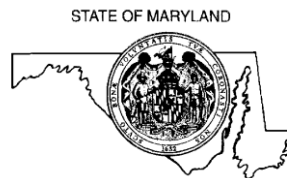


Modernization of the
Maryland Certificate of Need Program
Final Report

DRAFT



Maryland Health Care Commission
December 3, 2018

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Commissioner Randolph Sergent provided able leadership as Co-Chair of the Task Force during Phase 1 of the Commission's work, which culminated in development of an Interim Report in June 2018, and as Task Force Chairman during the second phase of the work. MHCC also thanks Frances Phillips, a former MHCC Commissioner, who served as Commissioner Sergent's Co-Chair during Phase 1.

MHCC also thanks the health care facilities, associations, and other organizations that have provided input to the Task Force and to MHCC on the subject matter of this report.

Lastly, MHCC acknowledges the valuable assistance of the Berkeley Research Group as consultants in the second phase of MHCC's work on this project, led by Patrick Redmon, and the assistance of Ascendent Health Care Consulting during Phase 1.

Introduction

On June 25, 2017, the Senate Finance and House Government Operations Committees (Legislative Committees) directed MHCC to review specific elements of the State’s Certificate of Need program, a mechanism for regulating the supply and distribution of certain types of health care facilities that is primarily implemented through a capital project review process, guided by regulations referenced as the State Health Plan. (Appendix A provides an overview of the current scope of CON regulation.)

The purpose of the requested review is twofold: (1) to assure that the CON program aligns with the State’s goals under the All-Payer Model of hospital rate regulation, implemented under an agreement with the federal Centers for Medicare and Medicaid Services; and (2) to reduce the administrative burden for applicants in a complicated project approval process. As the All-Payer Model shifts from a hospital-focused model to a population-based approach that addresses the “Total Cost of Care,” the State will need to develop approaches that dramatically change health care delivery and spending. MHCC has been directed to focus on:

- an examination of major policy issues to ensure that CON laws and regulations reflect the dynamic and evolving health care system, particularly with regard to capital approval requirements;
- a review of approaches that other states have undertaken to determine appropriate capacity;
- revisions to the enabling statutes related to capital approval processes;
- revisions to the State Health Plan (SHP) to create incentives to reduce unnecessary utilization, streamline chapters of the SHP to reduce administrative burden, develop clear criteria for service need in the context of the All-Payer Model, and create unambiguous criteria that are appropriately applied;
- consideration of what flexibility, through either legislative or regulatory changes, may be needed to streamline the CON approval process;
- identification of areas of duplication between MHCC and the Health Services Cost Review Commission (HSCRC) regarding the hospital capital funding process and other areas of hospital regulation; and
- other matters deemed necessary in the study.

The purpose of this report is to provide a set of recommendations for modernizing the 40-year old CON program, improving the efficiency of the program’s project review process, and aligning the program with the Total Cost of Care Model. This report will provide a set of recommendations to accomplish those goals and delineate the regulatory and statutory changes that would be required to facilitate those changes.

CON Modernization Task Force

The Legislative Committees, in their letter requesting this study, 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. In response to this request, MHCC convened a Task Force that included a range of stakeholders, including MHCC commissioners, representatives of the Maryland Department of Health, physicians, payers, employers, consumers, and representatives of regulated health care facilities.

The following table provides the membership roster of the Task Force.

MHCC CON Modernization Task Force

Task Force Member	Industry Sector or Representational Identification	Employment/Organizational Affiliations
Randolph Sergent, Chair [1]	MHCC Commissioner	Vice President & Deputy General Counsel CareFirst Blue Cross/Blue Shield
Regina Bodnar	hospices	Executive Director, Carroll Hospice/ Maryland Hospice & Palliative Care Network
Ellen Cooper	consumers	Former Chief, Antitrust Division, Maryland Office of the Attorney General
Lou Grimmel	nursing homes	Chief Executive Officer, Lorien Health Care/ Health Facilities Association of Maryland LifeSpan Network
Elizabeth Hafey	MHCC Commissioner	Attorney, Miles & Stockbridge
Ann Horton	home health agencies	Executive Director of Strategic Partnerships LHC Group/ Maryland-National Home Care Association
Andrea Hyatt	ambulatory surgical facilities	Director of ASC Operations, University of Maryland Faculty Physicians/ President, Maryland Ambulatory Surgery Association
Adam Kane	HSCRC Commissioner	Senior Vice President, Real Estate Acquisition & Corporate Affairs Erickson Living
Ben Lowentritt, M.D.	physicians ambulatory surgical facilities	Urologist, Chesapeake Urology Associates
Brett McCone	hospitals	Vice President, Maryland Hospital Association
Mark Meade	business/employers	Principal, Consulting Underwriters, LLC
Jeff Metz	MHCC Commissioner	President/Administrator Egle Nursing & Rehabilitation Center/ LifeSpan Network
Michael O’Grady	MHCC Commissioner	Senior Fellow, National Opinion Research Center & Principal, O’Grady Consulting
Rich Przywara [2]	alcoholism and substance abuse treatment intermediate care facilities	Senior Vice President, Operations Ashley Addiction Treatment
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)
Harsh Trivedi, M.D. [2]	psychiatric hospitals	President and CEO, Sheppard Pratt Health System/ Maryland Hospital Association
Renee Webster [2]	Maryland Department of Health	Assistant Director, Office of Health Care Quality, MDH

[1] Frances Phillips, Maryland’s Deputy Secretary for Public Health and a past MHCC Commissioner, served as Task Force Co-Chair until June 2018

[2] Added to the Task Force for Phase 2

The Task Force convened in two phases. Phase One of the group’s work was conducted between January and June of 2018 and was focused on establishing guidance on the key issues perceived with CON regulation that should frame recommendations for change and program reform. Input and information on the problems and issues perceived by stakeholders with CON regulation was gathered and priorities for reform were discussed by the Task Force. Based on this

input, an Interim Report by MHCC to the Legislative Committees was developed and forwarded to the legislators on June 1, 2018.

Phase Two of the work was designed to prioritize and develop recommendations to address the issues identified in Phase One, with the Task Force meeting six times between June 29 and December 3, 2018. During this second phase, the Task Force reviewed and discussed ideas for reform and modernization of CON regulation and heard presentations from Task Force members and other stakeholders outlining the specific views of regulated industry sectors.

The Total Cost of Care Model and the Impact of CON Regulation on the Model

For over 40 years, the federal government has waived federal Medicare hospital reimbursement rules to allow Maryland to set hospital payments for all payers at the State level. The federal waiver requires that all payers, including Medicare, Medicaid, commercial insurance companies, and individuals, pay the same rate for the same hospital service at the same hospital. By ensuring that Maryland's hospitals have stable financing, the system has been able to ensure that hospital care has been both accessible and affordable, especially in rural communities. In return for the Medicare waiver, Maryland was required by the federal government to meet an annual test evaluating the growth of inpatient hospital costs for each hospital stay. As national patterns and standards of care changed over the years, the waiver test became outdated.

In 2013, Maryland State officials and stakeholders negotiated federal approval of a new five-year Maryland All-Payer Medicare Model. This model's success metrics were based on per capita hospital growth and quality improvement, fundamentally changing the way hospitals are paid – shifting reimbursement away from fee-for-service payments towards a focus on total cost of care and increasing hospital payments for quality improvements. The State has met or exceeded the key All-Payer Model tests for limiting hospital cost growth on an all-payer basis, providing savings to Medicare, and improving quality.

In early 2017, the federal government and State officials, with input from Maryland health care leaders, began negotiations for a new model set to begin in January 2019. The new model is intended to move beyond hospital care to address Medicare patients' care in the community. Under the new Total Cost of Care Model, Maryland will be expected to progressively transform care delivery across the health care system with the objective of improving health and quality of care. At the same time, the rate or growth in Medicare spending at the state level must be lower than the national growth rate.

The Total Cost of Care Model will build on the investments that hospitals have made since 2014 to meet the challenges of the All Payer Hospital Model. Maryland will continue to encourage provider- and payer-led development of Care Redesign Programs¹ to support innovation.

¹ The Center for Medicare and Medicaid Innovation (CMMI) has approved three Care Redesign Programs: the Chronic Care Improvement Program, the Episode of Care Improvement Program, and the Hospital Cost Improvement Program. CMMI has also approved the establishment of the Maryland Primary Care Program, an initiative under the TCOC Demonstration that engages primary care physicians in delivery of advanced comprehensive primary care services to Medicare beneficiaries.

Throughout the development of implementation plans, the State will continue its commitment to privately led innovation, voluntary participation in Care Redesign Programs, and meaningful and ongoing stakeholder engagement to achieve the State’s vision for person-centered care, clinical innovation and excellence, and improved population health.

A recurring question in the Task Force discussion was the economic impact of CON programs on health care spending and quality. The genesis of state certificate of need (CON) programs in the late 1960s and early 1970s was the conclusion, derived from the health services research and health economics literature of that time, that an increased supply of health care facilities and services led to an increase in demand for services and higher health care expenditures. At this time, retrospective reimbursement was the common and overwhelming approach to paying for health care facility services and it provided guaranteed reimbursement, even for facilities with substantial excess capacity (Conover and Sloan, 1998). A challenge that all researchers face in conducting analyses on the impact of CON is that the credibility of CON programs varies substantially among the states. Even when CON programs are comparable, confounding or reinforcing policies within a given state may act as a drag or driver for a CON program.

These concerns about excess spending stemmed from a number of characteristics of health care markets that differ from economists’ traditional assumptions for the conditions necessary for efficient market activity. In the economist’s standard competitive model, consumers have complete information about prices for products and services of a given quality and can pursue those prices without transaction costs. Under those circumstances, knowledgeable consumers will seek the lowest available prices for a given service, forcing providers to keep prices low while maintaining quality of care. In reality, prices for consumers are not transparent; third-party payments often shield the patient from substantial portions of the actual cost of care; quality of care is not uniform and may be difficult to ascertain or understand; and the patient may require the assistance of a professional health care provider to diagnose the clinical issue as well as provide the care. With that provider acting as an agent on behalf of the patient, the level of care that is needed may be open to question if this “agent” is acting in response to financial incentives – increased volume due to fee-for-service incentives or stinting on care in response to capitated payments. Given these departures from the idealized version of the competitive market, there is a valid concern that market outcomes may not reflect the socially efficient level of service delivery.

With respect to this question of competition, the Federal Trade Commission and the Department of Justice’s Anti-Trust Division have consistently questioned the wisdom of state CON programs on the basis of their anti-competitive impact since the issuance of a report in 2004 that recommended that “States should decrease barriers to entry into provider markets” and, specifically, “should reconsider whether these programs (Certificate of Need) best serve their citizens’ health care needs.”² Earlier this year, in commenting on CON legislation in Alaska, the FTC noted “three serious problems with CON laws.” Such laws “create barriers to entry and expansion, which can increase prices, limit consumer choice, and stifle innovation. Second, incumbent firms can use CON laws to thwart or delay otherwise beneficial market entry or

² Improving Health Care: A Dose of Competition: A Report by the Federal Trade Commission and the Department of Justice, July, 2004

expansion of new or existing competitors. Third, CON laws can deny consumers the benefit of an effective remedy following the consummation of an anticompetitive merger.”³

CON laws are intended to limit overspending that could result from delivery systems that heavily rely on fee-for-service payment, primarily by third-party payers, by controlling the level of investment in health care services and, thus, limiting service capacity. In Maryland, the State has the ability to use both CON regulation and regulation of reimbursement for hospitals through the State’s Total Cost of Care Model with CMS. To the degree that changes in the CON statute and regulations have implications for the total cost of care and the quality of that care, they are directly linked to the model’s performance over the course of the demonstration.

A substantial literature exists addressing the impact of CON regulation on the cost of care, particularly for hospitals. Much of this literature is dated, an important caveat in light of the significant changes that have occurred in health care delivery, technology, and payment since many of the relevant research was conducted. Conover and Sloan (1998) found that mature CON programs are associated with a modest long-term reduction in acute care spending per capita, but not with a significant reduction in total per capita spending. Mature CON programs were found to correlate with a slight reduction in bed supply but also with higher costs per day and per admission, along with higher hospital profits. CON regulation, in general, was not found to have a detectable effect on diffusion of various hospital-based technologies.

Grabowski et al. (2003) found no significant growth in either nursing home or long-term care Medicaid expenditures associated with CON repeal, based on data from 1981 through 1998. Rivers et al. (2010) concluded that the mere existence of CON regulation does not appear to have an impact on hospital costs per adjusted admission but that increases in the stringency of CON regulation are associated with higher costs per adjusted admission, contrary to expectations. Rahman et al. (2016) find that Medicare and Medicaid spending in states with CON laws grew faster for nursing home care and more slowly for home health care, with the slowest growth in community-based care in states with CON programs regulating the supply of both nursing homes and home health agencies.

Some stakeholders stressed the role of CON in quality of care for patients in the State. While the original purpose of CON under the *National Health Planning and Resource Development Act of 1974* was to restrain health care costs and promote equal access to care, proponents of CON in the health services literature have claimed that CON laws can reduce mortality by limiting the supply and, as a result, concentrating utilization of some services at a smaller number of hospitals, when better outcomes are associated with higher case volume. (Bailey, 2018). However, research on the effect of CON on mortality for specific surgical procedures (especially heart surgery) has been mixed. DiSesa et al. (2006) found that CON regulation alone is not a sufficient mechanism to ensure quality of care for coronary artery bypass graft (CABG) surgery, finding that states with CON regulation of cardiac surgery had significantly higher CABG surgery volume but similar mortality compared with non-CON states. Popescu et al. (2006) concluded that patients with acute myocardial infarction were less likely to be admitted to hospitals offering coronary revascularization and to undergo early revascularization in states

³ Statement of the Federal Trade Commission to the Alaska Senate Committee on Labor & Commerce on Certificate-of-Need Laws and SB 62, February 6, 2018

with CON regulation, but these differences were not associated with mortality. Ho et al. (2009) found that states dropping CON regulation of cardiac surgery experienced lower CABG mortality, although the differential was not permanent, and this research found no similar differences among states with respect to percutaneous coronary intervention. Further, recent research by Bailey (2018) examined the effect of CON laws on all-cause mortality from 1992-2011 and did not find that the existence of CON regulation was correlated with lower all-cause mortality rates.

While the literature has focused on issues of costs and mortality, there are other aspects of provider behavior that were raised by Task Force participants as important roles for CON. A number stated the value of CON regulation as a “gatekeeper,” protecting Maryland patients by discouraging attempts to enter the market by under-resourced or irresponsible actors in certain types of care, a view based on the experience observed in some states without CON regulation or with a more limited scope of regulation. Fraudulent behavior and churning of patients were issues raised in the context of specific sectors, but none of the academic literature has specifically addressed this issue in the context of CON regulation. Other concerns raised by stakeholders were lack of resources (personnel and volunteers) by HHAs and hospices)

There are other dimensions of health care quality beyond mortality rates. Ford and Kaserman (1993) found that CON regulation of chronic renal dialysis significantly retarded new firm entry into provision of this service and total capacity expansion in the industry, restricting supply and fostering increased levels of industry concentration. Delia et al. (2009) found that CON restrictions on the supply of cardiac angiography in New Jersey contributed to historical disparities in access to these services between white and African American patients. No published studies addressing the relationship between CON regulation and patient satisfaction, hospital-acquired conditions, prevention quality indicators, and readmission rates were found and these are some of the important dimensions on which providers are currently measured.

As noted earlier, health services researchers’ interest in examining the impact of CON on quality and cost has weakened over the past decade. Aside from the Rahman’s and Bailey’s research, most of the studies were conducted much earlier. Interest has grown in examining health market concentration as single health care systems have become dominant in many metropolitan markets. Ginsburg et al (2017) and Richman (2012) are examples of prominent researchers that have pointed to the interlocking legal and regulatory barriers including CON, provider licensure requirements, and regulations limiting provider networks formation as major contributors to market concentration and higher costs. These same authors are largely dismissive of arguments by health systems that concentration of health care resources will yield greater efficiencies, higher quality, and lower costs, while fostering greater collaboration among providers. These forces have not played out in exactly this way in Maryland. No health system has achieved dominance in any of Maryland’s major urban markets. One system or another dominates most of the smaller regional markets and rural jurisdictions, but in many of these markets a single system has operated unchallenged for decades.

In Maryland, the unique regulatory environment may provide support for retaining some elements of CON regulation. Most directly, in a state with hospital rate regulation, direct consideration of need is a central concern, given the State’s ability to both regulate the rates that hospitals may charge and to compel payers and patients to pay those rates by law. Further, the

TCoC model requires the State to be accountable for the costs of care for Medicare beneficiaries beyond the hospital. Ignoring the interrelationships between the segments of the care continuum risks unintended consequences for the TCOC model, and these relationships were a substantial part of the focus of the Task Force's attention and are discussed below.

Principles for Reform

In reforming the Maryland regulatory system, a statement of principles for CON regulation was developed to guide consideration of recommended changes. A modern CON regulatory program should:

- Promote the availability of general hospital and long-term care services in all regions of Maryland and assure appropriate availability of specialized services that require a large regional service area to assure viability and quality;
- Complement the goals and objectives of the Maryland Total Cost of Care Model;
- Provide opportunities to enter the Maryland market for innovators committed to the delivery of affordable, safe, and high-quality health care;
- Minimize the regulatory requirements for existing providers to expand existing capacity or offer new services when those providers are committed to the delivery of affordable, safe, and high-quality health care;
- Reduce the burden of complying with CON regulatory requirements to those necessary for assuring that delivery of health care will be affordable, accessible, safe, and of high quality; and
- Maintain meaningful review criteria and standards that are consistent with the law and understandable to applicants, interested parties, and the public.

Reforming CON Regulation: Issues and Potential Solutions

Cross-Cutting Issues

A general consensus emerged in the meetings of the Task Force that the CON regulatory process, which is largely a process of evaluating applications describing capital projects, is overly complex and expensive for providers because its requirements do not advance a clearly identifiable policy purpose or do so in an inefficient manner. Because the requirements include elements that are not necessary or appropriate to a clear policy objective, the process requires excessive time to both complete an application for review and to process the application to reach a decision to approve or deny the project. There was general agreement that better alignment of the process with a clear policy objective(s) and streamlining the process is necessary.

There was also a recognition that the CON process should allow for innovation in care delivery, particularly when innovation consistent with the objectives of the TCOC model may involve facility projects subject to CON regulation. The existing program should be reformed when reforms can be reasonably expected to allow for improvements in regional access to services, more consumer choices among high-performing providers, and more opportunities to transform delivery in ways that enhance quality of care or reduce the cost of delivering care.

Potential Solutions

Several potential solutions were discussed, particularly with respect to streamlining CON regulation. With the exception of hospitals, there was a general consensus that it was not necessary or useful to have a capital spending “threshold” for health care facility projects that defines that project as one that requires issuance of a CON. For hospitals, the historic linkage between CON approval of capital projects and qualification of such projects’ costs (depreciation and interest on project debt) for consideration of rate adjustments is a policy concern that requires a more nuanced approach to streamlining. Further, with respect to CON regulation of hospital projects, there was consensus for a standardized approach to considering project financial feasibility and facility viability with better coordination and integration of effort by MHCC and HSCRC.

There was also consensus that the exemption from CON review process, which is a project review process in place for some types of projects and is intended to be a faster and more limited project review process than CON application review, should be more streamlined than it is, in its current form.

Benefits and Obstacles

Modifications of this type to the process would be expected to provide the benefit of fewer projects requiring CON approval and could also reduce some of the administrative burden for projects required to obtain CON approval or an exemption from CON review. Particular reform ideas also present particular obstacles. Meaningful reform of CON regulation will require changes in both statute and regulation. The “benefit/obstacle” framework is used to summarize the discussion of CON reform for specific topic areas covered in this section of the report.

The Commission can undertake minor and moderate reforms by modifying chapters of the State Health Plan and the procedural regulations (COMAR 10.24.01) that govern application, review and post- approval processes. Although these changes can be completed without statutory changes, such changes will still require provider engagement and support to be implemented. In the past, changes in State Health Plan regulations and the procedural rules have been time consuming and, sometimes, controversial. A comprehensive overhaul of the regulations, based on a radically different approach than that historically used by the Commission, will require a commitment by Commissioners, staff, and the regulated industry to an overarching vision of modernizing CON regulation and a collaborative approach to focusing on the essential elements of regulation and removing less critical elements that will undoubtedly have some constituency support or applicability in rare circumstances.

While the Commission can undertake substantial changes under its own authority, meaningful streamlining and realignment of the CON regulatory process cannot take place without some statutory changes to modify basic program requirements. This report advocates further study of ways in which the scope of CON regulation can be reduced by creating new and different responsibilities for MHCC or for other state agencies, with the objective of preserving perceived benefits of CON regulation but improving the efficiency of obtaining those benefits. The prime example that has emerged from the Task Force work is preservation of the “gatekeeper” role played by the existence of CON regulation, i.e., conceiving of an alternative approach to keeping “bad actors” or organizations likely to develop low-performing facilities from entering Maryland through means other than CON regulation and, thus, removing the burdens of CON regulation on

reputable providers with good performance indicators. These longer-term changes will require consensus building among stakeholders. There are rational bases for eliminating CON regulation of some types of facilities or some types of projects, beyond those that are now solely reviewable because of their expenditure amount, as a way of reducing the cost burden of regulation, increasing alternatives for consumers, facilitating innovation, and creating a more competitive market environment. MHCC believes that such further modernization of CON regulation will take time, but intends for this report to identify further opportunities for reform, which will serve as planning objectives for work on consensus-building around development of viable reform proposals.

Hospital Facilities and Services

For hospitals, Task Force discussion was primarily focused on process reforms without significant discussion of the more fundamental question of the need for CON regulation itself. In Maryland’s rate-regulated system, in which all payers are compelled by law to reimburse hospitals according to rates established by HSCRC, constraints on hospital capital spending are seen as a logical extension of the more comprehensive constraint on hospital revenue. However, there was stakeholder consensus that the current scope of regulation is outdated. Hospital representatives recommended that the capital expenditure threshold definition of a project requiring CON approval, as currently configured, should be reconsidered. They also suggested that excessive and duplicative information requirements exist in the hospital CON application process and that many standards included in State Health Plan regulations for hospital facilities and services are not needed and unnecessarily complicate the CON application review process without materially affecting the outcome of that process. Hospitals have also recommended greater alignment between the information requirements and staff work of HSCRC and MHCC in assessing CON project applications. They call for alignment of the SHP regulations and the current hospital payment model and care delivery transformation objectives and alternatives to conventional CON project review for some types of project. The following “discussion matrix” is intended to profile and summarize the issues and MHCC’s recommended ideas for reform of hospital CON regulation.

Hospital Services Issue and Potential Solution Matrix

<i>Issues</i>	<i>Potential Solutions</i>
<ul style="list-style-type: none"> • Scope of regulation is outdated – Use of capital expenditure threshold should be reconsidered • SHP is outdated and unclear, many standards are unnecessary. • SHP doesn’t align with current hospital payment model and care delivery transformation • Excessive time required for project review and request for exemption from CON review 	<p>UPDATE SHP CHAPTERS In consultation with hospital stakeholders and Commissioners, identify SHP chapters needing review and prioritize that work subject to availability of staff.</p> <p>ELIMINATE SOME REQUIRED CON CONSIDERATIONS AND SHP STANDARDS</p> <ol style="list-style-type: none"> 1. Change the required considerations in project review to only include a) alignment with the State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact on cost and charges, and e) Impact on access to services. This would remove the criteria pertaining to costs and effectiveness and identification of alternatives.

<ul style="list-style-type: none"> • Duplications or external inconsistencies <ul style="list-style-type: none"> ○ Excessive and duplicative information requirements ○ Contradiction between HSCRC and MHCC financial submissions ○ Align with HSCRC in capacity planning approach ○ Hospital’s CON approved projects still needed to request capital in rates • Alternatives to conventional CON project review are lacking • Underdeveloped capability to obtain broader community perspectives on regulated projects 	<ol style="list-style-type: none"> 2. Significantly reduce the number of CON standards in SHP regulations. Specific examples include: <ul style="list-style-type: none"> ○ Eliminate requirements on availability of charge information, charity care, and quality of care documentation ○ Eliminate standards that involve emergency department expansion (drawn from ACEP) ○ Delegate consideration of financial feasibility to HSCRC* <p>STATUTORY CHANGES TO MODERNIZE THE PROCESS</p> <ol style="list-style-type: none"> 3. Allow Commission to waive CON requirements for projects endorsed by HSCRC as fully aligning with TCOC model 4. Develop more rigorous requirements for obtaining interested party status—higher threshold for demonstrating adverse impact 5. Set capital expenditure threshold as a percentage of hospital revenue and only require review and approval if hospital is seeking adjustment of its global budget revenue (GBR) related to project cost (when the capital expenditure is the only basis for reviewing the project). For projects below the capital expenditure threshold, no CON would be required and financing decisions would be subject to HSCRC decisions about the adequacy of hospital’s GBR, the impact on TCOC, and other applicable factors as determined by HSCRC <p>STREAMLINE THE REVIEW PROCESS</p> <ol style="list-style-type: none"> 6. Limit full CON review requirements to: a) establishing or relocating hospitals or free-standing medical facilities (FMFs); b) introducing cardiac surgery or organ transplantation, and; c) contested projects. Create an expedited review process for other hospital project categories, when the project is not contested.* 7. Establish a standing Project Review Committee of Commissioners to handle expedited reviews.* 8. Make it a goal -- not a hard and fast requirement—to limit completeness review to one round of questions and responses before docketing an application as complete. (<i>This goal presupposes reforms to significantly reduce and better define SHP standards.</i>) <p><i>* Indicates that statutory changes may be required to accomplish.</i></p>
<p><u>Obstacles</u></p> <ul style="list-style-type: none"> • Potential solutions will require some statutory changes • Some potential solutions may require policy development by HSCRC • Uncertainty about the incentives in the TCOC model 	<p><u>Benefits</u></p> <ul style="list-style-type: none"> • Reduced administrative burden for both hospitals and MHCC • Better alignment of MHCC and HSCRC objectives • Enhanced opportunities for hospital competition • Potential for more direct input from communities and general public to MHCC’s regulatory review process

may make hospitals hesitant to consider major changes	
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Reform Recommendations Related to Hospital CON Regulation

- ***Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review. The following SHP and procedural regulation reforms are included under this recommendation***
 - a. ***Limit SHP standards to those addressing project need, project viability, access, project impact, and applicant qualifications.***
 - b. ***Create an abbreviated review process for all uncontested projects that do not involve: a) establishment of a health care facility; b) relocation of a health care facility; c) the introduction by a hospital of cardiac surgery or organ transplantation.***
 - c. ***Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines.***
 - d. ***Establish a process for consideration of changes in approved projects as a staff review function with approval by the Executive Director.***
(See last section of this report for more detail on this recommendation.)
- ***Create the ability for the waiver of CON requirements for a capital project that is endorsed by the HSCRC as a viable approach for reducing the total cost of care consistent with HSCRC's TCOC model and alternative models for post-acute care.***
- ***Replace existing hospital project capital expenditure thresholds with a requirement that hospitals obtain CON approval for a capital project with an estimated expenditure that exceeds a specified proportion of the hospital's annual budgeted revenue, but only if the hospital is requesting an extraordinary adjustment in budgeted revenue, based on an increase in capital costs.***
- ***Limit the required considerations in CON project review to: (1) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges; and e) Impact of the project on access to care. This would eliminate the current required consideration of the costs and effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.***
- ***Eliminate the requirement to obtain CON approval of changes in acute psychiatric bed capacity by a hospital.***

- ***Define “ambulatory surgical facility” in the CON statute as an outpatient surgical center with three or more operating rooms. (Current statute defines “ambulatory surgical facility” as a center with two or more operating rooms.) Limit the requirement for CON approval of changes in operating room capacity by hospitals to the rate-regulated hospital setting, i.e., a general hospital. Any person would have the ability, under the new definition of “ambulatory surgical facility,” to establish one or two-operating room outpatient surgical centers without CON approval, but with a determination of coverage after a plan review by MHCC staff.***
- ***Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process (see first recommendation) if final action by the Commission does not occur within 90 days.***
- ***Engage with HSCRC on ways in which hospital CON project review and the Total Cost of Care project can be further integrated. The objective would be to limit hospital projects requiring CON review and to improve MHCC’s use of HSCRC expertise in consideration of project feasibility and project and facility viability.***
- ***Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.***

Ambulatory Surgical Facilities

Because ambulatory surgical facilities (ASFs), which are defined in CON statute as facilities with two or more operating rooms, offer a relatively low-cost setting for surgical procedures, changes to CON that ease the entry of providers with more service capacity offer the potential for reducing health care costs under the TCoC model. Issues to be addressed include the outdated scope of the regulations, which includes post-CON approval performance requirements, the cost and time involved in obtaining an exemption from CON review (which is a process currently available to some types of provider for obtaining approval of a two-operating room ASFs), and the use of capital expenditure thresholds to define projects as needing a CON.

Potential solutions include elimination of CON regulation of ASFs or maintaining CON regulation but streamlining the review process in various ways. All require significant changes to statute and corresponding regulation. Significantly streamlining the process by allowing for development of two-operating room ASFs without CON approval requires a statutory change.

The benefits generated by these potential solutions would include the reduction of administrative burdens, the facilitation of more outpatient surgery in the lowest-cost setting, and the creation of a fairer environment in which hospitals and ASFs can compete for market share, given that hospitals are required to obtain CONs or exemptions from CON for operating room capacity in the hospital setting but have fewer development opportunities than non-hospital actors in the ASF setting.

To the extent that changes in CON regulation accelerate the movement of outpatient surgery from the hospital to the ASF setting, the payer mix of outpatient surgical patients in the hospital setting could be expected to contain higher proportions of Medicaid and uninsured patients, who have historically obtained little service in the ASF setting. HSCRC would need to monitor shifts in surgical volume and adjust hospital budgets accordingly or volume shifts to ASFs could adversely affect TCOC. The ASF matrix below provides additional detail around the issues and potential solutions to issues in CON regulation of ASFs and a review of benefits and obstacles of reform.

Ambulatory Surgical Facility Issues and Potential Solutions Matrix

<p><u>Issues</u></p> <ul style="list-style-type: none"> • Scope of regulation is outdated • Use of capital expenditure threshold should be reconsidered • Excessive time and expense required for CON project review and, potentially, for request for exemption from CON review • Post-CON approval performance requirements are outdated 	<p><u>Potential Solutions</u></p> <p>ELIMINATE SOME CON CRITERIA AND SHP STANDARDS</p> <ol style="list-style-type: none"> 1. Limit required considerations to (1) compliance with SHP standards, (2) project feasibility/facility viability, and (3) project impact on costs and charges* 2. Revise SHP so it is limited to standards addressing need for the project and considerations (2) and (3) above 3. Limit completeness review to one round of questions and response—docketing an application will not connote that application is complete <p>STATUTORY CHANGES TO MODERNIZE THE PROCESS</p> <ol style="list-style-type: none"> 4. Eliminate project expenditure level (capital expenditure) threshold defining a requirement to obtain a CON 5. Limit full CON review requirements to establishing or relocating an ASF (i.e., an ASF with three or more ORs) or contested reviews 6. Create a consent approval process for all other ASF project categories if not a contested review 7. Establish a standing Project Review Committee of Commissioners to handle consent approval process and contested reviews (eliminate individual Commissioner Reviewers) and allow the Project Review Committee to conduct public hearings 8. Allow the Commission to waive CON requirements for ASF projects endorsed by HSCRC as fully aligning with TCOC model 9. Eliminate CON regulation of ASFs and allow hospitals to develop ASFs (non-rate regulated facilities) without CON approval while maintaining CON regulation of hospital-based OR capacity, or alternatively, redefine the term “ambulatory surgical facility” in CON law to be an ASF with three or more operating rooms. Allow all persons, including
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	<p>hospitals, to establish outpatient surgical facilities (non-rate regulated facilities) with one or two ORs.</p> <p>OTHER</p> <p>10. Develop more rigorous requirements for obtaining interested party status, such as higher thresholds for demonstrating adverse impact*</p> <p>11. Work with HSCRC and Medicaid to incentivize ASCs to treat Medicaid patients.</p> <p><i>*Indicates that statutory changes may be required to accomplish.</i></p>
<p><u>Obstacles</u></p> <ul style="list-style-type: none"> • Significant streamlining will require significant statutory changes • If CON is maintained for hospitals (alternative in 10), hospitals will still be competitively disadvantaged by being the outpatient surgery setting for Medicaid patients, uninsured patients, and more complex patients • HSCRC must assure that hospital GBRs are sufficiently re-based over time as more surgical care exits the hospital to unregulated settings 	<p><u>Benefits</u></p> <ul style="list-style-type: none"> • Reduced administrative burden for ASF development • More outpatient surgery performed in the lower cost, non-rate regulated ASF setting, reduce the total cost of surgical care • More direct opportunities for hospitals and ASFs to compete for outpatient surgery market share • Potential for more direct input from communities and general public to MHCC’s regulatory review process

Reform Recommendations Related to ASF CON Regulation

- ***Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review. The following SHP and procedural regulation reforms are included under this recommendation***
 - e. Limit SHP standards to those addressing project need, project viability, access, project impact, and applicant qualifications.***
 - f. Create an abbreviated review process for all uncontested projects that do not involve: a) establishment of a health care facility; b) relocation of a health care facility; c) the introduction by a hospital of cardiac surgery or organ transplantation.***
 - g. Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines.***
 - h. Establish a process for consideration of changes in approved projects as a staff review function with approval by the Executive Director.***

(See last section of this report for more detail on this recommendation.)

- *Create the ability for the waiver of CON requirements for a capital project that is endorsed by the HSCRC as a viable approach for reducing the total cost of care consistent with HSCRC's TCOC model and alternative models for post-acute care.*
- *Eliminate the capital expenditure required for a non-hospital health care facility project as an element requiring CON approval, limiting all definitions of projects requiring CON approval to "categorical" projects involving establishment of facilities or specific types of change to an existing health care facility, no matter what capital expenditure is required.*
- *Limit the required considerations in CON project review to: (1) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges; and e) Impact of the project on access to care. This would eliminate the current required consideration of the costs and effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.*
- *Define "ambulatory surgical facility" in the CON statute as an outpatient surgical center with three or more operating rooms. (Current statute defines "ambulatory surgical facility" as a center with two or more operating rooms.)*
- *Limit the requirement for CON approval of changes in operating room capacity by hospitals to the rate-regulated hospital setting, i.e., a general hospital. Any person would have the ability, under the new definition of "ambulatory surgical facility," to establish one or two-operating room outpatient surgical centers without CON approval, but with a determination of coverage after a plan review by MHCC staff.*
- *Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days*
- *Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.*

Comprehensive Care Facility (Nursing Home) Services

Comprehensive care facilities, or nursing homes, have seen a long-term decline in their rate of use for long-staying patients needing "custodial" care in their final months or years of life and an increase in use by Medicare patients requiring relatively short stays for rehabilitation following a hospital stay. Issues identified in CON regulation of CCFs include the need for streamlining the project review process and creating a lighter regulatory burden for certain types of projects, e.g., projects in jurisdictions with bed occupancy rates exceeding a specified threshold.

Stakeholders identified a need for an updated bed need methodology and for more streamlined and more consistent post-approval processes. The long-standing requirements for CCFs to provide service to Medicaid patients at a specified minimum proportion of total patient volume was identified as unnecessary and counterproductive. Stakeholders felt that the CON process, generally, does not foster innovation.

Potential solutions include the establishment of an exemption from CON review process for projects in jurisdictions with high utilization and/or low quality outcomes, elimination of CON requirements associated with facility modernization projects, elimination of Medicaid participation requirements, and allowing the docketing of projects, regardless of need, if the project aligns with the TCOC model. Potential solutions also include allowing CCFs to provide home health agency services without obtaining a CON and allowing larger changes in bed capacity without CON approval (such expansions are now limited to a maximum of ten beds or ten percent of existing bed capacity).

The chief benefit that could be expected from these potential solutions would be reduced regulatory costs for facilities undertaking capital projects and more flexibility for facilities in adjusting bed capacity and targeting the most lucrative segments of the market. The CCF matrix below provides additional detail with respect to issues, potential solutions, obstacles, and potential benefits associated with reform of CON regulation of CCFs.

Comprehensive Care Facility Services Issues and Potential Solutions Matrix

<u>Issues</u>	<u>Potential Solutions</u>
<ul style="list-style-type: none"> • Excessive time and expense associated with CON project review process • Update bed need methodology • Ability to incrementally expand bed capacity without CON approval is too limited • Continuing care retirement communities are too limited in their ability to use CCF beds to respond to changing care preferences of residents • CON does not foster innovation • Eliminate the requirement to provide a minimum number of patient days to Medicaid patients (the Medicaid MOU). • CON processes need to align with TCOC • Post approval processes are excessive or inconsistent • 	<p>ELIMINATE SOME SHP STANDARDS</p> <ol style="list-style-type: none"> 1. In consultation with stakeholders and Commissioners, modify the CCF SHP chapter. 2. Establish an exemption from CON review process for project development in jurisdictions with occupancy rates above a specified threshold.* 3. Permit docketing of applications for new facility in a jurisdiction that has a percentage of CCFs that fell below MHCC-established quality standards 4. Permit docketing of applications in jurisdictions that have no need if the proposal is aligned with the TCOC model 5. Eliminate CON requirements for facility modernization if bed capacity is not changing 6. Allow changes in bed capacity of more than ten beds or ten percent of existing bed capacity without a CON <p>STATUTORY CHANGES TO MODERNIZE THE PROCESS</p>

	<p>7. Eliminate project expenditure level (capital expenditure) threshold defining a requirement to obtain a CON</p> <p>8. Allow CCFs to provide home health services to discharged patients without a CON</p> <p>9. Modify/eliminate direct admission restrictions at CCRCs for non-community residents into nursing homes if bed capacity is 10 percent or less of its independent living units</p> <p>Note: With respect to Solution1, an update of the CCF SHP regulations is currently underway. Proposed regulations, approved in October 2018, contain versions of Solutions 3 and 4.</p>
<p><u>Obstacles</u></p> <ul style="list-style-type: none"> • Projects that may align with the TCoC model have not been well defined by HSCRC or hospitals • Providing an ability for CCFs to expand into other types of post-acute care on an unregulated basis would require reciprocal flexibility for other post-acute care providers if an equitable approach to regulation is to be maintained • The industry opposes providing more opportunities for significant bed capacity development 	<p><u>Benefits</u></p> <ul style="list-style-type: none"> • Reduced administrative burden • Potential for more consumer choice in areas with poor performing providers • Opportunity for innovative project development if aligned with TCoC model that might not otherwise exist

Reform Recommendations Related to CCF CON Regulation

- ***Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review. The following SHP and procedural regulation reforms are included under this recommendation***
 - i. Limit SHP standards to those addressing project need, project viability, project impact, and applicant qualifications.***
 - j. Create an abbreviated review process for all uncontested projects that do not involve: a) establishment of a health care facility; b) relocation of a health care facility; c) the introduction by a hospital of cardiac surgery or organ transplantation.***
 - k. Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines.***
 - l. Establish a process for considering changes in approved projects as a staff review function with approval by the Executive Director.***

(See last section of this report for more detail on this recommendation.)

- *Create the ability for the waiver of CON requirements for a capital project that is endorsed by the HSCRC as a viable approach for reducing the total cost of care consistent with HSCRC's TCOC model and alternative models for post-acute care.*
- *Eliminate the capital expenditure required for a non-hospital health care facility project as an element requiring CON approval, limiting all definitions of projects requiring CON approval to "categorical" projects involving establishment of facilities or specific types of change to an existing health care facility, no matter what capital expenditure is required.*
- *Limit the required considerations in CON project review to: (1) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges; and e) Impact of the project on access to care. This would eliminate the current required consideration of the costs and effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.*
- *Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days*
- *Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.*

Home Health Agency Services

The basic model for CON regulation of home health agency (HHA) services was substantially reformed in 2017. The desired objective of quickly approving HHA projects by pre-qualifying applicants has not been realized, indicating a need for further reform.

Issues identified by stakeholders include revision of the CON application to better reflect HHA service delivery and a need for the CON process to be more responsive to changes in care access and initiatives to reduce CCF utilization. Charity care provision is cited as needing greater transparency and standardization in how it is handled in CON regulation. Reductions of unneeded SHP standards and elimination of review criteria could accelerate the process.

Potential solutions include exempting existing HHAs from CON requirements associated with expanding their service area to new jurisdictions or making this expansion process much easier for existing HHAs. CON review standards could be limited to consideration of applicant history and background and track record in providing quality care. Recent history indicates a need to revisit charity care standards. A long-term alternative solution is to eliminate CON regulation of HHAs altogether, in conjunction with establishing an alternative capacity for limiting the

opportunity to license a new HHA in Maryland if a rigorous review of the applicant’s background and experience indicates problems that prevent licensure under Maryland law and/or regulation.

Stakeholders note that changes to Medicare payment methodologies have the potential to disrupt the HHA sector, as implementation of value-based payment (VBP) models by the Centers for Medicare and Medicaid Services are ongoing. They also raise the concern that demand for HHA professionals is outstripping supply and this may worsen in coming years. Reforming CON regulation in ways that significantly increase establishment of new HHAs in Maryland may exacerbate this problem and may increase the potential for “bad actors” to move into Maryland, which currently enjoys relatively high marks for quality and few instances of fraud and abuse, when compared with most other states. It should be noted that CMS has initiated moratoria on the development of additional HHA providers in areas of Illinois, Florida, Michigan, and Texas due to fraud and abuse concerns.⁴

Benefits generated by these potential solutions could include more use of HHAs as a substitute for higher cost post-acute care, increased levels of competition and choice to the benefit of patients, and reductions in the cost of regulation. The HHA matrix below summarizes the issues, potential solutions, obstacles, and benefits of reform ideas.

Home Health Agency Services Issues and Potential Solutions Matrix

<u>Issues</u>	<u>Potential Solutions</u>
<ul style="list-style-type: none"> • The SHP’s method for creating opportunities for HHA development and expansion needs to be updated to evaluate actual access to care. • Maryland’s average home health agency quality scores are higher than the rest of the nation. Stringent quality standards are important to maintain the level of quality in home health in Maryland • Currently, charity care practices are inconsistent among providers and standardization and transparency are needed • The CON application for HHAs needs to be revised to better address the unique features of HHA services. • CON process needs to be responsive to changes in care access and initiatives to reduce CCF utilization • Fraud is a greater concern in non-CON states, as evidenced by the Health and Human Services 	<p>SHP CHANGES</p> <ol style="list-style-type: none"> 1. Modify the SHP to 2. Provide greater flexibility for existing providers to expand into additional jurisdictions* 3. Modify access standards related to charity care to provide more credit for serving the uninsured and persons dually eligible for Medicare and Medicaid <p>STATUTORY CHANGES TO MODERNIZE THE PROCESS</p> <ol style="list-style-type: none"> 4. Eliminate project expenditure level (capital expenditure) threshold defining a requirement to obtain a CON 5. Eliminate the need for certain existing facilities to obtain a CON to provide HHA services to patients discharged from their facility (e.g., hospitals and CCFs) 6. Limit CON review standards to a review of the provider’s history/quality in previous service provision

⁴ See “Provider Enrollment Moratorium”, Centers for Medicare and Medicaid Services, July 29, 2018, accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/ProviderEnrollmentMoratorium.html>

<p>Office of the Inspector General Fraud Task Force Report of 2017</p> <ul style="list-style-type: none"> • Work force adequacy is a major concern for HHAs. It is projected that the demand for HHA nurses, therapists and aides will reach unfulfillable levels within the next six years. • Maryland HHAs are currently engaged in value-based purchasing pilot programs with CMS • A new payment methodology for HHAs being implemented in 2019 (Patient-Driven Groupings Model) will cause further disruption to the home health sector 	<p>7. Eliminate CON regulation of HHAs and establish an alternative to CON for limiting the ability of “bad actors” to enter the Maryland HHA market</p>
<p><u>Obstacles</u></p> <ul style="list-style-type: none"> • Lack of support for significant deregulation by existing HHAs • TCOC experiment and HHA VBP are both currently underway. The home health community is concerned about making significant changes to the home health infrastructure in the state and the impact that might have on these two pilot programs. Consultation with CMS is recommended prior to making changes that will disrupt the marketplace. 	<p><u>Benefits</u></p> <p>Reduced regulatory cost burden More HHAs and more competitive HHA markets could potentially increase use of HHA services as a substitute for more expensive post-acute care More HHAs and more competitive HHA markets could benefit patients by providing more choices of quality providers</p>

Reform Recommendations Related to HHA CON Regulation

- ***Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review. The following SHP and procedural regulation reforms are included under this recommendation***
 - m. Limit SHP standards to those addressing project need, project viability, access, project impact, and applicant qualifications.***
 - n. Create an abbreviated review process for all uncontested projects that do not involve: a) establishment of a health care facility; b) relocation of a health care facility; c) the introduction by a hospital of cardiac surgery or organ transplantation.***
 - o. Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines.***
 - p. Establish a process for considering changes in approved projects as a staff review function with approval by the Executive Director.***
(See last section of this report for more detail on this recommendation.)

- *Create the ability for the waiver of CON requirements for a capital project that is endorsed by the HSCRC as a viable approach for reducing the total cost of care consistent with HSCRC's TCOC model and alternative models for post-acute care.*
- *Eliminate the capital expenditure required for a non-hospital health care facility project as an element requiring CON approval, limiting all definitions of projects requiring CON approval to "categorical" projects involving establishment of facilities or specific types of change to an existing health care facility, no matter what capital expenditure is required.*
- *Limit the required considerations in CON project review to: (1) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges; and e) Impact of the project on access to care. This would eliminate the current required consideration of the costs and effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.*
- *Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days.*
- *Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.*
- *Engage with the home health, hospice, alcohol and drug treatment, and residential treatment center sectors and the Maryland Department of Health on alternatives to conventional CON regulation for accomplishing the "gatekeeper" function of keeping persons or organizations with poor track records in quality of care and/or integrity from entering Maryland and accomplishing the objective of expanding the number of such facilities gradually. The objectives would be either to: (1) eliminate CON regulation for these health care facility categories with MDH incorporating the gatekeeper function into the facility licensure process; or (2) establish MHCC's role in regulating these facility categories solely as a gatekeeper (e.g., any facility of this type that gets a clean bill of health following a rigorous background check and character and competence review and is compatible with limitations for gradual expansion of new providers would be issued a CON, without further review). Establish specific deadlines for recommendations.*

General Hospice Services

CON regulation of general hospice services is perceived as outdated and there appears to be a consensus that the use of a capital expenditure threshold as an element defining the need for CON approval of a project and the regulation of hospice bed capacity are not necessary. The SHP is criticized as lacking charity care standards that expand access. The SHP regulations for hospice,

like most SHP regulations, predate implementation of the new hospital payment model, which is entering the new TCOC phase in 2019, so consideration of better alignment is needed to assure that post-acute care cost are controlled. The current CON regulations are also seen as limiting choice of hospice providers in many areas of the state and some believe that regulating the supply of hospices through CON is not needed. The existing providers generally support the need for CON as a check on market entry of new providers because they associate this “gatekeeping” function with higher quality and less questionable behavior among hospice providers in Maryland. Hospice operators reemphasized a longstanding concern that that removal of hospice from the scope CON would exacerbate the recruitment of qualified staff and volunteers. Finally, some aspects of CON regulation practice are viewed as duplicative of roles played by the Maryland Department of Health in its licensing and certification activities for hospices.

Potential solutions addressing these issues include modifying the CON regulations to permit hospices to expand into contiguous jurisdictions without CON approval, modifying the charity care requirements, eliminating CON for bed capacity changes, and reducing the review criteria and standards used in project review. A more radical approach to consider is removing hospice from the scope of CON regulation and developing alternative regulatory mechanisms for providing the “gatekeeper” function served by CON regulation.

The potential benefits arising from these changes would clearly include reduced expenditures by hospices seeking to implement projects currently regulated by MHCC. A less regulatory environment could potentially increase the use of hospice, a goal of MHCC embodied in the current SHP regulations. It could also provide a second choice of hospice provider for patients in jurisdictions that currently have only one authorized hospice (about half of the state’s jurisdictions). The following matrix profiles issues, potential solutions, obstacles, and benefits with respect to reform of hospice CON regulation.

General Hospice Services Issues and Potential Solutions Matrix

<u>Issues</u>	<u>Potential Solutions</u>
<ul style="list-style-type: none"> • Outdated scope of CON • Inadequate standards and criteria are not adequate • Limited hospice choice in many jurisdictions • SHP does not reflect new hospital payment model and coming TCOC model, which will require control of post-acute care • CON is not a necessary public policy tool for hospice. If more supply of hospices increases demand for hospice care, this is consistent with MHCC objectives if the care substitutes for more expensive hospital care at the end of life. • MHCC’s CON requirements unnecessary duplicate MDH regulatory requirements. • Eliminate CON for general hospices adding general inpatient units. 	<p>SHP CHANGES</p> <ol style="list-style-type: none"> 1. Reduce criteria and standards 2. Allow general hospices to expand into a contiguous jurisdiction with an expedited review process 3. Modify the charity care standards to expand access to hospice care <p>STATUTORY CHANGES TO MODERNIZE THE PROCESS</p> <ol style="list-style-type: none"> 4. Eliminate project expenditure level (capital expenditure) threshold defining a requirement to obtain a CON 5. Eliminate CON for changes in bed capacity at inpatient hospices 6. Remove hospice from the scope of CON regulation and create an alternative regulatory

	process to replace the “gatekeeping” function served by CON regulation
<p><u>Obstacles</u></p> <ul style="list-style-type: none"> • Previous modification of the State Health Plan has been strongly resisted by providers. • Statutory changes opposed by the industry have not been able to gain traction in the past 	<p><u>Benefits</u></p> <ol style="list-style-type: none"> 1. Reduced cost of regulatory compliance 2. Expanded availability and, possibly, use of hospice care 3. Increased competition providing more choices for patients and a spur to better quality of care and more effort in customer satisfaction

Reform Recommendations Related to General Hospice CON Regulation

- ***Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review. The following SHP and procedural regulation reforms are included under this recommendation***
 - q. Limit SHP standards to those addressing project need, project viability, project impact, and applicant qualifications.*
 - r. Create an abbreviated review process for all uncontested projects that do not involve: a) establishment of a health care facility; b) relocation of a health care facility; c) the introduction by a hospital of cardiac surgery or organ transplantation.*
 - s. Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines.*
 - t. Establish a process for considering changes in approved projects as a staff review function with approval by the Executive Director.*
(See last section of this report for more detail on this recommendation.)
- ***Create the ability for the waiver of CON requirements for a capital project that is endorsed by the HSCRC as a viable approach for reducing the total cost of care consistent with HSCRC’s TCOC model and alternative models for post-acute care.***
- ***Eliminate the capital expenditure required for a non-hospital health care facility project as an element requiring CON approval, limiting all definitions of projects requiring CON approval to “categorical” projects involving establishment of facilities or specific types of change to an existing health care facility, no matter what capital expenditure is required.***
- ***Limit the required considerations in CON project review to: (1) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges; and e) Impact of the project on access to care. This would eliminate the current required consideration of the costs and***

effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.

- *Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days.*
- *Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.*
- *Engage with the home health, hospice, alcohol and drug treatment, and residential treatment center sectors and the Maryland Department of Health on alternatives to conventional CON regulation for accomplishing the “gatekeeper” function of keeping persons or organizations with poor track records in quality of care and/or integrity from entering Maryland and accomplishing the objective of expanding the number of such facilities gradually. The objectives would be either to: (1) eliminate CON regulation for these health care facility categories with MDH incorporating the gatekeeper function into the facility licensure process; or (2) establish MHCC’s role in regulating these facility categories solely as a gatekeeper (e.g., any facility of this type that gets a clean bill of health following a rigorous background check and character and competence review and is compatible with limitations for gradual expansion of new providers would be issued a CON, without further review). Establish specific deadlines for recommendations.*

Alcoholism and Drug Abuse Treatment Intermediate Care Facility Services

Alcoholism and drug abuse treatment intermediate care facility (ICF) services are the only category of non-hospital substance abuse treatment facility regulated under the CON program. Proposed legislation that would eliminate CON regulation of these sub-acute inpatient facilities was introduced in 2018, but failed to advance. Stakeholders have stated that continued inclusion of ICFs as a CON-regulated facility category is necessary to prevent a substantial influx of new facilities providing poor quality care and engaging in undesirable practices aimed at maximizing revenue rather than effectively rehabilitating addicted patients. MHCC endorsed elimination of CON regulation in 2018 as part of an appropriate response to the opiate and opioid overdose crisis and the calls for more treatment programming. MHCC’s experience indicates that some existing ICFs are lack staff to prepare an adequate CON application to expand bed capacity and are unable to engage consultants to assist them in the process due to cost constraints.

Potential solutions include eliminating CON regulation of ICFs which would allow for unregulated expansion of treatment capacity by existing ICFs. This proposal is generally opposed by those ICFs for the reasons noted above.

Alternatively, changing the CON regulations and the SHP chapter for to significantly simplify the regulatory process may be the only politically acceptable path to reform. Statutory changes could eliminate the CON requirement for relocation or expansion of “Track 2” ICFs that provide a substantial level of service to indigent patients.

The benefits of reform could include faster and less costly expansion of needed treatment capacity and the consequent reduction in regulatory costs. The ICF matrix below provides a summary of issues, potential solutions, obstacles, and benefits perceived in reforming CON regulation of ICFs.

Alcoholism and Drug Abuse Treatment Intermediate Care Facility Services Issues and Potential Solutions Matrix

<p><u>Issues</u></p> <ul style="list-style-type: none"> • Scope of CON regulation in addictions treatment is a very narrow part of treatment spectrum – may dis-incentivize provision of this level of inpatient care • Existence of CON regulation may serve to insulate existing providers from new market entrants, perceived as a positive impact by most existing providers • The current regulations and process is highly challenging for recent Track 2 applicants 	<p><u>Potential Solutions</u></p> <p>SHP CHANGES</p> <ol style="list-style-type: none"> 1. Change SHP to simplify and reduce number of standards 2. Eliminate all standards with the exception of impact and financial access <p>STATUTORY CHANGES TO MODERNIZE THE PROCESS</p> <ol style="list-style-type: none"> 3. Eliminate project expenditure level (capital expenditure) threshold defining a requirement to obtain a CON 4. Eliminate all CON requirements for Track 2 ICFs 5. Eliminate all CON regulation of alcoholism and drug abuse services and develop alternative regulatory approach to serve “gatekeeper” function perceived as a positive characteristic of CON regulation
<p><u>Obstacles</u></p> <ul style="list-style-type: none"> • Opposition by existing providers to changing the scope of CON regulation 	<p><u>Benefits</u></p> <ul style="list-style-type: none"> • Reduced regulatory cost burden • Increased availability of ICF treatment capacity which may be needed • Increased competition providing patients with more choice and spurring providers to work harder to satisfy customers

Reform Recommendations Related to Substance Abuse ICF CON Regulation

- ***Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON***

application review. The following SHP and procedural regulation reforms are included under this recommendation

- u. Limit SHP standards to those addressing project need, project viability, project impact, and applicant qualifications.*
 - v. Create an abbreviated review process for all uncontested projects that do not involve: a) establishment of a health care facility; b) relocation of a health care facility; c) the introduction by a hospital of cardiac surgery or organ transplantation.*
 - w. Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines.*
 - x. Establish a process for considering changes in approved projects as a staff review function with approval by the Executive Director.*
- (See last section of this report for more detail on this recommendation.)*

- *Eliminate the capital expenditure required for a non-hospital health care facility project as an element requiring CON approval, limiting all definitions of projects requiring CON approval to “categorical” projects involving establishment of facilities or specific types of change to an existing health care facility, no matter what capital expenditure is required.*
- *Limit the required considerations in CON project review to: (1) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges; and e) Impact of the project on access to care. This would eliminate the current required consideration of the costs and effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.*
- *Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days.*
- *Eliminate the requirement to obtain CON approval of changes in bed capacity by an alcoholism and drug abuse treatment intermediate care facility or by a residential treatment center.*
- *Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.*
- *Engage with the home health, hospice, alcohol and drug treatment, and residential treatment center sectors and the Maryland Department of Health on alternatives to conventional CON regulation for accomplishing the “gatekeeper” function of keeping persons or organizations with poor track records in quality of care and/or integrity from entering Maryland and accomplishing the objective of expanding the number of such*

facilities gradually. The objectives would be either to: (1) eliminate CON regulation for these health care facility categories with MDH incorporating the gatekeeper function into the facility licensure process; or (2) establish MHCC’s role in regulating these facility categories solely as a gatekeeper (e.g., any facility of this type that gets a clean bill of health following a rigorous background check and character and competence review and is compatible with limitations for gradual expansion of new providers would be issued a CON, without further review). Establish specific deadlines for recommendations.

Residential Treatment Center Services

Residential treatment centers (RTCs), providing residential treatment for children and adolescents with behavioral disorders, have seen a long-term trend in declining demand. This trend would suggest that CON regulation of this dwindling service, which is largely a sector that responds to referrals generated by the juvenile justice system, could be safely eliminated without concerns for oversupplying the market. Others argue that eliminating CON regulation could still open Maryland to entry of new providers with poor track records in providing quality services or operating with integrity.

Potential solutions could include CON regulation of bed capacity changes and facility relocations, creating an uneven playing field for new entrants but allowing the small number of established RTCs to easily respond to any changes in demand for care. Eliminating CON regulation in its totality could be accompanied by regulatory initiatives that assure that new market entry is only made available to reputable persons and/or a regulatory process that assures acceptable vetting of new market entrants by the Maryland Department of Health.

Reducing regulatory costs would be the primary benefit of reducing the scope of CON regulation in this area. The RTC matrix below summarizes the issues, potential solutions, obstacles, and benefits associated with reforming CON regulation of RTC services.

Residential Treatment Center Issues and Potential Solutions Matrix

<p><u>Issues</u></p> <ul style="list-style-type: none"> • CON regulation of RTCs imposes costs that are hard to justify given the trend of declining demand for service, which largely arises from the juvenile justice system, and the types of projects that may be needed in this environment, such as modernizing existing facilities or making relatively small bed capacity additions or redistributions • The importance of CON regulation as a “gatekeeper” has been noted for RTC services. It keeps out “bad actors” by discouraging new market entry. 	<p><u>Potential Solutions</u></p> <p>STATUTORY CHANGES TO MODERNIZE THE PROCESS</p> <ol style="list-style-type: none"> 1. Remove RTCs from the scope of CON regulations and reform Maryland Department of Health licensing practices to serve as an alternative “gatekeeper” 2. Eliminate CON regulation of relocation and changes in bed capacity by existing RTCs
<p><u>Obstacles</u></p> <ul style="list-style-type: none"> • Deregulatory initiatives are likely to be resisted by existing providers. 	<p><u>Benefits</u></p> <ul style="list-style-type: none"> • Reduced regulatory costs

Reform Recommendations Related to RTC CON Regulation

- ***Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review. The following SHP and procedural regulation reforms are included under this recommendation***
 - y. ***Limit SHP standards to those addressing project need, project viability, project impact, and applicant qualifications.***
 - z. ***Create an abbreviated review process for all uncontested projects that do not involve:***
 - a) ***establishment of a health care facility; b) relocation of a health care facility; c) the introduction by a hospital of cardiac surgery or organ transplantation.***
 - aa. ***Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines.***
 - bb. ***Establish a process for considering changes in approved projects as a staff review function with approval by the Executive Director.***
(See last section of this report for more detail on this recommendation.)
- ***Eliminate the capital expenditure required for a non-hospital health care facility project as an element requiring CON approval, limiting all definitions of projects requiring CON approval to “categorical” projects involving establishment of facilities or specific types of change to an existing health care facility, no matter what capital expenditure is required.***
- ***Limit the required considerations in CON project review to: (1) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges; and e) Impact of the project on access to care. This would eliminate the current required consideration of the costs and effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.***
- ***Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days.***
- ***Eliminate the requirement to obtain CON approval of changes in bed capacity by an alcoholism and drug abuse treatment intermediate care facility or by a residential treatment center.***
- ***Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.***

- *Engage with the home health, hospice, alcohol and drug treatment, and residential treatment center sectors and the Maryland Department of Health on alternatives to conventional CON regulation for accomplishing the “gatekeeper” function of keeping persons or organizations with poor track records in quality of care and/or integrity from entering Maryland and accomplishing the objective of expanding the number of such facilities gradually. The objectives would be either to: (1) eliminate CON regulation for these health care facility categories with MDH incorporating the gatekeeper function into the facility licensure process; or (2) establish MHCC’s role in regulating these facility categories solely as a gatekeeper (e.g., any facility of this type that gets a clean bill of health following a rigorous background check and character and competence review and is compatible with limitations for gradual expansion of new providers would be issued a CON, without further review). Establish specific deadlines for recommendations.*

Recommendations

MHCC makes the following recommendations for modernizing CON regulation in Maryland. (These recommendations, as they affect CON regulation of specific health care facility project categories, have already appeared in the previous section of the report.) They are based on the engagement of MHCC Commissioners and staff with a Task Force of stakeholders that reviewed issues and perceived problems in CON regulation and discussed potential solutions to those problems and regulatory reform ideas for addressing identified issues over the course of 2018.

The recommendations are divided into three categories:

- Regulatory changes that can be started immediately through amendment of existing regulations;
- Regulatory reforms that require statutory changes that could be sought in the 2019 or 2020 General Assembly sessions, and
- Recommendations for further study of potential approaches to reforming CON regulation from which further regulatory and statutory changes are likely to emerge.

Short-term and longer-term recommendations are delineated below.

Since significant work has already been done on revising the recommendations [see meeting summary], include those revised recommendations here.

Regulatory Reforms to be Started Immediately

1. Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review. Among the changes implemented should be:
 - a. Limiting SHP standards to those addressing project need, project viability, project impact, and applicant qualifications. Any other standards that do not address these four specific criteria should only be included if absolutely necessary to the particular characteristics of a health care facility. Applicant qualification standards will allow for the establishment of performance or track record thresholds that must be met in order to become an applicant and, as such, will become the single way in which CON regulation addresses quality of care, as a “gatekeeper.” For example:
 - i. The SHP regulations for home health agencies could be streamlined to facilitate quicker approval of qualified applicants by eliminating extraneous standards or standards with low impact (such as charity care requirements).
 - ii. The SHP regulations for general hospices could be revised to create a pathway for facilitating the establishment of alternative choices for hospice care in jurisdictions with only one authorized hospice.
 - b. Creating an abbreviated review process for all uncontested projects that do not involve:
 - a) establishment of a health care facility; b) relocation of a health care facility; c) the introduction by a hospital of cardiac surgery or organ transplantation. The features of this review process will include:

- i. A goal -- not a hard and fast requirement -- to limit completeness review to one round of questions and responses before docketing an application as complete. *(This goal presupposes reforms to significantly reduce and better define SHP standards.)*
 - ii. Issuance of a staff recommendation within 60 days of docketing and final action by the Commission within 90 days of docketing.
 - c. Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines. Failure to timely obligate and initiate construction will void the CON. Timely obligation and initiation of construction will result in a 12-month extension with subsequent requirements to report progress (in essence, an annual progress report) and obtain additional 12-month extensions until project completion. Projects that do not involve construction will continue to have a deadline for completing the project.
 - d. Establish a process for review of changes in approved projects as a staff review function with approval by the Executive Director. Limit required change reviews to 1) changes in the financing plan that require additional debt financing and/or extraordinary adjustment of a hospital's budgeted revenue and 2) changes in "medical services" approved to be provided by the facility. Continue current list of impermissible changes.
- 2. Create the ability for the waiver of CON requirements for a capital project that is endorsed by the HSCRC as a viable approach for reducing the total cost of care consistent with HSCRC's TCOC model and alternative models for post-acute care.

Regulatory Reforms Requiring Statutory Changes to Be Sought in the 2019 or 2020 Legislative Session

- 3. Eliminate the capital expenditure required for a non-hospital health care facility project as an element requiring CON approval, limiting all definitions of projects requiring CON approval to "categorical" projects involving establishment of facilities or specific types of change to an existing health care facility, no matter what capital expenditure is required.
- 4. Replace existing hospital project capital expenditure thresholds with a requirement that hospitals obtain CON approval for a project with an estimated expenditure that exceeds a specified proportion of the hospital's annual budgeted revenue, but only if the hospital is requesting an extraordinary adjustment in budgeted revenue, based on an increase in capital costs.
- 5. Limit the required considerations in CON project review to: (1) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges. This would eliminate the current required consideration of the costs and effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.

6. Eliminate the requirement to obtain CON approval of changes in bed capacity by an alcoholism and drug abuse treatment intermediate care facility or by a residential treatment center.
7. Eliminate the requirement to obtain CON approval of changes in acute psychiatric bed capacity by a general acute care or special psychiatric hospital.
8. Eliminate the requirement to obtain CON approval of changes in hospice inpatient bed capacity or the establishment of bed capacity by a general hospice.
9. Define “ambulatory surgical facility” in the CON statute as an outpatient surgical center with three or more operating rooms. (Current statute defines “ambulatory surgical facility” as a center with two or more operating rooms.)
10. Limit the requirement for CON approval of changes in operating room capacity by hospitals to the rate-regulated hospital setting, i.e., a general hospital. Any person would have the ability, under the new definition of “ambulatory surgical facility,” to establish one or two-operating room outpatient surgical centers without CON approval, but with a determination of coverage after a plan review by MHCC staff.
11. Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days.

Areas for Further Study from which Further Regulatory and Statutory Changes Are Likely to Emerge

12. Engage with the home health, hospice, alcohol and drug treatment, and residential treatment center sectors and the Maryland Department of Health on alternatives to conventional CON regulation for accomplishing the “gatekeeper” function of keeping persons or organizations with poor track records in quality of care and/or integrity from entering Maryland and accomplishing the objective of expanding the number of such facilities gradually. The objectives would be either to: (1) eliminate CON regulation for these health care facility categories with MDH incorporating the gatekeeper function into the facility licensure process; or (2) establish MHCC’s role in regulating these facility categories solely as a gatekeeper (e.g., any facility of this type that gets a clean bill of health following a rigorous background check and character and competence review and is compatible with limitations for gradual expansion of new providers would be issued a CON, without further review). Establish specific deadlines for recommendations.
13. Engage with HSCRC on ways in which hospital CON project review and the Total Cost of Care project can be further integrated. The objective would be to limit hospital projects requiring CON review and to improve MHCC’s use of HSCRC expertise in consideration of project feasibility and project and facility viability.
14. Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review

committee. The objective would be further streamlining the review process and facilitating more public engagement.

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Appendices

Letters from Stakeholders On Proposed Reforms Developed during Part 2

Final Interim Report

Meeting summaries