as set forth in Regulation .02 of this chapter.

(14) "Health care services" means clinically related patient services.

(15) "Health Facilities Coordination Office" means that office of the Commission which acts as the entry and information point for applications for Certificate of Need.

(16) "Health maintenance organization" means a health maintenance organization under Health-General Article, §19-701, Annotated Code of Maryland.

**Commented [WJ3]:** MHCC should consider the need to define other organizations – ACO's, etc., as needed.

(17) "Health planning region" means the area used for planning for a particular service as provided in the State Health Plan.

(18) Home Health Agency.

(a) "Home health agency" means a health-related organization, institution, or part of an institution that, directly or through a contractual arrangement, provides to a sick or disabled individual in the residence of that individual, skilled nursing and home health aide services, and at least one other home health care service, that are centrally administered, as provided under Health-General Article, §19-401, et seq., Annotated Code of Maryland.

(b) "Home health agency" includes both parent (previously known as a branch) and subunit, as defined by the Centers for Medicare and Medicaid Services under 42 CFR §484.2.

(19) Initiation of Construction.

(a) "Initiation of construction" for a new health care facility or expansion of an existing health care facility means that an approved project has filed with the Commission appropriate documents and photographs establishing that the approved project has:

(i) Obtained permits, approvals, or both considered necessary by applicable federal, State, and local authorities to initiate construction;

(ii) Completed necessary preconstruction site work; and

(iii) Started the installation of the foundation system with placement of permanent components, such as reinforcing steel, concrete, and piles.

(b) "Initiation of construction" for the renovation of an existing health care facility means that an approved project has filed with the Commission appropriate documents and photographs establishing that the approved project has:

(i) Obtained permits, approvals, or both considered necessary by applicable federal, State, and local authorities to initiate renovation;

(ii) Begun the demolition or relocation of affected services necessary to undertake the renovation project.

(20) "Interested party" means a person recognized by a reviewer as an interested party and may include:

(a) The applicant for a proposed project;

(b) The staff of the Commission;

(c) A third-party payor who can demonstrate substantial negative impact on overall costs to the health care system if the project is approved;

(d) A local health department in the jurisdiction or, in the case of regional services, in the planning region in which the proposed service is to be offered; and

(e) A person who can demonstrate to the reviewer that the person would be adversely affected, in an issue area over which the Commission has jurisdiction, by the approval of a proposed project.

(21) "Jurisdiction" means the 23 counties of Maryland and Baltimore City.

(22) Licensed Bed Capacity.

(a) "Licensed bed capacity" means the number of beds in any of the medical service categories or subcategories in a health care facility identified in §B(25) of this regulation, as they appear in the Commission's inventories of service capacity.

(b) "Licensed bed capacity" does not mean the number of holding beds to support hospital emergency services, bassinets, or recovery beds to support ambulatory surgical services.

~~(23) "Limited service hospital" means a health care facility that:~~

~~(a) Is licensed as a hospital on or after January 1, 1999;~~

~~(b) Changes the type or scope of health care services offered by eliminating the facility's capability to admit or retain patients for overnight hospitalization;~~

~~(c) Retains an emergency or urgent care center; and~~

~~(d) Complies with the regulations adopted by the Secretary under Health-General Article, §19-307.1, Annotated Code of Maryland.~~

**Commented [MB4]:** Statutory change to eliminate.

(24) "Long-term significant relationship" means a relationship characterized by mutual economic dependence, demonstrated by evidence such as a joint lease or mortgage or power of attorney, and evidence of common legal residence shown by driver's licenses, voter registration, or other identification.

(25) "Local health department" means the health department in a jurisdiction or a body designated by that jurisdiction to perform health planning functions.

(26) "Maryland Health Care Commission (Commission)" means the agency established by Health-General Article, Title 19, Subtitle 1, Annotated Code of Maryland, that replaced the Health Care Access and Cost Commission and the Maryland Health Resources Planning Commission, effective October 1, 1999.

(27) "Medical service" means:

(a) Any of the following categories of health care services as they appear in the Commission's inventories of service capacity:

(i) Medical/surgical/gynecological/addictions;

(ii) Obstetrics;

(iii) Pediatrics;

(iv) Psychiatry;

(v) Rehabilitation;

(vi) Chronic care;

(vii) Comprehensive care;

(viii) Extended care;

(ix) Intermediate care; or

(x) Residential treatment; or

(b) A subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of medical services for which the State Health Plan provides a need projection methodology or specific standards.

(28) "Multiphased plan of construction" is a plan of construction for an addition, replacement, modernization, relocation, or conversion of an existing health care facility that:

(a) Costs more than $40,000,000; and

(b) Involves distinct elements of construction, demolition, or renovation that are initiated or completed before one or more subsequent elements of the overall project are initiated.

(29) "Operating room" means a discrete area where surgical services are provided, as defined in the State Health Plan under COMAR 10.24.11.

(30) "Participating entity" means a person recognized by the executive director as a participating entity and may include:

(a) A third-party payor;

(b) A jurisdiction in the health planning region that is used for purposes of determining need under the State Health Plan, where the proposed project will be located or from which an existing health care facility seeks to relocate; and

(c) A municipality where the proposed project will be located or from which an existing health care facility seeks to relocate.

(31) "Person" includes an individual, receiver, trustee, guardian, executor, administrator, fiduciary, or representative of any kind and any partnership, firm, association, limited liability company, limited liability partnership, public or private corporation, or other entity.

(32) Personal Physician.

(a) "Personal physician" means a physician licensed to practice medicine who:

(i) Was chosen by the individual;

(ii) Has an established physician-patient relationship with the individual; and

(iii) Has provided health care services to the individual.

(b) "Personal physician" may not be an owner, employee, under contract with, or have a material financial interest in the continuing care retirement community, its management company, or related entity.

(33) Predevelopment Costs.

(a) "Predevelopment costs" means all costs related to the preliminary development of a project which include, but are not limited to, the costs of preliminary plans, studies, surveys, architectural designs, plans, reports, application fees, legal fees, financing fees, consulting fees, working drawings, or specifications undertaken in preparation for the development or offering of a health care project.

(b) "Predevelopment costs" does not include activities routinely undertaken by a health care facility as a part of its internal management or long-range planning process.

(34) "Primary service area" means:

(a) The Maryland postal ZIP codes from which the first 60 percent of a hospital's patient discharges originate during the most recent 12-month period, where the discharges from each ZIP code are ordered from largest to smallest number of discharges and where two or more ZIP codes have the same numbers of discharges, the ZIP codes are ordered from the largest to smallest based on the percentage of ZIP code discharges to the hospital in the most recent 12-month period;

**Commented [WJ5]:** MHCC and HSCRC policies for PSA should be consistent. Consistent definition for primary and secondary service areas.

(b) Point ZIP codes physically within any of the ZIP codes designated in §B(33)(a) of this regulation;

(c) Maryland ZIP codes physically contiguous to any of the ZIP codes designated in §B(33)(a) of this regulation that provided 50 percent or more of their discharges to the hospital in the most recent 12-month period; and

(d) For a merged asset system, the ZIP codes are tabulated separately for each hospital, and all ZIP codes identified for each hospital are included in the primary service area of the merged asset system.

(35) "Public body obligation" means a bond, note, evidence of indebtedness, or other obligation for the payment of borrowed money issued by:

(a) The Maryland Health and Higher Educational Facilities Authority;

(b) The State, or any agency, instrumentality, or public corporation of the State;

(c) Any public body as defined in Article 31, §9, Annotated Code of Maryland;

(d) The Mayor and City Council of Baltimore; or

(e) A municipal corporation subject to the provisions of Article XI-E of the Maryland Constitution.

(36) "Rehabilitation facility" means an inpatient facility that:

(a) Is organized for the primary purpose of assisting in the rehabilitation of persons with disabilities through an integrated program of medical and other services which are provided under competent professional supervision;

(b) Is licensed as a special rehabilitation hospital; and

(c) Complies with the regulations adopted by the Secretary under Health-General Article, Title 19, Subtitle 3, Annotated Code of Maryland.

(37) "Reviewer" means one Commissioner, appointed by the Executive Director of the Commission, who:

(a) Evaluates each Certificate of Need application according to the entire record of written submissions and oral presentations by each applicant and interested party;

(b) Prepares a proposed decision for the consideration of the full Commission; and

(c) Serves as presiding officer at an evidentiary hearing on the application or applications, if the reviewer determines that an evidentiary hearing is warranted, according to the criteria set forth in Regulation .10D of this chapter.

(38) "Secretary" means the Secretary of Health.

(39) "State Health Plan" means the State Health Plan for Facilities and Services and its modifications or additions, adopted by the Commission pursuant to State health planning law, and incorporated by reference in this subtitle.

(40) "Threshold for capital expenditures" means:

(a) For a hospital project on a hospital campus , ~~$10,000,000 for the period June 1 through December 31, 2006, after that to be adjusted annually by the Commission according to the Consumer Price Index-Urban (CPI-U) for the Baltimore Metropolitan Area published by the U.S. Department of Labor, and rounded off to the nearest $50,000; and~~ the lower of twenty five percent of a hospital's annual regulated charges, or $50,000,000

**Commented [MB6]:** Corresponding statutory change required.

(b) For a health care facility other than a hospital, $5,000,000 for the period June 1 through December 31, 2006, after that to be adjusted by the Commission according to the Consumer Price Index-Urban (CPI-U) for the Baltimore Metropolitan Area published by the U.S. Department of Labor, and rounded off to the nearest $50,000.

**.02 Coverage.**

A. Except as provided in Regulations .03 and .04 of this chapter, a Certificate of Need is required before:

(1) A new health care facility is built, developed, or established;

(2) An existing health care facility is moved to another site, unless the relocation is:

(a) The result of a partial or complete replacement of an existing hospital or related institution, as defined in Health-General Article, §19-301, Annotated Code of Maryland, and is to another part of the site or immediately adjacent to the site of the existing hospital or related institution;

(b) Of an existing health care facility owned or controlled by a merged asset system, subject to the provisions of Regulation .03D or .04A(2) of this chapter, whichever is applicable; or

(c) A conversion of a general hospital to a Freestanding Medical Facility as specified in COMAR 10.24.17C ~~By a hospital converting to a limited service hospital, subject to the provisions of Regulation .04A(4) of this chapter, and is to a site within the immediate area, as determined by the Commission, as described in §B of this regulation;~~

(3) The bed capacity of a health care facility is changed, unless the change in bed capacity:

(a) Is for a health care facility that is not an acute general hospital, does not exceed ten beds or 10 percent of the facility's total bed capacity, whichever is less;

(b) Would increase or decrease the bed capacity of an existing medical service provided by an acute general hospital, if:

(i) The total licensed bed capacity of the hospital does not increase;

(ii) The change is maintained for at least 1 year, unless modified pursuant to a Certificate of Need or exemption from Certificate of Need approved by the Commission, or the annual recalculation of hospital licensed bed capacity required at Health-General Article, §19-307.2, Annotated Code of Maryland; and

(iii) The hospital notifies the Commission at least 45 days before the proposed change in bed capacity of its medical services;

(c) Is proposed pursuant to a merger or consolidation between health care facilities, and the Commission finds that the change:

(i) Is not inconsistent with the State Health Plan;

(ii) Will result in the delivery of more efficient and effective health care services; and

(iii) Is in the public interest;

(d) Is the result of the annual licensed bed recalculation for an acute general hospital provided under Health-General Article, §19-307, Annotated Code of Maryland;

(e) Is proposed for an acute general hospital in a jurisdiction with three or more acute general hospitals, and between acute general hospitals in a merged asset system located within the same jurisdiction, subject to the provisions of Regulation .03D(3) of this chapter; or

(f) Is proposed pursuant to Regulation .03C of this chapter, and meets the requirements of that subsection;

(4) The type or scope of any health care service offered by a health care facility is changed, and the change:

(a) Establishes a new medical service;

(b) Establishes a new open heart surgery or~~,~~ organ transplant surgery, ~~burn treatment~~, or neonatal intensive care program;

(c) Establishes a new home health agency, general hospice care program, or freestanding ambulatory surgical facility;

(d) Builds or expands ambulatory surgical capacity in any setting owned or controlled by a hospital, if the building or expansion would increase the surgical capacity of the State's health care system;

(e) Results in:

(i) The establishment of a new subunit by an existing home health agency;

(ii) The expansion of a home health agency into a jurisdiction not included in a previous Certificate of Need; or

(iii) A transfer of ownership of a subunit or a facility based home health care service of an existing health care facility that separates the ownership of the subunit from the home health agency or home health care service that established the subunit;

~~(f) Closes an existing medical service, except as provided in Regulation .03 or .04 of this chapter, or is a temporary delicensure that meets the requirements of Regulation .03C of this chapter;~~

**Commented [MB7]:** Delete. This will never apply.

(g) Closes an existing health care facility or converts it to a non-health-related use, with the exception of:

(i) The closure of an acute general hospital or its conversion to a ~~limited service hospital~~freestanding medical facility, as provided in ~~Regulation .03 or .04 of this chapter~~Regulation 10.24.17C; or

(ii) The temporary delicensure of a health care facility that meets the requirements of Regulation .03C of this chapter;

(5) A health care facility makes a capital expenditure, as defined in Health-General Article, §19-120 (k), Annotated Code of Maryland, and in this chapter, that exceeds the threshold for capital expenditures, as adjusted for inflation as provided in this chapter, including a capital expenditure:

(a) For the relocation of an existing health care facility owned or controlled by a merged asset system, except as provided in Regulation .03H(3) of this chapter; and

(b) By the relocated health care facility to permit the facility to offer a new health care service for which Certificate of Need is otherwise required.

B. Definition of Immediate Area for ~~Limited Service Hospital~~Freestanding Medical Facility Conversion.

(1) For the purpose of §A(2)(c) of this regulation, "immediate area" means a location on the site of the existing hospital, or on an adjacent site to the converting general hospital, unless:.

~~(2) A hospital may provide evidence as to why the Commission should approve a site for a limited service hospital beyond the immediate area of the converting hospital.~~

~~(3) The Commission will not approve a site for a limited service hospital unless the site is both within:~~

(~~a~~) The converting hospital is the only general hospital in the jurisdiction or is one of only two general hospitals in the jurisdiction and both belong to the same merged asset system; and

(b) The site is within ~~A~~a 5-mile radius ~~of the site of the hospital proposing the conversion; and~~and in the primary service area of the converting general hospital

~~(b) Its primary service area.~~

C. A person may not divide a project into component parts that could not be constructed independently except as permitted by this chapter. The Commission shall, on request, issue a determination regarding whether two or more apparently individual projects actually represent component parts of a single project, considering factors such as the timing of the projects, the functional areas of a facility to be affected, the number of construction contracts entered into, and whether expenditures under one contract depend upon the completion of a prior contract.

D. Proposed Change After Acquisition. If a person acquires an existing health care facility or service without a Certificate of Need, in accordance with Regulation .03A of this chapter, and proposes to change the health care services it provides or its bed capacity, the proposed change requires Certificate of Need review and approval in accordance with §A of this regulation.

E. A health maintenance organization, or health care facility directly or indirectly controlled by an HMO or group of HMOs, shall obtain a Certificate of Need before it builds, develops, operates, or participates in building, developing, or operating:

(1) A hospital;

(2) An ambulatory surgical facility; or

(3) Any other health care facility for which a Certificate of Need is required under §A of this regulation, if that health care facility is planned for or could be used by non-subscribers of the health maintenance organization or organizations.

F. Changes Not Covered By This Chapter. Changes to a health care facility not covered under §A of this regulation do not require Certificate of Need review and are not covered by this chapter. In instances when a person is uncertain whether the establishment of a new health care facility, or the expansion of an existing health care facility, is covered by Certificate of Need review requirements, the project requires, review for a determination of coverage under Regulation .14B of this chapter.

**.03 Non-Coverage by Certificate of Need Review Requirements.**

A. Acquisition of an Existing Health Care Facility.

(1) At least 30 days before closing on a contractual arrangement to acquire a health care facility that exists pursuant to a Certificate of Need or other authority recognized by the Commission, the person acquiring the facility shall notify the Commission in writing, with a copy to the local health officer in each affected jurisdiction, of the intent to acquire the facility, and include the following information:

(a) The health care services provided by the facility;

(b) The bed capacity, or jurisdiction served, if a community-based service;

(c) Complete data on admissions for the prior calendar year;

(d) Gross operating revenue generated during the last fiscal year; and

(e) Any other information, as required in the applicable chapter of the State Health Plan.

(2) In an acquisition of a home health agency, the purchaser may only acquire the authority to offer home health agency services in jurisdictions in which Commission records show that the

facility being acquired either provided that service during fiscal year 2001, or was granted a Certificate of Need after that date.

(3) If the person acquiring the health care facility files timely and complete notice with the Commission under §A(1) of this regulation, and the Commission does not find within 30 days of receiving notice that the health care services, bed capacity, or jurisdictions served, if a community-based service, of the facility being acquired will change as a result of the acquisition, the Commission shall issue a written notice to the person, with a copy to the local health officer in each affected jurisdiction and to appropriate State and federal agencies, that Certificate of Need review is not required.

(4) The notice of determination from the Commission that Certificate of Need review is not required is valid for 180 days.

(5) If the acquisition is completed, both buyer and seller shall sign a notice of completion of acquisition and file it with the Commission within 15 days of the completion of the acquisition.

(6) Within 90 days of the completion of the acquisition, the buyer shall seek licensure or certification from the Office of Health Care Quality, as appropriate, or file a letter of intent under Regulation .02 of this chapter to relocate the health care facility.

(7) If the notice of the acquisition is not filed as required in §A of this regulation, or the Commission finds that acquisition of the facility will result in a change in health care services, bed capacity, or jurisdictions served, if a community-based service, the Commission shall issue written notice to the person seeking the acquisition that Certificate of Need review is required.

B. Closure of an Acute General Hospital.

(1) A Certificate of Need is not required to close an acute general hospital or part of an acute general hospital in a jurisdiction with three or more acute general hospitals, or a State hospital in any jurisdiction, if the hospital provides notice to the Commission at least 45 days prior to the closing or partial closing and complies with the provisions of §B(4) of this regulation, if applicable.

**Commented [MB8]:** MHCC should review a complete timeline of requirements with affected Maryland regulatory bodies: MHCC, OHCQ, MIEMSS, , etc.

(2) A Certificate of Need is not required to close an acute general hospital or part of an acute general hospital in a jurisdiction with fewer than three acute general hospitals, if:

(a) At least 45 days before the closing or partial closing of an acute general hospital, a notice of the proposed closing or partial closing is filed with the Commission; and

(b) Within 30 days after the Commission receives notice of the hospital's intent to close, the hospital holds a public informational hearing in the jurisdiction where the acute general hospital is located, after consultation with the Commission to ensure that:

(i) Within 5 days of notifying the Commission of its intent to close, the hospital has provided public notice of the proposed closure and of the time and location of the required public

informational hearing, including publication in at least one newspaper of daily circulation in the affected area, and

(ii) Information will be presented at the public hearing regarding continued access to acute care services in the affected area, and plans of the hospital, or the merged asset system that owns or controls the hospital, for retraining and placement of displaced employees and reuse of the physical plant.

(3) Notice by the Commission to the Public, Elected Officials, and Other State Agencies.

(a) Within 5 days after it receives notice under this section that an acute general hospital intends to close, the Commission shall publish notice of its receipt in:

(i) At least one newspaper of daily circulation in the affected area, and

(ii) The next available issue of the Maryland Register.

(b) The Commission shall mail the same notice to elected public officials in whose district or county the hospital is located.

(4) If an acute general hospital that intends to close pursuant to this section has outstanding public body obligations issued on its behalf, written notification shall be given to the Maryland Health and Higher Educational Facilities Authority and the Health Services Cost Review Commission by the:

(a) Commission, within 5 days after receiving a written notification by the hospital of its intended closure;

(b) Hospital, within 10 days of filing with the Commission its written notification of its intended closure, along with a written statement of all public body obligations issued on behalf of the hospital that provides the information required by Article 43C, §16A(g), Annotated Code of Maryland; and

(c) Commission, that a hospital in a jurisdiction with fewer than three acute general hospitals, held a public information hearing in consultation with the Commission in the jurisdiction where the hospital is located.

C. Temporary Delicensure of Bed Capacity or a Health Care Facility.

(1) A temporary delicensure of licensed bed capacity or a licensed and operating health care facility does not require Certificate of Need review, and the Commission will retain the bed capacity or health care facility on its inventory for up to 1 year, if the owner or licensed operator:

(a) Provides written notice to the Commission at least 30 days before the proposed temporary delicensure;

(b) Identifies good cause for the proposed temporary delicensure;

(c) States the intention either to bring the bed capacity back onto the facility's license or relicense the health care facility at the end of the 1-year period, or to notify the Commission that it intends to take another of the actions permitted under this subsection; and

(d) Has received authorization from the Executive Director for the temporary delicensure.

(2) Bed capacity or a facility that has been authorized by the Commission to be temporarily delicensed is not subject to the provisions of this section:

(a) During the pendency at the Commission of a letter of intent to apply or an application for Certificate of Need approval involving the temporarily delicensed bed capacity or facility;

(b) If the Commission has issued a Certificate of Need to reimplement the facility's temporarily delicensed bed capacity, and that Certificate of Need remains in good standing;

(c) If the Commission has received and approved a request pursuant to Regulation .03 or .04 of this chapter to reimplement the bed capacity or facility, and has determined that the bed capacity or facility may be reimplemented without Certificate of Need approval or other finding by the Commission, including but not limited to actions that may be undertaken by a merged asset system of which the facility is a member;

(d) If the Commission receives a notice of acquisition of the temporarily delicensed bed capacity or facility and the buyer and seller timely complete the acquisition, in accordance with Regulation .03A of this chapter; or

(e) If the Commission receives written notification that the owner or operator of the temporarily delicensed bed capacity or facility has applied for relicensure.

(3) The requirements and procedures in this subsection do not apply to a proposal to close, on either a temporary or a permanent basis:

(a) An acute general hospital or part of a hospital, including a medical service, in a jurisdiction with fewer than three acute general hospitals; or

(b) A health care facility that provides any medical service approved by the Commission as a regional or Statewide health resource.

(4) A health care facility may not request authorization by the Commission to temporarily delicense bed capacity or the entire health care facility more than one time in a 12- month period.

(5) No fewer than 30 days before the end of the 1-year or other applicable period, a health care facility that has temporarily delicensed bed capacity or its entire facility shall notify the Commission that, before the end of the 1-year or other applicable period, it will:

(a) Apply to relicense the bed capacity or the entire facility temporarily delicensed pursuant to this subsection;

(b) Submit and receive the Executive Director's approval of a specific plan for the relicensure of the bed capacity or facility, that:

(i) Imposes stated time frames by which steps toward the relicensure of the bed capacity or facility will be accomplished, or the bed capacity or facility will be deemed abandoned, and

(ii) May be revised upon a proposal by the owner or operator, with the approval of the Executive Director;

(c) File a letter of intent, followed within 60 days by a Certificate of Need application, or request the applicable level of Commission action pursuant to Regulations .03 and .04 of this chapter, for the relocation of the bed capacity or facility, or for a capital expenditure deemed necessary to relicense the temporarily delicensed beds or facility;

(d) Execute a binding contract to transfer ownership of the health care facility, if the requirements of §A of this regulation are met;

(e) Execute a binding contract to transfer ownership of the previously licensed bed capacity, contingent on the filing within 30 days of a letter of intent to apply for Certificate of Need approval, or other applicable level of Commission action pursuant to Regulations .03 and .04 of this chapter if required, to relocate the bed capacity; or

(f) Relinquish the bed capacity, or seek the appropriate Commission approval to delicense and permanently close the health care facility.

(6) For extraordinary cause shown, the Executive Director may extend the period of a temporary delicensure under this subsection beyond 1 year, or the applicable time period.

(7) If bed capacity or a health care facility has been previously approved for temporary delicensure by the Commission:

(a) The time period provided under this subsection shall be deemed to expire 1 year from the date of the temporary delicensure, or 6 months from the effective date of these regulations, whichever is later; and

(b) The affected health care facility shall comply with the provisions of §C(5) of this regulation before the expiration of the applicable time period.

(8) Notwithstanding the provisions of §C(7) of this regulation, an application for a Certificate of Need to reimplement at another location any previously operating bed capacity that has remained delicensed under this subsection for 2 or more years from the effective date of its removal from the facility's license, or from the closure of the entire facility, shall demonstrate that the bed capacity continues to be needed in the jurisdiction.

(9) If, at the end of the 1-year period or other time period permitted under this section, the requirements of §C(5) or (7) of this regulation have not been met, and no request for an extension of time has been granted pursuant to §C(6) of this regulation, the bed capacity or health care facility is deemed abandoned by its owner or operator. The Commission shall issue a written notice to the owner of the affected facility, and to its licensed operator if the facility is not operated by its owner, of the opportunity to respond within 30 days before the abandonment is considered final, in order to demonstrate that the previously delicensed bed capacity or facility has been relicensed.

D. A Certificate of Need is not required to relocate an existing health care facility owned or controlled by a merged asset system, if:

(1) The proposed relocation is to a site in the primary service area of the health care facility to be relocated, as defined in the State Health Plan, and the relocation is not across jurisdictional boundaries;

(2) At least 45 days before the proposed relocation, notice is filed with the Commission, which will publish notice of the proposed relocation in the Maryland Register and a newspaper of daily circulation in the affected area; and

(3) The relocation of the existing health care facility does not:

(a) Change the type or scope of health care services offered; and

(b) Require a capital expenditure for its construction that exceeds the capital review threshold, adjusted for inflation, except as provided in §I of this regulation.

E. Change in Bed Capacity.

(1) A Certificate of Need is not required to change the bed capacity of a health care facility under the circumstances set forth in this section.

(2) For a health care facility that is not an acute general hospital, 2 years after its initial licensure or after its last change in licensed bed capacity, an existing health care facility may request that the Commission authorize an increase or decrease in bed capacity in the following medical services for which a health care facility shall obtain Commission approval and seek licensure or certification from the Office of Health Care Quality, if the increase or decrease in the total bed capacity of the facility does not exceed ten beds or 10 percent, whichever is less:

(a) A health care facility, including an acute general hospital, may add ten beds or 40 percent of the current bed capacity, whichever is less, in any of the following medical services for which it must obtain separate licensure:

(i) Special rehabilitation hospital;

(ii) Special care units, as defined in COMAR 10.07.02.14-1 and .14-2;

(iii) Intermediate care; or

(iv) A residential treatment center, as defined in Health-General Article, §19-301(p), Annotated Code of Maryland; and

(b) A hospital classified as a general hospital pursuant to Health-General Article, §19-307, Annotated Code of Maryland, may not seek to increase its acute care bed capacity under this subsection.

(3) A Certificate of Need is not required before an acute general hospital located in a jurisdiction with three or more acute general hospitals increases or decreases its bed capacity, if the change:

(a) Occurs on or after July 1, 2000;

(b) Is between hospitals in a merged asset system located within the same health planning region;

(c) Does not involve comprehensive care or extended care beds;

(d) Does not occur earlier than 45 days after a notice of intent to reallocate bed capacity is filed with the Commission; and

(e) Does not create a new health care service through the relocation of beds from one jurisdiction to another jurisdiction pursuant to this subsection.

(4) A Certificate of Need is not required if the increase or decrease in bed capacity is the result of the annual recalculation of licensed bed capacity in acute general hospitals provided under Health-General Article, §19-307.2, Annotated Code of Maryland.

(5) A Certificate of Need is not required to increase or decrease the bed capacity of an existing medical service at an acute general hospital, if:

(a) The total bed capacity of the hospital does not increase;

(b) The change is maintained for at least 1 year, unless modified pursuant to a Certificate of Need or exemption from Certificate of Need approved by the Commission, or the annual recalculation of hospital licensed bed capacity required by Health-General Article, §19-307.2, Annotated Code of Maryland; and

(c) The hospital notifies the Commission at least 45 days before the proposed change in bed capacity of its medical services.

F. A health maintenance organization is not required to obtain a Certificate of Need for a health care project that is planned for and will be used exclusively by the subscribers of that health maintenance organization, other than those set forth in Regulation .02 of this chapter, although notice to the Commission is required. This notice shall consist of the type of the project, location of the project (including street address), a brief description of services to be offered, and an initial estimate of the number of members to be served by the project.

G. A home health agency is not required to obtain a Certificate of Need to open a branch office (previously called a satellite office), as defined by Centers for Medicare and Medicaid Services at 42 CFR §484.2, although notice to the Commission is required.

H. Religious Orders.

(1) A Certificate of Need is not required before a religious order seeks licensure to operate a comprehensive care facility for the exclusive use of members of that religious order.

(2) For the purpose of this section, "religious order" means an incorporated, not-for-profit organization:

(a) That is, or is wholly operated by, an entity founded and operating for the sole purpose of carrying out religious precepts; and

(b) Whose members have taken the vows required by the order and have devoted their lives to religious service, to the exclusion of lay life and activities.

(3) At least 45 days before a religious order submits to the Department a request for licensure for a comprehensive care facility, the religious order shall submit a written request for determination of non-coverage by Certificate of Need review requirements, as described in Regulation .14B of this chapter. The request shall provide the following information:

(a) The name and address of the facility;

(b) The number of beds in the facility;

(c) The name of the religious order that will own and operate the facility;

(d) Assurance that the comprehensive care facility will be owned and operated by the religious order for the exclusive use of its members; and

(e) Agreement to participate in the Maryland Long-Term Care Survey, as authorized by COMAR 10.24.03.

(4) The Commission shall issue a determination under §H(3) of this regulation within 15 working days of receipt of the information required in that subsection.

I. Capital Expenditure.

(1) A Certificate of Need is not required before a health care facility makes a capital expenditure that exceeds the Certificate of Need review threshold for capital expenditures as adjusted for inflation, under the circumstances described in this section.

(2) A Certificate of Need is not required before a health care facility makes a capital expenditure for:

(a) Site acquisitions;

(b) The acquisition of a health care facility, if the provisions of §A of this regulation are met;

(c) Business or office equipment not directly related to patient care, including health care clinical information systems; or

(d) The acquisition and installation of major medical equipment.

(3) A Certificate of Need is not required by a hospital or a nursing home before a capital expenditure for equipment, construction, or renovation that is not directly related to:

(a) Patient care; and

(b) Any change in patient charges or other rates.

J. Hospital Capital Expenditures in Excess of Threshold.

(1) A Certificate of Need is not required by a hospital before it obligates an amount exceeding the review threshold for capital expenditure for physical plant construction or renovation, or before it receives a donated physical plant whose appraised value exceeds the review threshold, under the following circumstances:

(a) The capital expenditure may be related to patient care;

(b) The capital expenditure does not require, over the entire period or schedule of debt service associated with the project or plant, a total cumulative increase in patient charges or hospital rates of more than $1,500,000 for the capital costs associated with the project;

(c) At least 45 days before an obligation is made or the physical plant is donated, the hospital provides notice to the Commission and to the Health Services Cost Review Commission, in the form of a written request for determination of coverage, as provided in Regulation .14B of this chapter, which shall contain the following relevant financial information:

(i) A description of the proposed capital project, including whether it involves new construction, renovation of or additions to the existing physical plant, or the donation of a physical plant, with any necessary adaptations;

(ii) The total capital costs associated with the project;

(iii) The sources and uses of funds to be applied to the project, including hospital equity contributions, if applicable, as documented by audited financial statements of the hospital and relevant subsidiary corporations, if any, from which funds are to be taken;

(iv) A description of the financing arrangement, if applicable, for the proposed project, including the debt service schedule; and

(v) A statement by one or more persons authorized to represent the hospital that the hospital does not require a total cumulative increase in patient charges or hospital rates of more than $1,500,000 for the capital costs associated with the project.

(2) After consultation with the Health Services Cost Review Commission, the Commission shall issue a determination that Certificate of Need review is not required within 45 days after it receives the information specified in this section.

(3) If the Commission has not made the financial determination within 60 days of receipt of the relevant financial information by the Commission and by the Health Services Cost Review Commission, the Commission is considered to have issued a determination of noncoverage.

K. Continuation of Specific Exclusion from Certificate of Need for Continuing Care Retirement Communities.

(1) The number of comprehensive care beds excluded from Certificate of Need requirements and located on the campus of a continuing care retirement community may not exceed:

(a) 20 percent of the number of independent living units at a continuing care retirement community that has 300 or more independent living units;

(b) 24 percent of the number of independent living units at a continuing care retirement community that has fewer than 300 independent living units.

(2) Notwithstanding the provisions of Health-General Article, §19-114(d)(2)(ii), Annotated Code of Maryland, and Regulation .01B(12)(b)(ii) of this chapter, a continuing care retirement community does not lose its exclusion from Certificate of Need when the continuing care community admits an individual directly to a comprehensive care facility within the continuing care community under either of the following circumstances:

(a) Two individuals having a long-term significant relationship are admitted together to a continuing care retirement community and:

(i) The admission occurs after October 1, 1999;

(ii) The admission includes spouses, two relatives, or two individuals having a long-term significant relationship, as defined in Regulation .01B of this chapter and supported by

documentary proof in existence for at least 1 year before application to the continuing care retirement community, admitted at the same time, under a joint contract, who are jointly responsible for expenses incurred under the joint contract; and

(iii) One of the individuals admitted under the joint contract will reside in an independent living unit or an assisted living unit; or

(b) An individual is admitted directly into a comprehensive care bed at a continuing care retirement community and:

(i) The individual must have executed a continuing care agreement and have paid entrance fees that are at least equal to the lowest entrance fee charged by the continuing care retirement community for its independent or assisted living units;

(ii) The individual must pay the entrance fee by the same method, terms of payment, and time frame as a person who immediately assumes residence in an independent or assisted living unit at that continuing care retirement community; and

(iii) The individual admitted to the comprehensive care bed must have the potential for eventual transfer to an independent living unit or assisted living unit at that continuing care retirement community, as determined by the subscriber's personal physician, as defined in Regulation .01B of this chapter.

(3) Under §K(2)(b)(iii) of this regulation, an individual is deemed not to have potential for eventual transfer to an independent living unit or assisted living unit if the individual can qualify for hospice services under federal Medicare regulations or if the individual has an irreversible condition that would make it unlikely that the individual could transfer to an independent living unit or assisted living unit at the continuing care retirement community. Irreversible conditions include quadriplegia, ventilator dependence, and any end-stage condition.

(4) The total number of comprehensive care beds occupied by individuals who are directly admitted to comprehensive care beds pursuant to §K(2)(b) of this regulation may not exceed 20 percent of the total number of licensed and available comprehensive care beds at the continuing care retirement community.

(5) The admission of the individual directly into the comprehensive care bed pursuant to §K(2)(b) of this regulation may not cause the occupancy of the comprehensive care facility at the continuing care retirement community to exceed 95 percent of its current licensed capacity.

(6) Before admitting an individual directly into a comprehensive care bed pursuant to §K(2)(b) of this regulation, the nursing home administrator of the comprehensive care facility at the continuing care retirement community shall keep on file a statement, in a format required by the Commission and signed by the individual's personal physician, that the individual has the potential for eventual transfer to an independent living unit or an assisted living unit.

(7) The nursing home administrator of the comprehensive care facility at each continuing care retirement community who admits an individual directly to a comprehensive care bed under this section shall submit information quarterly to the Commission about each admission. The information shall be submitted within 30 days after the end of the reporting period, in the format required by the Commission and encrypted by the continuing care retirement community so that the individual's identity will not be disclosed. Information submitted by the nursing home administrator shall include:

(a) The number and utilization of licensed comprehensive care beds excluded from Certificate of Need requirements at the continuing care retirement community;

(b) The admission source of each individual admitted pursuant to §K(2)(b) of this regulation to a comprehensive care bed excluded from Certificate of Need requirements at the continuing care retirement community;

(c) For an individual admitted pursuant to §K(2)(b) of this regulation, the amount of and terms of payment for the entrance fee;

(d) The dates of admission and discharge of each individual admitted pursuant to §K(2)(b) of this regulation;

(e) The site to which an individual directly admitted pursuant to §K(2)(b) of this regulation is discharged; and

(f) Any other information as required by the Commission.

(8) A continuing care retirement community that admits an individual to a comprehensive care bed pursuant to §K(2)(b) of this regulation shall maintain documentation required by §K(6) of this regulation and documentation underlying the information submitted under §K(7) of this regulation and make the documentation available to the Commission upon request.

(9) Unless the conditions of §K(2)(a) or (b) of this regulation are met, the provisions of Health-General Article, §19-114(d)(2)(ii), Annotated Code of Maryland, apply; that is, a person may not be directly admitted to a CON-excluded nursing home bed of a continuing care retirement community.

**.04 Exemption from Certificate of Need Review.**

A. Subject to the procedural requirements of this regulation, the Commission may exempt from the requirement of Certificate of Need review and approval the following actions proposed by a health care facility or merged asset system comprised of two or more health care facilities:

(1) Merger or consolidation of two or more hospitals or other health care facilities, if the facilities or an organization that operates the facilities give the Commission 45 days written notice of their intent to merge or consolidate;

(2) Relocation of an existing health care facility owned or controlled by a merged asset system, if:

(a) The relocation is to a site outside the primary service area of the health care facility to be relocated but within the primary service area of the merged asset system; and

(b) The relocation of the existing health care facility does not:

(i) Change the type or scope of health care services offered; and

(ii) Does not require a capital expenditure for its construction that exceeds the capital review threshold, adjusted for inflation, except as provided by Regulation .03I of this chapter;

(3) A change in the bed capacity of an existing health care facility pursuant to the consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a facility to a nonhealth-related use, except as provided in Regulation .03I of this chapter;

(4) A change in the type or scope of the health care services offered by a health care facility, if, at least 45 days before increasing or decreasing the volume of one or more health care services, the Commission in its sole discretion finds that the proposed change is pursuant to the:

(a) Consolidation or merger or two or more health care facilities;

(b) Conversion of all or part of a health care facility to a non-health-related use; or

(c) Conversion of a hospital to a ~~limited service hospital~~freestanding medical facility;

(5) A capital expenditure that exceeds the review threshold for capital expenditure made as part of a consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a facility to a non-health-related use; or

(6) The closure of an acute general hospital or part of a hospital, in a jurisdiction with fewer than three acute general hospitals.

B. A complete notice of intent to seek exemption from Certificate of Need review shall be filed with the Commission at least 45 days before the intended action, and shall include:

(1) The name or names of each affected health care facility;

(2) The location of each health care facility;

(3) A general description of the proposed project including, in the case of mergers and consolidations, any proposed:

(a) Conversion, expansion, relocation, or reduction of one or more health care services;

(b) Renovation of existing facilities;

(c) New construction;

(d) Relocation or reconfiguration of existing medical services; or

(e) Change in bed capacity at each affected facility;

(4) The scheduled date of the project's completion;

(5) Identification of any outstanding public body obligation; and

(6) Information demonstrating that the project:

(a) Is not inconsistent with the State Health Plan;

(b) Will result in more efficient and effective delivery of health care services; and

(c) Is in the public interest.

C. Notice by the Commission to the Public, Elected Officials, and Other State Agencies.

(1) Within 5 days after it receives a complete Notice of Intent from a health care facility seeking exemption from Certificate of Need review, the Commission shall publish meaningful notice of its receipt, including but not limited to the following: ~~in~~:

(a) The commission's website

(b) At least one newspaper of daily circulation in the affected area; and

(~~b~~c) The next available issue of the Maryland Register.

(2) The Commission shall ~~mail the same notice to~~notify the elected public officials in whose district or jurisdiction the exemption from Certificate of Need review is proposed.

(3) The Commission shall solicit comment and relevant information from the affected public, in evaluating whether the action or project proposed for exemption from Certificate of Need review is in the public interest.

(4) If a hospital that intends to close or to convert to a ~~limited service hospital~~freestanding medical facility has outstanding public body obligations issued on its behalf, written notification of intended closure or conversion shall be given to the Maryland Health and Higher Educational Facilities Authority and the Health Services Cost Review Commission by the:

**Commented [MB9]:** Suggested language change to allow appropriate flexibility in exemption consideration.

(a) Commission, within 5 days after receiving a written notification by the hospital of intended closure or conversion, that it has received the hospital's notification and begun its review of the information provided pursuant to §B of this regulation;

(b) Hospital, within 10 days of filing with the Commission its written notification of intended closure or conversion, along with a written statement of any public body obligations issued on behalf of the hospital that provides the information required by Article 43C, §16A(g), Annotated Code of Maryland; and

(c) Commission, not later than 150 days before the scheduled date of the hospital's closure, that it has made the finding required by §E of this regulation.

Commented [MB10]: Review timeline with all regulatory requirements

D. Public Informational Hearing.

(1) Within 30 days of filing a notice of intent to seek exemption from Certificate of Need review, a public informational hearing shall be held in the jurisdiction where an acute general hospital or a State hospital is located that intends to:

(a) Close or partially close, if the hospital is located in a jurisdiction with fewer than three acute general hospitals; or

(b) Convert to a ~~limited service hospital~~freestanding medical facility.

(2) Before holding the public informational hearing, the hospital shall consult with the Commission, to ensure that:

(a) Within 5 days of notifying the Commission of its intent to close, the hospital has provided public notice of the proposed closure and of the time and location of the required public informational hearing, including publication in at least one newspaper of daily circulation in the affected area; and

(b) Information will be presented at the public hearing regarding continued access to acute care or other services in the affected area, and plans of the hospital, or the merged asset system that owns or controls the hospital, for retraining and placement of displaced employees and reuse of the physical plant.

E. The Commission shall issue a determination of exemption from Certificate of Need review to the health care facility or the merged asset system seeking this determination within 45 days after it receives the notice of intent required by §B of this regulation, if:

Commented [MB11]: Review timeline with all regulatory requirements.

(1) The facility or system has provided the information required by the notice of intent, and has held a public informational hearing if required by §D of this regulation; and

(2) The Commission, in its sole discretion, finds that the action proposed:

(a) Is in the public interest;

(b) Is not inconsistent with the State Health Plan or an institution-specific plan developed by the Commission under Health-General Article, §19-122, Annotated Code of Maryland; and

(c) Will result in more efficient and effective delivery of health care services aligning with Maryland's Total Cost of Care Model.

**.05 Ambulatory Surgical Facilities: Determination of Coverage and Data Reporting.**

A. Determination of Coverage by Certificate of Need.

(1) Determination of Coverage. A Certificate of Need is not required for any center, service, office, facility, or office of one or more health care practitioners or a group practice, as defined in Health Occupations Article, Title 1, Annotated Code of Maryland, if the entity does not have more than ~~one~~ two operating rooms.

(2) Change in Location. A determination of coverage letter for an office with ambulatory surgery capacity is issued only for the exact address specified. A change in address before the office is built, developed, or established requires a new determination of coverage.

(3) Change in Ownership. A determination of coverage letter for ambulatory surgery capacity is issued only for the person specified. A new determination of coverage will be required if the principal owner or a majority of other owners changes.

(4) Expiration Date of Coverage Determination Letter. A determination of coverage letter for new freestanding ambulatory surgical capacity is effective for 2 years from the date of the letter. If that capacity is not built, developed, or established within 2 years, that letter of determination is void.

(5) Notice.

(a) Before seeking to establish a new operating room or rooms, or making any change in the information provided for initial determination of coverage by Certificate of Need, a person shall provide notice to the Commission at least 45 days in advance.

(b) The notice shall include the intended start-up date of the proposed ambulatory surgical services at the specified location.

(c) The notice shall provide the following information:

(i) The name and address of the entity seeking to provide ambulatory surgical services, and the location where these services will be provided;

(ii) A statement that the operating room or rooms will meet the requirements relating to quality of care and patient safety necessary to obtain Medicare certification or State licensure, whichever is appropriate, for life and fire safety, control of infection, quality assessment and improvement, patient transfer, credentialing, and medical record keeping, with documentation of

having received licensure or certification, as appropriate, to be submitted in the next annual data survey conducted by the Commission;

(iii) The number of operating rooms at the location, and a drawing or plans showing the location and dimensions of each proposed operating room and other rooms in the office;

(iv) The names of each person and organization with an ownership interest in the entity, and its officers, directors, partners, and owners;

(v) The names of any other ambulatory surgical facilities in which individuals listed in response to §A(5)(c)(iv) of this regulation have an interest or other economic relationship, as an officer, director, partner, member, or owner;

(vi) A listing of each other ambulatory surgical facility at the same address;

(vii) Contractual relationships to provide ambulatory surgical services between the entity and other health care facilities or health care providers who are not employees of the entity, or exercise only medical practice privileges at the location; and

(viii) The names and specialties of each health care practitioner who will perform surgical services at the facility and the general types of surgery to be performed there.

(6) For purposes of this regulation, all centers, services, offices, facilities, or offices of one or more health care practitioners or a group practice primarily providing ambulatory surgical services that are located in the same building and that share any common ownership or control shall be considered one entity, and their operating rooms shall be considered together for purposes of determining coverage under Regulation .02 of this chapter, or this regulation.

~~(7) The office of one or more health care providers or a group practice performing ambulatory surgical services with two operating rooms may be exempt from Certificate of Need requirements if the Commission, in its sole discretion, determines that:~~

~~(a) A second operating room is necessary to promote the efficiency, safety, and quality of the surgical services offered; and~~

~~(b) The office meets the criteria for exemption from Certificate of Need review as an ambulatory surgical facility set forth in the State Health Plan under COMAR 10.24.11.~~

**Commented [MB12]:** This section is no longer relevant because two operating rooms are allowable under the ASF regulation.

(8) Except as provided in this regulation or permitted in the Certificate of Need or exemption criteria in the State Health Plan under COMAR 10.24.11, an ambulatory surgical facility or other entity primarily providing ambulatory surgical services may not relocate beyond an adjacent site or expand its number of operating rooms after June 1, 1995, without obtaining a Certificate of Need.

(9) A Certificate of Need is not required for ambulatory surgical services provided as part of an office of one or more individuals licensed to practice dentistry under Health-Occupations Article, Title 4, Annotated Code of Maryland, for the purpose of practicing dentistry, if the ambulatory surgical facility is not used in a medical practice other than dentistry.

B. Data Reporting and Annual Survey of Ambulatory Surgical Facilities and Providers.

(1) To provide information for the Commission's planning purposes and to determine changes in circumstances and operation that may affect coverage by Certificate of Need requirements, existing providers in offices or facilities primarily providing ambulatory surgical services shall provide annually to the Commission the information required by COMAR 10.24.04.

(2) A person providing ambulatory surgical services who is required to obtain a license under Health-General Article, §19-3B-02(a), Annotated Code of Maryland, shall annually provide the required information on a form provided by the Commission.

(3) The information to be provided includes the following:

(a) The information listed in §A(5) of this regulation, only if there have been any changes in this information during the reporting period;

(b) Cost, charge, and reimbursement data, including the amount of care reimbursed by Medicaid and Medicare, and the amount of uncompensated care provided by the entity;

(c) Utilization data, including types of procedures;

(d) Operating policies, including hours of operation;

(e) Patient-specific or patient-aggregate data, including demographic data, reimbursement source and levels, and patient disposition data; and

(f) Staffing requirements and patterns.

(g) Measures of service quality and outcomes consistent with Medicare requirements

(h) The number of patients and percentage of the facilities patients transferred to a general hospital

**.06 Access to Information and Facilities.**

To the extent permitted by law, an applicant shall provide access to general information, records, plans and specifications, meetings, sites, and facilities to the Commission upon proper notice and as is reasonable and necessary in the performance of the Commission's responsibilities. The Commission may require other providers of health care to provide similar information, to the extent permitted by law.

**.07 Application Required for Certificate of Need Review.**

A. Application Form.

(1) A proposed new health care facility or health maintenance organization, or an existing health care facility or health maintenance organization planning a change covered by these regulations or by State law, shall submit a formal application for Certificate of Need, in the form and manner prescribed by the Executive Director. The nature and extent of information required may vary according to the type or scope, or both, of the proposed project or services.

(2) The Commission publishes separately from these regulations the application forms to be used for various categories of projects, and these application forms may be revised periodically. However, an application is not complete unless the applicant has provided to the Commission all surveys required of the applicant by the Commission through regulation.

**Commented [MB13]:** The hospital field is submitting proposed revisions to the hospital application form.

(3) An applicant may petition the Commission, showing good cause why a survey required by the Commission through regulation has not been provided. The Commission shall docket the application as complete if it determines that good cause has been shown and the application is otherwise complete.

B. Submission to the Commission. A formal application for a Certificate of Need, or any information provided by an applicant in support of an application in accordance with Regulations .08—.10 of this chapter, shall be submitted to the Commission's Health Facilities Coordination Office.

C. Letter of Intent.

(1) A prospective applicant for a Certificate of Need shall submit to the Health Facilities Coordination Office a brief letter of intent, with a copy to each local health department in the health planning region. The Health Facilities Coordination Office shall formally log all letters of intent, upon receipt.

(2) The letter of intent shall include the following information:

(a) The identity of each person on whose behalf the letter of intent is filed, including:

(i) The name and address of each such person; and

(ii) In the case of a letter of intent filed on behalf of a person that is not a natural person, the date the entity was formed, the business address of the entity, and the identity and percentage of ownership of all persons having an ownership interest of 5 percent or more in the entity;

(b) A description of the proposed project;

(c) The quantity and types of beds or health services involved; and

(d) The specific location and each jurisdiction in which services will be provided, according to the relevant planning region in the State Health Plan for that facility or service.

(3) Letters of intent are valid for 180 days. If, at the end of 180 days from receipt of the letter of intent by the Health Facilities Coordination Office, an application for Certificate of Need has not been filed, the letter of intent is void.

(4) Upon docketing of an application, the letter of intent for that project is no longer valid for purposes of comparative review, as set out in Regulations .08—.10 of this chapter.

(5) The letter of intent shall be received by the Health Facilities Coordination Office not less than 60 days before the submission for docketing of a Certificate of Need application for the project. An application submitted before either the scheduled date for the submission of applications under Regulation .08A of this chapter or 60 days from the receipt of the required letter of intent may, at the discretion of the Commission, be held in abeyance and not formally reviewed until the next applicable review period.

(6) A prospective applicant may request that the Executive Director waive the 60-day waiting period before an application may be submitted, as provided in §C(5) of this regulation.

(7) If a letter of intent is submitted for a proposed health care project which might be comparable to a project application which has been submitted but not yet docketed, the 60-day period may not be waived. If the project proposed in the letter of intent and the project proposed in the application are determined to be comparable by the Commission, the projects shall be given a comparative review.

(8) If an applicant requests that the 60-day period be waived, the applicant shall agree that if a subsequent letter of intent for a similar health care project is filed within the period of time between submission of the applicant's application and the end of the 60-day period described in §C(5) of this regulation, the docketing of the applicant's project shall be suspended, and the comparative review shall be triggered in accordance with Regulation .08A(2) of this chapter.

(9) If a person submits a letter of intent for a proposed health care project that might be comparable to an application which has already been docketed, the Commission may not grant a waiver of the 60-day period and a comparative review may not be conducted.

(10) Letters of intent are subject to public inspection during normal business hours.

D. The Applicant.

(1) If a proposed facility would require licensure after Certificate of Need approval, the applicant is the person or persons who will be the licensee as specified in Health-General Article, §19-318 et seq., Annotated Code of Maryland. A person may file a letter of intent and an application in the person's own name, and, before docketing, designate an alternate legal entity that the person owns or controls as the intended licensee.

(2) Health care facilities or health maintenance organizations participating in the health care project are identified as co-applicants.

(3) One or more persons shall be officially authorized to sign for and act for the applicant for the specific project.

E. Preapplication Conference. After the filing of a letter of intent or as scheduled under Regulation .08A(2) of this chapter, the Commission staff shall arrange to meet with each person who filed a letter of intent to discuss:

(1) Commission procedures for reviewing the application or applications;

(2) Information and data to be included in the application or applications;

(3) The State Health Plan requirements that may affect the project; and

(4) Other matters relevant to the filing and processing of the application or applications.

F. The discussions in §E of this regulation are informal, and statements at the meetings are not admissible as evidence at a Commission proceeding.

**.08 Procedure for Review of Applications.**

A. Review Schedule.

(1) An application shall be submitted in accordance with the published review schedule established by the Commission in accordance with §D(1) of this regulation, but if no review schedule has been published for a service, an application may be submitted 60 days after the filing of the letter of intent, unless a shorter period has been approved by the Executive Director.

(2) An application for which a review is scheduled may only be reviewed according to that schedule.

(3) If the Commission has not published a schedule for Certificate of Need review for a specified service, and the current State Health Plan does not preclude new capacity for that service in the relevant planning region, a letter of intent may be submitted at any time for that service. Notice shall be placed in the Maryland Register, and a 30-day period initiated for the submission of any other letters of intent for the same service in the same planning region to be included in the same review.

(4) In a case when need for additional service capacity is projected, the Commission may not docket an application until it has made a final decision on each previously docketed application for a similar project.

B. Submission of Application.

(1) An application shall be submitted to the Health Facilities Coordination Office in accordance with the schedules set forth in §D(1) of this regulation.

(2) The application, and all information supplementing the application, shall be signed by at least one principal of the applicant, who shall sign a statement as follows: "I solemnly affirm under penalties of perjury that the contents of the application (or the supplementary information) are true to the best of my knowledge, information, and belief."

(3) At the time of filing an application for a Certificate of Need or a modified application, an applicant shall submit six copies of the application to the Commission, unless the Commission requests that additional copies be filed, and shall send one copy to each other applicant in the review, to the local health department in each affected jurisdiction, and to any other person designated by the Commission, and shall certify delivery of the copies in writing to the Commission within 5 working days of the filing of the application with the Commission.

C. Completeness Review and Docketing.

(1) Within ~~10~~ 15 business days of the filing of an application, the staff shall review the application for completeness to determine whether an application may be docketed for review.

(2) The staff shall schedule with the applicant an application review conference within the ~~10~~15-business day period for completeness review.

(3) The staff shall determine whether the application contains all the information required. Staff's requests for additional relevant information that is necessary to ensure that the application is complete shall specify in writing the information requested, and, shall reference the specific commission standard cited in requesting the additional information, which shall be submitted within ~~10~~ 15 business days. Additional information may be requested by staff beyond that required to make the application complete, which shall also be subject to a time limit for the applicant to supply the requested information. Requests for additional information and submission of additional information shall not automatically affect the required timeline for commission action on an application.

(4) If the staff's review of the application determines that the application is complete and conforms with the applicable docketing rules in the State Health Plan, staff shall docket the application for review as of the next available publication date of the Maryland Register.

(5) If an applicant fails to supply the required information within the specified time limit, staff may dismiss and return the application and proceed with the review. Staff may, at its discretion, extend the response time for an applicant in a noncomparative review, or, with the consent of all applicants, for an applicant in a comparative review, for up to an additional 10 business days.

(6) The reviewer, staff, or the Commission may request information from applicant during the course of the review and set reasonable time limits for the applicant to respond. Requests for

additional information and applicant responses should not automatically affect the required timeline for commission action on an application.~~:~~

~~(a) Request information from the applicant supplementing an otherwise complete application at any time during the review of an application; and~~

~~(b) Set reasonable time limits for the applicant to supply the requested information.~~

D. Notice to the Public.

(1) At least once each year, the Commission shall post on its website and publish in the Maryland Register, a schedule for conducting reviews of applications for designated services by health planning region, as follows:

(a) The schedule shall include the status of applicable need forecasts found in the State Health Plan or published elsewhere as required by the State Health Plan for conducting the reviews of the designated services by health planning region;

(b) The schedule shall establish application submission dates not sooner than 3 months following the publication of the proposed schedule; and

(c) The schedule shall identify scheduled reviews by health planning region and shall state the dates for the receipt of letters of intent, and for the simultaneous submission of applications.

(2) Within 10 business days, the Commission shall request that the Maryland Register publish notice of the receipt of an application and, when the application is complete, its docketing. The Commission shall also publish notice on its website and in a newspaper of general circulation in the area of the proposed project. This notice shall include:

(a) A citation to the Commission's enabling act and these regulations, the name of the applicant, the matter or docket number, and a general description of the project containing the information required in letters of intent;

(b) An explanation that a person who meets the definition of "interested party" in Regulation .01B of this chapter may become an interested party to the review of this application by submitting written comments on the application within 30 days of its docketing; and

(c) A statement that a person may request in writing that the Commission advise them of further notices of the proceedings on the application, and that any further notice of proceedings will only be sent to persons who have submitted a written request.

(3) If an evidentiary hearing is held in accordance with Regulation .10D of this chapter, the Commission shall provide notice to each person who has requested to be apprised of further proceedings on the application. The notice shall include a:

(a) Reference to the authority under which the hearing is to be held and the rules of procedure for the holding of an evidentiary hearing; and

(b) Statement that any person may attend the hearing.

E. Modifications to Letters of Intent and Applications.

(1) An applicant shall give written notice to the Health Facilities Coordination Office of any modifications to the applicant's letter of intent before submitting an application.

(2) An application may be modified until the 45th day after docketing or as a result of a project status conference held pursuant to Regulation .09A(2) of this chapter. After the 45th day,

(a) A~~a~~ modification to an application in a comparative review not made as the result of a project status conference requires the consent of each applicant; and

(b) ~~–~~In a noncomparative review, modifications to an application to reduce capital or operating costs, reduce annual projected revenue, reduce the level or number of beds and services requested, or to respond to relevant changes in the State Health Plan review criteria, policies, or need projections, are permitted at any time.

(3) If, in a noncomparative ~~review,~~ review, to which there are no interested parties, application considered approved if no staff recommendation at the 90th day, unless agreed upon by the applicant. ~~T~~

(~~3~~4) If an application is modified:

(a) The Commission shall provide:

(i) Notice of the changes by a dated posting on the Commission's website and in a newspaper of general circulation in the affected jurisdiction; and

(ii) A 10-business day period following the website posting for comments on the changes; and

(b) Each applicant in the review will be deemed to have waived the right to a final decision by the Commission within the statutorily prescribed time.

(54) Changes to those portions of an application referring to facilities and services that are not subject to Certificate of Need review are not considered a modification to an application.

(~~5~~6) The following modifications to a proposed project require a new Certificate of Need application:

(a) Changes in the fundamental nature of a facility or the services to be provided; or

(b) Increases in the total licensed bed capacity beyond that permitted by Health-General Article §19-307.2, Annotated Code of Maryland, or medical service categories.

F. Comments by a Person Seeking Interested Party Status or by a Participating Entity and Applicant's Response.

(1) Written Comments by a Person Seeking Interested Party Status.

(a) A person seeking interested party status shall file written comments on an application within 30 days of docketing.

(b) The comments shall include information that the interested party wishes the Commission to consider in reviewing an application.

(c) If a person seeking interested party status is opposing an application, the comments shall state with particularity the State Health Plan standards or the review criteria in §G of this regulation that the person seeking interested party status believes have not been met by the applicant and the reasons why the applicant does not meet those standards or criteria.

(d) Factual assertions made in comments by a person seeking interested party status that are not included in the record shall be accompanied by appropriate documentation or sworn affidavit, or both.

(e) In a review with only one applicant, the comments shall be 25 pages or fewer, double-spaced, excluding attachments.

(f) In a comparative review, the comments shall be 35 pages or fewer, double-spaced, excluding attachments.

(2) Written Comments by a Person Seeking Participating Entity Status.

(a) A person seeking participating entity status shall file written comments on an application within 30 days of docketing that:

(i) Include information that the participating entity wishes the Commission to consider; and

(ii) State with particularity the State Health Plan standards or review criteria in §G of this regulation that it believes have not been met by the applicant, and the reasons why the applicant does not meet those standards or criteria.

(b) A person granted participating entity status shall be copied on Commission documents in the review of the application.

(c) A person granted participating entity status shall have its comments on an applicant's conformance with State Health Plan standards and review criteria considered and analyzed by a reviewer in a proposed decision or by Commission staff in a staff report to an application.

(3) Response to Comments.

(a) An applicant is permitted to make one written filing responding to all written comments on its application within 15 business days of receipt of those comments.

(b) The response may not be more than 25 pages, double-spaced, excluding attachments.

(c) In a comparative review, the comments may not be more than 35 pages, double-spaced, excluding attachments.

(d) Factual assertions that are made in an applicant's response and are not included in the record shall be accompanied by appropriate documentation or sworn affidavit, or both.

G. Criteria for Review of Application.

(1) In proceedings on a Certificate of Need application, the burden of proof that the project meets the applicable criteria for review, by a preponderance of the evidence, rests with the applicant.

(2) Issuance of a Certificate of Need by the Commission. In reviewing an application for a Certificate of Need, the Commission shall consider the applicant's submissions, the responses of each other applicant and interested party, the recommendation, if any, of the local health department, and the information gathered during the Commission's review of the application, to which each applicant and interested party shall have been afforded an opportunity to respond.

(3) Criteria for Review of an Application for Certificate of Need.

(a) State Health Plan. An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

(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.

(c) ~~Availability of More Cost-Effective Alternatives~~Cost Effectiveness and the All Payer Model. ~~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.~~Applicant shall present information to support why the project is cost effective and how the project aligns with the goals of the All-Payer Model.

(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.

~~(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.~~

(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~~utilization, on costs and charges of other providers, and on costs to the health care delivery system.

**.09 Commission Decision and Action on Applications.**

A. Proposed Decision.

(1) Preparation of Proposed Decision.

(a) In a noncomparative review in which no interested party has submitted written comments opposing an application, or in a review in which no evidentiary hearing is held in accordance with Regulation .10D of this chapter, the staff shall review the application and prepare a staff report and recommendation.

(b) In all other reviews, the Executive Director shall appoint a ~~single~~ Commissioner and alternate Commissioner, who may be assisted by the staff of the Commission, to act as reviewer.

(2) Project Status Conference.

(a) The reviewer or staff, as appropriate, may request that a project status conference be held before the issuance of a proposed decision or staff report, to apprise each applicant, interested party, and participating entity of those aspects of a proposed project that appear to be inconsistent with applicable standards and review criteria.

(b) Following the project status conference, the reviewer or staff will send each applicant, interested party, and participating entity a summary of the project status conference that includes dates, as needed, for additional filings.

(c) The applicant shall send to each interested party and participating entity a copy of proposed project changes made pursuant to the project status conference.

(d) Each interested party and participating entity in the review of an application shall have 7 days to file comments on the proposed changes made pursuant to the project status conference.

(3) Opportunity to Present Oral Argument. Each applicant and interested party may request the opportunity to present oral argument to the reviewer before the reviewer prepares a proposed decision on the application for consideration by the full Commission, as follows:

(a) The request shall be made within the time period for an applicant's response to comments under Regulation .08F(2) of this chapter;

(b) The decision to grant oral argument is at the sole discretion of the reviewer;

(c) The reviewer may set reasonable time limits for oral argument; and

(d) The reviewer may, if there is a genuine dispute as to the credibility of a material witness on a matter of fact, require the witness to answer questions on that matter under oath during the oral argument portion of a Certificate of Need review.

(4) The proposed decision shall state the reviewer's determination as to whether:

(a) Each relevant State Health Plan standard or review criterion set forth in Regulation .08G of this chapter:

(i) Is met by the applicant,

(ii) Is not applicable to the project, or

(iii) Is applicable to the project and is not met by the applicant;

(b) In a comparative review, one or more of the projects should be preferred under a State Health Plan standard or criteria either as a result of meeting a preference standard or because an applicant complied with one or more criteria in a superior way relative to another applicant; and

(c) To recommend that a project or projects be granted a Certificate of Need.

B. Exceptions.

(1) Each applicant and interested party who has submitted written comments under Regulation .08F(1) of this chapter may submit written exceptions to a proposed decision and order by submitting written argument and supporting documentation from the record.

(2) Schedule.

(a) Upon issuance of a proposed decision, Commission staff shall issue a notice specifying the schedule for the submission of exceptions and any response, and the date on which the Commission shall hear oral argument on the exceptions.

(b) Unless otherwise agreed by each applicant and interested party, the schedule issued by Commission staff shall specify that exceptions shall be filed at least 15 days before the Commission meeting at which the proposed decision and order will be considered, and any response to the exceptions filed at least 10 days before the Commission meeting, except that a party filing exceptions has at least 7 days to file exceptions, and a party filing a response to exceptions has at least 5 days to file a response. The Commission staff may shorten these periods by agreement of the parties, or extend any deadlines set for good cause shown.

(3) Written exceptions shall specifically identify each finding and conclusion to which exception is taken, citing those portions of the record on which each exception is based.

(4) Oral arguments before the full Commission concerning the proposed decision are limited to 10 minutes per applicant and 10 minutes per interested party, unless extended by the Chairman of the Commission.

C. Participation By Participating Entity In Certain Reviews After Issuance of a Staff Report or Reviewer's Proposed Decision.

(1) Participating Entity Request to Address the Commission.

(a) In a project upon which it timely filed comments on an applicant's conformance with State Health Plan standards and review criteria, and after the issuance of a staff report or a reviewer's proposed decision, and at least 3 days before the scheduled Commission meeting that will consider an application, a participating entity may notify the Commission that it desires to address the Commission before Commission action on the application, specifying the points that it wants to make.

(b) The Chairman of the Commission, after consultation with the executive director, may permit a participating entity, or combination of participating entities, to make an oral presentation to the Commission on matters it addressed in written comments on the application.

(c) At least 1 day before the scheduled Commission meeting that will consider an application, the executive director shall advise each applicant, interested party, and participating entity in a review whether the Chairman will permit a participating entity or combination of participating entities, to make an oral presentation to the Commission, and shall specify the format of the presentation.

(2) An applicant may address the Commission in any review in which a participating entity is granted permission to address the Commission before action on an application.

(3) This section does not:

(a) Confer interested party status or aggrieved party status upon a participating entity; or

(b) Grant a participating entity the right to judicial appeal under State Government Article, Title 10, Annotated Code of Maryland.

D. Final Decision.

(1) The Commission shall issue a final decision based on the record of the proceeding. The final decision shall take one of the following two forms:

(a) A statement of exceptions that have been accepted, if any, and a statement that the proposed decision is adopted into the final decision except as otherwise noted; or

(b) A new final decision in the format for proposed decisions, as specified in §A(3) of this regulation.

(2) The Commission's decision shall do one of the following:

(a) Approve the application;

(b) Approve the application with conditions; or

(c) Deny the application.

(3) The decision of the Commission shall be by a majority of the quorum present and voting.

E. Action on the Application.

(1) The Commission shall act on an application for a Certificate of Need not later than 150 days after the application has been docketed. If no evidentiary hearing is held, the Commission shall act on an application within 90 days after the docketing of the application. As a standing item on the public meeting agenda, ~~S~~staff shall report to the Commission the status of all projects where a staff report is not issued for Commission action within 90 days, and the status of all applications acted upon that are under judicial review.

(2) The Commission shall notify the applicant and the local health department, and post on its website, of one of the following determinations:

(a) The project is granted a Certificate of Need;

(b) The project is granted a Certificate of Need with specific conditions; or

(c) The project is not granted a Certificate of Need.

(3) The decision of the Commission shall include findings of fact and conclusions of law.

(4) The decision of the Commission shall be by a majority of the quorum present and voting.

(5) The decision shall be in writing and shall state the reasons and grounds for the Commission's decision.

(6) The Commission may not render a final decision until:

(a) A proposed decision, including findings of fact and conclusions of law, has been served upon each party; and

(b) Each party adversely affected by the proposed decision has been given an opportunity to file exceptions and present oral argument before the Commission.

F. Judicial Review.

(1) The Commission's final decision is subject to the judicial review under State Government Article, Title 10, Annotated Code of Maryland.

(2) In order to take a judicial appeal, an interested party must be an aggrieved party.

(3) For purposes of judicial review, the record of the proceeding shall include:

(a) The application;

(b) Requests for additional information from the reviewer, the Commission, or Commission staff, and responses to them;

(c) Comments received from each interested party, and supporting documentation, affidavits, and responses from each applicant;

(d) Reports or recommendations from staff;

(e) Motions and pleadings;

(f) The prehearing conference report, if any;

(g) Prefiled testimony, if any;

(h) A recording or transcript of any hearing;

(i) The reviewer's proposed decision, and all exceptions and responses to exceptions; and

(j) The Commission's final decision.

(4) A decision of the Commission is a final decision for purposes of judicial review.

(5) A request for reconsideration in accordance with Regulation .19 of this chapter will stay the final decision of the Commission for purposes of judicial review until a decision is made on the reconsideration.

**.10 Miscellaneous Rules and Procedures.**

A. Filing of Documents with the Commission.

(1) In computing a period of time prescribed by these regulations, by order of the Commission, or by an applicable statute, the day of the action or default initiating the designated period of time is not included. The last day of the period so computed is to be included unless it is a day on which the office of the Commission is closed, in which event the period extends until the next day on which the office of the Commission is open.

(2) At the discretion of the reviewer, the Executive Director, or the Executive Director's designee, and upon a showing of substantial reasons by the submitting party, a period of time to submit a document or perform any act permitted or prescribed by these regulations may be extended for a reasonable period of time. This period of time shall be specified, and may add to the 90 day / 150 day time limit specified in regulation 10.24.01.09E.

(3) In all matters before the full Commission, filings may not be made directly to individual commissioners except at the direction of the reviewer, the Executive Director, or the Executive Director's designee.

B. Motion Practice.

(1) A motion shall be made in writing, except when made at a hearing or prehearing conference in accordance with Regulation .11 of this chapter, and shall state concisely the question which the Commission is called upon to determine, or the action the movant desires the Commission to take. It shall state all reasons, authorities, and citations in the body of the motion or in a supporting memorandum.

(2) A motion made in response to a determination by the Commission or its staff shall be filed within 20 days of the determination to which the motion responds.

(3) The following actions shall be taken by motion:

(a) A demand for an action which the movant desires the Commission, the reviewer, or the staff of the Commission to take;

(b) A request for reconsideration, under Regulation .19 of this chapter;

(c) An objection to the introduction of a statement or other evidence by a party during an evidentiary hearing held under Regulation .11 of this chapter;

(d) A challenge to a reviewer or other member of the Commission;

(e) An action that might be initiated properly or undertaken by a party to a review, and that is not otherwise provided for in these regulations; and

(f) Any other question that is justiciable.

(4) A motion need not be verified unless it is based on facts not apparent from the record or documents filed in the proceeding.

(5) A party to the hearing may file one written answer to a motion, in the same format required of motions.

(6) The reviewer, or, in a matter in which no reviewer has been appointed, a commissioner appointed as motions officer by the Executive Director, may hear oral argument on the motion at the request of a party.

C. Summary Decision.

(1) At any time after an application is docketed, staff may file a motion for summary decision to deny a docketed application if the proposed project is inconsistent with one or more standards of the State Health Plan that make the project unapprovable.

(2) The motion shall identify the grounds for the motion and the staff's position and argument. The motion need not address every State Health Plan standard. The affected applicant has the opportunity to respond to the motion in writing.

(3) If staff is reviewing the application, as specified in Regulation .09A(1)(b) of this chapter, a quorum of the full Commission shall decide the motion.

(4) If a commissioner is acting as reviewer, that commissioner shall decide the motion, subject to review by the full Commission. An affected applicant has 10 days to respond to the motion in writing and, at the applicant's request, to present oral argument to the reviewer before the reviewer rules on the motion.

D. Evidentiary Hearing.

(1) At the request of an interested party in a Certificate of Need review, an evidentiary hearing may be held on any Certificate of Need application for the construction of an acute general or special hospital.

(2) An evidentiary hearing may not be held on an application for an ambulatory surgical facility or new or expanded ambulatory surgical capacity in a setting owned or controlled by a hospital.

(3) If an applicant requests a hearing to show cause why a Certificate of Need should not be withdrawn, the Commission shall hold an evidentiary hearing before it withdraws a Certificate of Need, under Regulation .12 of this chapter.

(4) The Commission may hold an evidentiary hearing in a Certificate of Need review for a proposed new facility or service if, in the judgment of the reviewer, an evidentiary hearing is appropriate due to the magnitude of impact the proposed project would have on the existing

health care system, by meeting the requirements of this subsection and of §D(5) of this regulation. The project, if approved, would result in one of the following:

(a) A significant increase in public costs, or in costs and charges paid by a substantial number of patients and third-party payors;

(b) A significant decrease in the availability and overall quality of health care services in the affected area in a manner not consistent with policies or need projections set forth in the State Health Plan, such as by causing a loss of reasonable access to an essential medical service by a substantial number of patients;

(c) An additional demand on limited resources available to support health care facilities or medical services in a proposed service area that has existing budgetary and competitive constraints, such as a high penetration of managed care, or a high level of existing excess capacity; or

(d) Any impact that the reviewer concludes may be sufficiently serious to merit an evidentiary hearing.

(5) An evidentiary hearing will assist the reviewer in resolving questions of material fact or witness credibility.

(6) Request for Evidentiary Hearing.

(a) Each applicant and interested party may request that the reviewer conduct an evidentiary hearing on a proposed project by the 45th day after docketing, or within 30 days of a modification of an application in a review.

(b) The reviewer may hear oral arguments from any party on the question of whether to conduct an evidentiary hearing.

(c) An interested party may appeal an adverse ruling on this question by motion to the full Commission at its next regular meeting.

(7) The evidentiary hearing shall be conducted in accordance with Regulation .11 of this chapter.

E. Ex Parte Contacts. After the docketing of an application and until the Commission renders its decision under this regulation, the ex parte provisions of the Administrative Procedure Act, State Government Article, Title 10, Annotated Code of Maryland, apply.

F. Local Health Department Review and Comment.

(1) The Commission shall seek information and comment from each local health department in the health planning region in which a proposed project may be located, and consider any response from the local health department in making a final decision on an application.

(2) The Commission shall consider a positive recommendation of the local health department to be one measure of community support for a proposed project. If a local health department makes a recommendation on a specific project, and the Commission's decision differs from that proposed by the local health department, the Commission shall make a written, detailed explanation as to the basis for the difference to the local health department.

G. Required Approvals. Unless the Commission finds that the facility or service for which the proposed expenditure is to be made is not needed or is not consistent with the State Health Plan, the Commission shall approve an application for a Certificate of Need to the extent that the capital expenditure is made to eliminate or prevent an imminent safety hazard, as defined by federal, State, or local fire, building, or life safety codes or regulations, to comply with State licensing standards, or to comply with the accreditation standards for reimbursement under Title XVII of the Social Security Act or under the State Medical Assistance Program approved under Title XIX of the Social Security Act.

H. Notice of Certificate of Need Approval.

(1) Notice that a facility or project has been granted a Certificate of Need shall be posted on the Commission's website within 30 days~~,~~ and ~~made in writing~~provided by the Commission to those agencies responsible under the licensure program, and other agencies that may have interests or regulatory responsibilities related to the Commission's decision on the project.

(2) The notice shall be given at the same time that notice is given to each applicant, interested party, and the local health department.

(3) The notice of Certificate of Need approval shall contain the following information:

(a) The nature and scope of the approved health service or facility, described in suitable detail;

(b) The actual capital costs associated with the approved project, to include construction, equipment acquisition (whether by purchase or lease), architects' and consultants' fees, and all other costs, other than financing costs, to be incurred by the applicant in order to complete the project;

(c) The total principal amount of funds to be borrowed, if any, and a description of the terms of the financing mechanism through which this borrowing will be accomplished; and

(d) Each condition associated with the project approval.

I. Changes to an Approved Project. If an applicant proposes to make changes to an approved project, the applicant shall notify the Commission of the proposed change in accordance with the procedure established in Regulation .17 of this chapter.

J. Participation of Staff. The reviewer may seek the assistance of any member of the Commission staff in preparing a proposed decision.

**.11 Evidentiary Hearings.**

A. General.

(1) Informal Proceedings. At the request of an applicant, and if each interested party waives the right to present evidence, argument, and conduct cross-examination, the reviewer may establish at the prehearing conference informal rules for mediation, structured negotiation, or another consensual procedure for reaching a decision. The procedure shall produce a record upon which the proposed decision can be based.

(2) Reviewer as Presiding Officer.

(a) If an evidentiary hearing is held in accordance with Regulation .10D of this chapter, the reviewer shall preside at the hearing.

(b) The reviewer is empowered to:

(i) Make all rulings as to evidence, testimony, official administrative notice, and the conduct of the evidentiary hearing;

(ii) Set the date, time, and place of each hearing and prehearing and deadline for any submission, and the order for the examination and cross-examination of witnesses;

(iii) Administer oaths and affirmations;

(iv) Prepare oral and written summaries;

(v) Prepare a proposed decision with findings of fact and conclusions of law; and

(vi) Take other actions consistent with the commissioner's duties as reviewer.

(c) The reviewer may be assisted by one or more staff members and one or more assistant attorneys general assigned to the Commission.

(d) The reviewer may delegate to one or more individuals specified in §A(2)(c) of this regulation the responsibility for consideration of a motion for extension of time.

(3) Conduct of Evidentiary Hearings.

(a) An evidentiary hearing need not be conducted according to technical rules of evidence, but shall be conducted in accordance with the Maryland Administrative Procedure Act, State Government Article, Title 10, Annotated Code of Maryland, and these regulations.

(b) Reliable hearsay is admissible.

(c) Rules of privileges are effective to the extent they would be effective in a judicial proceeding in Maryland.

(d) Nonexpert opinion testimony may be considered.

(e) Qualification as an expert lies within the discretion of the reviewer. The qualification of an expert need not be based on academic degrees or learning. Reasonably extensive practical experience with the subject may be sufficient for an expert qualification.

(f) Reliable and probative documents previously filed with or compiled by the Commission or its staff or consultants that are relevant to issues being considered by the Commission may be incorporated by reference into the record of a proceeding by the Commission or, by leave of the reviewer, by a party to the proceeding, upon notice to the parties and an opportunity to object.

(g) The reviewer may take administrative notice of all judicially cognizable facts to the same extent as courts of this State, either on the reviewer's own motion or at the request of a party. The reviewer may also take official notice, without meeting formal evidentiary rules, of general technical or scientific facts within the specialized knowledge of a member of the Commission. A party to the hearing is entitled, on timely request, to an opportunity to show that the Commission should not take administrative or official notice of specific facts and matters, or that the fact or matter to be officially noticed is inapplicable to the proceeding or is incorrect or misunderstood by the Commission.

(4) A party to the hearing may be represented by counsel.

(5) The prehearing conference and the hearing shall be recorded. If an applicant or other person desires a transcript, that person shall make arrangements with ~~the~~ Commission staff~~stenographer~~.

(6) Documents filed in the proceeding shall be served on the reviewer, those specified in §A(2)(c) of this regulation, staff, and each interested party, and shall include a certificate of service.

(7) Motion practice is in accordance with Regulation .10B of this chapter.

B. Prehearing Procedures.

(1) The reviewer shall hold at least one prehearing conference before an evidentiary hearing.

(2) The reviewer shall notify each applicant and interested party of the prehearing conference in writing. The notification shall:

(a) Include the date, time, and place of the prehearing conference or conferences;

(b) Summarize the rules of procedure governing the evidentiary hearing; and

(c) State the dates, if known, for the submission of prefiled testimony and the date, time, and place of the evidentiary hearing.

(3) The principal purpose of the prehearing conference is to expedite the evidentiary hearing. To this end the reviewer may, among other things:

(a) Instruct the parties to:

(i) Formulate and submit a list of genuine contested issues to be decided at the hearing;

(ii) Identify each potential witness, the subject matter of each witness's testimony, and documents to be introduced; and

(iii) Raise and address issues that can be decided before the hearing;

(b) Encourage stipulations as to facts, law, and other matters;

(c) Schedule dates for the submission of prefiled testimony, further prehearings, the hearing, and submission of briefs and documents; and

(d) Rule on any pending motions.

(4) A written summary of the prehearing conference shall be made a part of the record of the proceeding.

~~(5) The reviewer may record the prehearing conference or have a stenographer present.~~

(~~6~~5) A request for the postponement of a hearing shall be made at a reasonable time before the hearing and is granted only for good cause shown, at the discretion of the reviewer.

C. List of Genuine Issues.

(1) The reviewer shall set the list of genuine issues for the evidentiary hearing.

(2) An evidentiary hearing may be held only on those genuine factual issues for which:

(a) There is a significant dispute as to factual issues; and

(b) One of the following is true:

(i) The reviewer designates a genuine issue;

(ii) An applicant or an interested party has made a prima facie case that a particular standard or criteria has not been met by an applicant;

(iii) An applicant has made a prima facie case that it deserves preference over another applicant under that standard or criteria; or

(iv) The reviewer determines that testimony on an issue would be helpful.

D. Direct Written Testimony.

(1) Direct testimony shall be in writing and may not be delivered orally.

(2) A party who wishes to present testimony at the evidentiary hearing shall file written testimony before the hearing in accordance with the schedule set by the Commissioner acting as reviewer.

(3) The written direct testimony shall set forth the conclusions of the person submitting it and all arguments and facts supporting these conclusions.

(4) Written direct testimony shall be verified either under oath at the hearing or by including the statement specified in Regulation .08B(2) of this chapter.

(5) Written direct testimony shall pertain solely to the proposed project and be relevant to that project. Upon notice with an opportunity to object, the reviewer shall separate irrelevant material from the remainder of the record and keep that material apart. Parts of the body of the written direct testimony judged irrelevant by the reviewer shall be so marked and may not be considered by the Commission in its deliberations.

(6) Persons submitting written testimony shall make themselves available for oral cross-examination. Submitted application materials are also subject to cross-examination. Letters submitted into the record which are not considered written testimony are not subject to cross-examination.

E. Cross-Examination.

(1) Cross-examination of each witness shall be live and under oath.

(2) The reviewer and each nonproponent applicant and interested party may conduct reasonable cross-examination of a witness who gave direct or rebuttal testimony.

(3) The reviewer may set reasonable time limits on the cross examination of witnesses.

(4) The reviewer shall set a deadline by which each party shall identify any witness for whom that party does not have cross-examination.

F. Rebuttal Testimony.

(1) After direct testimony has been completed, rebuttal testimony is permitted on any issue specified by the reviewer.

(2) Rebuttal testimony, whether specified by the reviewer to be written or oral, is subject to live cross-examination.

G. Post-Hearing Briefs.

(1) The reviewer may permit the filing of post-hearing briefs by each applicant and interested party.

(2) The reviewer may set a filing deadline and page limit for post-hearing briefs.

**.12 Effective Duration of Certificate of Need and Applicant Responsibilities.**

A. Good Standing. The Certificate of Need issued for a project by the Commission shall be maintained in good standing by the applicant up to completion, licensure, and first use of the approved project.

B. The Certificate of Need shall be issued with specific performance requirements, as follows:

(1) There shall be an obligation of not less than 51 percent of the construction and renovation ~~components~~portions of the approved capital expenditure, as documented by a binding construction contract or equipment purchase order;

(2) In the case of construction projects, the initiation of construction shall take place within 4 months of the effective date of a binding construction contract, and construction shall be continuous after that, subject to the following exception:

(a) If the approved project ceases continuous construction for a period in excess of 30 calendar days, the applicant shall notify the Commission in writing of the break in construction and submit for approval, documentation of the applicant's inability to control the break in construction within 35 calendar days of the work stoppage, and, within 45 calendar days of the work stoppage, submit to the Commission a plan of recommencement of construction not to exceed 90 calendar days, which period may be extended for a reasonable period if the applicant shows extraordinary circumstances; and

(b) The Commission shall consider any documentation submitted in determining whether good cause exists to grant a 6-month extension of the second performance requirement, in accordance with §E(1) of this regulation; and

(3) The applicant shall provide documentation that the approved project has been completed, has been licensed if required, or has otherwise met all applicable legal requirements and is providing the approved service or services within a specific time period beginning from the initiation of construction or from the effective date of a binding equipment purchase order.

C. Performance Requirements.

(1) Performance requirements shall be applied to approved projects with specific time limitations, beginning with the date of Certificate of Need approval, according to the nature and scope of the project.

(2) The requirements of §B(2) of this regulation apply to all approved construction projects.

(3) The requirements of §B(1) and (3) of this regulation apply, as follows:

(a) An approved new hospital has up to 36 months to obligate 51 percent of the construction and renovation ~~components~~ portion of the approved capital expenditure, and up to 36 months after the effective date of a binding construction contract to complete the project;

**Commented [WJ14]:** Consideration to align D & F-need new language in these sections

(b) Major (greater than $5,000,000) additions, replacements, modernizations, relocations, or conversions to an existing health care facility has up to 24 months to obligate 51 percent of the construction and renovation components of the approved capital expenditure, and up to 24 months after the effective date of a binding construction contract to complete the project;

(c) Except as provided in this subsection, a proposed new health care facility has up to 18 months to obligate 51 percent of the construction and renovation components of the approved capital expenditure, and up to 18 months after the effective date of a binding construction contract to complete the project;

(d) A major change in bed capacity (greater than 40 beds or 25 percent of total licensed capacity), additions, replacements, modernization, relocation, or conversions to an existing inpatient health care facility that involves a capital expenditure between the threshold specified in Regulation .01B of this chapter and $5,000,000 has up to 18 months to obligate 51 percent of the approved capital expenditure, and up to 12 months after the effective date of a binding construction contract to complete the project;

**Commented [MB15]:** This may need to be addressed with the new threshold.

(e) A minor change in bed capacity, which falls below the limits described in §C(3)(d) of this regulation but which requires review under Regulation .02 of this chapter, has up to 12 months to obligate 51 percent of its approved ~~capital expenditure~~construction and renovation costs, and up to 8 months after the effective date of a binding construction contract to complete the project;

(f) A change in bed capacity or services that requires review under Regulation .02 of this chapter but involves capital expenditure below the capital expenditure threshold specified in Regulation .01B of this chapter has up to 3 months to obligate 51 percent of the approved capital expenditure, and up to 6 months after the effective date of a binding construction contract to complete the project.

(g) In a multiphased plan of construction with only one construction contract approved for an existing health care facility, the project has:

(i) Up to 12 months after Certificate of Need approval to obligate 51 percent of the approved capital expenditure for the entire project;

(ii) Up to 24 months after the effective date of the binding construction contract to complete the first approved phase of construction; and

(iii) Up to 24 months after the completion of the previous phase to complete each subsequent approved phase;

(h) In a multiphased plan of construction with more than one construction contract approved for an existing health care facility, the project has:

(i) Up to 12 months after Certificate of Need approval to obligate 51 percent of the capital expenditure for the first phase of construction;

(ii) Up to 24 months after the effective date of a binding construction contract for the first phase to complete the first approved phase of construction;

(iii) 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 of construction; and

(iv) Up to 24 months after the effective date of a binding construction contract for a subsequent approved phase, to complete that phase;

(i) For a multiphased plan of construction, the Commission, upon a showing of good cause by an applicant, may authorize:

(i) Obligation for each approved phase of construction of a specified portion of the capital expenditure that is less than 51 percent of the approved capital expenditure for the entire project; and

(ii) Up to 36 months to complete each approved phase; and

(j) Home health agencies have up to 18 months from the date of the certificate of need to:

(i) Become licensed and, if applicable, Medicare certified; and

(ii) Begin operations in the jurisdiction for which the certificate of need was granted.

(4) If a project is classified as fitting more than one of the categories in §C(3) of this regulation, the category carrying the longer time frame applies.

(5) For State projects dependent solely on capital funds allocated by the Maryland General Assembly, the requirements of §B(1) of this regulation begin from the date of the Governor's approval of legislative appropriation of funds. If funds are not appropriated by the end of the second year following the granting of the Certificate of Need, the Certificate of Need is void.

D. Effective Date of a Certificate of Need. The effective date of a Certificate of Need is the date of issuance by the Commission. If a motion for reconsideration is timely filed, the effective date of the Certificate of Need is the date the Commission decides the motion. The filing of a petition for appeal does not stay enforcement of the Commission decision.

E. Extension of Performance Requirements.

(1) A person who holds a Certificate of Need may request only one extension of time, not to exceed 6 months, to meet each applicable performance requirement. The applicant shall provide reasonable assurance that it will meet the performance requirement by the end of the extended period. The Executive Director, for good cause, may approve a requested extension to an applicable performance requirement. The Commission shall fully document an extension approval.

(2) A request shall be:

(a) In writing, and

(b) Received at least 30 calendar days before the date by which the performance requirement is to be completed.

(3) For purposes of this section, a request is considered to show good cause if it demonstrates that circumstances completely beyond the control of the person who holds the Certificate of Need require the extension. Good cause does not include delays in securing financing.

F. Failure to Meet Performance Requirements.

(1) An approved project that fails to fulfill an applicable performance requirement within the specified time period is void. The sponsor of the project may reapply under the Certificate of Need review process, as set forth in Regulations .08—.10 of this chapter, and this resubmitted application shall be considered by the reviewing agencies as a new application.

(2) Nothing in this section precludes the approval of a project to be undertaken in phases, each of which would be judged in accordance with its own performance requirements, based upon the successive effective dates for each phase, as detailed in the Certificate of Need.

G. Failure of an applicant to carry out a contract or purchase order that was submitted as evidence of fulfillment of a performance requirement may render the project's Certificate of Need void, as in §F of this regulation.

H. Grounds for Withdrawal of a Certificate of Need. The Commission reserves the right to withdraw a Certificate of Need if the Commission finds that the:

(1) Applicant made a material misrepresentation upon which the Commission relied in granting the Certificate of Need;

(2) Applicant has failed to meet a performance requirement or condition in the Certificate of Need;

(3) Applicant has failed to provide quarterly reports required under Regulation .13B and C of this chapter; or

(4) Project differs from that approved by the Commission in the Certificate of Need.

I. Notice Before Withdrawal of a Certificate of Need.

(1) Before withdrawal of a Certificate of Need for failure to fully meet an applicable performance requirement, the Commission shall inform the applicant and the appropriate local health department, setting forth in writing the reasons for withdrawal. This notice shall set forth the right of the applicant to an evidentiary hearing, conducted in accordance with Regulation .11 of this chapter, to show cause why the Certificate of Need should not be withdrawn. The applicant may make a written filing in support of the applicant's position and present oral argument to the full Commission before the Commission takes final action on the notice of withdrawal.

(2) Final action by the Commission withdrawing a Certificate of Need shall:

(a) Be in writing;

(b) Include findings of fact and conclusions of law; and

(c) Be transmitted to the applicant and to the appropriate local health department within 30 days of the date of action by the Commission.

**.13 Conditions of Certificate of Need Approval.**

A. Approval with Conditions. A Certificate of Need may be issued with conditions if the Commission determines that approval with conditions is appropriate.

B. Quarterly Reports.

(1) As a general condition of an approved Certificate of Need, an applicant shall submit to the Commission timely, accurate, and complete quarterly reports of progress in completing the approved project, with a copy to each local health department in the health planning region.

(2) Reports shall be submitted in the form and manner prescribed by the Commission on a quarterly basis, or as otherwise specified by the Commission, beginning 3 months from the date of Certificate of Need approval, and continuing through the applicable time frame of any of the conditions.

**Commented [MB16]:** MHCC should review its quarterly reports and quarterly report process. Some of this information may not be needed.

(3) Failure to provide these reports may result in withdrawal of the Certificate of Need.

(4) If the review of these periodic reports by the Commission indicates that the project is not progressing satisfactorily, as set out in Regulation .12C of this chapter, or that it is not reasonably attempting to comply with any other specific conditions imposed, the Commission shall initiate the process set forth in Regulation .12I of this chapter for withdrawal of the Certificate of Need.

C. Good Standing. A Certificate of Need is considered to continue in good standing if the applicant provides:

(1) Acceptable quarterly status reports to the Commission and the local health department; and

(2) Written documentation of the fulfillment of applicable performance requirements and conditions within the time frames specified in the Certificate of Need.

D. Transferability. A Certificate of Need is not transferable.

**.14 Special Procedures.**

A. Declaratory Rulings.

(1) An affected person uncertain as to how a statute or regulation enforced by the Commission applies to a person or property may file with the Commission a petition for a declaratory ruling in accordance with the procedures in §A(2)—(11) of this regulation.

(2) The Commission may decline to issue a declaratory ruling for any of the following reasons:

(a) The petition is not in accordance with this section;

(b) The petition contains insufficient factual or legal information upon which to base a declaratory ruling;

(c) The petition raises issues adequately addressed in a final decision or regulation of the Commission;

(d) The petition fails to pose a significant issue;

(e) The petition is properly heard as part of an evidentiary hearing; or

(f) A declaratory ruling would not be in the public interest.

(3) Within 15 days of receipt of a petition, the Executive Director shall either assign the petition to the full Commission for a decision or appoint a Commissioner to make a proposed ruling on the petition, which shall be considered by the full Commission.

(4) Within 45 days, or by the second regularly scheduled Commission meeting following the filing of the petition, whichever is later, the Commission shall either rule or decline to rule on the petition. If the petition raises issues requiring further deliberation, the Commission by vote may postpone issuing its formal written declaratory ruling for up to 35 days.

(5) To secure a declaratory ruling, an affected person shall submit a petition for a declaratory ruling that contains the following information:

(a) The petitioner's name, address, and telephone number;

(b) A one or two sentence statement of each question on which a ruling is requested;

(c) A one or two sentence summary of the petitioner's position on each question;

(d) Citation to each provision that the Commission needs to interpret in order to answer each question posed;

(e) A brief statement of each relevant fact;

(f) The petitioner's factual, legal, and policy arguments, referring to documents, affidavits, data, and other relevant information, which shall be appended to the petition, unless the documents are readily accessible to the Commission; and

(g) A statement by the petitioner under penalties of perjury that each fact recited as relevant to the question posed is true to the best of the petitioner's knowledge, information, and belief.

(6) The Commission shall promptly publish notice of the receipt of a petition in the Maryland Register, and shall include the petition under new business on tentative meeting agendas until the Commission acts upon the petition.

(7) In rendering a declaratory ruling, the Commission, in addition to considering the materials submitted by the petitioner and comments from staff, may:

(a) Request and receive oral or written statements from any person;

(b) Consider any document, data, study, or other relevant material; or

(c) Require argument on the question on the record, giving the petitioner the opportunity to present argument and to proffer witnesses and documents for the Commission's consideration.

(8) The declaratory ruling shall be in writing, and state:

(a) Each question addressed;

(b) The Commission's ruling; and

(c) The factual and legal basis for the ruling.

(9) A declaratory ruling binds the Commission and the petitioner on the facts set forth in the petition, except when this binding effect violates the due process rights of a competing applicant in a comparative review.

(10) The Commission may revoke, alter, or amend a declaratory ruling, which may have prospective effect only.

(11) A petitioner may appeal the declaratory ruling as set forth in State Government Article, Title 10, Annotated Code of Maryland.

B. Determination of Coverage. A project that requires formal review to determine whether it comes under the law and regulations shall be dealt with in the following manner:

(1) A request for determination shall be made in writing to the Commission;

(2) The Executive Director of the Commission shall review the request and act on it within 30 business days of receipt;

(3) The requesting party shall provide any additional information requested by the Commission or staff, and the effective date of the Commission's determination shall relate back to the date the Commission received the requested information;

(4) The Commission shall notify the requesting party, appropriate local health department, and the agencies responsible under the Department's licensure program whether the project requires a Certificate of Need or other Commission review;

(5) The determination of coverage may be appealed by the requesting party through the procedures set forth in Regulation .09E of this chapter.

C. The procedures in this regulation provide a means by which an affected person may obtain an appealable decision from the Commission on specific issues. Nothing in this regulation prevents a person from writing the Commission, asking for its opinion or judgment on any matter, and relying on the Commission's response.

**.15 Commission Approval Required Before Certain Actions.**

A. Approval of Architectural Plans. Architectural plans and specifications for a project that requires a Certificate of Need may not be approved by the agency responsible for their review under health facility licensure requirements until the project has been issued a Certificate of Need by the Commission.

B. Approval of State or Federal Grants, Loans, or Mortgage Insurance under Department-Administered Programs. Applications by owners or sponsors of projects requiring Commission approval, for federal or State grants, loans, or mortgage insurance under Department-

administered programs for project construction, modernization, or equipment, may not be officially approved by the administering agency until the applicant and the administering agency have been formally notified of Certificate of Need approval or other action by the Commission.

C. Signing of Contracts Related to State Capital Improvement. State capital improvement projects for facilities administered by the Department, and requiring approval under the law and these regulations, may not have contracts signed for the development of architectural drawings, construction, or equipment until the Department's administering agency and the State agency responsible for the contracts have been formally notified of Certificate of Need approval or other action by the Commission.

D. Obligation of Capital Expenditure.

(1) A person may not incur an obligation for a capital expenditure that is subject to review under these regulations until the applicant receives a Certificate of Need or other approval required by the Commission.

(2) An obligation for capital expenditure is considered to be incurred by or on behalf of a health care facility when a contract, enforceable under State law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease, or financing of a capital asset, or when a governing body of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor, or, in the case of donated property, on the date on which the gift is completed under applicable State law.

E. Obligation of Predevelopment Expenditures. An applicant proposing predevelopment expenditures requiring review under Regulation .02 of this chapter may not enter into a binding contract or other obligation for these activities until the applicant receives a Certificate of Need or other approval required by the Commission.

F. Binding Commitments for Financing. A binding arrangement or commitment for financing a project may not be entered into by an applicant until the applicant receives Certificate of Need approval for the project to be financed.

**.16 Voluntary Withdrawal of an Application.**

During the review period, an applicant may voluntarily withdraw an application without prejudice. Written notice of the withdrawal shall be submitted to the Commission through the Health Facilities Coordination Office. A withdrawn application may be resubmitted at a later date, as a new application, requiring a new letter of intent, new docketing, and review.

**.17 Project Changes After Certificate of Need Approval.**

A. Notification to the Commission.

(1) If the project sponsor determines that it desires to change a project that has received Certificate of Need approval, the project sponsor shall notify the following parties in writing of the proposed changes:

(a) The Commission;

(b) The local health department; and

(c) In the case of a change in the location or address of a project involving the construction of a new health care facility, all health care facilities of that type located within the health planning region of the project.

(2) Notification shall be submitted through the Health Facilities Coordination Office, and shall be supported by appropriate documentation.

B. Commission Approval Required Before Project Changes. Any of the following changes that would place the project at variance with its Certificate of Need issued under these regulations, including any condition issued under Regulation .09D(1)(b) of this chapter, shall receive approval from the Commission:

(1) Before making a significant change in physical plant design;

(2) Before incurring capital cost increases that exceed the approved capital cost inflated by ~~an amount determined by applying the Building Cost Index published in Health Care Cost Review~~ five percent (5%) annually from the application submission date to the date of the filing of a request for approval of a project change;

(3) When total projected operating expenses or revenue increases exceed the projected expenses or revenues in the approved Certificate of Need Application, inflated by 10 percent per year;

(4) Before changing the financing mechanisms of the project;

(5) Before changing the location or address of the project.

C. Impermissible Modifications. The following proposed modifications to an approved project require a new Certificate of Need, and may not be considered by the Commission:

(1) Changes in the fundamental nature of a facility or the services to be provided in the facility from those that were approved by the Commission;

(2) Increases in the total licensed bed capacity or medical service categories from those approved;

(3) Any change that requires an extension of time to meet the applicable performance requirements specified under Regulation .12 of this chapter, except as permitted under Regulation .12E of this chapter.

D. Commission Action.

(1) Changes subject to review under §B of this regulation shall be reviewed by the Commission.

(2) Within 5 business days after the Commission's receipt of a written request to change the address or location of an approved project, which is subject to review under §B(5) of this regulation, the Commission shall:

(a) Arrange to publish notice of receipt of the change request on its website and in one newspaper in the appropriate health planning region; and

(b) Provide written notice of receipt of the change request to:

(i) Each member of the General Assembly in whose district the relocation is planned;

(ii) Each member of the governing body for the jurisdiction in which the relocation is planned; and

(iii) The county executive, mayor, or chief executive officer, if any, in whose county or city the relocation is planned.

(3) The Commission shall provide written notification to the applicant within 45 days of the Commission's receipt of the change request that:

(a) The proposed change is approved and is incorporated into a modified Certificate of Need for the project;

(b) The proposed change is approved in part or approved with conditions;

(c) The proposed change is not approved, with explanation; or

(d) The proposed change is of sufficient scope to warrant complete review in accordance with the Certificate of Need review process described in Regulations .08—.10 of this chapter, and may only be considered upon completion of this review.

E. Commission May Seek Advice. The Commission may seek the advice of any agency or person in the performance of a review under this regulation, including each existing health care facility currently operating within the intended service area of the approved or proposed project, and each applicant and interested party in the review that resulted in the grant of the original Certificate of Need.

F. When Commission Action is a New Final Decision. Action taken by the Commission under §D(2)(a) or (b) of this regulation does not constitute a new final decision by the Commission and may not be appealed. Action taken by the Commission following a complete review under §D(3)(d) of this regulation constitutes a new final decision of the Commission.

**.18 Review Required Before Licensing or First Use of Project.**

A. Request for First Use Review and Approval. Not less than 60 days but not more than 120 days before the first use of any portion of the facility or service, an applicant shall specify the anticipated date for first use and request in writing, through the Health Facilities Coordination Office, a final review.

B. Local Health Department.

(1) The local health department may review the project and services in relation to the Certificate of Need and any existing conditions.

(2) The local health department shall report its recommendation in writing to the Commission, with a copy to the applicant, as follows:

(a) The project, or a portion of the project, continues to conform with the Certificate of Need, and each condition and change approved under Regulation .17 of this chapter, and is recommended for licensure or first use, or both; or

(b) The project, or a portion of the project, no longer conforms with its Certificate of Need, for reasons stated.

C. Time Frame for Local Health Department Recommendation. In order to be considered by the Commission, the local health department's recommendation must reach the Commission not less than 20 days before the anticipated date of first use specified by the applicant under §A of this regulation.

D. Commission Action. The Commission shall review the local health department's recommendation and shall act on it within 10 days of receipt from the local health department. If a local health department does not perform this review, the Commission may use the time allotted to the local health department. Final notification shall be in writing to the applicant, the local health department, and the responsible licensing agencies, in the form of one of the decisions listed in §B of this regulation. The Commission's decision on first use is not a new final decision concerning a Certificate of Need and may not be appealed.

E. Nonconformance with Certificate of Need Approval. If the Executive Director finds that a project does not conform to its Certificate of Need, the applicant may not proceed to licensure or first use until the Executive Director issues a written finding that the project conforms with its Certificate of Need. Based on a finding that a project varies significantly from the project that was granted a Certificate of Need, the Executive Director may invoke the full review process established in Regulations .08—.10 of this chapter in order to reexamine this project.

F. Duration of First-Use Approval. First-use approval remains in effect for 90 days. A project that does not implement within that 90-day period each service for which first-use approval was granted shall reapply for first-use approval.

**.19 Reconsideration Procedures.**

A. Request for Reconsideration. For good cause shown, an aggrieved party may request that the Commission conduct a hearing to reconsider a Commission final decision to grant, to grant with conditions, or to deny a Certificate of Need application or determination of exemption issued under Regulation .04 of this chapter. This request shall be in writing and filed with the Commission within 15 business days of the date upon which the Commission renders its decision.

B. Good Cause. For purposes of this regulation, a request for a reconsideration shows good cause if it:

(1) Presents significant, relevant information which was not previously presented to the Commission and which, with reasonable diligence, could not have been presented before the Commission made its decision;

(2) Demonstrates that there have been significant changes in factors or circumstances relied upon by the Commission in reaching its decision; or

(3) Demonstrates that the Commission has materially failed to follow its adopted procedures in reaching its decision.

C. Notice of Reconsideration Request. Written notice of the date on which the Commission will consider the reconsideration request shall be provided at least 15 business days before the Commission considers the request to the person making the request, each applicant, each interested party, and each relevant local health department. Each interested party may file a written response. A request to present oral arguments shall be made at the time of filing an initial request for reconsideration or a response.

D. In considering the reconsideration request, the Commission shall initially determine whether good cause has been demonstrated. If so, the Commission may reevaluate its previous decision at that time. The Commission may affirm, reverse, or modify its previous decision.

E. Commission Decision Following Reconsideration. If the Commission changes its decision as a result of the reconsideration request, the Commission shall make written findings of fact and conclusions of law stating the basis for its decision within 30 days of its decision on the request.

F. Reconsideration Decision Is a New Final Decision. The decision of the Commission on reconsideration is the final decision of the Commission for purposes of appeal of the decision.

**.20 Emergency Certificate of Need.**

A. Commission May Issue an Emergency Certificate of Need. If a situation presents hazards to employees or patients of a health care facility or the closing of a facility by State licensing authorities requires changes or adjustments in other facilities to accommodate displaced patients, and the changes or adjustments would otherwise require that these facilities obtain a Certificate of Need under these regulations, the Commission may issue an emergency Certificate of Need.

B. Commission Action. The Executive Director of the Commission is authorized to grant or deny an emergency Certificate of Need after consultation with the Commission Chairman or the Chairman's designee. Before an emergency Certificate of Need is issued and before licensing action is taken, the Department's Office of Health Care Quality shall provide the Commission's Executive Director with suitably detailed written information explaining why action cannot be delayed. If, upon receipt of this information, the Executive Director agrees that an emergency situation exists, the Executive Director shall issue an emergency Certificate of Need to allow the Office of Health Care Quality to issue an appropriate provisional license. The Executive Director shall notify the Commission of the issuance of the emergency Certificate of Need at the next scheduled Commission meeting for confirmation.

C. Duration of Emergency Certificate of Need. The emergency Certificate of Need is temporary and may not exceed 165 days. During the first 30 days of this period, the facility shall submit a formal application for a Certificate of Need to the Health Facilities Coordination Office. The normal review period set forth in Regulations .08—.10 of this chapter applies.

D. Time Frame for Commission Action. Within 150 days of the filing of a complete Certificate of Need application, the Commission shall issue its decision regarding the Certificate of Need.

E. Inapplicability if Capital Expenditure is Involved. An emergency Certificate of Need may only be granted when the emergency change in licensure can be accomplished without a capital expenditure that exceeds the threshold for capital expenditure defined in Regulation .01B of this chapter.

**.21 Severability.**

If any provision of this chapter is declared void by a court of law, the remainder of this chapter shall be unaffected and of continued force and effect.

**.22 Effective Date.**

A. A letter of intent or application submitted after the effective date of these regulations is subject to their provisions.

B. Projects.

(1) Upon request, a project that has received Certificate of Need approval may be governed by this chapter. In making its determination on a request for conversion, the Commission may, at its discretion, invoke a full review of the project in accordance with this chapter.

(2) A request for a determination of coverage under Regulation .14B of this chapter, submitted after the effective date of these regulations, is subject to the provisions of this chapter.

Administrative History

Effective date: July 6, 1972

**Regulations .01—.16 amended effective February 4, 1976 (3:3 Md. R. 151)**

**Regulations .17 and .18 adopted effective February 4, 1976 (3:3 Md. R. 151)**

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**Chapter revised effective March 24, 1978 (5:6 Md. R. 466)**

**Regulations .01B; .02A, B; .05E; .06B, D—G, K; .07A, B, E; .08A, C; .09A; .11A, D; .15A, B; and .17A, B, D amended as an emergency provision effective July 1, 1978 (5:17 Md. R. 1321); adopted permanently effective December 15, 1978 (5:25 Md. R. 1855)**

**Regulations .01B; .02A; .06B, F, L; .09D; .11D; .19 amended effective January 25, 1980 (7:2 Md. R. 115)**

**Regulation .06B amended as an emergency provision effective February 4, 1981 (8:4 Md. R. 334); emergency status expired June 20, 1981 (Emergency provisions are temporary and not printed in COMAR)**

**Regulation .06M adopted as an emergency provision effective July 1, 1978 (5:17 Md. R. 1321); adopted permanently effective December 15, 1978 (5:25 Md. R. 1855)**

**Regulations .09E, .11E—G, and .16-1 adopted effective January 25, 1980 (7:2 Md. R. 115)**

**Regulation .16F repealed effective January 25, 1980 (7:2 Md. R. 115)**

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**Chapter revised as an emergency provision effective March 18, 1983 (10:6 Md. R. 536); emergency status extended at 10:17 Md. R. 1520, 10:22 Md. R. 1964, and 11:5 Md. R. 460 (Emergency provisions are temporary and not printed in COMAR)**

**Chapter revised effective April 23, 1984 (11:8 Md. R. 714)**

**Regulation .01 amended and recodified as .01-1, and Preface codified as new Regulation .01 effective November 17, 1986 (13:23 Md. R. 2480)**

**Regulations .01B, .03D, .07H, and .20B amended as an emergency provision and .03F and .21 adopted as an emergency provision effective August 1, 1985 (12:17 Md. R. 1694);**

**emergency status extended at 12:26 Md. R. 2540; emergency status reapproved effective April 4, 1987 (13:9 Md. R. 1021); emergency status extended at 13:14 Md. R. 1629 and 13:20 Md. R. 2206 (Emergency provisions are temporary and not printed in COMAR)**

**Regulations .01B, .02A, and .03B amended as an emergency provision and .03F adopted as an emergency provision effective February 28, 1986 (13:6 Md. R. 669) (Emergency provisions are temporary and not printed in COMAR)**

**Regulations .01B, .06C, E, .07A—D, F, P, .11, and .23 amended as an emergency provision and .06F adopted as an emergency provision effective March 15, 1986 (13:8 Md. R. 890) (Emergency provisions are temporary and not printed in COMAR)**

**Regulations .01-1, .03, .06, .07, and .11 amended as an emergency provision effective July 16, 1987 (14:16 Md. R. 1767); emergency status extended at 14:18 Md. R. 1962 (Emergency provisions are temporary and not printed in COMAR)**

**Regulations .01-1, .03, .06, .07, .11 and .23 amended as an emergency provision effective September 23, 1987 (14:21 Md. R. 2217); adopted permanently effective February 8, 1988 (15:3 Md. R. 304)**

**Regulations .01-1, .03, .06, .07, .09, .11, .15—.18, and .20 amended as an emergency provision effective March 9, 1989 (16:7 Md. R. 802); emergency status extended at 16:20 Md. R. 2178 and 17:3 Md. R. 295 (Emergency provisions are temporary and not printed in COMAR)**

**Regulation .01-1 amended effective February 13, 1995 (22:3 Md. R. 154)**

**Regulation .01-1B amended effective April 6, 1987 (14:7 Md. R. 831); October 30, 1989 (16:21 Md. R. 2262); March 19, 1990 (17:5 Md. R. 638)**

**Regulation .02A—C amended effective November 17, 1986 (13:23 Md. R. 2480); March 19, 1990 (17:5 Md. R. 638)**

**Regulation .02D amended effective March 19, 1990 (17:5 Md. R. 638)**

**Regulation .03 amended effective November 17, 1986 (13:23 Md. R. 2480); March 19, 1990 (17:5 Md. R. 638)**

**Regulation .03G—I amended effective February 13, 1995 (22:3 Md. R. 154)**

**Regulation .03H adopted effective April 6, 1987 (14:7 Md. R. 831)**

**Regulation .03K adopted effective June 13, 1988 (15:12 Md. R. 1447)**

**Regulation .03L adopted effective October 30, 1989 (16:21 Md. R. 2262)**

**Regulation .06 amended effective November 17, 1986 (13:23 Md. R. 2480)**

**Regulation .06C amended effective March 19, 1990 (17:5 Md. R. 638)**

**Regulation .07 amended effective November 17, 1986 (13:23 Md. R. 2480); April 6, 1987 (14:7 Md. R. 831); March 19, 1990 (17:5 Md. R. 638); June 6, 1994 (21:11 Md. R. 951)**

**Regulation .08C amended effective November 17, 1986 (13:23 Md. R. 2480); August 3, 1992 (19:15 Md. R. 1390)**

**Regulation .09A amended effective March 19, 1990 (17:5 Md. R. 638)**

**Regulation .11 amended effective November 17, 1986 (13:23 Md. R. 2480)**

**Regulation .11C amended effective February 13, 1995 (22:3 Md. R. 154)**

**Regulation .11E amended effective March 19, 1990 (17:5 Md. R. 638)**

**Regulation .15 amended effective March 19, 1990 (17:5 Md. R. 638); October 10, 1994 (21:20 Md. R. 1732)**

**Regulation .16E amended effective March 19, 1990 (17:5 Md. R. 638)**

**Regulation .17A amended effective March 19, 1990 (17:5 Md. R. 638)**

**Regulation .18 amended effective March 19, 1990 (17:5 Md. R. 638)**

**Regulation .20A amended effective March 19, 1990 (17:5 Md. R. 638)**

**Regulation .20B amended effective November 17, 1986 (13:23 Md. R. 2480)**

**Regulation .21 amended effective November 17, 1986 (13:23 Md. R. 2480)**

**Regulation .23 amended effective November 17, 1986 (13:23 Md. R. 2480)**

**Regulation .23B amended effective April 6, 1987 (14:7 Md. R. 831)**

**Regulation .23E, F amended effective February 13, 1995 (22:3 Md. R. 154)**

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Annotation: COMAR 10.24.01.06 cited in Doctors' Hospital v. Health Resources Planning Commission, 65 Md. App. 656 (1986)

Annotation: COMAR 10.24.01.07 cited in Sinai Hospital v. Health Resources Planning Commission, 306 Md. 472 (1986)

Annotation: COMAR 10.24.01.07 cited in Perini Services Inc. v. Health Resources Planning Commission, 67 Md. App. 189 (1986)

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**Regulations .01—.23 repealed and new Regulations .01—.22 adopted effective November 6, 1995 (22:22 Md. R. 1658)**

**Regulation .01B amended as an emergency provision effective November 9, 1995 (22:24 Md. R. 1874); amended permanently effective March 11, 1996 (23:5 Md. R. 379)**

**Regulation .01B amended effective August 21, 2000 (27:16 Md. R. 1523); February 5, 2001 (28:2 Md. R. 100); November 24, 2003 (30:23 Md. R. 1652); April 11, 2005 (32:7 Md. R. 680); October 23, 2006 (33:21 Md. R. 1675); April 9, 2007 (34:7 Md. R. 699)**

**Regulation .01B amended as an emergency provision effective January 23, 2009 (36:4 Md. R. 345); amended permanently effective April 20, 2009 (36:8 Md. R. 595)**

**Regulation .02 repealed and new Regulation .02 adopted effective August 21, 2000 (27:16 Md. R. 1523)**

**Regulation .02 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .02A amended effective February 5, 2001 (28:2 Md. R. 100)**

**Regulation .03 repealed and new Regulation .03 adopted effective August 21, 2000 (27:16 Md. R. 1523)**

**Regulation .03 amended effective August 21, 2000 (27:16 Md. R. 1523); April 11, 2005 (32:7 Md. R. 680)**

**Regulation .03A amended effective November 24, 2003 (30:23 Md. R. 1652)**

**Regulation .03B, J amended effective October 23, 2006 (33:21 Md. R. 1675)**

**Regulation .03I amended effective April 10, 2006 (33:7 Md. R. 672)**

**Regulation .03K amended effective April 9, 2007 (34:7 Md. R. 699)**

**Regulation .04 repealed and new Regulation .04 adopted effective August 21, 2000 (27:16 Md. R. 1523)**

**Regulation .04 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .05 repealed and new Regulation .05 adopted effective April 6, 1998 (25:7 Md. R. 527)**

**Regulation .05 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .07 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .08 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .08C, E amended effective April 10, 2006 (33:7 Md. R. 672)**

**Regulation .08D, F amended effective April 9, 2007 (34:7 Md. R. 699)**

**Regulation .08E, G amended as an emergency provision effective November 9, 1995 (22:24 Md. R. 1874); amended permanently effective March 11, 1996 (23:5 Md. R. 379)**

**Regulation .09 amended effective April 11, 2005 (32:7 Md. R. 680); April 9, 2007 (34:7 Md. R. 699)**

**Regulation .09A amended as an emergency provision effective November 9, 1995 (22:24 Md. R. 1874); amended permanently effective March 11, 1996 (23:5 Md. R. 379)**

**Regulation .09A amended effective April 10, 2006 (33:7 Md. R. 672)**

**Regulation .09C amended effective November 24, 2003 (30:23 Md. R. 1652)**

**Regulation .09D amended effective April 10, 2006 (33:7 Md. R. 672)**

**Regulation .10 amended as an emergency provision effective November 9, 1995 (22:24 Md. R. 1874); amended permanently effective March 11, 1996 (23:5 Md. R. 379)**

**Regulation .10 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .11 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .12 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .12C amended effective November 24, 2003 (30:23 Md. R. 1652); April 9, 2007 (34:7 Md. R. 699)**

**Regulation .13 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .13B amended effective May 5, 1997 (24:9 Md. R. 657)**

**Regulation .14 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .15 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .16 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .17 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .18 amended effective April 11, 2005 (32:7 Md. R. 680)**

**Regulation .19 amended effective April 11, 2005 (32:7 Md. R. 680)**
**Regulation .20 amended effective April 11, 2005 (32:7 Md. R. 680)**
**Regulation .20E amended effective April 9, 2007 (34:7 Md. R. 699)**
**Regulation .22 amended effective April 11, 2005 (32:7 Md. R. 680)**

# State Health Plan for Facilities and Services: Acute Care Hospital Services

**.01 Incorporation By Reference.** This Chapter is incorporated by reference in the Code of Maryland Regulations.

**.02 Introduction.**

**A. Purposes of the State Health Plan for Facilities and Services.**

Commented [MB1]: Updated preamble to align with the Maryland Model. This should be reflected in all chapters.

MHCC has prepared this chapter of the State Health Plan for Facilities and Services ("State Health Plan" or "Plan") to ensure access to quality health care, while reducing total health care spending per capita. Each chapter of the State Health Plan, should align with the goals and terms of Maryland's Total Cost of Care agreement with the Centers for Medicare & Medicaid Services (CMS) to implement the triple aim, by improving the patient experience, improving population health, and controlling total health care spending per capita. Maryland's health care system is legally bound by the terms of the model, agreed upon by the State of Maryland and CMS.

This chapter outlines the methodology to determine the need for services associated with hospital acute care, and, reflects MHCC's projection of that need. The appropriate level of health care services, and appropriate access to those services, should be targeted to meet the projected need. The State Health Plan should also consider both service quality and the impact on total spending per capita. The Commission views the State Health Plan, of which this Chapter is a part, as a policy blueprint for shaping and reshaping the health care system toward these ends, through the action of public agencies and the cooperation of private actors.

Through the State Health Plan, the Commission undertakes an active role in proposing changes in the system, including the allocation of resources to achieve a health care system that is cost-effective, and that balances considerations of affordability, access, and quality. The Commission should strive to anticipate and address future healthcare delivery considerations of a dynamic state health plan. In every aspect of the Plan, and in its individual Certificate of Need decisions, the Commission carefully weighs issues of quality of care and access to acute care hospital services as determined by the projected need, and aligned with the All-Payer Model.

The State Health Plan serves two purposes:

(1) It establishes health care policy to guide the Commission's actions and those of other health-related public agencies, and to foster specific actions in the non-governmental sector. Activities of State agencies must, by law, be

consistent with the Plan. The plan shall be consistent with the terms of the All-Payer Total Cost of Care Model.

(2) It is the legal foundation for the Commission's decisions in its regulatory programs. These programs ensure that appropriate changes in service capacity are encouraged. Changes are consistent with the Commission's policies, the projected service need, and the goals of the All-Payer Model. The State Health Plan, therefore, contains policies, standards, and service-specific need projection methodologies that the Commission uses in making Certificate of Need decisions.

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~~The Maryland Health Care Commission has prepared this Chapter of the State Health Plan for Facilities and Services ("State Health Plan") to meet the current and future health system needs of all Maryland residents.~~

~~The State Health Plan serves two purposes:~~

~~(1) It establishes health care policy to guide the Commission's actions. Maryland law requires that all State agencies and departments involved in regulating, funding, or planning for the health care industry carry out their responsibilities in a manner consistent with the State Health Plan and available fiscal resources.~~

~~(2) It is the foundation for the Commission's decisions in its regulatory programs. These programs ensure that changes in health care facilities and services are appropriate and consistent with the Commission's policies. The State Health Plan contains policies, methodologies, standards, and criteria that the Commission uses in making Certificate of Need ("CON") decisions.~~

~~The Commission views the State Health Plan as a policy blueprint for positive change in health care delivery that provides guidance on resource allocation decisions based on considerations of the appropriate balance among availability, accessibility, cost, and quality of health care.~~

**B. Legal Authority for the State Health Plan.**

The State Health Plan is adopted under Maryland's health planning law, Maryland Code Annotated, Health-General §19-118. This Chapter partially fulfills the Commission's responsibility to adopt a State Health Plan at least every five years and to review and amend the Plan as necessary. Health-General §19-118(a)(2) provides that the State Health Plan shall i~~nclude~~:

(1) Align with Maryland's All-Payer Model Agreement with the federal Center for Medicare and Medicaid Innovation

(2~~1~~) Include the methodologies, standards, and criteria for Certificate of Need review;

and

(2~~3~~) Reflect priority for conversion of acute capacity to alternative

uses where

appropriate.

**C. Organizational Setting of the Commission.**

The Commission is an independent agency located within the Department of Health and Mental Hygiene for budgetary purposes. The purposes of the Commission, as enumerated at Health-General §19-103(c), include responsibilities to:

(1) Develop health care cost containment strategies to help provide access to appropriate quality health care services for all Marylanders, after consulting with the Health Services Cost Review Commission; and

(2) Promote the development of a health regulatory system that provides, for all Marylanders, financial and geographic access to quality health care services at a reasonable cost by advocating policies and systems to promote the efficient delivery of and improved access to health care services, and enhancing the strengths of the current health care service delivery and regulatory system.

The Commission has sole authority to prepare and adopt the State Health Plan and to issue Certificate of Need decisions and exemptions based on the State Health Plan. Health-General §19-118(e) requires the Secretary of Health and Mental Hygiene to make annual recommendations to the Commission on the State Health Plan and permits the Secretary to review and comment on the specifications used in its development. However, Health-General §19-110(a) provides that the Secretary does not have power to disapprove or modify any determinations the Commission makes regarding or based upon the State Health Plan. The Commission pursues effective coordination with the Secretary and State health-related agencies in the course of developing the State Health Plan and plan amendments. As required by statute, the Commission coordinates with the hospital rate-setting program of the Health Services Cost Review Commission to assure access to care at reasonable costs, and compliance with Maryland's All-Payer Model agreement with the federal Center for Medicare and Medicaid Innovation. The Commission also

coordinates its activities with the Maryland Insurance Administration.

**D. Plan Content and Applicability.**

A Certificate of Need is required for: (1) the building, development, or establishment of

an acute care general hospital; (2) the relocation of an existing or previously approved acute care general hospital to another site; (3) a change in the bed capacity of an acute care general hospital, except for changes in licensed capacity that result from the annual recalculation made pursuant to Health-General §19-307.2; (4) certain changes in the type or scope of any "health care service"[1] offered by an acute care general hospital; and (5) a capital expenditure by an acute care general hospital that exceeds the current threshold for capital expenditures This Chapter of the State

[1] "Health care service" is defined at Health-General §19-120(a)(3) and (4) as "any clinically related patient service"
including a medical service. Medical service means any of the following categories of health care services: medicine, surgery, gynecology, addictions, obstetrics, pediatrics, psychiatry, rehabilitation, chronic care, comprehensive care, extended care, intermediate care, or residential treatment; or any subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of health care services for which need is projected in the State Health Plan. Hospitals have the ability to undertake certain capital expenditures that exceed the threshold requirement for CON review and approval under the terms of COMAR 10.24.01.03 and 10.24.01.04.

Health Plan supersedes any previously adopted Acute Inpatient Services Chapter of the State Health Plan, COMAR 10.24.10. and is applicable to all matters regarding acute care hospital services except for: obstetric services, addressed in COMAR 10.24.12; acute psychiatric facilities and services, addressed in COMAR 10.24.07; and acute alcoholism and drug abuse treatment services, addressed in COMAR 10.24.14.

**.03 Issues and Policies.**

**Commented [MB2]:** This entire section should be updated to reflect impacts after the All Payer Model implementation on January 1. 2014, and Total Cost of Care Model on January 1, 2019.

Certificate of Need (CON) regulation had its beginnings in Maryland in the early 1970s, a period during which about half the states were establishing such programs in an effort to gain control over a health care system that was expanding rapidly, in terms of spending and complexity, largely as a response to the major gains in private and public health insurance coverage (the Medicare and Medicaid programs were established in 1965), changes in health care service delivery, population growth, and physician workforce growth and specialization. Unlike most states, Maryland also responded more specifically to the issue of hospital price inflation in the 1970s by developing a hospital rate setting system and, unlike any other state, has maintained comprehensive hospital rate regulation through the present day.

The Maryland CON program has evolved during its existence and the scope of the program has become more focused on a limited number of health care facility and project categories, including the establishment of hospitals, the relocation and replacement of existing hospitals, adding beds or operating rooms at hospitals, and major hospital capital projects. Over the course of thirty years, CON and hospital rate regulation have influenced the shape of the hospital industry in Maryland. Maryland has fewer hospital beds than the nation as a whole (2.0 per thousand compared to the U.S ratio of 2.7 in 2005) and, until very recently, also had a lower rate of hospital admissions. (Maryland exceeded the national ratio in 2005, with 120.1 admissions per thousand compared with the U.S. rate of 117.9, after consistently trending below the U.S ratio from 1994 through 2004.) Because of a higher level of success in reducing the length of hospital stays, Maryland continues to trend below the nation in the demand for hospital days (569.2 per thousand population in 2005 compared to the U.S. rate of 666.4) but has achieved more efficient use of hospital beds (an average annual bed occupancy rate of 75% from 2001 through 2005 compared to the overall national occupancy rate of 66% during that same period). In 2005, Maryland recorded negligibly lower levels of inpatient surgical demand (MD: 33.7 per thousand population; U.S.: 34.1) and emergency department visits (MD: 385.7 visits per thousand population; U.S.: 388) than the nation as a whole. Maryland recorded a substantially lower rate of total outpatient visits to hospitals (which include

emergency department visits) than the U.S. in 2005 (1,205 visits per thousand population compared to the U.S. rate of 1,977) and a higher rate of hospital-based outpatient surgery (63.8 cases per thousand population compared to the U.S. rate of 59.0 per thousand), despite the fact that Maryland has more Medicare-certified ambulatory surgery centers per capita than any other state. Hospital expenditures per capita in Maryland have ranged from 84% to 93% of the U.S. hospital spending level between 1994 and 2005, with an advantage that is narrowing in recent years. (From 1994 through 1999, per capita hospital expenditures in Maryland averaged 86.4% of national spending levels. In 2000 through 2005, Maryland's per capita rate of hospital spending averaged 89.6% of the U.S. spending level.)[2]

Beginning January~~July~~ 1, 2014, the State of Maryland entered into a new agreement with the federal Centers for Medicare and Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI). This agreement requires the following:

1) Maryland's All payer, hospital spending per capita grow below 3.58%, the ten year average of Maryland Gross Domestic Product per Capita
2) Maryland's Medicare, hospital spending per beneficiary grow slower than the nation over a period of five years to produce $330 million in cumulative Medicare savings
3) Maryland's Medicare, total provider spending per beneficiary grow no more than 1% above the nation in any year, and, grow no more than nation in any two consecutive years.

These provisions create significant incentives to reduce unnecessary and avoidable service use, across all health care services. At the time of implementation, all of Maryland's hospitals entered into Global Budgeted Revenue (GBR) agreements that provide each hospital an annual, fixed amount regulated charges (gross revenues). Since the inception of the All-Payer Model agreement and Global Budgeted Revenue…. **INSERT UPDATED DEMAND STATISTICS AND HOW THEY TRACK VERSUS PREVIOUS PERIODS**

~~M~~aryland's hospitals are ~~overwhelmingly not for profit (46 of 47 general acute care h~~ospitals), all not for profit, there are no specialized surgical hospitals, and relatively few special hospitals of any kind (such as long-term care, psychiatric, or medical rehabilitation hospitals). There are no

[2] All statistics in this paragraph from the *AHA Hospital Statistics* series, 2000-2007.

public general hospitals in Maryland (i.e., general hospitals owned and operated by state or local government). Most of Maryland's general acute care hospitals (7553%) are affiliated with ~~other~~ M~~aryland general~~ other hospitals in ~~eight~~ multi-hospital systems, including three hospitals affiliated with only non-Maryland hospitals in other systems. The now mature rate setting system has resulted in a high-level of financial stability among the State's hospitals, with most hospitals recording margins adequate for assurance of long-term viability, few hospitals failing or in serious danger of failing, and a high proportion of hospitals demonstrating the ability to obtain funding for capital investment at favorable interest rates.

Hospital inpatient and outpatient care together represent the largest single category of health care expenditures in Maryland, accounting for nearly a third of the State's total health care expenditures in 2006; an estimated expenditure of approximately $10.3 billion in that year. Growth in spending for inpatient hospital care accounted for 24% of Maryland's overall growth in health care spending between 2002 and 2006 and spending for outpatient hospital care accounted for 11% of total expenditure growth. Hospital service expenditures increased at an annual average rate of 9% between 2002 and 2006, faster than the national experience, and narrowing the gap between per capita spending by Marylanders for hospital services, an average of $1,825 in 2006 and the national average, $2,077 in 2006.[3]

**Commented [MB3]:** Needs updating

The chief hospital policy objectives which serve as a practical focus for the Maryland Certificate of Need program in its fourth decade of operation are reflected in the following six policy statements, which are also consistent with the considerations outlined in Maryland regulation for use by the Maryland Health Care Commission in reviewing health care facility ~~c~~apital projects. ~~Given the return of growth in general hospital patient census which began in the late 1990s (after almost three decades of decline), the CON program should strive to allow for r~~easonable ~~increases in hospital bed capacity. It should consider hospital expansion plans with~~ The CON program should align with Maryland's All-Payer Model and its goals to treat patients in the lowest cost setting appropriate for his or her individual condition, and, to reduce unnecessary and avoidable hospital utilization. Hospitals continue to reconfigure their physical plants to reflect this realignment of hospital services from inpatient to outpatient, and from hospital located services to services that are not regulated by the Health Services Cost Review Commission.

[3] All figures in this paragraph from *State Health Care Expenditures, Experience from 2006*, MHCC, January, 2008.

~~an eye to avoiding the overbuilding that occurred in the 1960s and 70s, which failed to anticipate both the massive shift away from inpatient to outpatient services and the ability to shrink hospital inpatient stays. Hospitals continue to reconfigure their physical plants to more conveniently serve the continuing growth in outpatient service volumes. This often involves the creation of separate facilities and discrete service channels for outpatients and inpatients. There has also~~

~~been a strong emphasis on meeting the perceived market demand for private patient rooms and more technologically sophisticated space for the delivery of inpatient services to a patient population that is, on average, more acutely ill. The CON program should assure that this reconfiguration places an equally strong emphasis on achieving operational efficiencies, which is a reasonable expectation as the volume of service being delivered grows. It is also a necessity, g~~iven the tight supply of skilled labor for hospital jobs. CON regulation should also assure that facility designs reflect the state-of-the-art in facilitating safer patient care, improving patient outcomes, and minimizing negative environmental impacts. The CON program should continue to serve as a means for achieving a balance between geographic access to specialized services and the need for limiting the number of programs offering specialized services, when such "regionalization" of service delivery offers benefits in quality and cost-effectiveness.

**Policy 3.0 Acute care hospital services will be provided in the most cost-effective**

**manner possible, consistent with demand for those services, appropriately meeting the need for**

**such services and providing appropriate access to such services, consistent with the goals of Maryland's All-Payer Model.~~.~~**

**Policy 3.1 All Marylanders will have reasonable geographic and financial access to appropriate acute care hospital services. All Maryland hospitals and health systems will strive to address the needs of underserved populations and to reduce identified ethnic and racial disparities in the provision of acute hospital care.**

**Policy 3.2 All Maryland hospitals and health systems will consider smart and sustainable growth policies as well as green design principles in hospital siting decisions and facility design choices.**

**Policy 3.3 Hospitals and health systems will continuously and systematically work to improve the quality and safety of the care they provide. This will include planning and implementing integrated electronic health record systems that contribute to infection control, patient safety, and quality improvement and implementing the capability for sharing electronic health information, including clinical data, with other health care providers.**

**Policy 3.4 Specialized acute care services should be provided on a coordinated, regional basis.**

**~~P~~Policy 3.5 The ~~all-payer hospital rate setting system will be retained as an essential mechanism to contain increases in hospital and health system costs for all payers and as a means for promoting the maintenance of f~~inancial ~~stability in the Maryland hospital system.~~All Payer Model promotes the efficient and effective use of health care services in the lowest cost setting The CON**

**program will appropriately coordinate its capital project review ~~a~~ctivities with the hospital rate setting system with the objectives of the All-Payer Model and the Health Services Cost Review Commission's rate setting policies and methodologies to achieve savings under the All-Payer Model. ~~of~~**

**~~containing the cost of hospital facilities and services.~~**

**Standards.**

**A. General Standards.**

~~The following general standards encompass Commission expectations for the delivery of~~

a~~cute care services by all hospitals in Maryland.~~ (1) Each hospital that seeks a Certificate of Need for a project covered by this Chapter of the State Health Plan must:

(a) Be licensed, in good standing, by the Maryland Department of Health and Mental Hygiene;

Accredited by the Joint Commission; and

(c) In compliance with the conditions of participation of the Medicare and Medicaid programs.

(2) Should an application be submitted to create new services under this chapter, the Commission shall consult with the other regulatory agencies to determine the process and timing of satisfying subsection (1) a – c of this section

~~address and document its~~

~~compliance with each of the following general standards as part of its Certificate of Need application. Each hospital that seeks a Certificate of Need exemption for a project covered by this Chapter of the State Health Plan must address and demonstrate consistency with each of the following general standards as part of its exemption request.~~

~~**(1) Information Regarding Charges.**~~

~~Information regarding hospital charges shall be available to the public. After July 1, 2010, each hospital shall have a written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:~~

~~(a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet web site;~~

~~(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and~~

**Commented [MB4]:** Suggested revisions include striking most of this section, recommending that these measures be addressed by the Health Services Cost Review Commission that regulates hospital charges. For an existing hospital to seek a Certificate of Need, the hospitals should be licensed, accredited and participate in government payer programs. Charges, charity care and quality are regulated by the HSCRC.

Hospitals support quality and transparency. For **hospitals**, this should be managed by HSCRC.

~~(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.~~

~~(2) Charity Care Policy.~~

Commented [MB5]: See proposed revisions to Health General 19-214.1.

~~Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay.~~

~~(a) The policy shall provide:~~

~~(i) Determination of Probable Eligibility. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital must make a determination of probable eligibility.~~

~~(ii) Minimum Required Notice of Charity Care Policy.~~

~~1. Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;~~

~~2. Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital; and~~

~~3. Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.~~

~~(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.~~

~~(3) Quality of Care.~~

~~An acute care hospital shall provide high quality care.~~

~~(a) Each hospital shall document that it is:~~

~~(i) Licensed, in good standing, by the Maryland Department of Health and Mental Hygiene;~~

~~(ii) Accredited by the Joint Commission; and~~

~~(iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.~~

~~(b) A hospital with a measure value for a Quality Measure included in~~

~~the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it is taking to improve performance for that Quality Measure.~~

**B. Project Review Standards.**

Commented [MB6]: When the chapter is updated, these standards should be reviewed and revised.

The standards in this section are intended to guide reviews of Certificate of Need applications and exemption requests involving acute care general hospital facilities and services. An applicant for a Certificate of Need must address, and its proposed project will be evaluated for compliance with, all applicable review standards. An applicant for a Certificate of Need exemption must address, and its proposed project will 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 in terms of travel time for its likely service area population. Optimal travel time for general medical/surgical, intensive/critical care and pediatric services shall be within 30 minutes under normal driving conditions for 90 percent of the population in its likely service area.

**(2) Identification of Bed Need and Addition of Beds.**

Only medical/surgical/gynecological/addictions ("MSGA") beds and pediatric beds identified as needed and/or currently licensed shall be developed at acute care general hospitals.

(a) Minimum and maximum need for MSGA and pediatric beds are determined using the need projection methodologies in Regulation .05 of this Chapter.

(b) Projected need for trauma unit, intensive care unit, critical care unit, progressive care unit, and ~~care for AIDS patients~~ is included in the MSGA need projection.

Commented [MB7]: No longer needed.

(c) Additional MSGA or pediatric beds may be developed or put into operation only if:

(i) The proposed additional beds will not cause the total bed capacity of the hospital to exceed the most recent annual calculation of licensed bed capacity for the hospital made pursuant to Health-General §19-307.2; or

(ii) The proposed additional beds do not exceed the minimum jurisdictional bed need projection adopted by the Commission and calculated using the bed need projection methodology in Regulation .05 of this Chapter; or

(iii) The proposed additional beds exceed the minimum jurisdictional bed need projection but do not exceed the maximum jurisdictional bed need

projection adopted by the Commission and calculated using the bed need projection methodology in Regulation .05 of this Chapter and the applicant can demonstrate need at the applicant hospital for bed capacity that exceeds the minimum jurisdictional bed need projection; or

(iv) The number of proposed additional MSGA or pediatric beds may be derived through application of the projection methodology, assumptions, and targets contained in Regulation .05 of this Chapter, as applied to the service area of the hospital.

**(3) Minimum Average Daily Census for Establishment of a Pediatric Unit.**

An acute care general hospital may establish a new pediatric service only if the projected average daily census 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.

**(4) Adverse Impact.**

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

(a) If the hospital is seeking an increase in rates from the Health Services Cost Review Commission to account for the increase in capital costs associated with the proposed project, upon docketing, the Commission will consult with the Health Services Cost Review Commission.

(b) ~~and the Commission will include a recommendation from~~ the Health Services Cost Review Commission ~~in its application decision~~will provide the Commission a recommendation within 45 days from docketing

~~and the hospital has a fully adjusted Charge Per Case that exceeds the fully adjusted average Charge Per Case for its peer group, the hospital must document that its Debt to Capitalization ratio is below the average ratio for its peer group. In addition, if the project involves replacement of physical plant assets, the hospital must document that the age of the physical plant assets being replaced exceed the Average Age of Plant for its~~

~~peer group or otherwise demonstrate why the physical plant assets require replacement in order 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, or otherwise modifying a facility or service, the ~~a~~pplicant shall document that each proposed change will not inappropriately diminish, ~~for the population in the primary service area,~~ the availability or accessibility to care, based on service demand and service need in its primary service area, including access for the indigent and/or uninsured.

**(5) Cost-Effectiveness.**

A proposed hospital capital project should 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 ~~p~~rimary objective of its proposed project ~~and shall identify at least two alternative approaches that it considered for achieving these primary objectives. For each approach, the hospital must:~~

~~(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 provide supporting information to justify the capital and operational cost estimates ~~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 (a) above, 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 Title 5, Subtitle 7B of the State Finance and Procurement Article of the Annotated Code of

Maryland shall demonstrate:

(i) That it has considered, at a minimum, an alternative project site located within a Priority Funding Area that provides the most optimal geographic accessibility to the population in its likely service area, as defined in Project Review Standard (1);

(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 site or sites located within a Priority Funding Area.

**(6) Burden of Proof Regarding Need.**

A hospital project shall be approved only if there is demonstrable need. The burden of demonstrating need for a service not covered by Regulation .05 of this Chapter or by another chapter of the State Health Plan, including a service for which need is not separately projected, rests with the applicant.

~~**(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 rate increase proposed by the hospital related to the capital cost of the project shall 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.~~

**Commented [MB8]:** Hospitals believe this section is no longer required because the Total Cost of Care Model and HSCRC rate setting policies enforce efficiency.

~~**(8) Construction Cost of Non-Hospital Space.**~~

~~The proposed construction costs of non-hospital space shall be reasonable and in line 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 rate increase proposed by the hospital related to the capital cost of the non-hospital space shall 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~~ In general, the Health Services Cost Review Commission, should not consider costs for a rate adjustment related to non-hospital services, or, costs for space exceeding generally accepted construction standards.

~~for hospitals should not recognize the costs associated with construction of non-hospital space.~~

~~**(9) Inpatient Nursing Unit Space.**~~

~~Space built or renovated for inpatient nursing units that exceeds reasonable space standards per bed for the type of unit being developed shall not be recognized in a rate adjustment. If the Inpatient Unit Program Space per bed of a new or modified inpatient nursing unit exceeds 500 square feet per bed, any rate increase proposed by the hospital related to the capital cost of the project shall not include the amount of the projected 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.~~

~~**(10) Rate Reduction Agreement.**~~

~~A high charge hospital will not be granted a Certificate of Need to establish a new acute care service, or to construct, renovate, upgrade, expand, or modernize acute care facilities, including support and ancillary facilities, unless it has first agreed to enter into a rate reduction agreement with the Health Services Cost Review Commission, or the Health Services Cost Review Commission has determined that a rate reduction agreement is not necessary.~~

**Commented [MB9]:** This is already determined by the HSCRC.

**(11) Efficiency.**

**Commented [MB10]:** See comment on Section 7.

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

(a) summarize the expected operational efficiencies that will occur as a result of the project; or
(b) demonstrate why operational efficiencies will not be achieved

~~(a) 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 a~~chieved.~~

**(12) 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.

**(13) Financial Feasibility.**

A hospital capital project shall be financially feasible and shall not jeopardize

the long-term financial viability of the hospital as determined by the Health Services Cost Review Commission.

(a) Upon docketing, ~~T~~the Commission will provide the financial projections and accompanying assumptions to the Health Services Cost Review Commission

~~(a)~~ ~~W~~within 45 days of docketing, the Health Services Cost Review Commission will review the financial projections and notify Commission staff as to the feasibility of the financial projections~~.~~

~~(a) Financial projections filed as part of a hospital Certificate of Need application must be accompanied by a statement containing each assumption used to develop the projections.~~

~~(b) Each applicant must 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 charge levels, rates of reimbursement, contractual adjustments and 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~~

~~(iv) 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 Certificate of Need for a project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project when the hospital can demonstrate that overall hospital financial performance will be positive and that the services will benefit the hospital's primary~~ service area population.

**(14) Emergency Department Treatment and Observation Capacity and Space.**

(a) An applicant proposing a new or expanded emergency department, or observation services area, should reflect reasonably projected levels of visit volume and corresponding project costs.

~~shall classify 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~~

**Commented [MB11]:** These are relatively small expenditures, and emergency services are not explicitly defined by CON. ED standards could be eliminated, if no specific issues are identified in the updated Issues section of the plan.

~~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 or high range and the projected emergency department visit volume.~~

~~(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 or 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~~

~~(v) Any other relevant information on the unmet need for emergency d~~epartment or urgent care services in the service area.

**(15) 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:

(a) The applicant hospital must demonstrate that, 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) The applicant hospital must demonstrate that it has effectively managed its existing emergency department treatment capacity to maximize use; and

(c) The applicant hospital must demonstrate that it has considered the need for inpatient bed, outpatient observation and other facility and system capacity that will be affected by greater volumes of emergency department patients.

**(16) Shell Space.**

(a) Unfinished hospital shell space for which there is no immediate need or use shall 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 has a positive net present value that:

(i) Considers the most likely use identified by the hospital for the unfinished space;

(ii) Considers the time frame projected for finishing the space; and

(iii) Demonstrates that the hospital is likely to need the space for the most likely identified use in the projected time frame.

(c) Shell space being constructed on lower floors of a building addition that supports finished building space on upper floors does not require a net present value analysis. Applicants shall provide information on the cost, the most likely uses, and the likely time frame for using such 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 rate adjustment by the Health Service Cost Review Commission.

**.05 Methodologies for Projecting Acute Care Hospital Bed Need.**

**A. Period of Time Covered.**

(1) The base year from which projections are calculated is the most recent calendar year.

(2) The target year to which projections are calculated is ten years after the base year.

**B. Services and Age Groups.**

**(1) <u>Exclusions.</u>**

(a) No projections are made for newborn services.

(b) Patients classified as rehabilitation in the acute care hospital discharge abstract data base are excluded from the calculations.

**Commented [MB12]:** The net present value requirement of this standard has always been difficult to rationalize and address. It comes from concern for capital expenditure projects and determining efficiency.

**Commented [MB13]:** The following items should be considered when the methodologies to project need are updated.
- Age categories
- Projected changes (5 and 10 year averages)
- Use rate changes and other Model incentives due to expected changes in health care,
- Accounting for shifts to observation services and other outpatient sites
-Emerging technologies
- Relocations of an entire hospital
- Concentration of specialty services

**Md. HEALTH-GENERAL Code Ann. § 19-118**

§ 19-118. State health plan

**(a) Duty of Commission; contents of plan. --**

**(1)** At least every 5 years, beginning no later than October 1, 1983, the Commission shall adopt a State health plan.

**(2)** The plan shall; ~~include:~~

(i) Align with the Maryland's Total Cost of Care Model ~~All-Payer Model~~ agreement with the federal Center for Medicare and Medicaid Innovation; and

**(ii)** Include ~~The~~ methodologies, standards, and criteria for certificate of need review; and

**(iii)** ~~P~~Priorit~~y~~ize for conversion of acute capacity to alternative uses where appropriate.

**(b) Review of State plan; publication of changes. --** Annually, the Commission shall review each chapter of the state health plan, or upon written ~~Annually or upon~~ petition by any person, the Commission shall review a specific chapter in the State health plan to determine if a specific chapter requires revision. ~~and publish any changes in the plan that the Commission considers necessary, subject to the review and approval granted to the Governor under this subtitle~~.

(1) The Commission shall establish annually, at a public meeting the priority of State health plan chapters to be reviewed.

(2) Should the Commission determine that one or more of the State health plan chapters should be revised, the Commission shall establish, at a public meeting, the priority of the State health plan chapters to be revised.

(3) The Commission shall publish any changes in the chapter or chapters of the plan that the Commission considers necessary, subject to the review and approval granted to the Governor under this subtitle.

**(c) Rules and regulations to ensure public input. --** The Commission shall adopt rules and regulations that ensure broad public input, public hearings, and consideration of local health plans in development of the State health plan.

**(d) Standards and policies relating to certificate of need program. --**

**(1)** The Commission shall develop standards and policies consistent with the State health plan that relate to the certificate of need program.

**(2)** The standards:

**(i)** Shall address the availability, accessibility, cost, and quality of health care; and

**(ii)** Are to be reviewed and revised periodically to reflect new developments in health planning, delivery, and technology.

**(3)** In adopting standards regarding cost, efficiency, cost-effectiveness, or financial feasibility, the Commission shall take into account the relevant methodologies of the Health Services Cost Review Commission.

**(e) Duties of Secretary. --** Annually, the Secretary shall make recommendations to the Commission on the plan. The Secretary may review and comment on State specifications to be used in the development of the State health plan.

**(f) Duty of State agencies and departments. --** All State agencies and departments, directly or indirectly involved with or responsible for any aspect of regulating, funding, or planning for the health care industry or persons involved in it, shall carry out their responsibilities in a manner consistent with the State health plan and available fiscal resources.

**(g) Certain standards and requirements not duplicated. --** In carrying out their responsibilities under this Part II of this subtitle for hospitals, the Commission and the Secretary

shall recognize, but may not apply, develop, or duplicate standards or requirements related to quality which have been adopted and enforced by national or State licensing or accrediting authorities.

**(h) Transfer of functions. --** The Commission shall transfer to the Maryland Department of Health health planning functions and necessary staff resources for licensed entities in the State health plan that are not required to obtain a certificate of need or an exemption from the certificate of need program.

**Article - Health - General**

[Previous][Next]

§19–120.

(a) (1) In this section the following words have the meanings indicated.

(2) "Consolidation" and "merger" include increases and decreases in bed capacity or services among the components of an organization that:

(i) Operates more than one health care facility; or

(ii) Operates one or more health care facilities and holds an outstanding certificate of need to construct a health care facility.

(3) (i) "Health care service" means any clinically related patient service.

(ii) "Health care service" includes a medical service.

~~(4) "Limited service hospital" means a health care facility that:~~

~~(i) Is licensed as a hospital on or after January 1, 1999;~~

~~(ii) Changes the type or scope of health care services offered by eliminating the facility's capability to admit or retain patients for overnight hospitalization;~~

~~(iii) Retains an emergency or urgent care center; and~~

~~(iv) Complies with the regulations adopted by the Secretary under § 19–307.1 of this title.~~

(~~5~~4) "Medical service" means:

(i) Any of the following categories of health care services:

1. Medicine, surgery, gynecology, addictions;

2. Obstetrics;

3. Pediatrics;

4. Psychiatry;

5. Rehabilitation;

6. Chronic care;

7. Comprehensive care;

1

8. Extended care;

9. Intermediate care; or

10. Residential treatment; or

(ii) Any subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of health care services for which need is projected in the State health plan.

(b) The Commission may set an application fee for a certificate of need for health care facilities not assessed a user fee under this subtitle.

(c) The Commission shall adopt rules and regulations for applying for and issuing certificates of need.

(d) The Commission may adopt, after October 1, 1983, new thresholds or methods for determining the circumstances or minimum cost requirements under which a certificate of need application must be filed.

(e) (1) A person shall have a certificate of need issued by the Commission before the person develops, operates, or participates in any of the health care projects for which a certificate of need is required under this section.

(2) A certificate of need issued before January 13, 1987, may not be rendered wholly or partially invalid solely because certain conditions have been imposed, if an appeal concerning the certificate of need, challenging the power of the Commission to impose certain conditions on a certificate of need, has not been noted by an aggrieved party before January 13, 1987.

(f) Except as provided in subsection (g)(2)(iii) of this section, a certificate of need is required before a new health care facility is built, developed, or established.

(g) (1) A certificate of need is required before an existing or previously approved, but unbuilt, health care facility is moved to another site.

(2) This subsection does not apply if:

(i) The Commission adopts limits for relocations and the proposed relocation does not exceed those limits;

(ii) The relocation is the result of a partial or complete replacement of an existing hospital or related institution, as defined in § 19–301 of this title, and the relocation is to another part of the site or immediately adjacent to the site of the existing hospital or related institution;

(iii) Subject to the provisions of subsections (i) and (j) of this section, the relocation is of an existing health care facility owned or controlled by a merged asset

system and is to:

1. A site within the primary service area of the health care facility to be relocated if:

A. The proposed relocation is not across county boundaries; and

B. At least 45 days prior to the proposed relocation, notice is filed with the Commission;

2. A site outside the primary service area of the health care facility to be relocated but within the primary service area of the merged asset system if:

A. At least 45 days prior to the proposed relocation, notice is filed with the Commission; and

B. The Commission in its sole discretion, and in accordance with the criteria adopted by regulation, finds that the relocation is in the public interest, is not inconsistent with the State health plan, and will result in the more efficient and effective delivery of health care services; or

~~3. For a limited service hospital, a site within the immediate area as defined in regulation by the Commission; or~~

(iv~~v~~) The relocation involves moving a portion of a complement of comprehensive care beds previously approved by the Commission after January 1, 1995, for use in a proposed new related institution, as defined in § 19–301 of this title, but unbuilt on October 1, 1998, if:

1. The comprehensive care beds that were originally approved by the Commission in a prior certificate of need review were approved for use in a proposed new related institution to be located in a municipal corporation within Carroll County in which a related institution is not located;

2. The comprehensive care beds being relocated will be used to establish an additional new related institution that is located in another municipal corporation within Carroll County in which a related institution is not located;

3. The comprehensive care beds not being relocated are intended to be used to establish a related institution on the original site; and

4. Both ~~-~~the previously approved comprehensive care beds for use on the original site and the relocated comprehensive care beds for use on the new site will be used as components of single buildings on each site that also offer independent or assisted living residential units.

(3) Notwithstanding any other provision of this subtitle, a certificate of need is not required for a relocation described under paragraph (2)(iv) of this subsection.

(h) (1) A certificate of need is required before the bed capacity of a health care facility is changed.

(2) This subsection does not apply to any increase or decrease in bed capacity if:

(i) For a health care facility that is not a hospital, during a 2–year period the increase or decrease would not exceed the lesser of 10 percent of the total bed capacity or 10 beds;

(ii) 1. The increase or decrease would change the bed capacity for an existing medical service; and

2. A. The change would not increase total bed capacity;

B. The change is maintained for at least a 1–year period; and

C. At least 45 days prior to the change, the hospital provides written notice to the Commission describing the change and providing an updated inventory of the hospital's licensed bed complement;

(iii) 1. At least 45 days before increasing or decreasing bed capacity, written notice of intent to change bed capacity is filed with the Commission;

2. The Commission in its sole discretion finds that the proposed change:

A. Is pursuant to the consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a facility to a nonhealth–related use;

B. Is not inconsistent with the State health plan or the institution–specific plan developed by the Commission;

C. Will result in the delivery of more efficient and effective health care services; and

D. Is in the public interest; and

3. Within 45 days of receiving notice, the Commission notifies the health care facility of its finding; or

(iv) The increase or decrease in bed capacity is the result of the annual licensed bed recalculation provided under § 19–307 of this title.

(i) (1) Except as provided in paragraph (2) of this subsection, for a hospital

located in a county with three or more hospitals, a certificate of need is not required before the bed capacity is increased or decreased if the change:

(i) Occurs on or after July 1, 2000;

(ii) Is between hospitals in a merged asset system located within the same health service area;

(iii) Does not involve comprehensive or extended care beds; and

(iv) Does not occur earlier than 45 days after a notice of intent to reallocate bed capacity is filed with the Commission.

(2) A hospital may not create a new health care service through the relocation of beds from one county to another county pursuant to this subsection.

(j) (1) A certificate of need is required before the type or scope of any health care service is changed if the health care service is offered:

(i) By a health care facility;

(ii) In space that is leased from a health care facility; or

(iii) In space that is on land leased from a health care facility.

(2) This subsection does not apply if:

(i) The Commission adopts limits for changes in health care services and the proposed change would not exceed those limits;

(ii) The proposed change and the annual operating revenue that would result from the addition is entirely associated with the use of medical equipment;

(iii) The proposed change would establish, increase, or decrease a health care service and the change would not result in the:

1. Establishment of a new medical service or elimination of an existing medical service;

2. Establishment of a cardiac surgery, organ transplant surgery, or burn or neonatal intensive health care service;

3. Except as provided in § 19–120.1 of this subtitle, establishment of percutaneous coronary intervention services;

4. Establishment of a home health program, hospice program, or freestanding ambulatory surgical center or facility; or

5. Expansion of a comprehensive care, extended care,

intermediate care, residential treatment, psychiatry, or rehabilitation medical service, except for an expansion related to an increase in total bed capacity in accordance with subsection (h)(2)(i) of this section; or

(iv) 1. At least 45 days before increasing or decreasing the volume of one or more health care services, written notice of intent to change the volume of health care services is filed with the Commission;

2. The Commission in its sole discretion finds that the proposed change:

A. Is pursuant to:

I. The consolidation or merger of two or more health care facilities;

II. The conversion of a health care facility or part of a facility to a nonhealth–related use; or

~~III. The conversion of a hospital to a limited service hospital; or~~

III~~IV~~. The conversion of a licensed general hospital to a freestanding medical facility in accordance with subsection (o)(3) of this section;

B. Is not inconsistent with the State health plan or the institution–specific plan developed and adopted by the Commission;

C. Will result in the delivery of more efficient and effective health care services; and

D. Is in the public interest; and

3. Within 45 days of receiving notice under item 1 of this item, the Commission notifies the health care facility of its finding.

(3) Notwithstanding the provisions of paragraph (2) of this subsection, a certificate of need is required:

(i) Before an additional home health agency, branch office, or home health care service is established by an existing health care agency or facility;

(ii) Before an existing home health agency or health care facility establishes a home health agency or home health care service at a location in the service area not included under a previous certificate of need or license;

(iii) Before a transfer of ownership of any branch office of a home health agency or home health care service of an existing health care facility that

separates the ownership of the branch office from the home health agency or home

health care service of an existing health care facility which established the branch office; or

(iv) Before the expansion of a home health service or program by a health care facility that:

1. Established the home health service or program without a certificate of need between January 1, 1984 and July 1, 1984; and

2. During a 1–year period, the annual operating revenue of the home health service or program would be greater than $333,000 after an annual adjustment for inflation, based on an appropriate index specified by the Commission.

(k) (1) A certificate of need is required before any of the following capital expenditures are made by or on behalf of a hospital:

(i) Any ~~–~~expenditure that, under generally accepted accounting principles, is not properly chargeable as an operating or maintenance expense, if:

1. The expenditure is made as part of an acquisition, improvement, or expansion, and, after adjustment for inflation as provided in the regulations of the Commission, the total expenditure, including the cost of each study, survey, design, plan, working drawing, specification, and other essential activity, ~~is more than $10,000,000~~is more than the lower of:

a. Twenty five percent of the hospital's immediate prior year gross regulated charges, or~~;~~

b. $50,000,000

3. The expenditure results in a substantial change in the bed capacity of the hospital; or

4. The expenditure results in the establishment of a new medical service in a hospital that would require a certificate of need under subsection (i) of this section; or

(ii) Any expenditure that is made to lease or, by comparable arrangement, obtain any plant or equipment for the hospital, if:

1. The expenditure is made as part of an acquisition, improvement, or expansion~~, and, after adjustment for inflation~~ as provided in the rules and regulations of the Commission, the total expenditure, including the cost of each study, survey, design, plan, working drawing, specification, and other essential activity, ~~is more than $10,000,000~~~~is~~ is more than the lower of:

a. Twenty five percent of the hospital's immediate prior year gross regulated charges, or

b. $50,000,000

2. The expenditure is made as part of a replacement of any plant and equipment and is more than the lower of:

a. Twenty five percent of the hospital's immediate prior year gross regulated charges, or

b. $50,000,000

~~is more than $10,000,000 after adjustment for inflation is more than twenty five percent of the hospital's immediate prior year gross regulated charges as provided in the regulations of the Commission;~~

3. The expenditure results in a substantial change in the bed capacity of the hospital; or

4. The expenditure results in the establishment of a new medical service in a hospital that would require a certificate of need under subsection (i) of this section.

(2) A certificate of need is required before any of the following capital expenditures are made by or on behalf of a health care facility other than a hospital:

(i) Any expenditure that, under generally accepted accounting principles, is not properly chargeable as an operating or maintenance expense, if:

1. The expenditure is made as part of an acquisition, improvement, or expansion, and, after adjustment for inflation as provided in the regulations of the Commission, the total expenditure, including the cost of each study, survey, design, plan, working drawing, specification, and other essential activity, is more than $5,000,000;

2. The expenditure is made as part of a replacement of any plant and equipment of the health care facility other than a hospital and is more than $5,000,000 after adjustment for inflation as provided in the regulations of the Commission;

3. The expenditure results in a substantial change in the bed capacity of the health care facility other than a hospital; or

4. The expenditure results in the establishment of a new medical service in a health care facility other than a hospital that would require a certificate of need under subsection (i) of this section; or

(ii) Any expenditure that is made to lease or, by comparable arrangement, obtain any plant or equipment for the health care facility other than a hospital, if:

1. The expenditure is made as part of an acquisition, improvement, or expansion, and, after adjustment for inflation as provided in the regulations of the Commission, the total expenditure, including the cost of each study, survey, design, plan, working drawing, specification, and other essential activity, is more than $5,000,000;

2. The expenditure is made as part of a replacement of any plant and equipment and is more than $5,000,000 after adjustment for inflation as provided in the regulations of the Commission;

3. The expenditure results in a substantial change in the bed capacity of the health care facility other than a hospital; or

4. The expenditure results in the establishment of a new medical service in a health care facility other than a hospital that would require a certificate of need under subsection (i) of this section.

(3) A certificate of need is required before any equipment or plant is donated to a health care facility, if a certificate of need would be required under paragraph (1) or (2) of this subsection for an expenditure by the health care facility to acquire the equipment or plant directly.

(4) A certificate of need is required before any equipment or plant is transferred to a health care facility at less than fair market value if a certificate of need would be required under paragraph (1) or (2) of this subsection for the transfer at fair market value.

(5) A certificate of need is required before a person acquires a health care facility if a certificate of need would be required under paragraph (1) or (2) of this subsection for the acquisition by or on behalf of the health care facility.

(6) This subsection does not apply to:

(i) Site acquisition;

(ii) Acquisition of a health care facility if, at least 30 days before making the contractual arrangement to acquire the facility, written notice of the intent to make the arrangement is filed with the Commission and the Commission does not find, within 30 days after the Commission receives notice, that the health services or bed capacity of the facility will be changed, provided that, for a merger with or acquisition of an existing general hospice, the purchaser of the general hospice may only acquire the authority to provide home–based hospice services in jurisdictions in which the seller of the general hospice is licensed to provide home–based hospice services;

(iii) Acquisition of business or office equipment that is not directly related to patient care;

(iv) Capital expenditures to the extent that they are directly related to the acquisition and installation of major medical equipment;

(v) A capital expenditure made as part of a consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a facility to a nonhealth–related use if:

1. At least 45 days before an expenditure is made, written notice of intent is filed with the Commission;

2. Within 45 days of receiving notice, the Commission in its sole discretion finds that the proposed consolidation, merger, or conversion:

A. Is not inconsistent with the State health plan or the

institution–specific plan developed by the Commission as appropriate;

B. Will result in the delivery of more efficient and effective health care services; and

C. Is in the public interest; and

3. Within 45 days of receiving notice, the Commission notifies the health care facility of its finding;

(vi) A capital expenditure by a nursing home for equipment, construction, or renovation that:

1. Is not directly related to patient care; and

2. Is not directly related to any change in patient charges or other rates;

(vii) A capital expenditure by a hospital, as defined in § 19–301 of this title, for equipment, construction, or renovation that:

1. Is not directly related to patient care; and

2. Does not increase patient charges or hospital rates;

(viii) A capital expenditure by a hospital, as defined in § 19–301 of this title, for a project in excess of the lower of:

a. Twenty five percent of the hospital's immediate prior year gross regulated charges, or

b. $50,000,000

~~$10,000,000 twenty five percent of the hospital's immediate prior year gross regulated charges for construction or renovation that:~~

1. May be related to patient care;

2. Does not require, over the entire period or schedule of debt service associated with the project, a total cumulative increase in patient charges or hospital rates of more than $1,500,000 for the capital costs associated with the project as determined by the Commission, after consultation with the Health Services Cost Review Commission;

3. At least 45 days before the proposed expenditure is made, the hospital notifies the Commission;

4. A. Within 45 days of receipt of the relevant financial

information, the Commission makes the financial determination required under item 2 of this item; or

B. The Commission has not made the financial determination required under item 2 of this item within 60 days of the receipt of the relevant financial information; and

5. The relevant financial information to be submitted by the hospital is defined in regulations adopted by the Commission, after consultation with

the Health Services Cost Review Commission;

(ix) A plant donated to a hospital, as defined in § 19–301 of this title, that does not require a cumulative increase in patient charges or hospital rates of more than $1,500,000 for capital costs associated with the donated plant as determined by the Commission, after consultation with the Health Services Cost Review Commission, if:

1. At least 45 days before the proposed donation is made, the hospital notifies the Commission;

2. A. Within 45 days of receipt of the relevant financial information, the Commission makes the financial determination required under this item (ix) of this paragraph; or

B. The Commission has not made the financial determination required under this item (ix) of this paragraph within 60 days of the receipt of the relevant financial information; and

3. The relevant financial information to be submitted by the hospital is defined in regulations adopted by the Commission after consultation with the Health Services Cost Review Commission; or

(x) A capital expenditure made as part of a conversion of a licensed general hospital to a freestanding medical facility in accordance with subsection (o)(3) of this section.

(7) Paragraph (6)(vi), (vii), (viii), (ix), and (x) of this subsection may not be construed to permit a facility to offer a new health care service for which a certificate of need is otherwise required.

(8) Subject to the notice requirements of paragraph (6)(ii) of this subsection, a hospital may acquire a freestanding ambulatory surgical facility or office of one or more health care practitioners or a group practice with one or more operating rooms used primarily for the purpose of providing ambulatory surgical services if the facility, office, or group practice:

(i) Has obtained a certificate of need;

(ii) Has obtained an exemption from certificate of need requirements; or

(iii) Did not require a certificate of need in order to provide ambulatory surgical services after June 1, 1995.

(9) Nothing in this subsection may be construed to permit a hospital to build or expand its ambulatory surgical capacity in any setting owned or controlled by the hospital without obtaining a certificate of need from the Commission if the building

or expansion would increase the surgical capacity of the State's health care system.

(l) (1) A certificate of need is not required to close any health care facility or part of a health care facility if at least 90 days before the closing or if at least 45 days before the partial closing of the health care facility, including a State hospital, a person proposing to close all or part of the health care facility files notice of the proposed closing or partial closing with the Commission.

(2) A hospital shall hold a public informational hearing in the county where the hospital is located if the hospital:

(i) Files a notice of the proposed closing of the hospital with the Commission;

(ii) Requests an exemption from the Commission under subsection (o)(3) of this section to convert to a freestanding medical facility; or

(iii) Is located in a county with fewer than three hospitals and files a notice of the partial closing of the hospital with the Commission.

(3) The Commission may require a health care facility other than a hospital described in paragraph (2) of this subsection that files notice of its proposed closing or partial closing to hold a public informational hearing in the county where the health care facility is located.

(4) A public informational hearing required under paragraph (2) or (3) of this subsection shall be held by the health care facility, in consultation with the Commission, within 30 days after:

(i) The health care facility files with the Commission a notice of its proposed closing or partial closing; or

(ii) The hospital files with the Commission a notice of intent to convert to a freestanding medical facility.

(5) (i) The Commission shall establish by regulation requirements for a public informational hearing required under paragraph (2) or (3) of this subsection.

(ii) For a hospital proposing to close, partially close, or convert to a freestanding medical facility, the regulations shall require the hospital to address:

1. The reasons for the closure, partial closure, or conversion;

2. The plan for transitioning acute care services previously provided by the hospital to residents of the hospital service area;

3. The plan for addressing the health care needs of the residents of the hospital service area;

4. The plan for retraining and placing displaced employees;

5. The plan for the hospital's physical plant and site; and

6. The proposed timeline for the closure, partial closure, or conversion to a freestanding medical facility.

(6) Within 10 working days after a public informational hearing held by a hospital under this subsection, the hospital shall provide a written summary of the hearing to:

(i) The Governor;

(ii) The Secretary;

(iii) The governing body of the county in which the hospital is located;

(iv) The local health department and the local board of health or similar body for the county in which the hospital is located;

(v) The Commission; and

(vi) Subject to § 2–1246 of the State Government Article, the Senate Finance Committee, the House Health and Government Operations Committee, and the members of the General Assembly who represent the district in which the hospital is located.

(m) (1) Notwithstanding any other provision of this section, the Commission shall consider the special needs and circumstances of a county where a medical service, as defined in this section, does not exist; and

(2) The Commission shall consider and may approve under this subsection a certificate of need application to establish, build, operate, or participate in a health care project to provide a new medical service in a county if the Commission, in its sole discretion, finds that:

(i) The proposed medical service does not exist in the county that the project would be located;

(ii) The proposed medical service is necessary to meet the health care needs of the residents of that county;

(iii) The proposed medical service would have a positive impact on the existing health care system;

(iv) The proposed medical service would result in the delivery of more efficient and effective health care services to the residents of that county; and

(v) The application meets any other standards or regulations

established by the Commission to approve applications under this subsection.

(n) The Commission may not issue a certificate of need or a determination with respect to an acquisition that authorizes a general hospice to provide home–based hospice services on a statewide basis.

(o) (1) Except as provided in paragraphs (2) and (3) of this subsection, a person shall have a certificate of need issued by the Commission before a person establishes or operates a freestanding medical facility.

(2) A certificate of need is not required for the establishment or operation of a freestanding medical facility pilot project established under § 19–3A–07 of this title.

(3) (i) A certificate of need is not required to establish or operate a freestanding medical facility if:

1. The freestanding medical facility is established as the result of the conversion of a licensed general hospital;

2. Through the conversion, the licensed general hospital will eliminate the capability of the hospital to admit or retain patients for overnight hospitalization, except for observation stays;

3. Except as provided in subparagraph (ii) of this paragraph, the freestanding medical facility will remain on the site of, or on a site adjacent to, the licensed general hospital;

4. At least 60 days before the conversion, written notice of intent to convert the licensed general hospital to a freestanding medical facility is filed with the Commission;

5. The Commission in its sole discretion finds that the conversion:

A. Is consistent with the State health plan;

B. Will result in the delivery of more efficient and effective health care services;

C. Will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system as determined by the State Emergency Medical Services Board; and

D. Is in the public interest; and

6. Within 60 days after receiving notice under item 4 of this subparagraph, the Commission notifies the licensed general hospital of the

Commission's findings.

(ii) The Commission may approve a site for a freestanding medical facility that is not on the site of, or on a site adjacent to, the licensed general hospital if:

1. The licensed general hospital is:

A. The only hospital in the county; or

B. One of two hospitals in the county that are part of the same merged asset system, and are the only two hospitals in the county; and

2. The site is within a 5–mile radius and in the primary service area of the licensed general hospital.

(iii) Notwithstanding subparagraph (i) of this paragraph, a licensed general hospital located in Kent County may not convert to a freestanding medical facility in accordance with subparagraph (i) of this paragraph before July 1, 2020.

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**Md. HEALTH-GENERAL Code Ann. § 19-214.1**

Current through October 1, 2017, of the 2017 Regular Session of the Maryland General Assembly.

**§ 19-214.1. Financial assistance policy**

(a) Definitions. --
(1) In this section the following words have the meanings indicated.
(2) "Financial hardship" means medical debt, incurred by a family over a 12-month period, that exceeds 25% of family income.
(3) "Medical debt" means out-of-pocket expenses, excluding co-payments, coinsurance, and deductibles, for medical costs billed by a hospital.
(b) In general. --
(1) The Commission shall require each acute care hospital and each chronic care hospital in the State under the jurisdiction of the Commission to develop a financial assistance policy for providing free and reduced-cost care to patients who lack health care coverage or whose health care coverage does not pay the full cost of the hospital bill.
(2) The financial assistance policy shall provide, at a minimum:
(i) Free medically necessary care to patients with family income at or below 150% of the federal poverty level; and
(ii) Reduced-cost medically necessary care to low-income patients with family income above 150% of the federal poverty level, in accordance with the mission and service area of the hospital.
(3)
(i) The Commission by regulation may establish income thresholds higher than those under paragraph (2) of this subsection.
(ii) In establishing income thresholds that are higher than those under paragraph (2) of this subsection for a hospital, the Commission shall take into account:
1. The patient mix of the hospital;
2. The financial condition of the hospital;
3. The level of bad debt experienced by the hospital; and
4. The amount of charity care provided by the hospital.
(4)
(i) Subject to subparagraphs (ii) and (iii) of this paragraph, the financial assistance policy required under this subsection shall provide reduced-cost medically necessary care to patients with family income below 500% of the federal poverty level who have a financial hardship.
(ii) A hospital may seek and the Commission may approve a family income threshold that is different than the family income threshold under subparagraph (i) of this paragraph.
(iii) In establishing a family income threshold that is different than the family income threshold under subparagraph (i) of this paragraph, the Commission shall take into account:
1. The median family income in the hospital's service area;
2. The patient mix of the hospital;
3. The financial condition of the hospital;
4. The level of bad debt experienced by the hospital;
5. The amount of charity care provided by the hospital; and

6. Other relevant factors.
(5) If a patient is eligible for reduced-cost medically necessary care under paragraphs (2)(ii) and (64) of this subsection, the hospital shall apply the reduction that is most favorable to the patient.
(76) If a patient has received reduced-cost medically necessary care due to a financial hardship, the patient or any immediate family member of the patient living in the same household:
(i) Shall remain eligible for reduced-cost medically necessary care when seeking subsequent care at the same hospital during the 12-month period beginning on the date on which the reduced-cost medically necessary care was initially received; and
(ii) To avoid an unnecessary duplication of the hospital's determination of eligibility for free and reduced-cost care, shall inform the hospital of the patient's or family member's eligibility for the reduced-cost medically necessary care.
(c) Posting notice of policy throughout hospitals. -- A hospital shall post a notice in conspicuous places throughout the hospital, including the billing office, informing patients of their right to apply for financial assistance and who to contact at the hospital for additional information.
(d) A hospital shall determine the probable eligibility of a patient seeking financial assistance;
(1) Generally within two business days of a patient's request for financial assistance, application for medical assistance or both; and
(2) Provide the patient with this determination
(ed) Duties of Commission. -- The Commission shall:
(1) Develop a uniform financial assistance application; and
(2) Require each hospital to use the uniform financial assistance application to determine eligibility for free and reduced-cost care under the hospital's financial assistance policy.
(ef) Application. -- The uniform financial assistance application:
(1) Shall be written in simplified language; and
(2) May not require documentation that presents an undue barrier to a patient's receipt of financial assistance.
(fg) Information sheet. --
(1) Each hospital shall develop an information sheet that:
(i) Describes the hospital's financial assistance policy;
(ii) Describes a patient's rights and obligations with regard to hospital billing and collection under the law;
(iii) Provides contact information for the individual or office at the hospital that is available to assist the patient, the patient's family, or the patient's authorized representative in order to understand:
1. The patient's hospital bill;
2. The patient's rights and obligations with regard to the hospital bill;
3. How to apply for free and reduced-cost care; and
4. How to apply for the Maryland Medical Assistance Program and any other programs that may help pay the bill;
(iv) Provides contact information for the Maryland Medical Assistance Program; and
(v) Includes a statement that physician charges are not included in the hospital bill and are billed separately.
(2) The information sheet shall be provided to the patient, the patient's family, or the patient's authorized representative:
(i) Before discharge;

(ii) With the hospital bill; and
(iii) On request.
(3) The hospital bill shall include a reference to the information sheet.
(4) The Commission shall:
(i) Establish uniform requirements for the information sheet; and
(ii) Review each hospital's implementation of and compliance with the requirements of this subsection.
(hg) Availability of staff. -- Each hospital shall ensure the availability of staff who are trained to work with the patient, the patient's family, and the patient's authorized representative in order to understand:
(1) The patient's hospital bill;
(2) The patient's rights and obligations with regard to the hospital bill, including the patient's rights and obligations with regard to reduced-cost medically necessary care due to a financial hardship;
(3) How to apply for the Maryland Medical Assistance Program and any other programs that may help pay the hospital bill; and
(4) How to contact the hospital for additional assistance.