

Certificate of Need Modernization Task Force

Meeting of October 12, 2018



AGENDA

1. Call to Order, Welcome and Introductions
2. Approval of the October 1, 2018 Task Force Meeting Summary
3. Recap of Reform Discussion Focused on Specific Health Care Facility Categories - Task Force Meetings of August 10, September 7, and October 1, 2018
 - Scope of regulation
 - Compatibility of CON regulation with Total Cost of Care (TCOC) payment model
 - Scope of Review Criteria and Standards
 - Duplication of Regulatory Effort
4. The Project Review Process – Getting to a Decision by the Commission
 - The Standard Project Review Process
 - Imagining an Alternative Project Review Process for Certain Types of Project
 - What projects deserves less process?
 - The application/information requirements/State Health Plan standards
 - Completeness review and docketing
 - Certification of substantive compliance with applicable standards
 - Interested party participation - is it warranted for every type of project?
 - Fast-tracking to a decision for compliance-certified and unopposed projects
 - Improving the Standard Project Review Process
 - Completeness review and docketing
 - Procedural time limits and deemed approval

AGENDA (cont'd)

5. Regulatory Requirements After Project Approval - Changes in Projects and Implementing Projects
 - What project changes should be allowed without CON approval
 - Increases in the estimated cost of a project
 - Substantive changes in the physical facilities or services provided
 - Staff review for some changes and Commission review of others?
 - What are reasonable expectations for the performance of CON awardees in completing projects
 - Obligating a capital expenditure and initiating construction
 - Multi-phased projects
 - Licensing and initiating operations in the case of projects not involving construction
 - Monitoring progress and authorizing additional time for project completion
6. MHCC's limited authority to issue emergency CONs
 - Current authority is temporary and linked to natural disasters
 - National or state health care emergencies could trigger use of Emergency CON authority
7. Plans for the November 9, 2018 Meeting
8. Adjournment

RECAP OF REFORM DISCUSSIONS

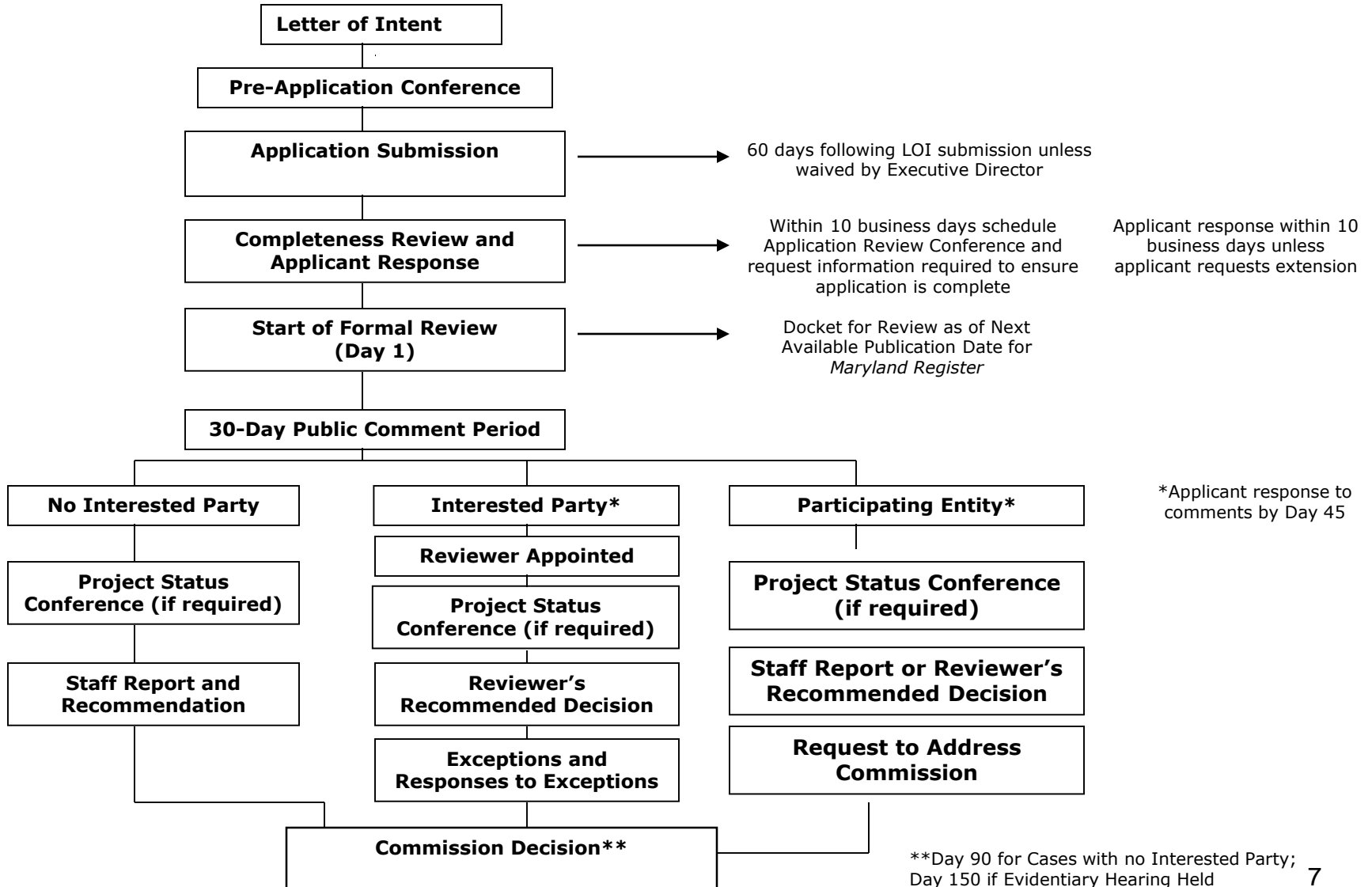
[See hard copies of material distributed for review
during this part of the meeting]

RECAP: TOPICS BY MEETING DATE

- August 10, 2018
 - Comprehensive Care Facilities (Nursing Homes)
 - Home Health Agencies
- September 7, 2018
 - Hospices
 - Alcoholism & Drug Abuse Treatment Intermediate Care Facilities
 - Residential Treatment Centers
- October 1, 2018
 - Ambulatory Surgical Facilities
 - Hospitals (General and Special)

THE PROJECT REVIEW PROCESS – GETTING TO A DECISION BY THE COMMISSION

CON Project Review Process - Maryland



Imagining an Alternative Project Review Process for Certain Types of Project

Applicability

Adding beds

Hospitals, comprehensive care facilities, hospices, intermediate care facilities, residential treatment centers

Adding ORs

Hospitals, ambulatory surgical facilities, freestanding medical facilities

Introducing New Services

Obstetrics

Hospitals

Pediatrics

Hospitals

Psychiatric

Hospitals

Adding Territory

Home health agencies, hospices

Non-Categorical Capital Expenditures

Hospitals

Imagining an Alternative Project Review Process for Certain Types of Project

Application/Information Requirements

Description of the project

Project budget

Pro forma Schedules of Revenues and Expenses

Isolating on the project itself

For the entire Facility

A description of how the project complies with the SHP (streamlined)

Need for the project

What alternatives were considered by the applicant

Financial feasibility of the project/long-term viability of the facility

Impact on cost and charges

Attestation of truthfulness

Imagining an Alternative Project Review Process for Certain Types of Project

Completeness review and docketing

Questions with three weeks of application filing (15 working days)

Response by applicant – three weeks but, in practice, more time would be allowed if requested

Docketing application within two to four weeks of receipt of response – docketing only connotes that questions were asked and a response was received

Publication of notice in *MR* starts 30 period for comments on project by interested parties

Imagining an Alternative Project Review Process for Certain Types of Project

Certification or non-certification of substantive compliance with applicable criteria and standards

If no persons seeking interested party status file comments within 30 days

**1) Staff issues brief report finding that the project is substantially in compliance with applicable criteria and standards
or**

**2) Staff issues brief report finding that the project is not substantially in compliance with applicable criteria and standards
or**

3) Staff issues brief report finding that a determination of substantial compliance cannot be made and identifies additional information required for determination

Imagining an Alternative Project Review Process for Certain Types of Project

Interested party participation - is it warranted for every type of project?

- Adding beds
- Adding ORs
- Introducing Some New Services
- Adding Territory
- Non-Categorical Capital Expenditures

If the need standards of the SHP limit capacity expansion based on use of existing capacity, is a concern with the impact of capacity expansion on other providers necessary?

If an objective of reform is allowing more competition (by qualified applicants), why should competitive impact be viewed as a legitimate basis for interested party participation?

Why are interested parties allowed in non-categorical CAPEX project reviews?

Imagining an Alternative Project Review Process for Certain Types of Project

Fast-tracking to a decision for compliance-certified and unopposed projects

If staff issues finding that the project is substantially in compliance with applicable criteria and standards, project goes on agenda of next Commission meeting

If staff issues finding that a determination of substantial compliance cannot be made, identifies additional information required for determination, and a satisfactory response is made by the applicant, project goes on agenda of next Commission meeting

If Staff issues finding that the project is not substantially in compliance with applicable criteria and standards, project goes on agenda of Commission meeting within 90 days – applicant may revise application

In all cases, project is deemed approved if staff does not issue a finding within 90 days of application filing (adjusted for longer completeness response time taken by applicant)

Improving the Standard Project Review Process

Completeness review and docketing

How do we compress this stage of review for “standard” reviews?

- establishing or relocating facilities
- introducing certain new services.

Getting a complete application is important docketing criteria in these cases, which are highly likely to draw interested parties.

Should we be very concerned about review times in these types of review, given their nature?

Procedural time limits and deemed approval

Should we have a hard time limit triggering deemed approval for such projects? If so, what is reasonable limit?

REGULATORY REQUIREMENTS AFTER PROJECT APPROVAL – CHANGES IN PROJECTS AND IMPLEMENTING PROJECTS

REGULATORY REQUIREMENTS AFTER PROJECT APPROVAL

Commission Approval of Changes in Approved Projects

- **Significant change in physical plant design;**
- **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 from the application submission date to the date of the filing of a request for approval of a project change;**
- **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;**
- **Changes in the financing mechanisms of the project; and**
- **Changing the location or address of the project.**

REGULATORY REQUIREMENTS AFTER PROJECT APPROVAL

Commission Approval of Changes in Approved Projects

Impermissible Modifications

- **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;**
- **Increases in the total licensed bed capacity or medical service categories from those approved;**
- **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.**

REGULATORY REQUIREMENTS AFTER PROJECT APPROVAL

Commission Approval of Changes in Approved Projects

What changes should be made in the list of changes requiring approval and impermissible changes?

What authority for approving changes can be vested in staff?

REGULATORY REQUIREMENTS AFTER PROJECT APPROVAL

What are reasonable expectations for the performance of CON awardees in completing projects?

- **Obligating a capital expenditure and initiating construction**
- **Multi-phased projects**
- **Licensing and initiating operations in the case of projects not involving construction**
- **Monitoring progress and authorizing additional time for project completion**

REGULATORY REQUIREMENTS AFTER PROJECT APPROVAL

Current requirements are project (and project cost) specific and have very limited flexibility – see hard copy

Ideas for reform

- **One time period for all construction projects to obligate and initiate construction**
- **Annual extensions of time after initiation of construction based on annual progress reports – no ultimate limit**

REGULATORY REQUIREMENTS AFTER PROJECT APPROVAL

Ideas for reform

- **Phased performance requirements customized based on application review**
- **No changes needed for non-construction projects**

First use approval requirements

Document final project cost – attest to consistency of finished project with approval – address conditions

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