

Modernization of the Maryland Certificate of Need
Program
Volume I: Interim Report



Maryland Health Care Commission
June 1, 2018

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Acknowledgements

The Maryland Health Care Commission (MHCC) is pleased to acknowledge the time and effort put forth by the CON Modernization Task Force during the first half of 2018. Over the course of five meetings, the members have discussed the problems and issues identified by others, asked relevant questions, contributed their own perspectives, and provided valuable input to MHCC staff and its consultants that has greatly assisted in the framing of this interim report. In particular, we wish to thank the Task Force Co-Chairs, Frances Phillips, a former MHCC Commissioner, and Randolph Sergent, a current MHCC Commissioner, for their leadership and advice.

We also thank the health care facilities, associations, and other organizations that have provided input to the Task Force and hope that these entities will continue to engage with MHCC in 2018 as it uses the findings of this interim report and other input to develop recommendations for modernizing CON regulation.

Finally, we acknowledge Ascendient Health Care Consulting that has supported the work of MHCC in this study effort as a contract consultant. In particular, we express our appreciation for Brian Ackerman and Daniel Carter, of Ascendient staff, for their work in preparing meeting materials, meeting summaries, and assistance in the drafting of this report.

INTRODUCTION

Study Request and the Purpose of this Report

On June 25, 2017, Maryland’s Senate Finance Committee and House of Delegates Health and Government Operations Committee (the Committees) requested that the Maryland Health Care Commission study specific elements of the Certificate of Need (CON) program. (See Appendix B.) This regulatory program has functioned in Maryland for over 40 years and is administered by MHCC. It primarily functions as a mechanism to influence the supply and distribution of certain types of health care facilities and services. Capital projects undertaken by or on behalf of certain health care facilities that fall within the scope of CON regulation must obtain State government approval prior to implementation. (Appendix A provides an overview of the current scope of CON regulation.)

Over its existence, CON regulation has changed in its scope and process. The legislative request cites two important reasons to study needed changes in CON regulation in 2018. First, four years ago, Maryland implemented a new All-Payer Model for regulating hospital revenue, based on an agreement between Maryland and the federal Centers for Medicare and Medicaid Services (CMS). The Committees stated that the new hospital payment model is “fundamentally changing the health care delivery landscape” of Maryland and asked MHCC to examine how the State Health Plan, the regulations that establish critical criteria and standards for CON regulation, can be used to determine service need in the context of Maryland’s All-Payer Model. The Committees specifically asked that MHCC, in consultation with the Health Services Cost Review Commission, the State agency that administers the All-Payer Model of hospital charge regulation, and the Maryland Department of Health, identify areas of regulatory duplication regarding the hospital capital funding process and other areas of hospital regulation.

Second, the Committees noted that the CON regulatory process used to review and act on health care facility capital projects is complicated, particularly for hospitals. The MHCC was asked to examine ways in which the administrative burden of CON regulation on the State’s health care facilities can be reduced so that Maryland’s “CON laws and regulations ... reflect the dynamic and evolving health care delivery system.”

MHCC welcomed the request from the General Assembly committees. MHCC has launched several attempts to modernize the State Health Plan for Facilities and Services (SHP or State Health Plan) and CON regulation over the past fifteen years with varying degrees of success. MHCC holds strong perspectives on areas of CON regulation that are appropriate for reform, but is mindful that any reform will require collaboration of the General Assembly, other executive branch agencies, regulated providers, and the public. Commissioners viewed the engagement of the General Assembly at an early stage as a promising sign that progress can be achieved.

Purpose of this Report. This interim report sets forth the progress of the MHCC to date in its study of the CON program. The MHCC has gathered input from stakeholders regarding the need for CON, the benefits and costs of CON, and the problems with CON as it is presently

implemented. This interim report, which summarizes that input, does not represent a final position by the MHCC with respect to these issues and does not present recommendations for CON reform.

CON Modernization Task Force

The Committees urged MHCC to “gather perspectives and views from a range of stakeholders” in conducting the study and identified stakeholder categories considered important for this effort. MHCC convened a CON Modernization Task Force for formal discussion and advice regarding CON modernization, which has held five meetings between January and May 2018. The membership of the Task Force, the “stakeholder” perspective that each brings to the study, and the current professional position of each member is outlined below.

MHCC CON MODERNIZATION TASK FORCE

Task Force Member	Industry/Sector	Title/Role/Affiliation
Frances Phillips, Co-Chair	Public Health	Acting Health Officer, Anne Arundel County
Randolph Sergent, Co-Chair	MHCC Commissioner Health Insurance	Vice President & Deputy General Counsel CareFirst BC/BS
Regina Bodnar	Maryland Hospice & Palliative Care Network	Executive Director, Carroll Hospice
Ellen Cooper	Consumers	Former Chief, Antitrust Division, Maryland Office of the Attorney General
Lou Grimmel	Nursing Homes	Chief Executive Officer, Lorien Health Care
Elizabeth Hafey	MHCC Commissioner	Attorney, Miles & Stockbridge
Ann Horton	Maryland-National Home Care Association Home Health Agencies	Executive Director of Strategic Partnerships LHC Group
Andrea Hyatt	Ambulatory Surgery Centers	President, Maryland Ambulatory Surgery Association & Director of ASC Operations, University of Maryland Faculty Physicians
Adam Kane	HSCRC Commissioner	Senior Vice President, Real Estate Acquisition & Corporate Affairs Erickson Living
Ben Lowentritt, M.D.	Physicians	Urologist, Chesapeake Urology Associates
Brett McCone	Hospitals	Vice President, Maryland Hospital Association
Mark Meade	Business	Principal, Consulting Underwriters, L.L.C.
Jeff Metz	MHCC Commissioner Nursing Homes	President/Administrator Egle Nursing & Rehabilitation Center
Michael O’Grady	MHCC Commissioner	Senior Fellow, National Opinion Research Center & Principal, O’Grady Consulting
Barry Rosen, Esquire	Health Care Law	Chairman & Chief Executive Officer Gordon Feinblatt LLC
Andrew Solberg	CON Consultant	Principal, ALS Consultant Services (Former Director of CON, Maryland Health Resources Planning Commission)

Key Process Components

The Committees asked that MHCC submit an interim report by May 1, 2018 and a final report with recommendations no later than December 1, 2018. MHCC is conducting the requested study in two phases: (1) the first phase, culminating with issuance of this interim report, focused on gathering input and information on the problems and issues perceived by stakeholders with CON regulation, considered the guidance of the General Assembly, and expresses a sense of the priorities among these issues; and (2) the second phase, which will culminate in a final report, will use this input to study and develop ideas for reform of CON regulation and to produce recommendations for changes in the law, regulatory standards (the SHP chapters regulating various facilities and services) and the project review process in the final study report. These reports will be shaped by stakeholder input, but each report will be issued by the Commission and will reflect the thinking of the Task Force and MHCC.

Questions Posed to CON-Regulated Providers

As a first step for phase one, in December 2017, MHCC solicited comments from all of the health care facilities included within the scope of CON regulation and the health care-related trade associations for these facility categories, as well as some additional organizations considered to have relevant perspectives on regulatory reform. In developing the Comment Guide given to health care facilities, MHCC staff looked to the specific elements of the Committees' study request and MHCC staff's perspective on the problems, issues, and ideas for reform of CON regulation that have been considered recently or that formed the background of previous regulatory changes. The basic guide format was modified, to a limited extent, to reflect particular issues for particular types of regulated facilities. A generic Comment Guide is included at Appendix D and the provider specific Comment Guides are available at:

https://mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_con_modernization.aspx.

Comments on CON Modernization

MHCC received 38 comments in response to its December 2017 solicitation. These comments were submitted by:

- Hospitals, hospital systems, and the Maryland Hospital Association [seven commenters];
- A nursing home, a nursing home system, a provider of continuing care retirement community services, and two affiliated associations, the Health Care Facilities Association of Maryland and LifeSpan Network [five commenters];
- Non-hospital providers of ambulatory surgery, the Department of Surgery of Johns Hopkins Medicine and the Maryland Patient Care and Access Coalition (with both of the latter two commenters addressing reform of CON regulation of ambulatory surgical facilities) [seven commenters];

- Home health agencies and the Maryland National Homecare Association [six commenters];
- Hospices and the Hospice and Palliative Care Network of Maryland [10 commenters];
- An alcohol and drug abuse treatment intermediate care facility;
- A county health department; and
- The Maryland Citizen Health Initiative.

The comments received in response to the December 2017 solicitation can be viewed at Appendix E. The comments can also be accessed on the MHCC website using the following link: https://mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_con_modernization.aspx

Task Force Meetings

The CON Modernization Task Force met monthly between January 22, 2018 and May 11, 2018. The meetings were organized around discussion of identified problems and issues in CON regulation, as outlined in comments received by MHCC and the perspectives of Task Force members. Meeting agendas provided for focused discussion of particular regulated facility sectors: hospitals; freestanding providers of ambulatory surgery; home health agencies; and hospice providers. The Task Force heard from the Health Services Cost Review Commission staff and facility sector spokespersons and/or Task Force members who volunteered to lead discussion of the regulatory issues and concerns of most importance and relevance for particular types of health care facilities. These discussions were intended to provide an overview of the key issues that should be considered in a program of modernization of CON regulation and, as such, to set an agenda for phase two of the study, in which MHCC will develop ideas for modernization and recommendations for statutory changes, changes to regulations, and changes to procedural processes based on these ideas.

Summaries of the five Task Force meetings can be found in Appendix C. The summaries and meeting materials can also be found on the MHCC website at the following link: https://mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_con_modernization.aspx

OVERVIEW OF COMMON THEMES

As noted above, the process used in development of this interim report included both a review of comments submitted by over 30 different organizations and discussion at each of the five Task Force Committee meetings. While clearly all the information reviewed and discussed varied based on the particular concerns of each organization, a number of consistent themes did emerge across a range of provider types and aspects of CON regulation. These common concerns and themes are helpful for understanding the more specific concerns raised with respect to individual provider types. While the findings below are not meant to represent the opinions of all, they do highlight the areas where similarities were present.

A summary review of information regarding common themes has been broken out into the following areas:

- Whether There is a Need for CON Regulation / Its Benefits and Costs
- Issues with the Scope and Role of CON Regulation
- Issues with the State Health Plan
- Issues with CON Project Review
- Issues with the Post-Project Review Process

Each of these areas is discussed in more detail below. With respect to the common issues it is important to note that while perceived issues have been segmented into separate categories they should not be considered in isolation. For example, changes related to the scope of CON or the structure and function of State Health Plan (SHP) regulations would have an impact on issues related to CON Project Review timelines.

Whether There is a Need for CON Regulation / Its Benefits and Costs

Comments on Perceived Need. With respect to each category of facility and with respect to CON regulation in general, the Task Force discussed whether CON regulation was necessary at all, the purposes that CON regulation was supposed to serve, and the costs that CON regulation imposed. Most of the health care facilities and others providing comments to MHCC expressed the view that CON regulation should be maintained, at least with respect to their particular category of facility, but should be reformed or modernized. At the same time, there was substantial discussion among the Task Force regarding whether CON regulation is necessary or appropriate for certain categories of facilities or certain circumstances within a category. Among the 38 total comments received, seven recommended elimination of CON regulation, elimination or substantial reduction in regulatory scope, or maintenance of CON regulation with substantial reductions in its scope with respect to hospital capital projects. MHCC recognizes that industry comments, which generally favor continuing CON for their particular facilities, must be weighed in light of a natural tendency to protect existing interests to the potential detriment of new market entrants.

The comments provided by two facility categories, ambulatory surgical facilities and hospices, deviated from this general pattern of support for CON, in some form, but strong recommendations for reform. Seven comments were received concerning CON regulation of ambulatory surgical facilities (ASFs) – six from facilities or multi-facility operators and one comment from an association, the Maryland Patient Care and Access Coalition (MPCAC), which describes itself as an association of “more than 300 physicians [that is] the voice of independent physician specialty practices . . . that deliver integrated, high quality, cost-efficient care to patients in the medical office and ambulatory surgery center settings.” Three ASFs supported elimination of CON regulation of ASFs.¹ A multi-facility operator, SurgCenter Development, which typically

¹ During Task Force meetings, the term freestanding ambulatory surgery facility (FASF) was often used. FASF include physician outpatient surgical centers (POSC) that contain one operating room and is not subject to CON review and ASFs that contain two or more operating rooms and are subject to CON regulation. POSCs are defined under MHCC regulations, at COMAR 10.24.11.08B(25).

develops ambulatory surgery centers as joint ventures with groups of physicians, supports elimination of CON regulation or, as an alternative, an exception from the need for CON approval for ASFs with up to two operating rooms. MPCAC supports elimination of CON regulation of ASFs. So, among this group of commenters, a majority of the comments favored deregulation in their facility category. Ten comments were received concerning CON regulation of general hospices, from nine general hospices and the Maryland Hospice Network, an association of hospices. All supported maintenance of CON regulation of hospices, in general, in its current form. Improvements in the timeliness of CON project review and some changes in the State Health Plan (which were not reductive in nature) were recommended but it is fair to say that this facility group's comments represent the strongest advocacy for maintenance, with only minimal changes, of the status quo in Maryland.

One hospital system commenter, among five that specifically addressed CON regulation of hospitals, supported continuation of CON regulation but with a substantially reduced scope of regulation, primarily with respect to hospital projects. This was the University of Maryland Medical System, the state's largest hospital system. The other four commenters, which included the Maryland Hospital Association, provide substantial commentary on needed reforms but did not propose broad reductions in the scope of CON regulation. One home health agency commenter recommended elimination or substantial reduction in regulatory requirements for home health agencies. Other home health agency commenters supported continuation of CON regulation.

Benefits of CON. The Task Force considered the overall benefits of CON regulation. Extensive literature was provided to the Task Force by MHCC staff, by the Chair of the Commission, and by Task Force member Barry Rosen. This literature shows that, in the abstract, the overall benefit of CON regulation is debatable. The literature did not provide strong evidence that CON reduces health care costs or improves quality, and contained some evidence that CON rules can reduce the number of available providers in some circumstances.

In comments to the Task Force, support for maintaining CON regulation without major changes was expressed in terms of maintaining a necessary tool for avoiding negative consequences associated with overcapacity, inequitable access, inappropriate care, and/or diminished quality of care. In addition, where significant capital expenditures are required to open or operate a facility, CON regulation may provide some protection to the entity that is investing in the facility, because future competitors would have to meet certain standards before entering the market place.

CON necessarily must work together with the All-Payer Rate system, which is itself engaged in the fifth year of a modernization process, the success of which will be measured across a broader scope of health care cost growth than just hospitals. Given a payment model for regulating hospital charges that is explicitly pegged to containing growth in the cost of care, most hospitals and most other regulated health care facilities appear to perceive that CON is necessary. CON regulation is a way to regulate health care facility supply and capacity and these factors, if not also controlled by a state regulatory process rather than the market forces at play in Maryland, are viewed as having the potential for reducing Maryland's ability to contain the total cost of care. Most perceive CON regulation as attempting to appropriately limit the number of providers. However, operating a regulatory system such as CON so that it helps Maryland to stay within the

Total Cost of Care guardrails in use will require a broader and more nuanced set of CON policies that go beyond just holding the line on proliferation of facilities or expansion of facility capacity. Moving more demand to the least costly setting in which demand can be appropriately handled is likely to require contraction of systems capacity in some areas and expansion in others. CON regulation is also perceived by many as a “reasonableness check” on project and applicant aspirations that may sometimes go beyond what is likely to be sustainable.

CON regulation is described by some commenters as necessary for controlling the distribution of limited resources. While financial resources are obviously a consideration, many believe that without limits inherent in CON regulation, the supply of providers that might enter a given market could have a negative impact on the ability to staff facilities with qualified personnel. Qualified employees are scarce in some job categories and would be more thinly distributed across a greater number of organizations, if market entry and growth in the supply of facilities is unchecked through some mechanism.

For some, CON is also viewed, primarily by virtue of its mere existence, as a valuable mechanism for preventing fraudulent providers from entering the Maryland market. The stark difference in the amount of fraud and abuse occurring in non-CON states compared to its more limited occurrences in Maryland, for certain services, particularly home health agency services and hospice services, are cited.

CON regulation is the primary mechanism through which the Commission can implement policies it has adopted for influencing change in the institutional sector of the health care delivery system.

Costs of CON. Commenters seeking elimination or reform of CON cited its costs, including the costs of preparing CON applications, hiring legal and other types of consultants for assistance with the regulatory process, and the costs involved in litigation, that may come into play as the last stage in contested project reviews. Commenters also cited the costs associated with project delays, either in order to prepare to file for CON approval or during the CON process. These costs are often reported by applicants as quite substantial and are often cited as a frustrating feature of CON regulation and a particular concern of some Commissioners, based on a perspective that the value added by the regulatory process relative to this cost burden for applicants is doubtful.

The Task Force also recognized that CON regulation might, in some areas, artificially reduce the number of providers or prevent new market entrants that may have innovative new approaches. The impact of CON on limiting competition in ambulatory surgery is cited by one commenter as “driving up” costs and being “at odds with the goal of providing Maryland patients with convenient access to the highest quality and most innovative care.” This comment is echoed by a commenter who operates home health and residential service agencies, who recommended elimination of the regulatory program, expressing the view that CON regulation “perpetuates low quality home health agencies with poor clinical and/or patient satisfaction outcomes by blocking high quality operators from entering the market.”

The Task Force also discussed that some of the cited benefits of CON regulation, such as ensuring quality of health care and ensuring that “bad actors” remain outside of the system, are

appropriate regulatory goals but using CON regulation may be a problematic and inefficient approach. Health care quality, for example, is an issue that may be best addressed through licensure regulation, rather than the one-time, front-end review offered by CON regulation. A robust licensure process should be more effective than CON regulation in ensuring that health care facilities and providers are operated soundly and under responsible ownership. The Task Force discussed at length the extent to which such issues could be better regulated by CON or through a strong licensing program.

Issues with the Scope and Role of CON Regulation

Most commenters recommended that the scope and role of CON should be reconsidered and modernized in light of continued changes in the regulated health care facility sector at the state and national levels. Specifically, the list of services regulated under CON is viewed as a somewhat “dated” legacy of the program’s early history, with few changes since the mid-1990s. Members of the Task Force frequently expressed a need for the scope of CON regulation be re-evaluated for appropriateness and necessity.

In addition to the number of facilities and services regulated, others questioned the need for a full/conventional CON project review for certain project categories, especially when no interested parties are contesting approval of a project. While keeping the requirement for approval in place, the view was expressed that less burdensome alternatives to conventional reviews would be appropriate to expedite the project review process and free-up MHCC resources to concentrate on projects having the most impact on costs and access to care. The current convention used in CON regulation is to measure a project, described in a comprehensive application, against criteria and standards, with an expectation that the project must comply with all the applicable standards in order to obtain approval. Alternatives that alter this framework for simpler project reviews, designed along the lines of favoring approval if key basic project elements are in place and a few specified disqualifiers are absent can be envisioned. This approach would require a new type of SHP regulation.

The need for and the level of capital expenditure thresholds used in CON regulation and the corresponding impact on the volume of CON applications were a common feature of comments discussed by the Task Force. Many commenters believe that current thresholds are unnecessarily low and should be reevaluated or eliminated.

Another common concern relates to the perceived duplication that occurs in some elements of the CON project review process and regulatory oversight exercised by other agencies. The issue areas most frequently cited with respect to this concern are oversight of quality of care, project financial feasibility, and the requirements for the provision of charity care. Questions were raised regarding the scope of MHCC’s authority in hospital regulation as it relates to the work of HSCRC and, across a range of health care facility categories, relative to the role of the Maryland Department of Health in licensing health care facilities.

At the same time, as previously noted, there is recognition that the existence of some aspects of the scope of CON appear to deter development of facilities that would otherwise be likely to enter Maryland in very large numbers. Fully removing this barrier creates a concern that

the Maryland Department of Health would experience an overwhelming increase in its need for resources to adequately oversee health care facility quality, safety, and efficiency. This would not necessarily be a reason to keep CON regulation – but the removal of CON regulation should be coupled with steps to ensure an adequate licensure program.

Issues with the State Health Plan – Complexity, Structure, and Application

A number of different concerns with the SHP were expressed during phase one of this study. However, in general, three common themes emerge: (1) some standards and need methodologies of the SHP are outdated; (2) some standards of the SHP lack sufficient clarity; and (3) other standards are overly complex. The latter two themes are frequently raised in an update of SHP chapters when the Commission staff attempts to balance flexibility and specificity in defining how standards must be met.

There is concern that the SHP is not aligned with the current All-Payer hospital payment model and a general consensus that the SHP should be revised to ensure that the guidance that it provides in assessing the need for facilities and services is consistent with the payment model. A chapter-by-chapter review was requested to make sure that all areas and standards are up-to-date, with specific concerns referenced in relation to the SHP chapter for psychiatric services.

Some commenters also noted that the combination of the current SHP and financial constraints could have the unintended consequence of driving increased levels of health care facilities consolidation.

Some standards in the SHP are viewed as potential barriers to innovation in health care delivery, and there were some expressions of a desire for the SHP to find a balance between the appropriate regulation of supply and the potential to facilitate, not just allow, new care delivery initiatives. In other words, CON should be careful not to hinder useful innovations from reaching the market.

Some commenters expressed the view that the SHP has numerous standards that are unnecessary or largely irrelevant. One Task Force member expressed this viewpoint in terms of “problems,” urging MHCC to develop the SHP so that it is focused on problems in health care delivery and limit standards development to ones that directly address these problems. A “cluttered” SHP, in this view, results in more work in project review, taxing the applicant and MHCC resources unnecessarily and increasing the complexity of the CON project review process and lengthening the time required for reviews without a commensurate benefit for the decision-making process. Specifically, although only one or two items are often viewed as key considerations or as most relevant in a given review, all of the standards and sub-standards must be addressed as part of the review. Some commenters view this as not only adding time to what would otherwise be a simple, uncontested review process, but also something that can extend contested reviews by providing opposing interested parties with opportunities to challenge relatively unimportant standards. Thus, there is a common theme that standards within the SHP should be re-evaluated for applicability and necessity. If it is determined that standards need to be maintained, consideration should be given to assuring that they are clear and explicit in their intent and purpose, to minimize opportunities to use them inappropriately in contested applications.

Finally, commenters stated that some methodologies for determining unmet need are too complex or unclear. Some viewed the lack of a method for determining need in certain SHP chapters as a deficiency. Thus, thematically, as the SHP is revised over time, need methodologies should be reevaluated to ensure they are appropriate, clearly described and defined, and incorporate the most relevant and accurate assumptions with respect to demand for service and the capacity needed to address service volume. Additionally, when a method for determining service need is absent, consideration should be given to whether inclusion of a need methodology would improve the decision-making process.

Issues with CON Project Review – Application Filing, Application Completeness Review, and the Project Review Process

The primary concern related to the CON project review process centers on the length of time necessary for reviews. It is important to note that several issues previously discussed can profoundly affect review timelines, either directly or indirectly, by affecting the number of projects requiring review or dictating the depth and breadth of application review requirements. Such issues include:

- The number of regulated facilities and services;
- The types of projects that require full project review;
- The capital expenditure review threshold applied in establishing review requirements;
- The number of standards established in SHP chapters for given project reviews; and
- The nature of need methodologies in SHP chapters.

Each of these factors affect the resource levels that must be expended to review CON applications. There is no flexibility in how these factors come into play in any given project review. To a large extent, consideration of how modernization of CON will affect these factors could alter the time and effort required for project reviews, in addition to weeding out considerations in project review that may be redundant or duplicative because they are adequately addressed by other agencies or organizations. As ideas for reforming or modernizing the scope of CON and the features of the SHP are considered, the potential for shortening project review timelines should be a key part of the consideration and changes should be developed with that objective in mind.

While changes in the scope of CON oversight and SHP standards listed above may have the most significant potential for affecting the project review timeline, there are other areas where many believe the review process, as currently established, could be streamlined. Common themes raised by commenters include:

- MHCC staff numbers and subject matter expertise are insufficient and not able to flex as needed when the project review caseload changes;
- Insufficient effort is made to adhere to established timelines for completing steps in the process. (Commenters acknowledged that, in some instances, applicants are also a source of delays);

- Multiple rounds of completeness review questions occur and are seen as excessive relative to ensuring an application's readiness for review;
- The exemption from CON review process is insufficiently streamlined to meaningfully reduce the burden on the applicant and the review time, as the process was designed to do; and,
- The criteria and standards for exemption from CON reviews need to be reconsidered and updated.

Issues with the Post-Project Review Process – Performance Requirements, Progress Monitoring, and Conditions

Similar to issues previously discussed, portions of the post-project performance review process are considered to be outdated, often duplicative of other agencies' responsibilities, and in need of re-evaluation. Commenters requested that post-review requirements either be changed significantly or eliminated altogether. Specific examples included:

- Quarterly reporting forms are viewed as complicated and excessive, particularly for large projects;
- Projects that do not involve new beds or services should have fewer post-CON monitoring and performance requirements;
- Greater flexibility for considering post-CON changes in approved projects is desirable, in terms of the changes that require approval and the process for granting changes. Specifically, the need for approval of changes to an approved project that do not have significant cost consequences and are uncontested was questioned; and
- Some performance requirement timelines are too short relative to the reality of obtaining local approvals, other project development requirements, and construction, especially in the case of nursing home projects.

PROBLEM STATEMENTS BY HEALTH CARE FACILITY CATEGORY

This section of the interim report is an attempt to state specific problems or issues that should frame the work of MHCC in phase two of the CON Modernization Study. They are not intended to represent any universal agreement on problems or issues, but are intended to represent a rough consensus by Task Force members of problem statements that should be taken as a starting point for the next phase of the study.

The final study report will address these problem statements and, whenever possible, outline changes in the law, regulation, or practices of MHCC that have the potential for ameliorating the problem or concern without exacerbating or creating other problems. Comments intended to amplify the reader's understanding of certain problem statements are also provided.

The list of facility categories here is not complete with respect to the full scope of CON regulation but covers the facilities that account for the overwhelming majority of project reviews. Regulated health care facilities not included here include residential treatment centers and alcohol and drug abuse treatment intermediate care facilities, and intermediate care facilities for individuals with intellectual disability. Some specific services provided in the hospital setting are also categorically regulated. Not unexpectedly, it will be noted that the same general problem statement with respect to the scope of CON and regulatory process appears in the same or similar form on each facility category list and would also be generally applicable to the review of the other facility categories not specifically listed here.

A. HOSPITALS

1. The scope of hospital CON regulation is outdated and should be reconsidered. In particular, the need for a capital expenditure threshold should be reconsidered.

Comment: Hospital CON regulation presents the biggest challenge in changing the way in which project cost is used to define the scope of CON regulation because: (1) CON approval of capital projects has historically been used as the gateway for consideration by HSCRC of charge adjustments intended to provide the hospital with the money required for depreciation and interest expenses associated with a capital project; and (2) hospitals are the only health care facilities that have been able to avoid the requirement of obtaining a CON even when the capital expenditure threshold has been breached, by “pledging” not to seek more than nominal charge adjustments over the life of the project. The current capital expenditure threshold applicable to hospital projects is \$12 million. It is indexed to inflation and adjusted for inflation annually.

2. Portions of some State Health Plan Chapters are outdated and unclear.

Comment: COMAR 10.24.07, which includes standards for acute psychiatric inpatient services, is the most outdated. COMAR 10.24.10, which includes standards for review of general acute care hospital projects, is the key regulation that should bring general hospital project CON regulation in better alignment with the hospital payment model that was initiated in 2014 and

should also reflect CON regulation of hospitals using a total cost of care model, planned for implementation in 2020.

3. The State Health Plan does not align with the current hospital payment model.

Comment: COMAR 10.24.10 was last overhauled in 2009, five years before implementation of the current hospital payment model.

4. The State Health Plan does not facilitate care delivery transformation.

5. The State Health Plan has too many standards that are unnecessary or do not address key priorities in hospital or hospital service development. This increases the need for MHCC resources and the complexity of the CON project review process and may be a cause for extended timelines associated with completeness review, application review following docketing, and any appeal processes.

6. The average period of time needed to docket a hospital application and complete the review of an application is excessive.

Comment: See Appendix G.

7. The information requirements associated with hospital CON regulation are excessive and, in some cases, duplicative with respect to the regulatory activities of other entities (e.g. financial feasibility analysis and compliance with charity care policies),

8. Alternatives to conventional CON project review are lacking.

Comment: More efficient and less burdensome procedures could be developed for certain categories of project review.

9. Exemption from CON review is still, in many cases, insufficiently streamlined.

Comment: Changes to this review process could reduce the burden on applicants whose projects qualify for this type of review.

10. The capability to obtain broader community perspectives on regulated projects is underdeveloped.

Comment: The standard CON project review process does not include any requirements for public hearings or any formalized structures for obtaining input from communities or the general public. Informational meetings may be required for some facility or service closures and are a required feature of hospital conversions to freestanding medical facilities. The current venues for the

community to provide substantive input on proposed projects may be inadequate when considering the most impactful types of project.

B. NURSING HOMES (Licensed in Maryland as “Comprehensive Care Facilities”)

- 1. The scope of nursing home CON regulation is outdated. In particular, the capital threshold for nursing homes could be viewed as insufficiently accounting for the capital-intensive nature of the business as compared to similar thresholds for facilities such as home health agencies, hospices, and ambulatory surgical facilities, all of which share the same threshold.**

Comment: The current capital expenditure threshold for all non-hospital projects is \$6 million. . It is indexed to inflation and adjusted for inflation annually.

- 2. The State Health Plan does not account for nor facilitate total cost of care improvement across the full care continuum.**

Comment: Planned evolution of the hospital charge regulation in Maryland will use the total cost of care as a measure of success. COMAR 10.24.08, the SHP regulations outlining standards for the review of nursing home projects was last updated in 2007. An update process is underway in 2018.

- 3. The use of quality measures in CON regulation of nursing home projects is inadequate.**

Comment: The CMS Nursing Home Compare Star Rating System is an obvious place to start in considering incorporation of quality measures in CON regulation. However, it may lack adequate sensitivity for use in docketing rules. The NHC Star Ratings are being considered for use in the 2018 update of COMAR 10.24.08.

- 4. The use of the Medicaid Memorandum of Understanding requirement to set minimum required levels of Medicaid participation is outdated.**
- 5. The average period of time needed to docket a nursing home application and complete the review of an application is excessive.**

Comment: See Appendix G.

- 6. Exemption from CON review is still, in many cases, insufficiently streamlined.**

Comment: Changes to this review process could reduce the burden on applicants whose projects qualify for this type of review.

7. Post-CON approval performance requirements are outdated.

Comment: Changes which more appropriately account for the complexities associated with nursing home development should be considered.

8. The CON program does not support development of innovative models of post-acute care.

Comment: The “silo” nature of facility classification and project review under CON regulation discourages a perspective on how acute and post-acute care might be better integrated if facilities had more flexibility in expanding their range of service offerings (e.g., can hospitals and post-acute care providers be allowed to more freely develop comprehensive care facility services, home health services, and general hospice services in order to better manage the full hospital and post-hospital care management process and reduce the total cost of care?)

C. HOME HEALTH AGENCIES (HHAs) & GENERAL HOSPICES

1. The scope of home health agency and hospice CON regulation may be outdated. In particular, the use of a capital expenditure threshold should be reconsidered.

Comment: The current capital expenditure threshold for all non-hospital projects is \$6 million. It is indexed to inflation and adjusted for inflation annually.

2. There may be a more efficient means for preserving a key value perceived in CON regulation of home health agencies and general hospices.

Comment: A key value of regulating these largely non-institutional health care facilities appears to be the barrier to market entry created by the mere existence of CON regulation. There is evidence suggesting that this is the main reason that Maryland has far fewer home health agencies and general hospices, when compared with non-CON states. The perceived value in this more limited supply of providers in Maryland lies in the improved ability it provides for regulatory oversight and it does appear that there is better relative performance of these providers, compared to other states, and a lower incidence and prevalence of fraud and abuse among such providers, compared to other states. There is some evidence that states without CON regulation are more likely to have higher levels of fraud. According to the Department of Justice’s Health Care Fraud and Abuse Control Program Annual Report for FY 2017 (issued April 2018), the Medicare Strike Force “highlights” included six major investigations in home health – five of which are in states with no CON for home health.²

3. The State Health Plan does not account for nor facilitate total cost of care improvement across the full care continuum.

² Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2017
<https://oig.hhs.gov/publications/docs/hcfac/FY2017-hcfac.pdf>.

- 4. The average period of time needed to docket an HHA or general hospice application and complete the review of an application is excessive.**

Comment: See Appendix G.

- 5. Charity care requirements for HHAs and general hospices are not well-aligned with the level of need.**
- 6. State Health Plan methodologies for determining unmet need are either too complex, unclear, or, in the case of inpatient hospice beds, non-existent.**
- 7. Portions of the CON application are not fully applicable to home health and/or hospice providers.**
- 8. Neither the application nor the review processes fully allow for the leveraging of publicly available State data, quality measures, and patient survey findings.**

Comment: A better alignment could reduce the burden on applicants and reduce project review time.

- 9. The primary roles and objectives of CON and facilities licensure, as implemented by the Maryland Department of Health, are potentially duplicative.**

D. AMBULATORY SURGICAL FACILITIES (ASFs)

- 1. The scope of ASF CON regulation may be outdated. In particular, the use of a capital expenditure threshold should be reconsidered.**

Comment: The current capital expenditure threshold for all non-hospital projects is \$6 million. It is indexed to inflation and adjusted for inflation annually. Some consideration of the current regulatory scheme that provides for an ability to establish outpatient surgical centers with no more than one operating room outside the scope of CON should be considered. If Maryland can move toward a landscape of fewer but, on average, larger ASFs, delivery of outpatient surgery might be more efficient and effective.

- 2. The overall CON application and review process is too complex, requiring outside resources and additional costs for applicants.**

Comment: One change that should be considered in limiting the completeness review process for docketing applications, such as limiting MHCC to one round of completeness questions. Limiting information requirements for a complete application is a necessary part of this reconsideration.

3. Post-CON approval performance requirements are outdated.

E. ALCOHOL & DRUG ABUSE TREATMENT INTERMEDIATE CARE FACILITIES (Certified in Maryland as Medically-Monitored Intensive Inpatient Withdrawal Management or Treatment Programs – ASAM Level 3.7)

1. The scope of CON regulation in the alcohol and substance abuse detoxification and treatment sector is unbalanced, only touching a very narrow part of the treatment spectrum.

Comment: CON regulation by MHCC is limited to regulation of medically-monitored, intensive inpatient withdrawal management (or detoxification) and treatment (referred to as ASAM Level 3.7 and 3.7 WM). This is a very narrow segment of the substance abuse treatment spectrum. This unbalanced approach to regulation may create disincentives for operators to establish ASAM Level 3.7 facilities when the level of care is needed by the communities they serve.

F. RESIDENTIAL TREATMENT CENTERS (RTCs)

1. The scope of RTC CON regulation may be outdated. In particular, the necessity of including residential treatment centers in the scope of CON regulation is questionable given the way in which demand for this service has changed.

Comment: Residential treatment of behavioral health disorders of children and adolescents has shrunk in importance in recent decades as a component of the spectrum of mental health facilities and services needed for this population and has reached a point at which state agencies serving troubled youth are the overwhelming source of referrals for this service and state funding programs the major source for payment for care. Because this level of institutional service has been actively discouraged for the last two decades in favor of less institutional alternatives, the numbers of RTCs and RTC capacity has been substantially reduced. Most of the demand for RTC placement arises from the juvenile justice authorities. These developments would suggest that continuing CON regulation of RTCs may be unnecessary. The state agencies serving as the primary referral sources are in the best position to determine if more capacity is needed and it would seem highly unlikely that market conditions exist for excessive development of capacity to occur that would raise concerns with costs.

PHASE TWO OF THE CON MODERNIZATION STUDY: Recommended Solutions to Identified Problems

Phase two of the study will use the problem statements outlined in this interim report as an agenda for generating ideas to address the problems, obtain input and engage stakeholders in discussion of those ideas, and attempt to reach consensus on the best ideas and the best ways in which to implement the needed changes. This work will be incorporated into the final report with recommendations to the General Assembly and a plan for implementation of changes by MHCC that do not require statutory changes.

Several Task Force members suggested that the next phase of the study should begin with a set of guiding principles that articulates a broad theory of the values that MHCC believes regulation of health care facilities should embody and that MHCC can use in weighing the merits and potential negative consequences of changes proposed to address the identified problems with the current CON program. MHCC endorses this first step for phase two.

Organizationally, MHCC will reform a stakeholder group using the phase one CON Modernization Task Force as a base for establishment of the phase two CON Modernization Task Force. It will serve as the primary forum for generation and discussion of ideas, the development of relevant questions on the practicality, feasibility, and potential problems with these ideas that will be posed to MHCC staff, consultants, and providers, and development of consensus on the changes that need to be made in CON regulation.

APPENDICES

A. Overview of the Current Scope of CON Regulation

http://mhcc.maryland.gov/mhcc/pages/home/workgroups/documents/CON_modernization_workgroup/con_modernization_workgroup_slide_deck_presentation_20180122.pdf

B. Letter from General Assembly Committee Chairs

[Charge Letter](#)

C. Task Force Meeting Summaries

[Summary of January 22, 2018 Meeting](#)

[Summary of February 23, 2018 Meeting](#)

[Summary of March 23, 2018 Meeting](#)

[Summary of April 20, 2018 Meeting](#)

[Summary of May 11, 2018 Meeting](#)

D. Comment Guide

[Hospitals](#)

[Comprehensive Care Facilities \(Nursing Homes\)](#)

[Home Health Agencies](#)

[Hospice Agencies](#)

[Ambulatory Surgery Facilities](#)

[Others](#)

E. Comments on CON Modernization

[Hospitals](#)

[Comprehensive Care Facilities](#)

[Home Health Agencies](#)

[Hospice Agencies](#)

[Ambulatory Surgery Facilities](#)

[Others](#)

F. Fact Sheets

[Hospital Fact Sheet](#)

[Nursing Home Fact Sheet](#)

[Home Health Fact Sheet](#)

[Hospice Fact Sheet](#)

[Ambulatory Surgery Facility Fact Sheet](#)

[Alcohol and Drug Abuse Treatment Intermediate Care Facility Fact Sheet](#)

[Residential Treatment Center Fact Sheet](#)

G. The Time Required for CON Project Review