Modernization of the Maryland Certificate of Need Program

Final Report

DRAFT

Maryland Health Care Commission

November 9, 2018

Contents

Acknowledgements

[insert]

Introduction

Study Request and Purpose of this Report

On June 25, 2017, the Senate Finance and House Government Operations Committees (Legislative Committees) directed the MHCC to review specific elements of the State's Certificate of Need (CON) program. The purpose of the review is twofold: (1) to be sure that the CON program aligns with the State's goals under the All-Payer Model with the federal Centers for Medicare and Medicaid Services and (2) to reduce the administrative burden for applicants in a complicated 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. The 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 MHCC flexibility, through either legislative or regulatory changes, may be needed to streamline the CON approval process;
- identify areas of duplication between the 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 streamlining the CON process based on the Task Force's work. The goal is to improve that efficiency of the process while modernizing and aligning the process 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, asked that MHCC submit an interim report by May 1, 2018 and a final report with recommendations no later than December 1, 2018. In response to this request, the MHCC has convened a Task Force that included a range of stakeholders, including MHCC commissioners, representatives for the Maryland Department of Health, and representatives from hospitals and health systems, physicians, post-acute care providers, ambulatory surgery facilities, behavioral health and substance abuse treatment providers, employers, health care carriers, health care consumers, along with local health departments and public health experts.

The membership of the Task Force, the health care sector that each represents, and the current professional position of each member is presented in the table below.

MHCC CON Modernization Task Force

Task Force Member	Industry/Sector	Title/Role/Affiliation
Frances Phillips, Co-Chair*	Public Health	Acting Health Officer, Anne Arundel County
Randolph Sergent, Chair	MHCC Commissioner Health Insurance	Vice President & Deputy General Counsel CareFirst BC/BS
Regina Bodnar	Maryland Hospice & Palliative Care Network	Executive Director, Carroll Hospice
Ellen Cooper	Consumers	Former Chief, Antitrust Division, Maryland Office of the Attorney General
Lou Grimmel	Nursing Homes	Chief Executive Officer, Lorien Health Care
Elizabeth Hafey	MHCC Commissioner	Attorney, Miles & Stockbridge
Ann Horton	Maryland-National Home Care Association Home Health Agencies	Executive Director of Strategic Partnerships LHC Group
Andrea Hyatt	Ambulatory Surgery Centers	President, Maryland Ambulatory Surgery Association & Director of ASC Operations, University of Maryland Faculty Physicians
Adam Kane	HSCRC Commissioner	Senior Vice President, Real Estate Acquisition & Corporate Affairs Erickson Living
Ben Lowentritt, M.D.	Physicians	Urologist, Chesapeake Urology Associates
Brett McCone	Hospitals	Vice President, Maryland Hospital Association
Mark Meade	Business	Principal, Consulting Underwriters, L.L.C.
Jeff Metz	MHCC Commissioner Nursing Homes	President/Administrator Egle Nursing & Rehabilitation Center
Michael O'Grady	MHCC Commissioner	Senior Fellow, National Opinion Research Center & Principal, O'Grady Consulting
Barry Rosen, Esquire	Health Care Law	Chairman & Chief Executive Officer Gordon Feinblatt LLC
Andrew Solberg	CON Consultant	Principal, ALS Consultant Services (Former Director of CON, Maryland Health Resources Planning Commission)
Note: Co-Chair Frances Phillips resigned from the Task Force in June 2018. In September, Ms. Phillips was named Deputy Secretary for Public Health. Commissioner Sergent was named Chair in June.		

CON Modernization Task Force

The Committees urged MHCC to "gather perspectives and views from a range of stakeholders" in conducting the study and identified stakeholder categories considered important for this effort. MHCC convened a CON Modernization Task Force for formal discussion and advice regarding CON modernization, which has held five meetings between January and May 2018.

The Task Force convened in two phases. Phase One of the group's work was conducted between January and June of 2018 and established the broad set of issues that needed to be considered under this study. The first phase of this work focused on gathering input and information on the problems and issues

perceived by stakeholders with CON regulation and discussed priorities among the issues surrounding the process. The Task Force submitted an interim report to the MHCC on May 17, 2018. The MHCC submitted the Final Interim Report to the Legislative Committees on June 1, 2018.

Phase Two of the work was designed to prioritize and develop recommendations to address the issues identified in the phase one, with the Task Force meeting between August and December 2018. The Task Force met six times to discuss the general issues to be addressed with the CON process as well as to address the specific issues that are unique to each health care sector covered by CON regulation, while members responded to specific issues both in oral discussions at meetings and in writing to supplement the Task Force discussion.

Total Cost of Care Model

For over 40 years, the federal government has waived federal Medicare rules to allow Maryland to set hospital payments at the State level. The federal waiver requires that all payers—Medicare, Medicaid, and commercial insurance companies—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 beginning 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, State growth rate in Medicare spending must be lower than the national growth rate.

The Total Cost of Care Model will build on the investments that hospitals make during 2014 through 2018. Maryland will continue to encourage provider- and payer-led development of Care Redesign Programs[1] to support innovation. Throughout the development of implementation plans, the State will continue its commitment to privately led innovation, voluntary participation in Care Redesign Programs,

[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 Improcement 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 advanced comprehensive primary care services to Medicare beneficiaries.

and meaningful and ongoing stakeholder engagement to achieve the State's vision for person-centered care, clinical innovation and excellence, and improved population health.

CON Impact on TCOC Model

A recurring question in the Task Force discussion was the economic impact of CON programs on health care spending and quality. The genesis of certificate of need (CON) programs was the conclusion from the health services and economics literature that an increased supply of facilities and capital equipment led to higher health care expenditures. At the inception of CON, retrospective reimbursement provided guaranteed reimbursement, even for facilities with substantial excess capacity (Conover and Sloan, 1998).

Further, 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 are valid concerns to worry that market outcomes may not reflect the socially efficient level of services. CON laws were designed to attack overspending that could result from delivery systems financed on a fee-for-service basis with third-party payments by controlling the level of investment in health care services.

This potential relationship provides an important link between CON and the State's Total Cost of Care Model with CMS. To the degree that changes in CON statue and regulations have implications for total cost of care and quality of that care, they are directly linked to the model's performance over the course of the demonstration.

A substantial literature exists measuring the impact of CON on costs of care, particularly for hospitals but also for nursing homes and home health. Ford and Kaserman (1993) find that CON regulation of dialysis significantly retarded new firm entry and total capacity expansion in the industry, restricting supply and fostering increased levels of industry concentration. Conover and Sloan (1998) find 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. There is no surge in facility acquisition or costs following removal of CON regulations. Mature CON programs also result in a slight reduction in bed supply but higher costs per day and per admission, along with higher hospital profits. CON regulations generally had no detectable effect on diffusion of various hospital-based technologies.

Rivers et. al. (2010) concluded that the mere existence of CON regulation is not associated with hospital costs per adjusted admission but that increases in CON stringency was associated with higher costs per adjusted admission, contrary to expectations.

Grabowski et. al. (2003) find no significant growth in either nursing home or long-term care Medicaid expenditures associated with CON repeal, based on data from 1981 through 1998. 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 state with CON for both the nursing home and home health industries.

A number of 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 reduce mortality (Bailey, 2018). However, research on the effect of CON on mortality for specific surgical procedures (especially heart surgery) has been mixed. Further, recent research by Bailey (2018) examined the effect of CON laws on all-cause mortality from 1992-2011 and does not support such a conclusion that CON reduces all-cause mortality rates. While proponents of CON have claimed that they reduce mortality by concentrating care into fewer, larger facilities that learn by doing, the author notes that restrictions on supply of services could in theory result in higher mortality as well. This statistical analysis finds no statistically significant effect on all-cause mortality at conventional levels of statistical significance.

DiSesa et. al. (2006) find that CON alone is not a sufficient mechanism to ensure quality of care for coronary artery bypass graft (CABG) surgery – CON states have significantly higher CABG surgery volume but similar mortality compared with non-CON states. Popescu et. al. (2006) show that patients with acute myocardial infarction were less likely to be admitted to hospitals offering coronary revascularization and to undergo early revascularization in states with CON, but these differences were not associated with mortality. Delia et. al. (2009) suggest that CON restrictions on supply of cardiac angiography in New Jersey contributed to historical disparities in access to these services between white and African American patients. Ho et. al. (2009) found that states dropping CON experienced lower CABG mortality, although the differential was not permanent, and no difference for PCI.

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 voiced concerns over the need for CON as a gatekeeper in the system to protect Maryland patients against the entrance of under-resourced or irresponsible actors in certain types of care, based on the experience of other states. Fraudulent behavior and churning of patients were issues raised in the context of specific sectors, but none of the academic literature has addressed these issues specifically in the context of CON regulation.

There are other dimensions of health care quality beyond mortality rates, but there were no published studies available to address those aspects of care. Other aspects such as patient satisfaction, hospital-acquired conditions, prevention quality indicators (PQIs), and readmission rates are some of the important dimensions on which current providers are measures, but none of the published studies on the effect of CON addressed these dimensions of care.

In Maryland, the unique regulatory environment provides other reasons for continued 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. These considerations are discussed below.

General Principles for Reform

In developing reforms for the Maryland regulatory system, a number of principles were developed to guide the process in a direction to achieve a set of policy goals that would serve as the guideposts for the CON reform process. They were designed to promote access to care, promote the goals of the Total Cost of Care Model, and reduce the administrative burden of the regulatory process while maintaining meaningful and purposeful standards for CON project review. Specifically, the principles are to

- Promote the availability of general hospital and long term care services in all regions of Maryland. 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.
- Maintain meaningful review criteria and standards that are consistent with the law and understandable to applicants, interested parties, and the public.

CON Reform: General Issues and Potential Solutions

Cross-Cutting Issues

In the Task Force discussions, there was consensus on a number of issues. The Task Force members generally raised concerns about the CON process, that the process is complex and expensive for providers seeking a CON approval while current requirements include elements that do not advance a policy purpose. Because the requirements include elements that are not appropriate and purposeful, the process requires excessive time to docket an application and compete a review. There was general agreement that aligning and streamlining the process is necessary. An element of that change is to make more effective use of quality metrics and public data, reducing the duplication of reporting requirements in a CON application with data that are already reported to State agencies, particularly the MHCC itself, for example.

On a larger scale, there was a recognition that the CON process should be modified to allow for innovation, particularly in light of the TCOC model. Beyond traditional concepts of need, can the process better reflect regional access to services, allow for consumer choice among providers of high-quality services, and embrace opportunities to transform delivery in ways that are not currently conceived of?

Potential Solutions

Several potential solutions were advanced, particularly toward streamlining the CON process. With the exception of hospitals, there was general consensus toward eliminating capital thresholds that establish the requirement of a CON based on the projected budget for the project expenditure. For hospitals, the capital threshold would be linked to its revenue, recognizing that capital expenditures may require additional funding through regulated hospital rates with the Health Services Cost Review Commission (HSCRC). Further, Task Force members argued that the CON process could be streamlined by requiring one set of financial analyses for hospital projects from state agencies rather than the current practice of requiring analyses based on different assumptions from MHCC and HSCRC. Members also suggested that exemption requirements be clarified and streamlined.

Benefits and Obstacles

These modifications to the process would reduce the administrative burden for providers seeking a CON, but the CON process is governed by statute and by regulation, and some of the changes would require a change in statute before they could be implemented. This framework is used to summarize the Task Force's discussion by CON issue area in specific topic areas below.

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 the application, review, and post-approval processes. Although these changes can be completed without statutory changes, most changes require provider engagement. In the past changes to State Health Plan chapters and the procedural rules have been time consuming and often controversial. Prior to starting a comprehensive review, the Commission should emphasize the overarching goals of the CON modernization effort of which the regulatory changes are the first step.

While the Commission can undertake substantial changes under its own authority, complete streamlining and realignment of the CON process cannot take place without statutory changes to modify legal designations and specified requirements within the CON process. For the longer-term changes, interagency changes – both regulatory and statutory – are needed to facilitate the needed changes to the current system while further consideration will be needed to develop the policies needed to regulate the health care system in the future. Where services might be removed from CON regulation, for example, another State agency may need to assume the gatekeeper role serviced by CON. These longer-term changes will also require greater consensus among the CON-regulated providers, consumers, and State agencies. Removing some services from CON regulation will take time, but setting major endpoints for reform will help build momentum for establishing gatekeeper capabilities.

Hospital Services

For hospitals, stakeholders discussed extensively the need for reform but not the need for CON itself. In a rate-regulated system where all payers are compelled by law to reimburse according to rates established by the HSCRC, CON constraints were a logical extension of the regulatory system. Stakeholders noted, however, that the scope of regulation is outdated and that many CONs do not involve a service that is statutorily subject to CON review. Hospital representatives suggested that the capital expenditure threshold for a CON should be reconsidered. They also suggested that there are duplications and external inconsistencies rising from excessive and duplicative information requirements that have arisen over time as new requirements in the process have been layered onto the process without comprehensive review. They also noted that many standards are unnecessary and complicate the CON review process without a purpose in current policy outcomes. The process embodies duplications or external inconsistencies such as contradictions between HSCRC and MHCC financial submissions (models that require differing inflation assumptions for the financial analysis). The process could be streamlined with better alignment between HSCRC and MHCC in planning capacity and a clearer link between the CON process and the implication for a hospital's HSCRC-approved rates to reflect any needed capital to finance a proposed project.

Other general issues were that the SHP does not align with the current hospital payment model and care delivery transformation, that alternatives to conventional CON project review are lacking, and that there is an underdeveloped capacity to obtain boarder community perspectives on CON projects. The discussion is described in the following table.

Hospital Services Discussion Matrix

Issues	*Potential Solutions*

• Scope of regulation is outdated – Use of capital expenditure threshold should be reconsidered
• Many CONs do not involve a service that is statutorily subject to CON review
• 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
• Duplications or external inconsistencies
  ○ Excessive and duplicative information requirements
  ○ Contradiction between HSCRC and MHCC financial submissions. Little value to submit financials without inflation
  ○ 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
	UPDATE SHP CHAPTERS
	In consultation with hospital stakeholders and Commissioners, identify SHP chapters needing review and prioritize that work subject to availability of staff.
	
	ELIMINATE SOME CON CRITERIA AND SHP STANDARDS
	1. Change the CON statute to include only a) alignment with the State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact on cost and charges. This would remove the criteria pertaining to Cost Effectiveness and identification of alternatives, and Compliance with the terms and conditions of previous CONs the applicant has received*
	2. Significantly reduce the CON standards in SHP chapters.
	  ○ Eliminate information on charges, charity care, and quality of care documentation
	  ○ Eliminate standards that involve emergency department expansion (drawn from ACEP)
	  ○ Delegate consideration of financial feasibility to HSCRC*
	STATUTORY CHANGES TO MODERNIZE THE PROCESS
	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 it global budget revenue (GBR) related to the project (where the capital expenditure is only reviewable aspect of 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*
	STREAMLINE THE REVIEW PROCESS
	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 all other hospital project categories – unless the project is 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. *(This goal presupposes reforms to significantly reduce and better define SHP standards.)*
	
	**** Indicates that statutory changes would be required to accomplish.***

Obstacles	*Benefits*
• Potential solutions will require significant statutory changes • Potential solutions 1 and 4 may require policy development by HSCRC • Uncertainty about the incentives in the TCOC makes hospitals hesitant to consider major changes	1. Reduced administrative burden for both hospitals and MHCC 2. Potential for better alignment of MHCC and HSCRC objectives 3. Enhanced opportunities for hospital competition 4. Potential for more direct input from communities and general public to MHCC's regulatory review process

Ambulatory Surgery Facilities

Because ASFs offer a relatively low-cost setting for surgical procedures, changes to CON that ease the entry of high-quality providers 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, that seeking any exemption from the CON process is costly and time consuming, and that the use of capital expenditure thresholds should be eliminated.

Potential solutions include elimination or streamlining of CON regulation for ASF, limiting the completeness review process, with the full CON remaining applicable in contested cases; a revision of the requirements for interested party designation; permitting the MHCC to waive CON for projects found compliant with TCOC by the HSCRC. All require significant changes to statute and corresponding regulation. Further, the State Health Plan (SHP) needs to be revised to accomplish CON streamlining, and the MHCC should investigate establishing a Project Review Committee of Commissioners, to standardize the streamlined CON process for ASF. This would eliminate individual Commissioner review of CON proposals (such changes would require regulatory revision).

Benefits generated by these potential solutions include the lessening of administrative burdens, the shifting of care to a lower-cost setting and permitting competition between hospitals and ASF, and allowing communities and public to have a greater, more direct impact on the CON review process.

Changes directly or indirectly affecting hospitals could lead to negative pressure on hospital budgets, if payer mix of patients served shifts primarily to Medicaid. Additionally, the HSCRC would have to monitor surgical volumes and adjust the GBR for hospitals accordingly or volume shifts to ASFs could adversely affect TCOC. The ASF matrix below provides additional detail around the Issues and Potential Solutions to ASF CON process, along with corresponding obstacles to and benefits of reform.

Ambulatory Surgery Facility Matrix

Issues	*Potential Solutions*
• Scope of regulation is outdated • Use of capital expenditures threshold should be reconsidered • Excessive time and expense required for project review and request for exemption from CON review • Post-CON approval performance requirements are outdated	**ELIMINATE CON CRITERIA AND SHP STANDARDS** 1. Limit required criteria to (1) SHP, (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 project and criteria (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 **STATUTORY CHANGES TO MODERNIZE THE PROCESS** 4. Eliminate capital threshold 5. stablish a standing Project Review Committee of Commissioners to handle consent approval process and contested reviews (eliminate individual Commissioner Reviewers)—allow for public to speak to Project Review Committee 6. Limit full CON review requirements to establishing or relocating an ASF (i.e., an ASF with three or more ORs) or contested reviews 7. Create a consent approval process for all other ASF project categories if not a contested review 8. Develop more rigorous requirements for obtaining interested party status – higher threshold for demonstrating adverse impact 9. Allow the Commission to waive CON requirements for ASF projects endorsed by HSCRC as fully aligning with TCOC model 10. 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 hospitals, to establish outpatient surgical facilities (non-rate regulated facilities) with one or two ORs. 11. Work with HSCRC and Medicaid to incentivize ASCs to treat Medicaid patients.
Obstacles	*Benefits*
• Significant streamline 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 • Total cost of care could rise if hospital global budgets are not sufficiently adjusted to avoid double payment for surgical services	1. Streamlined administrative burden for ASFs 2. Aligning CON to allow more outpatient surgery to move to the lower cost, not-rate regulated setting may reduce the total cost of care for Maryland patients 3. Enhanced opportunities for hospital and ASF competition 4. Potential for more direct input from communities and general public to MHCC's regulatory review process

Comprehensive Care Facility Services

Comprehensive Care Facilities are an important contributor to the health care continuum and offer a relatively low-cost alternative to care in acute care facilities under certain clinical circumstances. CON issues pertaining to CCFs include allowing for an exemption from and expediting/streamlining of CON for certain types of circumstances and projects when occupancy rates are above specified ceilings in certain jurisdictions. Recommendations from stakeholder include: needs-based review standards for bed capacity need to be revised, post-approval processes need more consistency, and the Medicaid MOU should be eliminated. Stakeholders felt that the CON process generally does not foster innovation.

Potential solutions include the establishment of an exemption process for projects in jurisdictions with high utilization and/or low quality outcomes, elimination of CON requirements to modernize, and to allow the docketing of projects, regardless of need, if TCOC alignment exists (all solutions require changes to statute and corresponding regulations. Potential solutions also include allowing CCFs to provide home health services, allow changes in bed capacity by expanding the waiver bed rule, and eliminate/modify direct admission restrictions from, non-community residents under certain circumstances.

Benefits generated by these potential solutions include the encouragement of SNF use, as opposed to acute settings, increase provider competition, and the streamlining of administrative burdens. The CCF matrix below provides additional detail around the Issues and Potential Solutions to CCF CON process, along with corresponding obstacles to and benefits of reform.

Comprehensive Care Facility Services Matrix

Issues	*Potential Solutions*

• Exemptions for certain circumstances /projects.
• Allow project development without CON review when occupancy rates in a jurisdiction are above an agreed ceiling.
• Modify needs-based review standards on bed capacity
  o Expand waiver bed formula to create greater flexibility for limited expansion by existing operators
  o CCRCs need flexibility 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
• Identify projects eligible for expedited review process
• Streamline CON exemption process
	ELIMINATE SOME CON CRITERIA AND SHP STANDARDS
	In consultation with stakeholders and Commissioners, modify the SHP chapter.
	1. Establish an exemption process for project development in jurisdictions with occupancy rates above a specified threshold.*
	2. Permit docketing of applications for new facility in a jurisdiction that has a percentage of CCFs that fell below MHCC-established quality standards*
	3. Permit docketing of applications in jurisdictions that have no need if the applicant's proposal is well-aligned with the TCOC demonstration*
	4. Eliminate CON requirements for modernization without volume increase
	5. Allow changes in bed capacity of more than 10 percent without needing a CON – expand the waiver bed rules
	
	STATUTORY CHANGES TO MODERNIZE THE PROCESS
	6. Eliminate capital expenditure thresholds
	7. Allow CCFs to provide home health services to discharges without needing a CON
	8. 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 *note: 1,2,3 have been included in proposed permanent regulations adopted in October 2018.
Obstacles • Potential solutions 2, 4, 5 require statutory changes • What constitutes TCOC alignment has not been defined by the State or hospitals • Lack of sufficient qualified personnel and knowledge of the home health environment for CCFs to expand into home health	*Benefits* 1. Encourage availability and use of skilled nursing facilities instead of acute care when clinically appropriate 2. Increase competition among providers (on a limited basis) to improve patient alternatives or choice of providers 3. Streamline administrative burden

Home Health Agency Services

Issues pertaining to Home Health Agency services (HHAs) include updating the needs-based methodology (the current methodology is not need-based, but rather based on quality indicators and the HHI) to reflect access to care; the application for HHS needs to be revised to reflect home health, and not facility-based care; the CON process needs to be responsive to changes in care access and initiatives to reduce CCF utilization; charity care provision needs greater transparency and standardization; changes to payment methodologies have the potential to disrupt the sector, as VBP models with CMS are ongoing; demand for HHS professionals will outstrip supply in the coming years; and loosening of the CON process would the increase the potential for bad actors to move into Maryland, which currently enjoys high marks for quality and few instances of fraud and abuse, which is more prevalent in other states.

Potential solutions include exempting entities with existing CON from the CON process for home health agency services, limiting CON review standards to history and quality of care. Further, the SHP should be amended to allow existing providers to expand into contiguous jurisdictions with relative ease, and to modify charity care access standards. A long-term alternative is to eliminate CON altogether for this service, in conjunction with establishing a licensing process within the Maryland Department of Health (MDH). This approach has the potential to adversely impact current demonstrations with CMS, however.

Benefits generated by these potential solutions include the use of HHAs as opposed to the more expensive CCF and SNF, increased competition to the benefit of patients, and the streamlining of administrative burdens. The HHA matrix below provides additional detail around the Issues and Potential Solutions to the HHS CON process, along with corresponding obstacles to and benefits of reform.

Home Health Agency Services Matrix

Issues	*Potential Solutions*

• The current needs-based methodology 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 address home health and not facility-based care
• 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 OIG Fraud Task Force 2017 Report
• Workforce is a major concern for the home health agency community. 2024 projections are predicting the demand for nurses, therapists and aides at levels higher than achievable.
• Maryland home health agency providers currently engaged in value-based purchasing pilot with CMS
• New payment methodology for home health being implemented in 2019 (PDGM) will cause further disruption to the home health sector
	ELIMINATE CON CRITERIA AND SHP STANDARDS
	1. Modify the SHP to
	  • Provide greater flexibility for existing providers to expand into additional jurisdictions by replacing filing requirements or creating an exemption
	  • Modify access standards related to charity care—provide credit for serving uninsured and Medicaid duals
	STATUTORY CHANGES TO MODERNIZE THE PROCESS
	2. Eliminate capital threshold
	3. Exempt facilities already subject to CON from obtaining a CON to provide home health agency services to their patients (for hospital, CCF, and hospice)
	4. Limit CON review standards to a review of the provider's history/quality of previous services
	Longer term statutory changes
	5. Eliminate CON
	  • Establish a rigorous licensure/re-licensure process at MDH

Obstacles	*Benefits*
• Statutory changes required to implement solutions 2, 3, and 4 • Lack of sufficient qualified personnel and knowledge of the home health environment for other providers to expand into home health • TCOC experiment and HHVBP 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.	1. Encourage availability and use of home health instead of acute care or skilled nursing facilities when clinically appropriate 2. Increase competition among providers (on a limited basis) to improve patient alternatives for care 3. Streamline administrative burden

General Hospice Services

Issues pertaining to General Hospice Services (Hospice) include: the scope of CON is outdated despite the 2013 update of this chapter of the SHP. This is indicated by the use of capital expenditure thresholds, and the requirement that CON is required to change inpatient bed capacity. Further, standards and criteria are not adequate. Specifically, the SHP methodology makes assumptions in defining unmet need. Charity care standards do not expand access, and there is a lack of TCOC facilitation across the care continuum. CON is also seen as limiting choice, and is viewed as generally inapplicable to the Hospice market, as Hospice is not a supply-sensitive industry. As such, the MHCC and MDH served duplicative roles.

Potential solutions include modifying the CON regulations to permit Hospices to expand into contiguous jurisdictions, modify access standards related to charity care, eliminating CON for bed capacity changes at inpatient hospices, and reduce review criteria and standards. A long-term approach to consider is removing Hospice from scope of CON, relying instead on revised licensure requirements to control and maintain the quality of care provided by new providers in Maryland.

Benefits generated by these potential solutions include the lessening of administrative burdens, expanding the use and availability of hospice, and encouraging competition among providers, which will expand and improve patient care alternatives. The Hospice matrix below provides additional detail around the Issues and Potential Solutions to Hospice CON process, along with corresponding obstacles to and benefits of reform.

General Hospice Services Matrix

<table>
<tr>
<td><u>Issues</u>
• Outdated scope of CON
  ○ Eliminate both use of capital expenditure thresholds in defining a hospice services project that requires CON approval
  ○ Eliminate requirements that a change in bed capacity by a hospice requires CON approval.
• Standards and criteria are not adequate
  ○ SHP methodologies for defining unmet need assume more hospices produce more choice and use
  ○ Charity care standards do not expand access
  ○ Role of CON in promoting quality is underdeveloped
  ○ Hospice SHF lacks inpatient bed need methodology
• CON limits choice
• SHP does not account for/facilitate TCOC across full care continuum
• CON is not applicable to hospice because it is not supply sensitive Roles of MHCC and MDH are duplicative</td>
<td><u>Potential Solutions</u>
ELIMINATE SOME CON CRITERIA AND SHP STANDARDS
1. Modify the SHP to
2. Allow general hospices to expand into a contiguous jurisdiction with expedited review
3. Modify access standards related to charity care—give credit for serving uninsured and Medicaid duals
4. Update the SHP to reduce review criteria/standards
STATUTORY CHANGES TO MODERNIZE THE PROCESS
5. Eliminate capital threshold
6. Eliminate CON for changes in bed capacity at inpatient hospices
7. Remove hospice from the scope of CON oversight and establish
  • Expanded licensure requirements
  • Limits to new licensure applications approved within a given time period through MDH</td>
</tr>
<tr>
<td><u>Obstacles</u>
• Previous modifications to State Health Plan have been resisted by providers.
• Change 2 and 3 would require statutory changes</td>
<td><u>Benefits</u>
1. Streamline administrative burden
2. Expand availability and use of hospice when clinically appropriate
3. Increase competition among providers (on a limited basis) to improve patient alternatives for care</td>
</tr>
</table>

Benefits generated by these potential solutions include the lessening of administrative burdens, expanding the use and availability of hospice, and encouraging competition among providers, which will expand and improve patient care alternatives. The Hospice matrix below provides additional detail around the Issues and Potential Solutions to Hospice CON process, along with corresponding obstacles to and benefits of reform.

Alcoholism and Drug Abuse Treatment Intermediate Care Facility Services

Issues pertaining to Alcoholism and Drug Abuse Treatment Intermediate Car Facility Services (ICF) include: whether minimal financial requirements add to current cost, whether to exempt ICF from CON, and leave monitoring to licensing, and whether to expand use of emergency CON in light of the opioid crisis. Additionally, there is a need to add a definition of "quality of care" to COMAR, and to address the increased need for inpatient treatment space.

Potential solutions include changing the SHP to streamline CON process, eliminating relocation and change in bed capacity for Track 2 providers, and reducing review standards for all providers. Some Task Force members expressed concern about out-of-state bad actors, coupled with a high level of abuse in the industry could have deleterious effect on Maryland. Further, the elimination of CON in the following circumstances has also been proposed: for Track 2 providers, for all Track providers with the exception of impact and financial information, and the elimination all CON requirements, relying instead on a modified licensing process for new providers in the State to serve as a gatekeeper for quality entrants.

Benefits generated by these potential solutions include encouraging the availability and use of ICF, increasing competition, and streamlining administrative burden. The ICF matrix below provides additional detail around the Issues and Potential Solutions to ICF CON process, along with corresponding obstacles to and benefits of reform.

Alcoholism and Drug Abuse Treatment Intermediate Care Facility Services Matrix

<table>
<tr>
<td><u>Issues</u>
• Review whether minimal financial requirement adds to current cost
• Exempt ICF from CON processes, leaving monitoring to licensing
• Expand use of existing regulation for emergency CON (opioid crisis)
• Consider adding definition of "quality of care" to COMAR
• Scope only touches a narrow part of treatment spectrum
• Address increased need for inpatient treatment space</td>
<td><u>Potential Solutions</u>
ELIMINATE SOME CON CRITERIA AND SHP STANDARDS
1. Change SHP to streamline CON processes
• Eliminate relocation and change in bed capacity requirement for existing Track 2 ICFs
• Update SHP to reduce review criteria and standards for all providers
STATUTORY CHANGES TO MODERNIZE THE PROCESS
2. Eliminate capital threshold
3. Eliminate criteria and standards for Track 1 & 2 ICFs, with the exception of impact and financial access for reviews involving establishment/expansion
4. Eliminate all CON requirements for Track 2 ICFs
5. Eliminate all CON regulation of alcoholism and drug abuse services
• Expand licensure/re-licensure authority at BHA</td>
</tr>
<tr>
<td><u>Obstacles</u>
• Changes 2-4 require statutory action
• Providers argue that bad actors from other states poses a threat to quality of care for patients in Maryland</td>
<td><u>Benefits</u>
1. Encourage availability and use of alcohol and drug abuse treatment intermediate care facilities when clinically appropriate
2. Streamline administrative burden for ICFs.</td>
</tr>
</table>

• Significant level of abuse in this sector compared to other sectors	3. Increase competition among providers (on a limited basis) to improve patient alternatives

Residential Treatment Center Services

Issues pertaining to Residential Treatment Center Services (RTC) include the challenges in evaluating the need for juvenile services, and whether RTC should be included in the scope of CON, given how demand for the services has changed.

Potential solutions include eliminating bed capacity and relocation requirements for existing RTCs. Additionally, removing RTCs from scope of CON and requiring a license from MDH has also been proposed as a potential solution.

Benefits generated by these potential solutions include encouraging the availability and use of RTC, and the streamlining of administrative burdens. The RTC matrix below provides additional detail around the Issues and Potential Solutions to the RTC CON process, along with corresponding obstacles to and benefits of reform.

Residential Treatment Center Services Matrix

Issues • Challenges of evaluating need for juvenile services • Should RTC be included in scope of CON, given the way in which demand for services has changed	*Potential Solutions* **STATUTORY CHANGES TO MODERNIZE THE PROCESS** 1. Eliminate relocation and change in bed capacity requirement for existing RTCs 2. Remove RTCs from the scope of CON regulations 3. Require MDH to license RTCs that are supported by state juvenile agencies and MDH
Obstacles • Changes 2-3 require statutory action	*Benefits* • Encourage availability and use of residential treatment centers when clinically appropriate • Streamline administrative burden

Recommendations

Based on the Task Force discussions, stakeholder comments and MHCC staff comments, the Task Force developed the following recommendations. They are divided into three categories:

- Regulatory changes that can be started immediately with no statutory changes required,
- Statutory changes that could be sought in the 2019 or 2020 legislative sessions, and
- Regulatory or statutory changes in areas that require further study from which further regulatory and statutory changes are likely to emerge.

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

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 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.

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

1. Eliminate capital expenditures by a health care facility as an action requiring or permitting CON approval, leaving all definitions of projects requiring CON approval as categorical with respect to the changes in a health care facility, no matter what capital expenditure is required.

2. Replace existing capital expenditure threshold with a requirement that hospital obtain CON approval for a project with an estimated expenditure that exceeds a specified proportion of the hospital's annual budgeted revenue and for which it is requesting an extraordinary adjustment in budgeted revenue, based on an increase in capital costs.

3. Change the CON statute to include only these criteria: a) alignment with the State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact on cost and charges. This would remove the criteria pertaining to Cost Effectiveness and identification of alternatives, and Compliance with the terms and conditions of previous CONs the applicant has received.

4. Eliminate from CON review changes in bed capacity by an alcoholism and drug abuse treatment intermediate care facility that has level 3.7 beds or by a residential treatment center.

5. Eliminate requirement of CON review changes in acute psychiatric bed capacity by a hospital.

6. Eliminate requirement of CON review changes in hospice inpatient bed capacity or the establishment of bed capacity by a general hospice.

7. Define ambulatory surgical facility as an outpatient surgical center with three or more operating rooms instead of the current definition's threshold of two operating rooms.

8. 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 and any other entity 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 staff.

9. 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

1. 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.

2. 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.

3. 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.

References

Bailey, James (2018) "The Effect of Certificate of Need Laws on All-Cause Mortality," *Health Services Research*, Vol.53, No. 1, pp.49-62.

Conover, Christopher J., and Frank A. Sloan (1998) "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?" *Journal of Health Politics, Policy and Law,* Vol. 23, No. 3 (June).

DeLia, Derek, Joel C. Cantor, Amy Tiedemann, and Cecilia S. Huang (2009) "Effects of Regulation and Competition on Health Care Disparities: The Case of Cardiac Angiography in New Jersey," *Journal of Health Politics, Policy, and Law* Vol. 34, No. 1, pp. 63-91.

Verdi J. DiSesa, MD; Sean M. O'Brien, Ph.D.; Karl F. Welke, MD; Sarah M. Beland, MS; Constance K. Haan, MD; Mary S. Vaughan-Sarrazi, Ph.D.; Eric D. Peterson, MD, MPH (2006) "Contemporary Impact of State Certificate-of-Need Regulations for Cardiac Surgery: An Analysis Using the Society of Thoracic Surgeons' National Cardiac Surgery Database," American Heart Association, Print ISSN: 0009-7322. Online OSSM: 1524-4539.

Ford, Jon M. and David L. Kaserman (1993) "Certificate-of-Need Regulation and Entry: Evidence from the Dialysis Industry," *Southern Economic Journal*, Vol. 59, No. 4 (April), pp. 783-791.

Grabowski, David C., Robert L. Ohsfeldt, and Michael A. Morrisey (2003) "The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures." *Inquiry*, Vol. 40, Summer, pp. 146-157.

Ho, Vivian, Meei-Hsiang Ku-Goto, and James g. Jollis (2009) "Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON," *Health Services Research*, Vol. 44, No. 2 (April), pp. 483-500.

Popescu, Ioana, MD, Mary S. Vaughan-Sarrazin, Ph.D.; and Gary E. Rosenthal, MD (2006) "Certificate of Need Regulations and Use of Coronary Revascularization After Acute Myocardial Infarction," *Journal of the American Medical Association*, Vol. 295, No. 48, pp. 2141-2147.

Rahman, Momotazur, Omar Galarraga, Jacqueline S. Zinn, David C. Grabowski, and Vincent Mor (2016) "The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures," *Med Care Res Rev,* Vol. 73, No. 1, pp. 85-105.

Rivers, Patrick A., Myron D. Fottler, and Jemima A. Firmpong (2010) "The Effects of Certificate of Need Regulation on Hospital Costs," *Journal of Health Care Finance*, Vol. XX, No. YY, pp. ____.

Appendices

Letters from Stakeholders On Proposed Reforms Developed during Part 2

Final Interim Report

Meeting summaries