Modernization of the Maryland Certificate of Need Program
Volume II: Appendices

Maryland Health Care Commission
June 1, 2018

Appendix A

Overview of the Current Scope of CON Regulation

Maryland's Certificate of Need Program

Scope of Authority and Modernization

January 22, 2018

The MARYLAND
HEALTH CARE COMMISSION

Scope of the Maryland CON Program

- **Applicable only to "health care facilities" and HCF capital projects. These are**
  - **Hospitals**
  - **Nursing homes**
  - **Ambulatory surgical facilities (2+ operating rooms)**
  - **Intermediate care facilities for addiction treatment***
  - **Home health agencies**
  - **General hospices**
  - **Freestanding medical facilities (Emergency Centers)**
  - **Residential treatment centers**
  - ****May be eliminated as CON-regulated HCF n 2018***

Scope of the Maryland CON Program

- **Applicable to "capital projects" of HCFs. These are the categories of project that require a CON:**
  - **Establish an HCF**
  - **Relocate an HCF**
  - **Add new capacity at an HCF – beds, operating rooms**
  - **Introduce new "medical services" at an HCF – core acute and post-acute**

MSGA
Obstetric
Pediatric
Psychiatric
Rehabilitation
Chronic care
Comprehensive care
Extended care
Intermediate Care
Residential Treatment

Scope of the Maryland CON Program

Categories of capital projects of HCFs that require a CON (continued):

- **Introduce new specialized services at an HCF**
  Cardiac surgery **Percutaneous coronary intervention (PCI)**
  Burn treatment **Organ transplantation surgery**
  Neonatal intensive care
- **Expand authorized service area (jurisdiction) of a home health agency or general hospice**
- **A capital expenditure by an HCF for any purpose above an indexed threshold**
  As of March, 2017 - $12 million for hospitals
  $ 6 million for all other health care facilities

Scope of the Maryland CON Program

CON LITE – Exemptions from CON can be used to authorize certain projects

- **Merger/consolidation of HCFs**
- **Relocation if the HCF is owned or controlled by a merged asset system**
- **Addition of bed capacity if pursuant to merger/consolidation of HCFs or conversion of an HCF to a nonhealth-related use**
- **Introduce new services if pursuant to merger/consolidation or conversion of an HCF to a nonhealth-related use**
- **Capital expenditure by an HCF above the indexed threshold made as part of merger/consolidation of HCFs or conversion of an HCF to a nonhealth-related use**
- **Conversion of a hospital to a freestanding medical facility or limited service hospital**
- **Introduction of PCI services by a hospital**

CON and Exemptions from CON

- Both are application review processes with final action by full Commission
- More criteria and standards in CON review (State Health Plan)
- No interested party status for opponents in CON exemption review
- Shorter review time expectation in CON exemption review
  - 45-60 days for CON exemption
  - 90-150 days for full CON review

Modernizing CON Regulation

Report to General Assembly due in December, 2018

1. Examine major policy issues to ensure that CON laws & regulations reflect the dynamic and evolving health care delivery system
2. Review approaches other states with similar delivery models have taken to determine appropriate capacity
3. Recommend revisions to the enabling statutes relating to capital approval processes
4. Recommend revisions to the State Health Plan (SHP) including

a. **Creating incentives to reduce unnecessary utilization**
b. **Eliminating, consolidating, or revising individual chapters of the SHP**
c. **Developing criteria that determine service need in the context of Maryland's All-Payer Model**
d. **Assuring that criteria are clear, unambiguous, and appropriately applied**

Modernizing CON Regulation

Report to General Assembly due in December, 2018 (continued)

5. Consideration what MHCC flexibility, legislative or regulatory, may be needed to streamline the CON approval process
6. Consult with HSCRC and MDH to identify areas of regulatory duplication regarding the hospital capital funding process & other areas of hospital regulation

Modernizing CON Regulation – the SHP

Substantial Modernization Achieved

- General Hospice Services – 2013
- Cardiac Surgery & PCI - 2014
- Home Health Agency Services – 2016
- Organ Transplantation Surgery – 2017

Substantial Modernization in Process

- General Surgical Services – 2018

New SHP Chapter

- Freestanding Medical Facilities - 2017

Modernizing CON Regulation – the SHP

Substantal Modernization Needed

- Acute Psychiatric Services – planned for 2018 – last update 1997
- Nursing Home Services – planned for 2018 – last update 2007
- Acute Hospital Services – last update 2009
- Intermediate Care Facility Services – Substance Abuse Treatment – last update 2002

Updating Needed

- Acute Rehabilitation Services – last update 2013
- Obstetric Services – established 2003 – never updated
- Neonatal Intensive Care Services - last updated 2006

Revisions Planned

- Cardiac Surgery and PCI – planned for 2018

Appendix B

Letter from General Assembly Committee

THE MARYLAND GENERAL ASSEMBLY
ANNAPOLIS, MARYLAND 21401-1991

June 23, 2017

Mr. Ben Steffen
Executive Director, Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Mr. Steffen:

Under the All-Payer Model agreement, the State is moving to a population-based approach that addresses total health care spending. The model directly impacts hospitals, and indirectly impacts physicians and other health care providers, since ultimately all health care providers share responsibility for managing growth in health care spending per capita. The All-Payer Model focuses on the "Triple Aim" of health care, which calls for reduced costs, enhanced quality and patient experience, and improved health. The model, therefore, calls for dramatic changes in health care delivery and spending, and the Certificate of Need (CON) program must also recognize these changes.

We are well aware that the Maryland Health Care Commission (MHCC) has authority over CON, including the drafting of the State Health Plan, which regulates health care services provided in Maryland. CON approval is required to establish certain health care services or for health care capital spending in excess of a defined threshold.

We believe it is time to study specific elements of CON. Such a study is required for the following two important reasons. Maryland's All-Payer Model, under the State's agreement with the federal Centers for Medicare and Medicaid Services, is fundamentally changing the health care delivery landscape in our State. At the same time, the CON application and approval process is complicated and may be an administrative burden, particularly for hospitals.

We request that MHCC undertake a comprehensive and thorough review of the CON application requirements and processes in the State, focusing on the following:

(1) an examination of the major policy issues that the State should explore to ensure that CON laws and regulations, particularly the capital approval CON requirements, reflect the dynamic and evolving health care delivery system;

(2) a review of approaches other states with similar delivery models have taken to determine appropriate capacity;

(3) recommended revisions to the enabling statutes relating to capital approval processes;

(4) recommended revisions to the State Health Plan, including:

a. creating incentives to reduce unnecessary utilization;

b. eliminating, consolidating, or revising individual chapters of the State Health Plan;

c. developing criteria used that determine service need in the context of Maryland's All-Payer Model; and

d. an understanding that any criteria are clear, unambiguous, and appropriately applied;

(5) a consideration of what MHCC flexibility, either through legislative or regulatory changes, may be needed to streamline the CON approval process;

(6) in consultation with the Health Services Cost Review Commission and the Maryland Department of Health, identify areas of regulatory duplication regarding the hospital capital funding process, and other areas of hospital regulation; and

(7) any other related matters as deemed necessary in the study.

We urge that as MHCC conducts its study staff should gather perspectives and views from a range of stakeholders, including:

(1) MHCC commissioners;

(2) the Maryland Department of Health; and

(3) representatives of the following groups:

a. hospitals and health systems;

b. physicians;

c. post-acute service providers;

d. ambulatory surgical facilities;

e. behavioral health and substance abuse treatment providers;

f. employers;

g. health care carriers;

h. health care consumers; and

i. local health departments and public health experts.

It is our hope that the study propose legislative and regulatory recommendations that the State should undertake to adapt the CON process to today's health care environment. The recommendations should be reasonable, actionable, and executable. The study should begin as soon as possible with an interim report completed no later than May 1, 2018, and a final report completed and submitted to the Senate Finance and the House Health and Government Operations committees no later than December 1, 2018.

Thank you for your consideration of this important matter. If you have any questions please contact Linda Stahr or David Smulski.

Very truly yours,

Mac Middleton

Thomas McLain Middleton
Senate Co-chair

Shane E. Pendergrass /ls

Shane E. Pendergrass
House Co-chair

TMM:SEP/DAS/nb

cc: Members, Senate Finance Committee
Members, House Health and Government Operations Committee

Appendix C

Task Force Meeting Summaries

Meeting Summary
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Monday, January 22, 2018
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance:
Frances Phillips, Co-Chair
Randy Sergent, Co-Chair
Regina Bodnar
Ellen Cooper
Lou Grimmel
Elizabeth Hafey (phone)
Anne Horton
Andrea Hyatt
Adam Kane
Ben Lowentritt, M.D.
Brett McCone
Mark Meade
Jeff Metz (phone)
Michael O'Grady Barry
Rosen
Andrew Solberg

MHCC Staff in Attendance:
Linda Cole
Eileen Fleck
Kevin McDonald
Paul Parker
Ben Steffen
Suellen Wideman

Others in Attendance:
Patricia Cameron
Jack Eller
Peggy Funk
Keith Hobbs
Bob Gallian
Donna Kinzer
Anne Langley
Stan Lustman
Jerry Schmith
Katie Wunderlich

1. Introductions and Review of the Charge

Ben Steffen called the meeting to order at approximately 9 a.m. He introduced himself, welcomed and thanked those in attendance, and introduced the two Co-Chairs of the Task Force.

Co-Chair Fran Phillips introduced herself and also thanked everyone for attending. She welcomed a robust discussion of the CON program, stressing that there should be no concern with right or wrong ways to approach CON modernization or reform. She urged everyone to feel uninhibited about asking questions. She noted that she had recently left the Commission because of changes in her employment situation but was honored to serve as Co-Chair of the Task Forces. She noted that people could keep up with MHCC activity via YouTube, where recordings of the monthly meetings could be found.

Co-Chair Randy Sergent introduced himself and also welcomed and thanked the attendees. He asked the Task Force members and principal staff to briefly introduce themselves, which they did.

Mr. Steffen reviewed the charge to MHCC as outlined in the June 23, 2017 letter of Senator Middleton and Delegate Pendergrass, Chairs, respectively, of the Senate Finance Committee and House Health and Government Operations Committee. He noted that the directive is broad but priority of place is given to an assessment of how to assure the alignment of CON and the evolving all payor model of hospital charge regulation, administered by the Health Services Cost Review Commission. He noted that CON had not been standing still. Important changes had been made in recent years in State Health Plan (SHP) regulations for cardiac surgery, PCI, general surgery, organ transplantation, hospice, and home health agency services and these changes represented important updates to MHCC's approach to CON regulation, building in more use of quality metrics and opening up the ability for market entry of new providers into several service categories that were largely closed off under previous iterations of the SHP. MHCC recognizes the need that is often expressed for changes in the regulatory process and, after review, believes that statutory changes are needed to accomplish significant procedural reforms.

Mr. Steffen noted that the CON study will have two phases and that today's meeting kicks off Phase 1 focused on reaching consensus on the problems and issues with CON regulation. This phase will culminate in an interim report to the legislature. Phase 2 will focus on solutions to those problems and changes in law and regulation that will address identified issues. He expressed the view that this process is a good way to start. He noted that anyone describing a problem will usually have some ideas about solving the problem "in their back pocket," but the Task Force should try to keep the initial focus on fleshing out problems without immediately gravitating to solutions as a good way to give everyone a better opportunity for broad input on the best ideas for change. A conscientious approach to first identifying and describing the problems should improve the ability of the Task Force to better think through the best approach to addressing problems and issues in the regulatory program and process.

2. Initial Ice Breaker Discussion

The Co-Chairs introduced this initial area of discussion as an approach to getting a sense of how the Committee understands the purpose of CON regulation, its effects, and its practical value, guided by three questions:

- Why does Maryland need Certificate of Need (CON) regulation?
- What would Maryland's health care system look like without CON regulation?
- How does CON regulation contribute to or detract from furtherance of the Triple Aim? The Triple Aim is defined as: o Improving the patient experience of care, including quality and satisfaction; o Improving the health of populations; and o Reducing the per capita cost of health care

Co-chair Sergent expressed his view that an initial discussion of these broad questions would be a useful prelude to the more complicated debate and discussion on specific program and process reforms that will follow. Co-chair Phillips emphasized that all of the Commissioners are fully engaged on the issue of modernizing CON regulation. She noted that most Commission meetings have at least one agenda item that lends itself to a discussion of the scope and process of CON regulation and this interest in change predates the changes in the hospital payment model or administrations. She also emphasized that everyone is affected by CON regulation even though direct interest and involvement tends to be concentrated in the regulated facility owners, opeators, and their consultants and that the work of the committee should reflect that employers and consumers are stakeholders in the debate as well. She encouraged the Task Force to think about opportunities for doing good with CON regulation, in terms of access and quality of care.

With that, remarks were requested from Task Force members. They provided brief introductions of their relevant professional and public roles and responded to the icebreaker questions, as summarized below.

Michael O'Grady is a Commissioner and said the Commission is often struck by the time and expense imposed by CON. So, it is important to assure that Maryland is getting a return on the investment it is requiring on the part of health care facilities. Striking the right balance is how he perceives the challenge. On the one hand, regulating supply may be important if questionable demand for service is induced by supply, or to assure sufficient volume is maintained at a particular program when volume and quality of outcomes are related, or to avoid duplication of expensive resources. On the other hand, the regulation should not unduly restrain trade, becoming

protectionist, and should not diminish access to needed services. CON can serve to keep out bad actors but allowing new market entry also has value because limiting competition and innovation can be costly.

Barry Rosen stated that we need to recognize that CON is designed to restrict supply and we need to ask if such restriction is ever good. He outlined the arguments put forward as to why this is sometimes viewed as necessary and good for controlling cost and controlling overuse of health care. While restricting supply involves some limits on access, it can also be viewed as, in some cases, insuring access for populations that might otherwise be abandoned. He noted that there should be some ability to use the experience of the 15 states without CON regulation to shed some light on the questions of how CON regulation affects access and overuse. HSCRC needs to weigh in on these questions.

Adam Kane noted that issues of state funding were an important foundation of CON regulation. There was concern that the state would pay for oversupply and overbuilding. The relevance and importance of this concern has changed over time and this is related, to some extent, to the evolution of HSCRC policy. CON regulatory policy must also evolve. With respect to quality, he cautioned against trying to do too much through the CON program. Other agencies have the primary responsibility for monitoring quality on an ongoing basis.

Andrea Hyatt is concerned with redundancy of effort in regulation and quality reporting and wants to check growth in what she perceives as a growing trend in duplicative effort. Having experience in the private ambulatory surgical facility sector and also now working in a hospital system, she has a perspective on how regulation must strike a balance between the differing needs and roles played by different types of providers.

Andrew Solberg noted that, in his role as a consultant, he rarely works on hospital projects that do not start out larger at the beginning of the regulatory process. CON does have that impact. The regulatory process tends to "follow the numbers," it is not aspirational, and we would lose that focus if CON is eliminated. The SHP needs to be a better approach to dealing with the real problems that facilities have – that should be the basis for SHP standards. He does not think CON has a significant role in quality assurance and there are areas that should be deregulated.

Co-Chair Sergent clarified for the participants that reporting on the quality of care and the performance of health care facilities, in general and not in the context of a specific facility interested in a capital project, was a major mandate of MHCC that is separate and apart from discussions of the role that CON regulation might or might not play in quality assurance. He wanted everyone to understand this, given that discussion of quality assurance in the context of CON regulation is obviously a part of the Task Force work.

Lou Grimmel emphasized the importance of the "waiver" (the new payment model, as of 2014, for regulating hospital charges, through an agreement with the federal government) and the next phase of the payment model's evolution to oversee the total cost of care. The Task Force needs to look at how CON can help to make this evolution successful. Secondly, he emphasized the importance

of manpower availability and limitations as an important factor in considering the appropriate way in which to regulate the supply of facilities and services.

Ellen Cooper noted that, because of her professional background as an anti-trust regulator, she was primarily interested in the way in which CON regulation affected competition.

Ben Lowenstritt noted that health care delivery is changing dramatically, apart from the direct impact of the hospital payment model changes, and HSCRC must take advantage of these changes to make the payment model work in the way desired. We need to avoid restricting patients from getting into a less costly environment. With respect to quality, CON is limited to initial assessment of applicants but cannot be a factor in maintenance of quality over time. With respect to eliminating CON regulation, an unfettered ability to move services around within the health care system clearly threatens some individual practitioners and communities and these effects should be a concern of MHCC

Ann Horton reflected on the very different views among her "constituencies." Medicare- certified home health agencies want continued CON regulation as a control on the supply of home health agencies. Some residential service agencies want to become Medicare-certified home health agencies (HHAs) and CON is a major barrier. She is eager to learn about how CON may stifle innovation. She noted that some states without CON controls have had significant problems with Medicare and Medicaid fraud and CON is probably a factor that helps reduce the incidence of this problem. The TF needs to keep in mind the vulnerability of patients engaging with home-based services, often alone in their homes and how changes in regulatory policy may be related to maintenance of a safe patient environment.

Mark Meade stated that a balanced regulatory process is needed. Unfettered access to markets in a changing insurance environment market may have unwanted consequences. Regulatory policy should not limit the ability to control utilization in positive ways. Regulations can be streamlined but CON probably needs to continue to exist in a modified form.

Brett McCone noted that the Maryland Hospital Association (MHA) convened a work group of hospitals to look at CON regulation in 2016 that concluded that CON is necessary to control distribution of limited resources. Maryland hospitals are committed to the program for reform of hospital currently underway and changing the service delivery system. These changes need to continue to control cost of care and improve care. However, CON regulation needs to be modernized and a second work group has been convened to recommend specific changes. The group will have recommendations that will inform the MHCC study.

Regina Bodnar stated that hospice programs support CON regulation but appreciate the need for streamlining the regulatory process. It is costly but not having CON regulation would also be costly in other ways.

Jeff Metz noted that the nursing home industry has long relied on the CON regulatory model because so much of its payment sources are tied to government and regulation is perceived as a

necessary check on oversupply and higher cost. He identified himself as "a free market guy who believes some costs of the regulation should be reduced through streamlining the process. However, it would be difficult to apply total free market principles to widely open up nursing home development.

Randy thanked the TF members for their initial remarks. Commissioner O'Grady asked about the literature on CON regulation and the value of comparing a sample of states with CON and a sample of states without CON to gain insights.

Paul Parker stated that, in his view, the literature addressing the effects and value of CON regulation is a "mixed bag" and that some of the research is fairly old with work on CON tapering off in recent years. But the TF will be considering this literature. He expressed the view that, for many areas of the health care system, it is difficult to see that CON regulation has resulted in clear differences in the supply and distribution of facilities and services, the population's use of services, or cost, when states with and without CON regulation are compared. He attributes this to the fundamental weakness of most CON regulatory systems, as operated in the U.S., to shape the health care system when more powerful market forces and payment systems mitigate against the controls on supply that CON might otherwise achieve. He did note a few areas in which CON regulation clearly resulted in differences in supply and industry characteristics – home health, hospice, specialty hospitals. CON regulation varies from state to state and noted that Maryland's unique approach to regulating ambulatory surgery is an example of how the barrier represented by CON regulation can channel development in a particular direction. In this case, it has resulted in far more ambulatory surgery centers per capita, most with one operating room or no operating rooms, in Maryland than seen in any other state.

Mr. Steffen stated that we will be looking at the research comparing states with and without CON regulation or with differences in their regulatory environments.

Mr. McCone noted that MHA focuses on northeast states that have had some historic experience with rate setting in looking for meaningful comparisons. Ms. Hyatt noted that some state associations may be able to tap into research and data gathered by their national association counterparts for useful information for the TF.

3. Current Authority of MHCC and HSCRC

Mr. Parker presented an overview of the current scope of CON regulation and the status of the SHP, with respect to recent updates and the priority for updating older chapters of these regulations. (His slides can be accessed on the MHCC web site at: http://mhcc.maryland.gov/mhcc/pages/home/workgroups/documents/CON_modernization_workgroup/con_modernization_workgroup_slide_deck_presentation_20180122.pdf

A brief discussion followed in which it was clarified that HHAs and hospices are defined as "health care facilities" in CON law and the origins of the scope of CON regulation were discussed. Mr. Parker said that the list of services that are regulated under CON can be viewed as a legacy of the

first two decades of the program's evolution and a reluctance to make changes in statute over time. The presumed relationship between service volume and outcomes was a consideration and this relationship is still considered important in cardiac surgery and percutaneous coronary intervention, organ transplantation, and neonatal intensive care. In Maryland, freestanding diagnostic and treatment centers providing such services as magnetic resonance imaging, computed tomography, nuclear medicine imaging, and radiation therapy are unregulated through the CON program. Other states, such as Virginia, that regulate hospital facilities and services with a CON-style program, like Maryland, often do regulate these services and have much more stringent regulation of all freestanding outpatient surgery centers than Maryland. This characteristic may be related to Maryland's regulation of hospital charges, that blunts the competitive impact on hospitals. Maryland has prohibitions on self-referral by physicians that Virginia does not have and this is a different regulatory barrier on development of physicianowned diagnostic and treatment centers. In short, while the scope of CON has changed over time, the current scope has changed little since the mid-1990s and represents a balance that much of the regulated facilities have come to accept and support, fearing change. Co-Chair Sergent stated that the TF will need to consider the list. Mr. Rosen stated that one service, neonatal intensive care, is always approved and, in such a case, should be considered for removal. It was clarified that statutory changes would be needed to make substantive changes in the scope of CON regulation. Some additions can be made through regulation.

Mr. Rosen stated that CON largely works to chill development rather than through denying project requests. Mr. Parker agreed, stressing that CON regulation has been around for over 40 years and would be expected to work in this way. Ms. Hyatt noted how avoidance of CON is obviously the basis for Maryland's large number of single operating room surgery centers.

Mr. McCone stressed a need to look at per capita use of services when trying to understand possible impact of CON regulation and the need to look at use rates beyond just the facilities and services that are directly regulated.

b. All Payer Model

Donna Kinzer, Executive Director of HSCRC was introduced and she introduced other HSCRC staff in attendance. She contrasted the consideration of hospital capital projects prior to 2014 and how initiation of the global budget-based payment model has changed interaction between HSCRC and MHCC. Capital expenditures must be supported by revenue available to hospitals in both cases. A pass through of capital is not desirable. Volume increases could support capital expenditures. For very large projects, HSCRC would consider a rate increase related to capital but the hospital would need to have charges at or below the average for similar hospitals.

The new payment model moves to total hospital cost per capita and global budget revenue (GBR) bring that per-capita cost down to the hospital level. Adjustments of the GBR are made for volume adjustments (population change and aging) and market shifts. HSCRC still expects most capital projects to be funded through the existing GBR but will adjust GBRs for very large projects. It looks for cost effectiveness to be demonstrated on a per capita basis in the hospital's service area.

Policies are still under development, e.g., how to treat shifts in market share. She gave examples of how MHCC and HSCRC review worked in some recently considered hospital relocation project reviews. In the case of Washington Adventist Hospital, the original project was scaled back and the hospital was given partial funding of its request for additional revenue authority. In the case of Prince George's Hospital, a regional approach to changing the Dimensions system allowed the project to move forward with an expectation that the overall GBR for a relocated hospital and a hospital conversion to an FMF would not require extraordinary expansion of the overall global budget for that capital project. This was a good outcome for a hospital with high costs. More recently, a project went forward without additional consideration for capital funding even though the applicant had sought this as a source of funding for the project. There will continue to be a focus on avoidable admission and reducing excess capacity in the hospital system.

Co-Chair Sergent asked about opportunities to reduce regulatory oversight by eliminating duplication of effort by the two agencies. Ms. Kinzeer noted that HSCRC is relied upon for financial analysis as part of CON review with MHCC and HSCRC doing "blocking and tackling" in the hospital project review process.

Dr. Lowenstritt noted how hospital reimbursement and the incentives created by the new payment model are quite different from the environment downstream from the hospital and finding a common denominator to make the system respond in a more integrated way is needed. Mr. McCone noted that, historically CON approval has been the key that unlocks the door to getting charges adjusted. The new model is modifying how hospitals ask for rate adjustments.

Ms. Kinzer suggested that CON regulation may need to be more regional in its perspective as inpatient demand continues to decline. Opportunities to shrink the hospital system by saying no to some replacement projects will be necessary.

Mr. O'Grady suggested that the analytic capabilities of MHCC and HSCRC should be considered by the TF. We must ask if we have the best tools to manage a complex system.

Mr. Rosen offered his view that the regulatory system has a difficult time easing out struggling hospitals. If HSCRC props up a struggling hospital it hurts everyone else. Mr. Kane asked about projects that do not expand GBR. Are cost just being reallocated? Ms. Kinzer reiterated the need to look at everything from a per capita cost perspective. Even if GBR is not expanded to assist in funding a capital project, per capital cost in the service area may change because of the changes in service delivery related to the project. There may be a substitution of regulated with unregulated spending. She noted that HSCRC has had set asides for GBR adjustment as part of its annual update process to account for changes such as new hospitals coming on line and this maintains overall net revenue neutrality. It can be thought of as taking a little out of every GBR to fund a new or expanded GBR. CON should be able to work as a cost containment tool within such a system. The GBR system may incentivize systems consolidation but CON may help avoid hospitals becoming "too big to fail." Watching the growth rate is the key consideration.

Co-Chair Sergent asked why CON is necessary if the GBR system constrains growth in hospital costs. Is CON needed to stop someone from doing something foolish? Ms. Kinzer noted that there is still a need to manage supply. Too many hospitals are still convinced that demand for service will decline everywhere but at their hospital but this is changing. There is still some adjustment to the new reality going on and some statutory walls may need to stay in place. A free for all may threaten the bond market. The system still has excess bed capacity.

4. Approach to Conducting the Study – Review of the Work Plan

Mr. Steffen reviewed the preliminary work plan through May of this year. It will undoubtedly be refined and adjusted over time. A small procurement for contract support is underway that extend the ability of MHCC staff to support the work of the TF.

5. Adjournment

The meeting adjourned at approximately 11:10 am.

Meeting Summary
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Friday, February 23, 2018
4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance:

Frances Phillips, Co-Chair
Randy Sergent, Co-Chair
Regina Bodnar
Ellen Cooper
Lou Grimmel
Elizabeth Hafey
Ann Horton (Phone)
Andrea Hyatt
Adam Kane
Brett McCone
Mark Meade
Michael O'Grady (Phone)
Barry Rosen
Andrew Solberg

MHCC Staff in Attendance:

Ben Steffen
Courtney Carta
Linda Cole
Theressa Lee
Kevin McDonald
Paul Parker

Others in Attendance:

Brian Ackerman
Patricia Cameron
Daniel Carter
Bob Gallion
Anne Langley
Adam Malizio
Bruce Richey (Phone)
Laura Russell
Howard Sollins

Call to Order

Co-Chair Philips called the meeting to order.

Ben Steffen remarked that most input received to date has been from health systems. He suggested that the most efficient way to move forward regarding the comments, given the time limitation of the day's meeting, was to let Brett McCone provide input from hospitals and health systems on behalf of the Maryland Hospital Association (MHA) rather than having individual health systems speak. Mr. Steffen clarified that there will be opportunities for all stakeholders to comment as the group moves forward in the process.

Paul Parker informed the attendees that the draft January meeting summary will be open to input and comments for the next couple of days. Moving forward, meeting summaries will be provided prior to the meeting for input and comments.

Mr. Parker introduced Ascendient Healthcare Advisors, the vendor who will provide technical support to the task force. Brian Ackerman provided a brief introduction to Ascendient and noted that he will be attending all task force meetings as the primary point of contact on behalf of Ascendient.

Andrea Hyatt informed the group that she has access to CON information from other states. Mr. Parker volunteered to be the point person to distribute to the vendor and those who are interested. He also informed the group that there two binders had been put together, one of which contains copy of journal article from the research literature on CON regulation compiled by Robert Moffitt, the Commission Chairman and Barry Rosen, and one with hard copies of the comments received to date in response to MHCC solicitation of comments for the Task Force's review. The literature will soon be posted for the task force members.

Comments to Date

Mr. Parker reported on the hospital comments that were received and made note of the point that in general those providing comments were interested in retaining CON regulations with a focus on establishing a more modernized and streamlined process. Questions and concerns largely related to how the Task Force might refine the scope and depth of the process, while modifying procedures to allow for simpler and more timely reviews.

Mr. Parker indicated that the focus for today's meeting will be on the hospital sector and describing the key problems and issues for hospital CON regulations that may also be applicable to CON in general. He requested that attendees review the summary of hospital comments for major themes. It was pointed out that eight hospital organizations provided comments, including MHA. Mr. Parker noted that one of the hospitals, University of Maryland Medical System (UMMS), proposed the most significant changes in the scope of hospital and other health care facility CON regulation among hospital commenters. Specifically, with respect to hospital capital projects, UMMS proposed that only establishing and relocating hospitals outside of a hospital's service area should remain within the scope of CON regulation. In addition, UMMS indicated the need to maintain some regulation of inpatient psychiatric services, if such services would not participate in serving Medicaid patients, and also recommended shortening the list of services that need CON if introduced by hospitals as new services.

Mr. Parker also indicated that the MHA has a task force working on reviewing these same issues and anticipates preliminary recommendations associated with that work to be available near the conclusion of the first phase of the Task Force process.

MHA Perspective

Mr. McCone provided a summary of the comments submitted by MHA and also provided a caution against looking at CON in other states as a reference point for CON modification in Maryland due to Maryland's unique payment system. Mr. McCone informed the group that MHA has assembled a CON work group that has been and will continue to meet throughout the year. The group includes representatives who have expertise in health planning, policy, and operations, and will be evaluating the CON program from two primary perspectives: content (what to regulate) and process. Mr. McCone indicated that MHA's recommendations will tackle the CON review process issues first, and then go chapter by chapter through the State Health Plan, focusing first on acute care hospitals and special hospital psychiatric facilities in order to develop recommendations.

Mr. McCone indicated that the current payment model has been a good thing for the state and hospitals would like to extend it as a vehicle for addressing the total cost of care, as planned. However, under this approach, hospitals are the only facilities held accountable for costs from a pricing and volume perspective. Mr. McCone acknowledged that the current focus is on limiting the growth of payments per Medicare beneficiary. That focus, along with the regulation of the supply of services, provides incentives for addressing avoidable utilization.

Mr. McCone noted that the current payment model runs parallel to CON, but also sometimes perpendicular, noting the migration of services out of the hospital and into lower cost settings, e.g., ambulatory surgery centers (ASCs). The ASCs disruption can vary from market to market, with some geographic areas experiencing an increase in competition while others, like Baltimore, experiencing decreased competition.

CON needed with Maryland's unique payer system?

From MHA's perspective, Mr. McCone indicated that CON is a necessary tool to ensure there are high quality, appropriate services available to Maryland residents. He also pointed out that within a payment model focused on total cost of care growth, CON is necessary to regulate supply, which ultimately has an influence on the total cost of care. Mr. McCone made the point that CON is necessary to ensure that there are quality, cost-effective services given. Hospitals are held accountable for hospital revenues under the current payment model.

Andrew Solberg stated that hospitals are trying to have it both ways when it comes to cost and quality, suggesting that if cost and quality are regulated by other entities then it should no longer matter relative to CON. Mr. McCone responded by saying that the CON process is required to establish the initial need for a service, then the HSCRC determines the associated cost, but the CON process must first determine need. For example, in the case of cardiac surgery, there is a minimal volume requirement, so, in that way, the CON serves as a permit that is related to quality assurance. However, going forward operationally, quality and costs are regulated by the Office of Health Care Quality, HSCRC and national quality standards.

Innovation and costs

The Task Force discussed the role of CON, whether it stifles innovation, and its overall impact on the rising cost of care in Maryland. Some expressed concern that CON may set such a high hurdle that it is much easier for existing providers to meet the standards; thereby hindering new market entrants and innovation.

- Mark Meade pointed out the examples of the Aetna/CVS merger and Amazon, which provide a challenge to the market and are driving the location where services are delivered. Mr. Meade made the point that while he favors CON regulaton, he believes that CON limits the response to new market dynamics and asked that the Commission take that into consideration.

- Bruce Richey stated that both free market and non-free market forces play a role in innovation. In a completely free market, the market will determine how much innovation is desired. The

fact that hospitals are regulated and many other entities are not puts hospitals at a disadvantage when considering the entire service line, which may limit the ability to innovate.

- Randy Sergent pointed out the need to understand that sometimes the total cost of care is reduced by having someone other than the hospitals provide the care. As a result, the Task Force needs to look carefully at when CON is being used to protect something at the hospital, rather than looking at the best way to lower the total cost of care. Mr. Sergent requested that we be sure to ask the question as to whether we are protecting institutions rather than reducing the cost of care as the priority.

- Mr. McCone offered that the presence of global budgets and the level of alignment in Maryland is unique and serves as an example of how Maryland hospitals are innovating. He pointed out that CON exists for ASCs and skilled nursing services, and nothing about CON regulation is stifling those services from an innovation perspective. He also pointed out that there is no CON regulation for physician-based services, which is further indication of additional areas for potential innovation.

Members also discussed the connection between CON, the HSCRC, and the current payment model.

Barry Rosen responded to a prior question about the connection between CON and the all payer system, stating that CON helps hospitals on the payment side, as HSCRC struggles to come up with a bundle of funds for new or replacement hospitals (Prince George's and Germantown, for example) because it comes out of the funds for the whole state. Meanwhile, other hospitals still have the same overhead that they had before. Mr. Rosen stated that the HSCRC eventually will need to adopt normative standards and consider lowering rates. The CON process helps HSCRC do its job. In this way the HSCRC and the CON connect with each other and with the global budget payement system. However, it is a real problem that there is not a normative approach for managing hospitals' costs, and Mr. Rosen expressed that this issue needs to be addressed.

Based on Mr. Rosen's comment, Adam Kane made the point that how we manage capacity is also part of the discussion. He stated that compared to rates, capacity is even more important for a hospital. Is it HSCRC or CON's responsibility to address the issue of capacity? Mr. McCone replied that hospitals are getting a CON exemption to change some campuses to outpatient only, but that exemption process needs to be easier. He stated that we must look at those rules to see where we can improve. Mr. Rosen stated that if we are trying to make the system cheaper, then we need to make certain processes easier.

How to streamline the process, including perceived duplication between MHCC/CON and HSCRC

Mr. McCone stated that most hospitals have the opinion that CON is still needed in Maryland, but the process should be modernized by taking into consideration the following:

- Consider eliminating financial feasibility review and the regulation of charity care from the scope of MHCC's work, leaving these tasks to the HSCRC and/or via licensure requirements:
  - Potentially include HSCRC in the process earlier.
  - CON regulation can be likened to the process of obtaining a building permit. After you obtain it, it is still necessary to obtain and maintain an occupancy permit. As such, the CON process itself should exclude items more appropriate for other entities to review/monitor operationally.
- Significantly raise capital expenditure thresholds or eliminate them altogether, particularly for projects not involving introduction of new services.
- Revisit the State Health Plan (SHP) to ensure that its overall goals and purpose and how it addresses demand/need are consistent with the current hospital payment model. Make sure each chapter is up-to-date, particularly for psychiatric services, while also continuing to update other standards, where applicable.
  - The SHP should focus on reducing avoidable and unnecessary utilization with methodologies that are clear, data driven, and consistent.

Meeting attendees also discussed completeness review questions:

Mr. McCone reported that there is a general agreement among hospitals that there should only be one round of completeness review questions which are limited to things that are essential to making the decision. Questions must include only those that are appropriate and useful for decision making. Consideration should also be given to the fact that applicants have different skills related to completing the application itself.

Mr. Steffen pointed out that UMMS provided some data on completeness reviews. He also made the point that the flip side of multiple rounds of questions is trying to get a complete application up front. Without it, some applicants may be rejected. This becomes a dilemma for staff, especially thinking of the varied expertise of the applicants.

Mr. Solberg indicated that there is an opinion that completeness reviews often go beyond the completeness aspect and become more of an opportunity to extend decision making. He suggested that the process should be focused solely on ensuring application completeness and stop there. Any review period extension should be separate and identified as such.

Mr. Rosen stated that there are currently nine standards, each with seven sub-standards, which equals 63 different factors to review. He also pointed out that there is a lengthy appeal process that can take up to three years and provides opposing parties the time to pick apart any of those 63 factors. He suggested that perhaps the SHP should outline and streamline a list of factors that are most relevant and request that applicants write a letter stating why they deserve a CON. Mr. Rosen pointed out that often just one or two items are the real issue, and the remaining 60 are not as critical to the decision-making process.

Mr. Sergent commented that regarding standards, there may be an opportunity to change the general bias from proving that something is needed and feasible, to whether something is not needed or infeasible.

The topic of adjusting the capital expense threshold was also brought up again, with Mr. Parker making the point that obtaining a CON for larger expenditure projects has historically been the way in which hospitals are enabled to go to HSCRC and seek increased rates to cover higher depreciation and interest expenses. He reminded the Task Force that hospitals already have the ability to avoid CON regulation for projects that only require review because of the size of the expenditure by taking the pledge that they will not ask for increased charges above a nominal amount to help in paying for the project. Any changes in this aspect of CON regulation must take that into consideration how this will affect HSCRC policy on when and how hospitals can seek global budget adjustments to account for higher capital costs. If we eliminate the capital expenditure threshold for CON, do we allow all hospitals an ability to request increases in rates whenever they undertake projects and increase their capital costs? Mr. Parker made the point that, from his perspective, addressing this topic involves talking about investment risk and how much risk it is appropriate for hospitals to take.

Mr. Kane then asked the question that if the HSCRC is linking charges to GBR growth, does the CON process even serve as a true gateway or just a scheduling triage?

Members of the meeting then discussed timelines and standards:

- Mr. McCone suggested that the Commission look to improve in the area of maintaining schedules/timelines, understanding that hospitals themselves can be the source of delays, on occasion.
- Mr. McCone pointed out that MHA is not advocating for reducing the standards in the SHP but suggesting that efforts be made to make the standards more explicit, especially in competing applications, making the point that interested parties should have to continue to demonstrate impact and involvement, but in a way that is supported by good, data-driven analysis.
- Mr. McCone suggested that there is potential to eliminate some review requirements and/or provide an expedited review in instances where no interested parties are present.
- In addition, Mr. McCone suggested that the post-approval requirements need to be addressed and either changed significantly or eliminated altogether.
- Mr. McCone also recognized that the MHCC has its own capacity and resource restrictions, and the potential to add incremental manpower with subject matter expertise could help with process times.
- Mr. Solberg commented that any standards should only be in place if they specifically address a demonstrated problem that the Commissioners feel needs to be addressed, and all other standards be eliminated…with the issue of charity care being cited as an example.
- Mr. McCone agreed, saying that charity care is built into prices and part of HSCRC rate-setting authority. It is audited every year and therefore already addressed elsewhere.
- Ms. Phillips acknowledged the apparent duplicative nature of charity care but suggested that there might also be additive information that should not be eliminated given the importance of access.
- Mr. Kane noted that things change over time, so what is important is also changing. Mr. Kane asked if there was a way to have a process that would allow the Commission and applicant to clarify which standards are more relevant to the project to provide some level of flexibility.

- Mr. Steffen pointed out that some states are politics-ridden, so sometimes flexibility can lead to undue influence from powerful stakeholders. He recognized that he too would like to see flexibility but would like to see some protections in place to ensure some foundation upon which decisions can be made on the basis of transparent standards and criteria.

Community Input

Ms. Phillips revisited the building permit (CON) and operating permit (OHCQ/HSCRC) analogy, suggesting that building permits are created with a tremendous amount of local community input; however, consumers do not currently feel they have a sufficient chance to provide input on health planning projects. Ms. Philips noted that we might say community input is provided by board members but wondered if that was truly sufficient.

Mr. McCone agreed that community input needed to be part of the process and commented that the statute changed to say that there had to be public hearings and community input from the local communities.

Mr. Solberg pointed out that historically CON decisions were mostly consumer driven, which often resulted in local area recommendations that did not make sense relative to broader health planning concerns. Mr. Solberg noted that in terms of exemptions, the public hearing process is very effective. People who have concerns or are very active are represented. For those kinds of projects, Mr. Solberg stated that public input is very effective. He also noted that most of the exemption process is not really exemption, but more a CON process, stating that an applicant must still show consistency with the SHP and that exemptions are still regulated by the Commission.

As a consumer representative, Ellen Cooper noted that this area of regulation is difficult to understand for most of the general public, so it is difficult for the general public to know how to make their voice heard. She suggested that there needs to be a less formalized way to make comments, such as a public hearings or some other way, so one can understand and communicate those issues without understanding the entire process.

On Mr. Solberg's point regarding exemptions, Mr. Steffen agreed that he was accurate, but pointed out that the MHCC is simply following the statute that is in place. Mr. Steffen also acknowledged that all of these types of discussions are why we are going through this process, pointing out that raising good questions related to the complexity of exemptions is a good "white board" item for further discussion.

Mr. McCone concluded this line of discussion by making the point that the current statute requires that hospitals must notify the public of changes to key services.

Mergers/Consolidation

Commissioner Michael O'Grady stated that the task force should consider the dynamic of the current market, including the need to be realistic about incentives within the broader context. Mr. O'Grady suggested that the pressures of the current plan and financial constraints can lead to consolidation at a time we want to ensure innovation. Mr. O'Grady asked that we ensure that we

are not creating incentives that may harm innovation and quality. He asked that the committee keep in mind current incentives and goals when recommending any changes.

Relative to consolidation, Ms. Cooper noted that due to the regulatory rate structure in Maryland, the Federal Trade Commission (FTC), Department of Justice (DOJ), and the Attorney General (AG) do not look at consolidation in Maryland like they do in most other states. Those entities defer to local regulatory agencies like the MHCC to ensure that the amount of consolidation achieved in order to achieve better cost, quality and innovation is not excessive or dramatically affecting the competitive environment.

Mr. Kane noted that in other states the FTC looks at the effect of consolidation on contracting with payers, but given the payment model in Maryland that is not a significant consideration.

Ms. Cooper noted that state policy encourages mergers and affiliation, but then supervises those activities through rate regulations.

Howard Sollins agreed but noted that in the instance of for-profit acquisitions of Maryland hospitals the AG has special statutory authority and oversight in those unique instances.

Mr. Parker pointed out that the MHCC has asked for clarity on this but acknowledged that the answer is somewhat "muddled." Specifically, MHCC has the authority to review mergers and consolidations via exemption; however, the acquisition of a facility does not require a CON. As a result, MHCC's authority in this area is dependent on whether a transaction is considered a merger/consolidation or an acquisition.

Mr. O'Grady then stressed that the committee remain realistic about pressures on hospitals and incentives to bend the cost curve, acknowledging that the presence of only two to three health systems in Maryland would fundamentally change this entire process. Mr. O'Grady made the point that we can regulate all we might want, but if only a few control the supply, regulation doesn't really control things any more. Mr. O'Grady concluded by stating that this is clearly an issue that deserves more discussion.

Meeting Conclusion:

Ms. Philips thanked everybody for their time and noted that the next meeting is on March 23 and may be extended by 30 minutes. Mr. Steffen acknowledged that the group also wants to cover freestanding surgery centers but given the scope of hospital conversations they will be deferred to later meetings. He noted that the focus of the March 23rd meeting would be long-term care, including nursing homes, home health agencies, and hospices.

Meeting Summary
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Friday, March 23, 2018
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance:
Frances Phillips, Co-Chair
Randy Sergent, Co-Chair
Regina Bodnar
Ellen Cooper
Lou Grimmel
Elizabeth Hafey
Anne Horton
Andrea Hyatt
Brett McCone
Mark Meade
Michael O'Grady (Phone)
Barry Rosen
Andrew Solberg
Ben Lowentritt, M.D.

MHCC Staff in Attendance:
Julie Deppe
Paul Parker
Ben Steffen
Sarah Pendley
Kevin McDonald

Others in Attendance:
Brian Ackerman
Keith Hobbs
Anne Langley
Ann Mitchell
Tyler Pickrel
Laura Russell
Howard Sollins
Noson Weisbord

March 23, 2018 Task Force Meeting
Meeting Summary

Co-Chair Sergent called the meeting to order.

Comments related to the January meeting minutes were requested and Paul Parker asked the Task Force to review the February meeting summary document and provide any comments. Mr. Parker also noted that today's meeting would be divided into three primary components related to nursing homes, home health agencies, and hospices. Discussion related to nursing home comments then began.

Nursing Home Discussion

Mr. Parker introduced the process and comment summary regarding nursing home CON regulations and pointed out some of the key issues, including:

- Overall, the nursing homes that commented supported maintaining CON regulation.
- Some concerns related to capital expenditure threshold were expressed.
- Desired improvements related to performance requirements post-approval and the overall regulatory process were also expressed.

The group reviewed the nursing home fact sheet and profile document that was provided to attendees. Howard Sollins was then asked to speak on behalf of the nursing home provider community.

Mr. Sollins introduced himself and provided an overview of regulations on nursing homes. He noted that he had helped HFAM and LifeSpan write their comments and would summarize the comments for the group today starting with the more significant issues.

CMS's Five-Star System

Mr. Sollins stated that using the Five-Star ranking system as a gating requirement is problematic. Mr. Sollins provided background on the ranking system and noted that CMS uses survey results as quality metrics. Mr. Sollins is concerned that this is a moving ranking regarding performance relative to peers within a particular state. This can be problematic as a facility can be only a Two-Star program in Maryland, but a One-Star program in a different state.

He also stated that the CMS Five-Star System ranks based on deficiencies or absence of violations, and not the actual quality of care. For example, Mr. Sollins compared the system to ranking a restaurant Five-Stars because nobody has died of food poisoning from eating at the restaurant. He also stated that the results of the system are not adjusted or weighted and CMS sometimes changes the criteria, which can cause a facility to drop to a lower rating after measures have changed.

Mr. Sollins provided an example of a significant issue associated with a nursing home that wants to impact total cost of care by tying its medical records with hospitals. In the example, this partnership has resulted in some of the best turnaround times for hip fractures; however, this facility also has a dementia unit. In that unit one event occurred where a resident walked out the door (elopement) but was immediately identified and brought inside. Due to that one elopement, the facility would drop to One-Star, regardless of the quality of other areas. Mr. Sollins made the

point that to transform care, Maryland should be lobbying for changes in the regulatory system to allow for more effective evaluation across the continuum of care.

Medicaid MOU

Second, Mr. Sollins stated, both HFAM and LifeSpan feel strongly that the Medicaid MOU should no longer be a requirement as it is an outdated measure. The Medicaid MOU was relevant years ago, when it was sometimes difficult to place Medicaid patients in nursing homes. The MOU was established to improve the access issue. Mr. Sollins contended that this lack of access has significantly improved as some facilities, including some owned by major chains, have 80 percent Medicaid occupancy levels.

Mr. Sollins emphasized that it seems counterintuitive to have a system to punish facilities for not being able to maintain a certain percentage of Medicaid patient days. Mr. Sollins suggested that instead of Medicaid MOU, the task force can enforce Medicaid access by requiring that all facilities accept Medicaid, without imposing a certain percentage that facilities must reach.

Capital Cost Threshold Differential between Nursing Homes and Hospitals

Third, Mr. Sollins noted that the capital cost differential can be problematic and that the Task Force should collectively consider the threshold and what types of project can be exempted from CON to make the process more straightforward and efficient. Mr. Sollins stated that it does not make sense that the capital expenditure threshold of capital-intensive organizations such as nursing homes is comparable to home health agencies, when there are better parallels to hospital projects where the capital threshold is over $12 million. Mr. Sollins also questioned why it is necessary for a facility to have CON approval if it wants to replace a building on the same campus/location given that the cost increase is already accounted for in the rates.

Other Issues

Mr. Sollins identified other issues that he brought to the attention of the Task Force.

1. Waiver Beds – Mr. Sollins expressed that if a nursing home has doubles/triples/quads and wants to increase the number of private rooms but needs an extra 10 beds in order to pay for that, the nursing home should be able to use its waiver beds. Mr. Sollins noted that this doesn't mean we throw the barn door open because CON is needed/wanted by most.

2. Performance Requirements – Mr. Sollins stated that CON regulations are inconsistent as they allow up to 24 months to complete a CON for improvements to an existing facility, but only 18 months for a CON to construct new facilities. He further argued that the Commission should have more flexibility to approve phased capital projects. Under current rules, an applicant has only one opportunity for to extend performance requirements. As a consequence, applicants must pay extra money to bring on extra staff to meet deadlines, which causes an unnecessary waste of resources.

3. Changes in configuration of ownership after CON, but before construction completion – Mr. Sollins noted that currently, adding/changing even minority investment isn't allowed. He stated that this is sometimes a concern when an applicant wants to bring in a small equity investor as the project is being developed. He suggested that this impermissible change should modified to allow for instances where small ownership changes do not materially alter the integrity of the project.

Mr. Sollins also briefly mentioned other minor issues related to looking again at occupancy thresholds, unchecked competition for nursing facilities, and performance requirements related to zoning.

In summary, Mr. Sollins made the point that his main concerns fall into three primary buckets:

1. Avoid using Five-Star Rankings as gatekeeper indicator
2. Eliminate MOU or make it more limited
3. Update CON requirements to enable entities to modernize facilities when there was no planned expansion in the number of beds.

Mr. Randolph said that he appreciated Mr. Sollins comments regarding the suggested areas for improvement as opposed to completely removing CON. Mr. Randolph then asked for any comments or questions.

Barry Rosen asked for an explanation regarding how nursing homes are paid now. Mr. Sollins observed that that nursing homes used to be reimbursed based on cost basis but Medicare is now using the RUGS (Research Utilization Groups) methodology, although there are ongoing discussions that Medicare may be potentially moving away from RUGS approach because it is heavily dependent on therapy as a metric for measuring outcome. Mr. Sollins noted that on the Medicaid side, up until a few years ago Maryland was the last cost-based reimbursement state. Now, Maryland has a version of the RUGS system with some factors that are regional, based on rural or urban/suburban areas.

Mr. Sollins emphasized that the key issue for the Commission is that capital is not unlimited as an evaluation is in place to ensure facilities do not pay for excessive capital costs. He said that to Mr. Rosen's point, some of the considerations of CON to monitor excessive costs are not as necessary as they once were.

<u>Discussion – Future of Nursing Homes</u>

Mr. Rosen asked if there are going to be nursing homes in the future given that assisted living is making its move into the nursing space, along with other factors. Mr. Sollins stated that demographics alone with drive up demand, but the question of demand for what types of services remains given evolving consumer expectations.

It was noted that we have real opportunity to re-make the capital infrastructure of nursing homes in Maryland. It was suggested that there should be a path for those that want to go into assisted living or other opportunities, and for those willing/able to make capital investments with oversight, they should be encouraged to do so, with oversight but not micromanagement.

Discussion - Quality

Ben Steffen asked the group whether using specific quality measure was preferable to a composite measure such as the Five-Star Measure. He also asked the group regarding whether there should be efficiency metrics that could be tied to metrics in the planned Total Cost of Care Demonstration.

Lou Grimmel commented that regarding quality measure, he agreed with Mr. Sollins that any one issue can knock a Five-Star facility to One-Star facility and that it was more important to look at performance in the long-term rather than a single incident. Regarding Mr. Rosen's question on the need for nursing homes, Mr. Grimmel believed the answer is no and yes. No for traditional nursing home models and yes for those that fit in the waiver/total cost of care to help hospitals and the State meet the need for lower cost of care. He stated that traditional nursing home patients will have other alternatives that offer better patient satisfaction and provide lower cost alternatives to patients. Traditional models of nursing homes, in turn, will be phased out. Mr. Grimmel suggested that regulations need to catch-up with what industry needs to do to attract new customers and match to total cost of care. The question of how to compliment the hospital better should also become a priority.

Regarding CON performance requirements issues, it was noted that hospitals already have a campus and the right zoning, so they can start building after CON approval. However, nursing homes often do not even have the land available at the time of submission. Once CON approval is issued there is another process to go through to obtain needed zoning approvals. Performance requirements force some facilities to take advantage of whatever wiggle room there is to achieve their goals.

Mr. Sollins noted that community-based services used to be the focus, now total cost of care is the focus. The CON process should be established to look towards the future and quality shouldn't be a gating issue. He stated that the Commission should have flexibility to assess quality, and facilities will need to defend their quality, but there shouldn't be a gating standard.

Andrew Solberg addressed the group and stated that he disagreed with Mr. Sollins' remarks that there shouldn't be a standard. Mr. Solberg expressed that was not a good idea because there has to be some sort of standard if you want to use quality, which relates back to the point Mr. Steffen raised, what can/should CON contribute in quality area given the fact that licensing already reviews quality.

It was noted that although the group could not think of an instance where a nursing home was denied because of quality, it may want to keep that ability to do so in order for CON to serve as a gatekeeper to keep out entities that the State wouldn't want to admit in. Co-Chair Fran Phillips then asked for clarification from Mr. Sollins on his suggestion that there should be no quality standard.

Mr. Sollins clarified that he believed there should be a quality standard, but that the Five-Star system might not be best/only approach. He made the point that the Five-Star ranking shouldn't be a barrier to applying if you achieve a certain standard. You should be able to come in with best evidence on how you will meet the standard, there shouldn't be a barrier.

Mr. Parker clarified for the group that we do look at the Five-Star ratings for CON applicants. If you're not above a certain level you cannot submit an application. He said that applicants need to show performing above a certain level before even spending time reviewing the application and that the intent is to promote expansion of quality providers who have a good track record by requiring that they reach these levels to get through the gate. The question is, is there some merit in looking at past performance?

Mr. Sollins emphasized that the Five-Star system should not serve as a gating issue but should be considered along with other relevant metrics/measures. He believes that entity shouldn't be prohibited from applying for a CON because it failed to meet a metric that the Commission does not control.

Discussion – Medicaid MOU

Ms. Phillips then shifted the conversation back to the discussion of Medicaid MOU and requested further information and clarification. Mr. Sollins stated that the MOU had outlived its usefulness. He suggested that if eliminating the MOU is not palatable, then an alternative is to require that you accept Medicaid, but without requiring a certain percentage. He expressed concern that it's responding to a problem that is no longer an issue.

Brett McCone was asked for any comments from the hospital perspective. He stated that he felt it was important to maintain a CON process but to ensure flexibility given that the need for the services as shown/demonstrated at some point. Second, Mr. McCone stated that he agreed with the need to ensure alignment with total cost of care efforts and stated that within the preamble to the State Health Plan or elsewhere, the point regarding the alignment with total cost of care should be made.

Ann Horton then contributed a comment from a CMS official on the Five-Star rating system from a few years ago who stated that they weren't really sure how the use of these rankings were going to work out. She provided the analogy that the Five-Star system is like looking at a snapshot in time, such as one month of financials instead of an entire year, plus that snapshot reflects performance that is often more than a year in the past.

Given time constraint, Mr. Randolph suggests the group shift focus to discussion of next topic, home health.

Home Health Discussion

Linda Cole provided a review of the home health fact sheet and profile document provided to attendees, noting that innovation efforts among home health facilities include value-based

purchasing programs and joint ventures with hospital systems. Home health, in fact, is the only type of home care provider that require CONs, residential service facilities are not regulated.

Reflecting on information from the fact sheet, Mr. Randolph asked if CON has caused more utilization per provider in Maryland and why is there CON at all in home health given the low capital investment and presence of licensure requirements?

Ms. Cole responds by noting that the patient population is one that is very vulnerable, and CON serves as a way to protect them. Mr. Randolph followed by wondering if that was more of an issue for licensure and not CON? To which Ms. Cole responded by questioning if that was possible given the level of resources and capacity of licensure.

Regina Bodnar then stated that CON does protect quality, noting that the absence of CON would open the market to too many providers. From OHCQ perspective, the present staffing at OHCQ would not be able to monitor influx of entrants. Ms. Bodnar then echoed Ms. Cole's statement about vulnerable patients, indicating that is very real in today's home health and hospice environments.

Ms. Horton then provided and overview of the home health comments. She stated that for home health and private duty Residential Service Agencies (RSAs), it's very difficult to come up with a single position on this issue as there are varying opinions among the constituencies. She stated that it is clear that home health plays critical role in serving triple aim, and it is necessary in order to achieve the goals of the all payer system. Ms. Horton than noted the following information for Maryland:

- 67% of Medicare home health patients have multiple chronic diseases.
- 79% of MD home health agencies are at or above the national star average.
- Compared to nearby markets, close to 60 percent of Maryland agencies are in the Four to Five-Star category. In Virginia, a non-CON state, only 27 percent of agencies are in those categories...and 29 percent in D.C.
- Maryland is also involved in CMS experiment in home health value-based purchasing, currently involved in five-year program that involves payment adjustments of 3 to 8 percent depending on certain quality standards. Penalties and bonuses are being done starting 2018.

Ms. Horton summarized that the comments from home health can be grouped into two main categories:

1. The need for CON
2. Ways to refine the process

<u>Need for CON</u>

Ms. Horton stated that most home health providers agree that there is a need to keep CON. She made the point that CON assists with fraud prevention given the potential inability to otherwise manage oversight if the number of home health agencies grew rapidly in the absence of CON. Ms.

Horton stated that workforce is another big concern, given that there is already inadequate skilled workforce to serve all the home health providers in Maryland.

Ms. Horton made the point that home health provides an enormous cost savings in terms of total cost of care and asked the question of why hospitals are not using home health more.

Need for Refinement of the Process

Ms. Horton reported that the consensus (particularly the RSAs) is that CON process offer more flexibility for organization trying to enter the market. Ms. Horton also introduced the idea that in some instances CON can lead to lower quality ratings because it keeps high-performing organizations from entering markets in which the incumbent providers have lower quality ratings. Additional thoughts expressed by Ms. Horton included:

- Provide for a more streamlined process, including providing the ability to use available State data instead of recompiling and resubmitting data.
- Ensure that the star rating system uses updated data with each release. Related to that is the question of how we deal with that when those values change in the middle of the CON process?
- Clarify the ability to allow RSA providers to get a CON. Particularly, how does CON evaluate RSAs?
- Decrease level of complication associated with RSA provider CONs.
- Streamline the process for those applicants who are longstanding, high-quality providers in Maryland.
- Improve applicability of portions of home health CON application to home health services vs. general/other facility services, which might not be applicable to home health.
- Ensure clear and timely communication with applicants and protesting organizations to avoid them having to communicate directly with each other.

Ms. Horton suggested that additional concerns related to providers being uncomfortable releasing CON-required financial and referral source information for public view.

Mr. Randolph asked about doubling the number of providers and if that would increase uptake, or is utilization dependent on something else? Ms. Horton commented that utilization in Maryland is just slightly lower than the national average, but the expectation is it should be slightly higher given all payer model. She noted that the State is working on that already, and it's difficult to come up with one reason why. At a later point in the conversation Mr. Rosen pointed out that the notion of capped hospital payment is relatively new and goes against 30-years of history, so it should not be a surprise that utilization of home health hasn't caught up yet.

Discussion - Quality

Mr. Steffen raised the question, if home health CON is not well-aligned with the proposed TCOC Demonstration, should we be relying on it all? Are we creating a situation where we are protecting existing business, limiting innovation, and constraining success under the proposed TCOC Demonstration?

Ms. Horton followed up on that question by asking if we are convinced that the Five-Star system is sustainable long-term. She stated that the system is not as meaningful as it used to be. Ms. Hyatt then commented that it appears we are using CON to compensate for things that should be taken care of in licensure.

Ms. Horton further responded by stating that it is really a question about how big you want the funnel to be for licensure through OHCQ. She observed that it could range from very open to highly selective. Under the CON, OHCQ can maintain a fairly open process because CON acts as the screener. Without CON, licensure would need be more selective. Ms. Horton observed that OHCQ does not have the capacity to deal with the situation. She also raised another issue related to inadequate number of skilled workers available to support all of these types of post-acute providers.

Mr. Grimmel then brought up the point that MHCC has provided multiple grants for telehealth and telemedicine, which has facilitated the reduction of not only ED visits, but also admissions. Mr. Grimmel explained his efforts to offer bundled payments and the use of nursing homes to efficiently stabilize high-risk patients, returning them to home using telehealth, which provides a low-cost/high patient satisfaction alternative. Mr. Grimmel explained he is currently limited to doing this just for certain payer classes and would be interested in expanding those efforts to have a more dramatic impact on the overall total cost of care in Maryland.

Discussion – Urban/Rural

Mr. Rosen pointed out that it's important to note the difference between a rural and urban/suburban markets. For some rural providers, the notion of limiting who can provide home health or hospice makes sense given there's not enough population to support more than one provider. It doesn't make sense, however, to restrict urban/suburban providers. Mr. Rosen made the point that while CON does help to keep the fraudsters out, a significant license fee could accomplish the same objective.

Ms. Horton countered that he has had conversation with providers and the opposite is true. Rural areas where population and demand are low should be opened up, because if you're willing to go as a licensed home health provider you should be able to go. Ms. Horton than made the point that opening up the urban areas will lead to us becoming Texas or Florida, with increased fraud.

Mr. Parker stated that the State has already opened rural areas (Eastern, Southern, Western) but have received limited interest because market limitations have overwhelmed the providers. He stated that there is very little interest in serving rural areas. The process is simple and welcoming for organization with a good track record, but there has been little interest because the market is too small.

Discussion – Alternatives to CON

Mr. Parker then stated that the evidence suggests that the presence of CON indirectly impacts quality as it results in far fewer agencies that we would have otherwise. Mr. Parker than suggested that if growth is the main concern, why not just limit growth through OHCQ? Maybe permit only

a certain number each year and rather than CON, there could be a lottery system that limits the number of new agencies. One could provide the standards that must be met to put your name in the hat. Mr. Parker explained that this would provide the benefit of CON while letting people go into areas they want to go. If we do that, Mr. Parker wondered about the value of CON in a system like that.

Ms. Horton asked about the unintended consequences of such an approach and wondered if it had been done elsewhere. Ms. Horton stated that a vision for what that process would need to be created and evaluated.

Mark Meade then stated that what we're talking about here is the continuum of care, noting that we all represent different aspects of the continuum. He stated that we must ensure that the CON process is not building Chinese walls to prevent our ability to put patients in best quality/lowest cost sites of care.

Mr. Randolph then asked about the difference between CON and a more robust licensure structure. Mr. Solberg concluded that CON does help to keep out bad providers, but in doing so, it also keeps out good providers of home health services. He stated that the ability for a health planner to project the need for a number of agencies is fiction. There might be other reason to keep CON, such as ensuring access to charity.

Mr. Steffen reminded the group of the time and need to transition conversation to hospice.

Hospice Discussion

Ms. Cole provided a review of the hospice fact sheet and profile document provided to attendees, noting that utilization in increasing overall, but has decreased recently for minorities.

Ms. Bodnar was introduced as representing the Hospice Network of Maryland to summarize comments for the group. Ms. Bodnar began by providing a brief CON history for hospice, noting that in 2003, hospice CON in Maryland was recalibrated and limited the geographies based on the jurisdictions that facilities provided care to for the 12-month period prior to Dec 31 of 2001. As a result, many hospice providers in the State received CON for jurisdictions that they didn't have robust presence in. Ms. Bodnar stated that right now there are some jurisdictions where hospice providers have a CON but they don't have a significant presence. Ms. Bodnar also reported that in 2010 the Commission reevaluated its position on CON for inpatient beds and since that time a CON is required if you want to expand beds or put beds in a joint venture.

Ms. Bodnar then explained that there are four levels of care associated with hospice, including routine home health hospice (90% of patients fall in this category), respite care, continuous care, and general inpatient care. Ms. Bodnar noted that the number of hospices by jurisdictions varies, but all have at least one general hospice service.

Ms. Bodnar then explained that the comments from hospice providers largely echoed home health comments, including the desire to maintain some level of CON, with modifications.

Need for CON

Ms. Bodnar provided several pieces of information and opinion related to the need to maintain CON for hospice services, including:

- The loss of CON would result in large influx of providers, majority of whom would be for-profit entities. She provided an example: Maryland has 27 hospices, compared to nearly 300 in Pennsylvania.
- CON provides mechanism to ensure quality as demonstrated by the fact that Maryland has had no incidence of fraud while patterns of fraud exist across the country.
- Non-profit hospice organizations depend heavily on donations and the presence of additional providers would heighten competition for donated dollars.
- CMS requires volunteers to provide at least five percent of total patient care hours provided by paid staff. Competition for limited resources of volunteers is already a challenge, along with the ability to recruit a qualified workforce.
- Presence of additional providers would escalate cost of care because it would negatively impact the current economies of scale used by existing providers. For example, one receptionist is needed whether you have 300 patients or just 10 patients.
- Hospitals see hospices as strong partners. Ms. Bodnar's hospice hospital readmission rate less than one percent.

Need for Refinement of the Process

Ms. Bodnar then provided suggestions for improving the current CON process, which included:

- Simplify the methodology for determining unmet need for establishment of new programs.
- Establish a methodology for determining the need for inpatient beds. This methodology does not currently exist, yet providers must still go through the CON process to expand.
- Consider establishing thresholds for minority utilization, particularly for jurisdictions with higher minority demographics. Recognizing that this may be a challenge given it's less an access issue and more an acceptance issue.
- Include a weighted focus on publicly reported quality measures when reviewing applications.
- Utilize survey data and actual complaint data during review process.
- Ask any application docketing for a CON how they propose to maintain and facilitate a decrease of the total cost of care.
- Ensure all applicants are held accountable for adhering to required timelines for review.

Mr. McCone confirmed that hospice is in fact included in the total cost of care relative to the waiver.

Discussion – Provider Types, Geography, and Demographics

Mr. Grimmel then highlighted the difference between for-profit and non-profit hospices. Indicating that the numbers for-profit providers have exploded and that non-profit facilities do a much better job keeping patients for only the appropriate length of stay. In this instance CON can act as an effective watchdog for Maryland.

Ms. Bodnar then explained that hospice payment is the same regardless of how many/any staff in patients' home, so the opportunity to provide less than adequate care for purposes of improved profitability is significant.

Mr. Rosen then reiterated the point regarding the difference between rural and suburban given the distance between homes in rural markets, stating that there's no point of CON for urban and suburban regions except for keeping out fraudsters. It was stated that Maryland had a moratorium on hospice for 15 years and, as a result, Maryland has one of the lowest hospice penetration rates in the country.

Mr. Rosen also stated that we must be careful saying that the minority population doesn't want care, as it could also be a history of racism on the provision of care to minorities that's driving some of the low use. Mr. Rosen also cautioned against the assumptions that all for-profit providers are bad given that a number of good for-profit providers do exist. Ms. Bodnar responded by saying her comment was certainly not making a sweeping assumption that all for-profits are not good but suggested that there is research showing that for-profits do have larger bottom lines due to differences and staffing and visit intensity.

The point was then brought up that the real issue is not access but acceptance. Often, the number one complaint about hospice is that families wish they knew about it sooner. As a result, the focus should be going to non-traditional sources to get the word out, and that the number of hospice providers in the State doesn't necessarily dictate utilization.

Mr. Solberg then remarked that when hospice puts a unit in a hospital, the number of people that die in a hospital bed drops markedly. Maybe the commission should consider a policy that encourages such units around the State as a way of decreasing total cost of care.
Discussion – Impact on Innovation

Mr. Steffen then stated that he agreed with Mr. Rosen and Ms. Bodnar's remarks. He also raised the question on whether CON stifles innovation by making the point that all existing providers are going to say that they have been innovative. Mr. Steffen wondered if maybe we have to realize there might be other ways to innovate that we're simply not aware of in Maryland and that we might be slower to innovate in Maryland because we have 30 years of historical referral patterns and nobody else is able to enter the market and provide a difference perspective.

Ms. Horton responds by agreeing that many small independent providers across the State home health and hospice arenas don't have the experience and exposure, but many others can bring back what we're experiencing across the country. Ms. Bodnar commented that the hospice network does an incredible job in working with providers across the State and sharing best practices; Maryland is respected across the country

Meeting Conclusion

Mr. Randolph then declared that the group was out of time for this session and asked the Task Force to review the hospital draft problem statements and provide any comments, which will be discussed at a later date to allow sufficient time for discussion.

Mr. Parker thanked Ascendient for their efforts to develop materials and a meeting summary for the February meeting and reminded the members that hard copies of all materials and comments are available. Mr. Steffen stated that for those that want to provide additional comments, please feel free to do so and let the Commission know within the next ten days so the comments may be incorporated into April 20th meeting.

Mr. Steffen then stated that the next meeting will consider Ambulatory Surgery issues, a review of problem statements, and a discussion of the structure of the interim report. Mr. McCone asked a process question related to the timing of MHA sharing suggested solutions from its workgroup before June. Ms. Phillips requested that MHA not provide that information until after June to remain focused on understanding issues at this time.

Meeting Summary
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Friday, April 20, 2018
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance:
Frances Phillips, Co-Chair
Randy Sergent, Co-Chair
Ellen Cooper
Lou Grimmel
Elizabeth Hafey
Anne Horton
Andrea Hyatt
Ben Lowentritt, M.D.
Brett McCone
Mark Meade
Michael O'Grady (Phone)
Jeff Metz (Phone)
Barry Rosen
Andrew Solberg

MHCC Staff in Attendance:
Paul Parker
Ben Steffen
Suellen Wideman

Others in Attendance:
Brian Ackerman
Daniel Carter
Erin Dorrien
Peggy Funk
Keith Hobbs
Danna Kaffman
Anne Langley
Pat O'Connor
Laura Russell
Noson Weisbord

April 20, 2018 Task Force Meeting
Meeting Summary

Co-Chair Frances Phillips kicked off the meeting by asking task force members who are on the phone to identify themselves.

Commissioner Michael O'Grady stated that he had joined the meeting by phone.

Ms. Phillips asked visitors from Johns Hopkins University to introduce themselves. The group consisted of Professor Thompson accompanied by three Master in Health Care Management students (Prateek, Jessica, and Marvin) and Emanuel, Program Manager.

Ms. Phillips asked everyone to review the meeting minutes from February and March and provide feedback. Ben Lowentritt and Elizabeth Hafey noted that they were not on the list as having attended the March meeting but had been present; the minutes will be updated to reflect this change.

Ambulatory Surgery Facility Discussion

Ms. Phillips introduced the process of the meeting. She stated that MHCC staff would provide a brief introduction and an industry representative would expand and elevate issues for the Task Force to discuss. Ms. Phillips then turned to Paul Parker for an introduction of Ambulatory Surgery Facilities (ASFs) from the staff perspective.

Mr. Parker provided a brief introduction to the Ambulatory Surgery fact sheet and compared/contrasted Ambulatory Surgery Facilities in Maryland to that of other states. Lou Grimmel then requested feedback from the group regarding what impact the waiver has on Maryland's ASFs. Mr. Parker responded that the most powerful effect was there was no perennial warfare between hospital and physicians. In contrast, the main point of contention between Virginia physicians and hospitals was to loosen up regulation to let more physicians have the ability to do surgery in ASFs. So far, physicians had lost because hospitals didn't have rate regulation to fall back on. Hospitals were hanging on to the regulation because they needed ambulatory surgery profitability to offset other hospital losses. Ms. Hyatt commented that one of the negatives to Virginia's set-up was that no oversight or quality reporting exist when a case is completed in an office-based setting.

Andrew Solberg responded to Mr. Grimmel's question by stating that the waiver incentivizes hospitals to develop off-campus sites.

Barry Rosen also responded to Mr. Grimmel stating that the waiver allowed Maryland hospitals to charge higher prices for Medicare and Medicaid patients because HSCRC required it. He also made the point that one-room ASFs are not particularly efficient, and questioned why there were regulatory barriers of any sort in place for those?

Mr. Parker addressed Mr. Rosen's question by stating it is not difficult to get an additional operating room added to a one-room ASF. The Commission has recently reformed the ASF chapter of the State Health Plan (SHP) so there is now an updated exemption process for some types of providers. The Commission also now allows hospitals to swap out decommissioned hospital ORs for a two-room ASFs.

Andrea Hyatt, representing Maryland Ambulatory Surgery Association (MASA), introduced herself and gave her background. She thanked the Commission for the opportunity to participate and comment. She stated that the ASF industry had promoted Institute for Healthcare Improvement (IHI) Triple Aim and had helped Maryland providers cut costs without compromising safety and quality. MASA had chosen to not take a single position on need and CON regulation given multiple different opinions from ASF operators in the State. Ms. Hyatt noted that the one-room ASF approach had caused increases in single room ASFs in the State, much more so than surrounding states. She stated that MASA supports a competitive environment, and that the growth over the past few years had been relatively flat, serving as evidence that the competition had been weeding out those facilities that were not competitive enough.

Ms. Hyatt highlighted several MASA comments and recommendations as the following:

- MASA supports recent changes in the SHP, which have eliminated many barriers to entry.
- MASA believes that exemptions should not be eliminated.
- MASA recommends certain criteria about alternatives and elimination of minimum utilization.
- MASA supports more emphasis in place for operational requirements.
- MASA supports the elimination of capital expenditure threshold, providing the example that an increase in construction cost beyond 15% should not delay the project.
- MASA endorses the use of technology to submit automated and form-based applications.
- Relative to duplication of CON with other agencies. MASA recommends:
    - Removal of requirement of application to address quality of care in other locations.
    - Removal of entire section of transfer agreements.

Dr. Lowentritt, who acknowledged he was speaking on behalf of the physician community, then raised several issues with current CON oversight from his perspective, including:

- Lack of clarity within the ASF chapter of the SHP relative to any clear delineation between hospitals and ASFs, particularly related to applicable standards.
- Regarding the new two-room ASF exemption, lack of clarity regarding the amount of work necessary for the exemption process, noting that information on items such as need and charity care were still necessary.
- Amount of regulations and quality monitoring in place outside of CON is already significant, so what is the biggest concern from the Commission's standpoint that CON helps to address?

- Inefficiencies and limited economies of scale associated with one-room ASFs given certain basic minimums associated with sterility and staffing.

Dr. Lowentritt concluded by stating that ASFs have much lower cost. From an efficiency standpoint, given that a considerable amount of infrastructure and staffing are required to operate an ASF, one solution might be to allow two-room ASFs as the starting point.

Randolph Sergent thanked Ms. Hyatt and Dr. Lowentritt for their comments. He acknowledged that the group's desire seemed to be to make the starting point of regulation for two-OR facilities. He asked, what was the magic number of rooms to optimize efficiency? What would be the maximum number of rooms, if there was one?

Ms. Hyatt responded to Mr. Sergent's question. She agreed that there was more efficiency in increasing from one to two ORs, noting that two rooms give physicians more flexibility in scheduling procedures. She also noted that ASFs performing multiple specialties would achieve even further increased efficiency with additional rooms beyond two. She observed that biggest efficiency gains occur when facilities expand in increments of two.

Mr. Rosen commented that he didn't believe there was a need for regulation for this industry given the resource requirements associated with the CON process and the lack of efficiencies associated with smaller ASF locations. He questioned why there is such a "deli-counter ticket" requirement at all.

Ellen Cooper asked if there was a limit to what could be done in ASFs compared to what could be done in the hospital? Ms. Hyatt responded by saying that there had been a lot of pressure on ASFs to perform appropriate cases for appropriate patients. She noted that Medicare and private payers define the range of surgical procedures that they will reimburse at an ASF. Mr. Parker commented, ASFs are required to admit and discharge a patient in under 23 hours. There are also certain procedures that payers, including Medicare, don't have codes for and therefore reimbursement does not exist.

Mr. Solberg stated that if there were no regulation for ASFs, there would be a proliferation of ASFs based on aspiration alone, many of which would be forced to shut down due to insufficient volume. Mr. Sergent questioned why it mattered if many ASFs open and then close? Dr. Lowentritt agreed that there was no real justification for CON given numerous financial check points. If no CON regulation existed, many existing facilities would go out of business.

Mr. Sergent addressed the group, stating that we've heard the case against regulation, so he wondered about the reasons for regulation.

Commissioner O'Grady commented that providers generate demand in this industry. Without CON, ASFs would not go out of business but find ways to fill their waiting rooms. Demand had been dictated by the provider and it would be unlikely that that market would take care of that if CON went away. Commissioner O'Grady expressed his concern that ASFs would be able to prop up inefficient operations for years on the backs of taxpayers and premium payers.

Mr. Solberg countered by stating that many ASFs have been built based on private dollars and that it wouldn't be that easy to switch gears and generate a different business and maintain or pass many accreditation/requirements. He stated that many centers were in fact closing now due to competition.

Commissioner O'Grady responded to Mr. Solberg's comments by saying that there was a provider has a tremendous amount of discretion in the timing of a procedure. These factors affect utilization but didn't fall into the category of medically unnecessary. Deregulation would provide motivation to take action to perform surgeries instead of watchfully monitoring, which would put upward pressure on insurance premiums.

Mr. Sergent commented that it would be great to understand empirically how CON would impact demand. Today payers are much more assertive in assessing whether surgical services are necessary. In the current environment, Mr. Sergent questioned the impact of CON and asked staff to provide evidence. Ms. Hyatt in agreeing that payers were becoming more assertive, stated that Medicare had strict criteria that must be met when someone sought cataract surgery, for example. Commissioner O'Grady stated that he agreed with Ms. Hyatt from that perspective. He acknowledged that payers are more pro-active in assessing surgical appropriateness. He clarified that he objected to the notion that opening the market for surgical services would necessarily produce market equilibrium where supply balances with real demand.

Brett McCone stated that the group certainly needs to think about how to change/transform care. He noted that from the commercial payer perspective utilization was managed; however, that isn't the case for Medicare. He acknowledged that as transformation takes place the Commission must monitor ASF volume increases relative to hospital volume declines.

Ms. Hyatt observed a reason for the overall ASF volume increase was likely to because doctors have backlogged cases in hospitals. She contended that sometimes physicians could only block time one day a week in the hospital OR, but that same physician could block considerably more time an ASF. Ms. Hyatt also stated that some hospitals are trying to direct patients to their ASF, but some payers were putting up roadblocks because they believed they were already paying the hospital under the global budget arrangement.

Mr. McCone stated that all members needed to rethink what was regulated by the HSCRC on the outpatient side as services were moving to unregulated side of the organization.

Ben Steffen restated that one-room ASFs were not regulated and that the outcome of the current policy overall should be taken into account current impact, including the view that one OR ASFs are not the best site from vantage point of OR efficiency and patient safety.

Ms. Hyatt stated that the work done previously regarding amendments to the State Health Plan for Surgical Services that went into effect in January should be revisited in relation to this topic. Mr. McCone agreed, stating that he believed the amendments to State Health Plan for Surgical Services was well thought out, but further changes were needed.

Ms. Phillips concluded that ASFs were going through significant transformation/innovation and that the staff should crystalize ideas and circulate back to the group. She concluded this segment of the conversation and moved to the next item on the agenda.

Other Provider Categories Discussion

Mr. Parker introduced the discussion first on Residential Treatment Centers (RTCs), noting that until recently the sector that was in decline. Mr. Parker noted that there were only 470 beds in the State now, and geographic distribution was very limited. He also noted that within the past two years there had been only one application, which was withdrawn but recently has been re-submitted again.

Mr. Parker then discussed CON regulation Alcohol and Drug Rehabilitation Facilities. He noted that data limitations exist as these facilities. Many do not report utilization or patient-level data. He observed that the treatment spectrum for substance abuse withdrawal management includse outpatient, inpatient, and acute inpatient care. Although these facilities cover a wide spectrum of care, Mr. Parker noted that the only the medically-monitored intensive inpatient treatment level of care (which is not acute hospital care) and acute hospital-level care is regulated through CON. Mr. Parker stated that there were 18 acute inpatient substance treatment facilities in the State, referred to as Level 3.7 facilities, using the American Society for Addictions Medicine definitions of levels of care. He noted that there had been hardly any activity in this field for years, but over the past eighteen months, four new facilities were approved.

Ms. Hyatt asked the group, given the recent experience, was there any public policy reason to continue to regulate them? Mr. Parker responded by stating that the Commission had proposed to remove acute inpatient substance treatment from the scope of CON, given that these facilities constituted a small share of the treatment spectrum. He stated that most development activity in this treatment segment was arising from for-profit companies that did not participate in Medicare or Medicaid. He noted that the federal government had announced in August 2017 that Medicaid would pay for this level of inpatient drug treatment in facilities of any size. He suggested this change would likely not deter the Commission from its assessment that CON regulation was not the appropriate regulatory stance.

Ms. Phillips commented that access to acute inpatient substance abuse treatment was an issue because of the opioid crisis in the State. She stated that people needed treatment and CON appeared to be imposing unneeded barriers. It was noted that the Commission proposed to remove acute inpatient substance abuse treatment from the scope of CON, but the proposal was challenged in the House of Delegates because facilities that currently operate do not want new market entrants or competition.

Mr. Solberg then asked about whether the regulation for residential treatment centers was necessary? Mr. Parker reported that the Commission hasn't studied that in order to take a position. He stated that it was likely that the existing providers would oppose an effort to deregulate.. Mr. Parker agreed that, given current trends in this field, it was his opinion that regulating Residential Treatment Centers was of questionable necessity.

Mr. Parker then addressed the topic of regulated Special Hospitals, which include special medical rehab, special psychiatric, pediatric, and chronic care. Mr. Parker noted that applications for these facilities are relatively rare. Ms. Cooper questioned whether the reason for this might relate to reimbursement, to which Mr. Parker noted that most acute inpatient rehabilitation patients, the most common form of special hospital patient, are Medicare.

Mr. Sergent asked the group for reasons why these services were regulated when regulation wasn't necessary. In response, Mr. Parker stated that there had been explosive in this long-term care hospitals (in Maryland, chronic care) and, to a less extent, in acute rehab, over the last 20 years in some non-CON states. This was not seen in Maryland

Ms. Cooper then shifted the conversation back to the previous discussion, by asking about withdrawal management (detox) and if outpatient withdrawal management or rehabilitation is covered by CON? Mr. Parker answered by saying no, outpatient substance treatment was not governed by CON.

Ms. Cooper made the point that there should be a balance between access, fraud protection, and quality. Fraud, as the group has discussed before, had been an issue in Florida. Ms. Phillips noted that the rigorous review of quality and data was still in infancy stage right now.

Ms. Hyatt asked whether the group would recommend deregulation of CON across the board? Mr. Parker responded by saying that the Commission would let this process play out and that aside from inpatient detox, the Commission hadn't taken a formal position on reducing the scope of CON regulation in recent years.

Mr. McCone confirmed that recommendations from the Task Force on this topic was a required part of Phase II.

Given available time, the topic of alignment between CON regulation and the Maryland payment model was discussed briefly, but the Task Force agreed sufficient time wasn't available to discuss fully, and Ms. Phillips directed the group to the next agenda item, lessons from other states.

CON Reform – Lessons from Other States Discussion

Mr. Daniel Carter from Ascendient Healthcare Advisors provided a brief history of CON reforms that had taken place in other states. Mr. Carter prefaced his comments by stating that any discussion of reform from other states was highly dependent on the current regulatory scheme in each state. Most states, Mr. Carter continued, had initiated CON reform for a handful of reasons, such as:

- External factors related to the impact of ACA and associated/expected responses.
- Internal factors like challenges from physicians or responses to specific issues, such as challenges in rural health care or behavioral health access issues.

Mr. Carter stated that reform efforts generally fall into three categories:

- What services were regulated
- How those services are regulated and planned
- The CON process itself, including pre-submission, application submission, limiting the review periods, limiting who may comment/oppose on the applications, limiting the appeal periods, discovery, or number of depositions.

Mr. Carter then provided several examples of CON reforms, including:

- Georgia passed a bill recently to define a microhospital and provide definitions with regard to what geographies might qualify for an exemption process for development of a microhospital.

- North Carolina now has provisions associated with hospitals that close in rural areas, including ability of applicants to apply to open a microhospital or operate a freestanding ED in lieu of the full-service acute care hospital.

- North Carolina also has loosened regulations and developed a more streamlined process for applicants proposing to operate psychiatric beds in lieu of acute care beds, or providers who want to convert hospital-based ORs to freestanding ORs.

- South Carolina has eliminated per se regulation for equipment such as PET and MRI, but capital threshold requirements still exist.

- Florida deregulated virtually all outpatient services many years ago largely due to growth in the senior population, which was driving increased demand. Florida was seeking to remove barriers for those that wanted to move patients from higher to lower cost settings.

Brian Ackerman from Ascendient then introduced himself and provided more specific examples of other states' CON modernization efforts in light of healthcare transformation, noting that given recency some of the outcomes/details were yet to be finalized.

- **Kentucky**:

  Rather than attempt to eliminate CON, Kentucky has focused on trying to understand how to embrace CON to drive systematic change in healthcare delivery, improve care coordination and ensure access for all. Mr. Ackerman provided a few specific examples of what Kentucky has done, including:

  - Established uniform review criteria related to participation in state-wide health information exchange and required documentation of a plan for treatment of indigent and underserved.
  - On the outpatient side, removed large outpatient centers, or hospitals without beds, from its SHP. These centers are considered hospitals without beds and include their own medical staff, primary care providers, operating rooms, imaging services, and 24-hour emergency department.

- Removed certain need methodologies from the SHP, including for ASFs.

- **Connecticut:**

  - Proposed to incorporate reviews of mergers/acquisitions into the CON process in an effort to ensure that mergers don't impact cost dramatically.
  - Recommended to limit/eliminate the majority of medical equipment requirements.
  - To assist with expediting decision timelines, proposed allowing the agency to hire subject matter experts as needed to assist with the preview process.

Ms. Phillips asks if any research has been done on Skilled Nursing Facilities (SNF), home health and hospice? Mr. Carter responded that there has been a trend among CON regulations in making it easier to shift toward lower cost of care. There was a balance between understanding that there needed to be some degree of control for SNF, assisted living, and home health, and improving the availability of these facilities to allow more patients to be treated in a lower cost setting.

Ms. Phillips discussed the need for a comprehensive literature review process to understand the impact of CON vs. non-CON in states across the country.

Interim Report Outline and Next Steps Discussion

Ms. Phillips initiated discussion of the interim report outline. Mr. McCone began the discussion by commenting on items included in the outline relative to Hospitals by stating that MHA strongly disagreed with the conclusion in #7, and would prefer instead that clear rules are established and followed rather than developing alternatives for CON project reviews. Relative to item #9, Mr. McCone disagreed with the use of the word "inadequate," preferring that the Task Force focus more on refining the community input process based on what makes the most sense relative to care transformation and CON.

Ms. Horton commented that it would be helpful if this group could review and/or reconfirm the process before any discussions of details. Ms. Steffen summarized the overall process stating that by December 2018 the group would deliver recommendations to the Committee chairs. Upon identifying problems during this current phase (Phase I), the staff would develop the draft interim report and share with the Task Force prior to the May 11th meeting. The May 11th meeting would be devoted to review of the report. The final interim report would be presented to the Commissioners at the May 17th meeting. The interim report would be submitted to the Committee Chairs shortly after the May meeting. Mr. Steffen stated that Phase II of the Task Force would commence in June.

Mr. Rosen suggested the articulation of some guiding principles for Phase II, stating that efforts in Phase II could be greatly enhanced if principles were in place. He also suggested having a matrix in place to guide decision making during Phase II. Mr. Rosen recalled that during similar efforts in 2005, the group had adopted a scorecard to keep track of details and that the same should be done for this process.

Ms. Horton agreed with the need for guiding principles. Mr. Sergent added that if the Task Force could agree on the purposes of CON, then each purpose could be tied with a principle, and problems could be related back to them.

Ms. Cooper raised the point that consumers want to know if CON had accomplished the correct goals such as quality, access, innovation, cost, and charity care. If CON isn't accomplishing this, Ms. Cooper wondered if the group should recommend an alternative?

Mr. Solberg stated that so far, the group had been in information gathering mode and would agree that going forward criteria for evaluating industry-based issues should be established. Mr. Steffen stated that the Commission should circulate those 2005 documents/principles.

Mr. Steffen agreed that principles should be established for Phase II but acknowledged that sufficient time was not available to include those within the interim report. Instead, those principles should be considered the first priority with the start of Phase II.

Mr. Parker noted that the current focus was setting an agenda for Phase II. The goal was to have well-articulated problems that could be focused on; however, much of the minutia should be excluded. The report should include problems that were identified as well as supporting information on why these problems must be addressed.

Mr. Solberg asked whether the Commission expected this group to adopt some form of the problem statements as final? Mr. Parker confirmed that was the goal and Mr. Steffen suggested that the Task Force should not attempt to reach full agreement on each problem statement, but to instead focus on determining if a broad consensus is in place for the problem statements.

Ms. Phillips thanked the Task Force for the day's discussion and concluded the meeting.

Draft **Meeting Summary**
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Friday, May 11, 2018
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance:
Frances Phillips, Co-Chair
Randolph Sergent, Co-Chair
Regina Bodnar
Ellen Cooper
Lou Grimmel
Elizabeth Hafey
Ann Horton
Andrea Hyatt (Phone)
Adam Kane (Phone)
Ben Lowentritt
Brett McCone
Michael O'Grady (Phone)
Barry Rosen
Andrew Solberg

MHCC Staff in Attendance:
Paul Parker
Ben Steffen
Suellen Wideman

Others in Attendance:
Brian Ackerman
Pat Cameron
Daniel Carter
Linda Cole
Peggy Funk
Marta Harting
Anne Langley
Patricia O'Connor
Dawn Seck
Shelley Steiner
Noson Weisbord

May 11, 2018 Task Force Meeting
Meeting Summary

Co-Chair Frances Phillips called the fifth meeting of the Task Force to order.

Adam Kane, Andrea Hyatt, and Mike O'Grady joined the meeting via phone.

Ms. Phillips asked for comments on the draft summary of the April 20, 2018 meeting. She asked for introductory remarks from Ben Steffen.

Mr. Steffen noted that this meeting would conclude Phase I of the study on modernizing CON regulation with the primary focus of the meeting being consideration of an interim study report. He asked that members of the Task Force provide any additional comments not presented at this meeting on the draft interim report by Monday, May 14. He stated that the draft report, with any revisions or other changes emerging from today's Task Force meeting would be considered by the Commission on Thursday, May 17, 2018 and would be submitted to the General Assembly Committee chairs by June 1. Phase II meeting dates will be distributed to the Task Force members in the near future. The Commission will be considering how to reconstitute the Task Force, which will probably involve some expansion, for the next phase.

Co-Chair Randolph Sergent noted that the Task Force was not required to endorse everything included in the document, but the goal is to ensure consensus that the items included in the report represent what had been discussed up to this point in the process.

Paul Parker took the lead in review of the draft by the Task Force by asking for questions, comments, and discussion section by section.

Report Section - Introduction

A few individuals provided edits to the Task Force roster. Adam Kane noted that he only represented HSCRC and did not officially represent continuing care retirement communities. Ann Horton corrected the spelling of her name and the name of her employer. Ms. Horton also stated that she should be identified as representing the Maryland National Capital Home Care Association.

Report Section - Overview of Common Themes: Need for CON/Benefits and Costs

Dr. Ben Lowentritt, Mr. Parker and Mr. Sergent discussed the references to two categories of facility commenters, on page six, which the report stated deviated from the general pattern of comments from other facility categories. Mr. Parker stated that the two categories were the ambulatory surgical facilities, where a number of commenters recommended elimination of CON regulation, and hospices, where the comments uniformly supported maintenance of CON regulation with few changes. This contrasted with the comments submitted by other types of regulated facilities, which tended to support maintenance of CON regulation in some form but with substantive changes in scope and process. Mr. Sergent suggested making changes to clarify this characterization.

Mr. McCone commented about page seven's reference to hospitals and total cost of care in the second paragraph. He noted that the content was fine but suggested changing the wording from "with respect to hospitals" to "with respect to health care services."

Mr. Sergent asked, how would non-hospital CONs be affected by the all payer model? For example, if there was a CON for a nursing home, would it be expected to be reviewed relative to the all payer model?

Barry Rosen stated that a CON program that regulated hospital bed supply could be assisting in the control of costs because HSCRC may have lower capital costs that need to be accounted for in global budgets. In contrast, for example, if there was a proliferation of hospices, the cost of care might go down. On the one hand, CON helps to control some costs. On the other, CON might be limiting the ability to have a positive impact on costs.

Mr. Kane clarified that HSCRC did not regulate hospital charges on a line-item basis by facility type under the planned total cost of care model.

Regina Bodnar reminded the Task Force that more hospice providers did not increase hospice utilization, which is evident in Baltimore as the city has the highest number of providers and the lowest hospice use rate in the state. The theory that more providers may increase utilization and decrease cost has not been proven.

Mr. Steffen stated that the idea of broadening CON was good. CON should be viewed as a tool, but how it was being deployed relative to total cost of care is going to be different by sector. The idea that CON was going to constrain was probably too narrow a framework. In some instances, it may enable while in others it may constrain.

Mr. Sergent commented that with hospitals, there is a technical "need" for review. Mr. Steffen commented that the issue was the word "need." He wondered if driving things to the most cost-effective venue was considered a need. Maybe there should be new ways of looking at CON as more than just population need or need for capacity. Maybe need should be redefined based on cost effectiveness.

Andrew Solberg commented on the benefits section. He suggested that the report needed to state that CON regulation is the primary mechanism through which the Commission can implement policies it has adopted for influencing change in the institutional sector of the health care delivery system.

Mr. Sergent stated that it didn't matter if CON was a tool if it was not a good tool. Ms. Phillips reflected on Mr. Solberg's remarks, saying that CON was a mechanism, not classified as good or bad, but only wanted to note it was a tool.

Mr. Rosen gave an example that argued for "opening up" CON. If care could be more efficient in an ambulatory setting rather than a hospital, then allowing for deregulation of ASCs that have two operating rooms or even larger would help the all payer model.

Mr. Kane asked Mr. Parker and Mr. Steffen if HSCRC commented on CON applications involving non-hospital projects? Mr. Parker responded that it did not. Mr. McCone stated that the implication was that for HSCRC to be of increased value then it would be necessary to expand its

review reach. It was then noted that over the last five years, HSCRC had reviewed hospice projects in certain instances and that does seem to be the direction things are heading.

Mr. Parker noted that MHCC has assumed that an all payer model addressing the total cost of care would change the collaborative relationship that has been the norm between MHCC and HSCRC. In the past year there had been a nursing home applicant considering an alternative payment model involving partnering with hospitals. In that instance the commission asked HSCRC to review the materials that applicant had provided. The Commission has considered collaborative relationships between hospitals and nursing homes aimed at reducing the total cost of care as something that the State Health Plan (SHP) might incorporate as an innovation justifying more flexibility with respect to bed need limitations that would otherwise apply in a particular jurisdiction.

Mr. McCone commented that, with controlling the total cost of care as a framework for the All Payer Model, an administrative process for non-hospital applications that involve a relationship with hospitals would be needed.

As discussion of this section was concluding, Mr. Parker stated that he would remove the wording relating to "pure market forces" given the existence of hospital rate regulation as an obvious limitation on this concept.

Ms. Phillips then recapped the main points discussed so far:

1. Change the first statement regarding "all payer system" to "health care services"
2. Capture the technical understanding of the redundancy between MHCC and HSCRC
3. Characterize CON as a policy lever
4. Remove reference to pure market forces

Ms. Phillips transitioned conversation to the Scope and Role Section.

Report Section - Overview of Common Themes: Scope and Role of CON Regulation

Mr. Parker noted that many comments were received regarding the need to alter the scope of CON regulation in various ways, with a particular emphasis on eliminating or modifying the use of a capital expenditure threshold. For hospitals, he stated that it was important to think about how changing the threshold would be accomplished because it has played a different role in hospital CON regulation than in the non-hospital sector. Changes for non-hospital facilities would be simpler.

Mr. McCone commented that the second portion of the second paragraph in the scope and role section on page eight should be removed given that it started to provide a solution rather than just identifying problem statements. The third sentence of the second paragraph of this section that begins with "one alternative concept" should be removed.

Mr. Rosen stated that that sentence may just need to be rephrased as a problem. Mr. McCone reminded the group that two paragraphs later, the point was addressed regarding duplication.

Report Section – Overview of Common Themes: State Health Plan

Mr. Solberg pointed out that on the bottom paragraph of page nine of the draft report, the problem was that the SHP standards didn't address documented problems. Rather, they represented things that the staff believed were good ideas. Going forward, the Commission should identify the problems and then consider which SHP standard(s) is needed to address the problem.

Mr. McCone made a point that on the second paragraph of the SHP section, it was not just a hospital payment model. Also, regarding the third paragraph about consolidation, he was unsure if the group had sufficient discussion on this topic.

To Mr. McCone's question, Mr. Steffen answered that the group had two different conversations related to the impact on consolidation, as well as innovation, but those items were not discussed in depth.

Commissioner O'Grady also stated that the topic of consolidation was brought up a few meetings ago and the discussion related to incentives being in place for consolidation, but that consolidation was also criticized.

Dr. Lowentritt commented that he was struck by the statement that consolidation stifles innovation. In his view, the two phenomena are not mutually exclusive, so he recommended that innovation and consolidation should be addressed as two separate concerns. Ms. Philips stated that the consensus within the group was that these topics were discussed, but there was not consensus on their interrelationship, as described in the draft.

Mr. Sergent and Dr. Lowentritt commented that consolidation should not be characterized as a blanket negative. Unintended consequences can sometimes be positive and sometimes negative.

Report Section – Overview of Common Themes: Project Review and Post Project Review

Mr. Solberg suggested adding another issue to the post project review process. Why did projects have to undergo a full review by MHCC if they are not in a competitive review? There ought to be classes of projects that don't have to go to through a full Commission review Mr. Sergent suggested adding a bullet point to address this issue.

Report Section – Problem Statements Section

Mr. McCone expressed some concern about the problem statement related to community input, stating that anybody could write a letter or try to obtain interested party status in any CON application review. He believed that there were opportunities for substantive input, but questioned how far that element of the review process needs to go - where does it end? Ms. Phillips suggested using "underdeveloped" instead of "inadequate." Mr. Solberg also suggested softer language, using "might be", as there was no evidence that the current process isn't sufficient for many if not most project reviews. Mr. Steffen argued that the statement should be framed to reflect that the Task Force is anticipating potential problems, not only looking at problems historically.

Mr. Grimmel commented that the line was being blurred between the All Payer system and total cost of care. HSCRC only controlled 60 percent of costs, what about the other 40 percent? CON might be able to help address the 40 percent. Mr. Grimmel proposed that when a hospital discharges a patient to a nursing home, the nursing home is held accountable for readmission. The same should be true for hospice and home health agencies. Dr. Lowentritt stated that problem statement eight under nursing homes identified the problem, but Mr. Grimmel was providing a solution to the problem. Mr. Grimmel argued that this is, in fact, a problem and that nursing homes not being held accountable for readmission rates is a problem that we need to articulate.

Ms. Phillips asked, in response, how that was a CON problem? Could that point be put under problem statement five under section B or reframed and put under the scope section?

Mr. Grimmel agreed to changes in the wording in the last problem statement under section B that the CON program and the SHP did not support the development of innovative models. He noted that hospitals had an exemption for post-acute care units and CCRCs had an exemption for CCF beds, so precedents had been set in these instances.

Mr. Rosen stated that this was a broader issue as there are now "siloes" between assisted living, nursing home, home health, and hospice, which is an unintended consequence of how CON regulation is structured.

Ms. Phillips summarized the conversation on this section:

1. Augment the last bullet related to nursing homes
2. Add to the discussion of the scope of CON regulation the problem of separated health care facility "siloes" hindering the development of more integrated referral handoffs between acute and sub-acute providers and different types of sub-acute providers.

Ms. Phillips transitioned discussion to next steps and Phase Two of the study.

Phase II/Next Steps

Mr. Steffen stated that the draft report would be revised over the next few days and would then be presented to the Commission. After approval by the Commission, the report would be made available to the Chairs and available for public comment. Comments would be collected over the next three to four weeks, which would become the starting point for Phase II. Phase II would begin in June and continue through October, with a report to the Commissioners in November. It will be a tight timeline, but it is achievable. Additionally, the Task Force would probably add a couple of representatives from other organizations, with a twenty-member maximum.

Mr. McCone noted that public comments or a public hearing would be important in the process.

Mr. Steffen stated that now was also the time to think about the guiding principles. Those that were used in 2005 would be shared and other thoughts were welcomed as well. The guiding principles would be a topic at the next Task Force meeting. Mr. Grimmel commented that the 2005 principles were fine as a baseline but would need to be modified for the realities of 2018.

Mr. Steffen thought that the 2005 principles were fairly broad and would still apply but needed to be more specific as this group would want more guidance in evaluating modernization ideas and making "concrete" recommendations.

Mr. McCone asked how recommendations that are provided during Phase II would be reviewed? Mr. Steffen responded that the Task Force could be the first step in vetting the suggestions and that the Commission would also make some decisions regarding if direct responses are necessary. It was also noted that if certain items sounded promising but required additional detailed staff analysis, then the Task Force might be unable to make a final decision on those items in December.

Appendix G

Task Force members also reviewed and discussed information provided by staff on the time required to complete CON application reviews. Mr. Parker outlined the elapsed time for the last 49 final actions or docketed application withdrawals at MHCC, noting the differences seen in average and median review times for contested cases and uncontested cases. He opined that part of the problem in the excessive average and median times taken in contested reviews was the failure to effectively manage the two tracks created by the "triage" approach used by staff. While ensuring that most simple and uncontested project reviews get completed more quickly, the longer time frames for review of larger, more complicated, and contested reviews continue to have too much "dead time" occurring, as short-term work to process the simpler projects fills up staff time. The process itself creates time line expectations that require more rigorous adjustment of priorities as the work load changes.

Closing

Mr. Parker thanked Ascendient and Mr. Sergent for the roles they played in drafting the report. Mr. Sergent thanked the staff and Task Force for their diligent work and input. Ms. Phillips echoed thanks and opened up the floor for the audience to ask any questions.

Anne Langley made note of the fact that there was a section in the viability criterion about the community[1] that wasn't typically used, and she wondered if that was a way to get more community input where it was relevant.

Ms. Langley was thanked for her suggestion and the meeting was then concluded.

[1] Ms. Langley is referring to COMAR 10.24.01.08G(3)(d) "Viability of the Proposal. The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project."

Appendix D

Comment Guide

COMMENT GUIDANCE – HOSPITAL
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's adoption of global budgets for hospitals, its commitment to achieve the goals of the Triple Aim, and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry.

Need for CON Regulation

Which of these options best fits your view of hospital CON regulation?

- ☐ CON regulation of hospital capital projects should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13 to 15.]

- ☐ CON regulation of hospital capital projects should be reformed.

- ☐ CON regulation of hospital capital projects should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on Hospital Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among hospitals?

2. Does CON regulation impose substantial barriers to market entry for new hospitals or new hospital services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

3. How does CON regulation stifle innovation in the delivery of hospital services under the current Maryland regulatory scheme in which hospital rate-setting plays such a pivotal role?

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish or relocate a hospital, expand bed capacity or operating room capacity at ta hospital, introduce certain services at a hospital, or undertake capital projects that exceed a specified expenditure threshold. For a

*more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at: http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there hospital projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there hospital projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

6. Should the ability of competing hospitals or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated?Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?
7. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for hospital facilities and services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

9. Do State Health Plan regulations focus attention on the most important aspects of hospital projects? Please provide specific recommendations if you believe that the regulations miss the mark.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review
Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

12. If you believe that CON regulation of hospital capital projects should be eliminated, what, if any, regulatory framework should govern hospital capital projects?

13. What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of hospital licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain hospital facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care? Are there ways (other than those touched on in earlier questions) in which the regulation of hospital charges could be adapted as a substitute for CON regulation?

The Impact of CON Regulation on Hospital Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing hospitals and new market entrants? If so, please provide detailed recommendations.

16. Should Maryland shift its regulatory focus to regulation of hospital and health systems merger and consolidation activity to preserve and strengthen competition for hospital services?

Scope of CON Regulation

17. Should the scope of hospital CON regulation be more closely aligned with the impact of hospital projects on charges?
    A. Should the use of a capital expenditure threshold in hospital CON regulation be eliminated? For example, should hospital capital projects or certain types of hospital project only require a CON if the hospital seeks an increase in its global budget to cover project-related capital cost (depreciation, interest, and amortization) increases? Alternatively, should CON

regulation be based on the overall impact of projects on hospital revenues (related to coverage of both capital and operating expenses, which could increase substantially even for low cost projects if new services are being introduced?)

B. Should Maryland's system of hospital rate regulation include capital spending growth targets or capacity growth targets that shape the scope of CON regulation? If so, how would this work? For example, should CON regulation be redesigned to move away from single project review(s) for a multiple hospital system to a broader process of reviewing systems resource development needs and priorities? Such a process

C. could resemble a periodic budget planning process with approval of a capital spending plan that incorporates a set of capital projects for a given budget period.

18. Should MHCC be given more flexibility in choosing which hospital projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the hospital to undergo CON review.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

20. Are there specific steps that can be eliminated?

21. Should post-CON approval processes be changed to accommodate easier project modifications?

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

23. Would greater use of technology including the submission of automated and form-based applications ion improve the application submission process?

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

24. Are there areas of regulatory duplication in the hospital capital funding process that can be streamlined between HSCRC and MHCC, and between MHCC and the MDH?

25. Are there other areas of duplication among the three agencies that could benefit from streamlining?

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry.

You have the option of responding to all or only a subset of questions. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

COMMENT GUIDANCE – NURSING HOME
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of nursing home CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of nursing home CON regulation?

- ☐ CON regulation of nursing home capital projects should be eliminated. *Note: If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 to 13.*

- ☐ CON regulation of nursing home capital projects should be reformed.

- ☐ CON regulation of nursing home capital projects should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on Nursing Home Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among nursing homes?

2. Does CON regulation impose substantial barriers to market entry for new nursing homes or new nursing home services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

3. How does CON regulation stifle innovation in the delivery of nursing home services under the current Maryland regulatory scheme?

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[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish or relocate a nursing home, expand bed capacity at a nursing home, or undertake capital projects that exceed a specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there nursing home projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there nursing home projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

6. Should the ability of competing nursing homes or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

7. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for nursing home facilities and services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

9. Do State Health Plan regulations focus attention on the most important aspects of nursing home projects? Please provide specific recommendations if you believe that the current regulations miss the mark.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in

the development process for State Health Plan regulations, please provide specific recommendations.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

12. If you believe that CON regulation of nursing home capital projects should be eliminated, what, if any, regulatory framework should govern nursing home capital projects?

13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of nursing home licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain nursing home facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The Impact of CON Regulation on Nursing Home Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing nursing homes and new market entrants? If so, please provide detailed recommendations.

15. Should Maryland shift its regulatory focus to regulation of nursing home merger and consolidation activity to preserve and strengthen competition for nursing home services?

The Impact of CON Regulation on Nursing Home Access to Care and Quality

16. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
    Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

Scope of CON Regulation

17. Should the use of a capital expenditure threshold in nursing home CON regulation be eliminated?

18. Should MHCC be given more flexibility in choosing which nursing home projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the nursing home to undergo CON review.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

20. Are there specific steps that can be eliminated?

21. Should post-CON approval processes be changed to accommodate easier project modifications?

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

23. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Duplication of Responsibilities by MHCC and MDH

24. Are there areas of regulatory duplication in nursing home regulation that can be streamlined between MHCC and MDH?

Thank you for your responses.

COMMENT GUIDANCE – HOME HEALTH AGENCIES
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of home health agency CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of nursing home CON regulation?

- ☐ CON regulation of home health agencies should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

- ☐ CON regulation of home health agencies should be reformed.

- ☐ CON regulation of home health agencies should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on Home Health Agency Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among home health agencies?

2. Does CON regulation impose substantial barriers to market entry for new home health agencies or expansion of home health agency service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

3. How does CON regulation stifle innovation in the delivery of home health agency services under the current Maryland regulatory scheme?

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

4. Outline the benefits of CON given that home health services do not require major capital investment, do not induce unneeded demand, are not high costs and do not involve advanced or emerging medical technologies.

Scope of CON Regulation

*Generally, Maryland Health Care Commission approval is required to establish a home health agency or expand the service area of an existing home health agency into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at: http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

5. Should the scope of CON regulation be changed?
   A. Are there home health agency projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there home health agency projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

7. Should the ability of competing home health agencies or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for home health agencies provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

[2] Under Maryland CON law, home health agencies are classified as "health care facilities."

10. Do State Health Plan regulations focus attention on the most important aspects of home health agency projects? Please provide specific recommendations if you believe that the regulations miss the mark.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of home health agencies should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of home health agency licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that home health agencies are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The Impact of CON Regulation on Home Health Agency Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing home health agencies and new market entrants? If so, please provide detailed recommendations.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of home health agencies to preserve and strengthen competition for home health agency services?

The Impact of CON Regulation on Home Health Agency Access to Care and Quality

1. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
   Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

Scope of CON Regulation

2. Should MHCC be given more flexibility in choosing which home health agency projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the home health agency to undergo CON review.

3. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

4. Are there specific steps that can be eliminated?

5. Should post-CON approval processes be changed to accommodate easier project modifications?

6. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

7. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Duplication of Responsibilities by MHCC and MDH

8. Are there areas of regulatory duplication in home health agency regulation that can be streamlined between MHCC and MDH?

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry.

COMMENT GUIDANCE – GENERAL HOSPICE SERVICES
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of general hospice CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of general hospice CON regulation?

- ☐ CON regulation of general hospices should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]
- ☐ CON regulation of general hospice services should be reformed.
- ☐ CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?
2. Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?
3. How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

4. Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a general hospice, increase the bed capacity (general inpatient hospice care) of a general hospice, or expand the service area of an existing general hospice into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

5. Should the scope of CON regulation be changed?
   A. Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

7. Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

[2] Under Maryland CON law, home health agencies are classified as "health care facilities."

10. Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the regulations miss the mark.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The Impact of CON Regulation on General Hospice Program Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?

The Impact of CON Regulation on General Hospice Access to Care and Quality

17. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

Scope of CON Regulation

18. Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

20. Are there specific steps that can be eliminated?

21. Should post-CON approval processes be changed to accommodate easier project modifications?

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

23. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Duplication of Responsibilities by MHCC and MDH

24. Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?

Thank you for your responses.

COMMENT GUIDANCE – FREESTANDING AMBULATORY SURGICAL FACILITIES (FASFs)
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of FASF CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of FASF CON regulation?

- ☐ CON regulation of FASFs should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]
- ☐ CON regulation of FASFs should be reformed.
- ☐ CON regulation of FASFs should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on FASFs Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among FASFs?
2. Does CON regulation impose substantial barriers to market entry for new FASFs or expansion of FASFs? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?
3. How does CON regulation stifle innovation in the delivery of ambulatory surgical services under the current Maryland regulatory scheme?

Scope of CON Regulation

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

Generally, Maryland Health Care Commission approval is required to establish an FASF, which is an outpatient surgical center with two or more sterile operating rooms, to relocate an FASF, to expand the operating room capacity of an FASF, or to undertake a capital expenditure that exceeds a specified expenditure threshold.[2] For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there FASF pojects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there FASF projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

6. Should the ability of competing FASFs or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

7. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for FASFs provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

9. Do State Health Plan regulations focus attention on the most important aspects of FASF projects? Please provide specific recommendations if you believe that the regulations miss the mark.

[2] Most outpatient surgical centers established in Maryland have no more than one sterile operating room and were not required to obtain CON approval for their establishment. Only a determination of coverage issued by MHCC staff is required for such centers, which are called "physician outpatient surgical centers" in Maryland.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation

12. If you believe that CON regulation of FASFs should be eliminated, what, if any, regulatory framework should govern establishment, relocation, and expansion of FASFs?

13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of FASF licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that FASFs are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The Impact of CON Regulation on FASF Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing FASFs and new market entrants? If so, please provide detailed recommendations.

15. Should Maryland shift its regulatory focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition for these services?

Scope of CON Regulation

16. Should the use of a capital expenditure threshold in FASF CON regulation be eliminated?

17. Should MHCC be given more flexibility in choosing which FASF projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider

staff's recommendation not to require CON approval or, based on significant project impact, to require the FASF project to undergo CON review.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

19. Are there specific steps that can be eliminated?

20. Should post-CON approval processes be changed to accommodate easier project modifications?

21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

22. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Duplication of Responsibilities by MHCC and MDH

23. Are there areas of regulatory duplication in FASF regulation that can be streamlined between MHCC and MDH?

Thank you for your responses.

COMMENT GUIDANCE
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's adoption of global budgets for hospitals, its commitment to achieve the goals of the Triple Aim, and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of hospital CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of health care facilities CON regulation?

- ☐ CON regulation of hospital capital projects should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13 to 15.]

- ☐ CON regulation of hospital capital projects should be reformed.

- ☐ CON regulation of hospital capital projects should, in general, be maintained in its current form. Please provide a brief explanation of this position.

ISSUES/PROBLEMS

The Impact of CON Regulation on Hospital Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among health care facilities?

2. Does CON regulation impose substantial barriers to market entry for new health care facilities or new health carel services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

3. How does CON regulation stifle innovation in the delivery of health care services under the current Maryland regulatory scheme?

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish or relocate a health care facility, expand bed capacity or operating room capacity at health care facilitiesl, introduce certain services at a health care facility, or undertake capital projects that exceed a

specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there health care facility projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there health care facility projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

6. Should the ability of competing health care facilities or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

7. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for health care facility and service projects provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

9. Do State Health Plan regulations focus attention on the most important aspects of health care facility projects? Please provide specific recommendations if you believe that the regulations miss the mark.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review
Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

12. If you believe that CON regulation of health care facility capital projects should be eliminated, what, if any, regulatory framework should govern health care facility capital projects?

13. What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of health care facility licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain health care facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care? Are there ways (other than those touched on in earlier questions) in which the regulation of hospital charges could be adapted as a substitute for CON regulation?

The Impact of CON Regulation on Hospital Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing health care facilities and new market entrants? If so, please provide detailed recommendations.

16. Should Maryland shift its regulatory focus to regulation of health care facility and health systems merger and consolidation activity to preserve and strengthen competition for hospital services?

Scope of CON Regulation

17. Should MHCC be given more flexibility in choosing which health care facility projects require approval and which can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending and the pattern of service delivery, and that is based on the proposals received in a given time period.

The Commission could consider and adopt staff's recommendation not to require CON approval or, based on significant project impact, require the health care facility to undergo CON review.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

19. Are there specific steps that can be eliminated?

20. Should post-CON approval processes be changed to accommodate easier project modifications?

21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

22. Would greater use of technology including the submission of automated and form-based applications ion improve the application submission process?

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

23. Are there areas of regulatory duplication in health care facility regulatory processes that can be streamlined between HSCRC, MHCC, and MDH?

24. Are there other areas of duplication among the three agencies that could benefit from streamlining?

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry.

Appendix E

Comments on CON Modernization

Anne Arundel Medical Center

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askAAMC.org

January 24, 2018

Paul Parker
Director, Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
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paul.parker@maryland.gov

RE: MHCC CON Study, 2017-2018

Dear Paul:

In response to the request dated November 17, 2017 for input on the efforts of the Maryland Health Care Commission to "achieve the goals of the Triple Aim and to bring health care spending under a total cost of care model," Anne Arundel Medical Center is pleased to provide these comments on the 25 questions you posed. Also, please be aware that our organization is an active participant in the Maryland Hospital Association's Certificate of Need (CON) and State Health Plan Work group. As such, we are largely in support of the position paper and responses they are providing on behalf of Maryland's hospitals and health systems.

Need for CON Regulation

Which of these options best fits your view of hospital CON regulation?

a. CON regulation of hospital capital projects should be eliminated. (If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13 to 15).

b. CON regulation of hospital capital projects should be reformed.

c. CON regulation of hospital capital projects should, in general, be maintained in its current form.

b. The best option is the one that allows CON regulation to be aligned with the new payment model, Global Budget Revenue (GBR), that was implemented in 2014 and the next version, which will be Total Cost of Care (TCOC) in 2019. What would be valued is a CON process that preserves the principles of ensuring adequate access to high quality, low cost hospitals and health care related services that are currently regulated. Another important design principle is flexibility with incentives for innovation.

Projects that are being reviewed only because the capital threshold has been exceeded (i.e. the current the capital threshold of $11M) should qualify for a modified, more efficient process.

The Impact of CON Regulation on Hospital Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among hospitals?

Hospitals are already intensely competing, albeit more so in some markets than others. The competition is not limited to other hospitals. Health systems can operate several or all pieces of the continuum of care and therefore, compete with post-acute and non-acute providers. Standalone hospitals compete with other providers. In some instances, providers of unregulated services such as urgent care centers, freestanding radiation centers and freestanding surgery centers, create an uneven playing field for hospitals as the barriers to entry are lower and other regulations and restrictions are not as stringent. Competition to provide high quality, low cost and accessible health care can benefit Maryland's communities. Likewise, encouraging innovation by incenting vertical and clinical integration via the regulatory channels of CON, exemption from CON and oversight is a good idea. As a result of competition, an environment where a health system is growing and developing in a way that aligns with the attributes of a TCOC environment versus being stifled by regulatory barrier, should be encouraged and supported.

2. Does CON regulation impose substantial barriers to market entry for new hospitals or new hospital services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

Yes, CON regulation imposes substantial barriers. The focus and priority should be on having sufficient barriers to prevent TCOC from increasing due to new, for-profit entrants in the unregulated environment. Competition usually chases high margins. Given the tight constraints on hospital margins, and the sufficient (if not excess) capacity in some markets, we are unlikely to see new hospitals. However, sometimes these barriers also present formidable challenges to providing accessible, needed health care, as is the case in bringing more inpatient mental health care to a region. There are some critical needs as identified by the local community health needs assessments (CHNA). Some of these needs can only be met by adding services. If the CON regulatory process poses a barrier to adding these services versus creating access, regulation of these services should be evaluated. An example of one service would be mental health services. If a CHNA has identified mental health as a top priority, the MHCC should consider deregulating the service from CON. Need has been proven and the community deserves access.

3. How does CON regulation stifle innovation in the delivery of hospital services under the current Maryland regulatory scheme in which hospital rate-setting plays such a pivotal role?

The CON process is too rigid, too cumbersome and too slow. Hospitals are not afraid of innovation. Indeed, they continually investigate ways to be better, safer, more efficient and less costly. Regulation and innovation should not be mutually exclusive.

4. Should the scope of CON regulation be changed?
   a. Are there hospital projects that require approval by the Maryland Health Care Commission that should be deregulated?

There should be reconsideration of the capital threshold requirement for a CON. Hospitals will not undertake projects if they did not have the capital for them. They also would not avoid projects that are needed by the community because a CON is required. It's less about de-regulation and more about incentives to change behavior that align with the goals of TCOC model and the triple aim. The goal should be reducing unnecessary utilization and providing the right care in the right setting at the right cost.

   b. Are there hospital projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

There should be exemptions from CON but still requiring quality oversight of some projects such as urgent care.

<u>The Project Review Process</u>

5. What aspects of the project review process are most in need of reform?

Adherence to timelines. Timelines are too often not followed. This leads to longer decision times, higher expenses and greater frustration.
Subject matter experts are necessary to evaluate some specialty projects.
In addition, some aspects of the project review process that tend to slow the process down are:

- ***Project modifications (perhaps criteria for modifications can be revaluated and/or streamlined)***
- ***Completeness questions (subject matter experts could be a valuable resource) – perhaps narrowing or focusing the scope of the completeness questions.***
- ***HSCRC review of financial feasibility and viability (could be earlier in the process)***
- ***The role of interested parties (they are incentivized to slow down the process)***
- ***Ensure that are at least 2 reviewers well acquainted with or assigned to the project (not relying on one who may have limited knowledge of the subject or who may have schedule conflicts)***
- ***The backlog of applications (give priority to large scope projects, outsourcing smaller scope projects to experts, consultants with specified timeframes for review completion)***

6. Should the ability of competing hospitals or other types of providers to formally oppose and appeal decisions on projects be more limited?

Yes. Interested parties may be restricted on certain projects such as a hospital modernizing with its own capital, in its own service area and not asking for rates. Interested parties should demonstrate adverse impact first, acting as a threshold standard early on in the CON process, not during the project.

7. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12)

Yes, but they are not adhered to and there should be shorter time frames for smaller scope projects.

<u>The State Health Plan for Facilities and Services</u>

8. In general, do State Health Plan regulations for hospital facilities and services provide adequate and appropriate guidance for the Commission's decision-making?

The regulations are outdated in some cases, and do not reflect the current environment of the waiver demonstration project, the Affordable Care Act, and the potential new model (ie TCOC, Waiver 2.0). For example, the assessment of need is based on retrospective and historical patterns of utilization under a fee-for-service model versus a forward thinking, predictive analysis under a new payment model (i.e. value-based, utilization avoidance of high cost settings of care).

One of the older chapters in the SHP is for psychiatric services (COMAR 10.24.07). With the exception of a minor modification to the occupancy standard in 2013, the chapter has not been updated in over 20 years. Psychiatric services are one of the most critically needed services in our state.

What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

<u>Chief strengths</u> – largely open and transparent, fair

<u>Chief weaknesses</u> – cumbersome, outdated, "old world of health care" thinking, not in alignment with new reimbursement models, consumer preferences

9. Do State Health Plan regulations focus attention on the most important aspects of hospital projects? Please provide specific recommendations if you believe that the regulations miss the mark.

The policies should be critically evaluated in COMAR 10.24.10 – last approved 1/26/09. Currently, there are 19 standards plus service-specific standards. Each should be critically evaluated for relevance, and alignment with the new world order and environment. Specifically, on general standards:

Make these part of a "pre-application process" that must be reviewed before a CON is submitted:

- ***Charges – evaluate how helpful a list of representative charges is to consumers? Is there a better way to inform consumers about charges given the policies and practices of Maryland hospitals? Ask consumers what would be most helpful to make informed decisions. Study other states for best practices.***
- ***Charity care –this should not be a part of the CON process as it is regulated by the HSCRC and embedded in the all payor model.***
- ***Quality - appropriate to be considered as part of CON but coordinate with OHCQ, JCAHO, etc, other agencies.***

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

There should be more regular updates, not only when there is a project in the wings. Eliminate or critically evaluate the role of AELR, petitioning the State for changes – only after all avenues have been exhausted. Does the whole commission need to approve need methodology or definitions? Can this be a staff function (can the statute be changed to facilitate technical changes?)

11. Are these general criteria adequate and appropriate? ***See #9 above***

    Should other criteria be used?

    Should any of these criteria be eliminated or modified in some way?

<u>Alternatives to CON Regulation for Capital Project –</u>

12. If you believe that CON regulation of hospital capital projects should be eliminated, what, if any, regulatory framework should govern hospital capital projects?

No CON should be required for a project when there is no additional revenue being requested for capital or services.

13. What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?

It is unclear what exact modifications would be needed, but it would be necessary to have an oversight role for the HSCRC to evaluate and approve capital projects.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of hospital licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain hospital facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care? Are there ways (other than those touched on in earlier questions) in which the regulation of hospital charges could be adapted as a substitute for CON regulation?

Consider a streamlined, expedited process for low capital-intensive, non-hospital based settings of care such as home health, SNF, hospice, NICU, behavioral health and expansions of beds. CON would be necessary only in the case of a new hospital, new hospital-based regulated services, new market entrants that are UNAFFILIATED with existing systems or hospitals. Create a level playing field.

Impact of CON Regulation on Hospital Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing hospitals and new market entrants? If so, please provide detailed recommendations.

Incent health system and hospitals to add non-hospital sites of care. Spend less time and give less power to opposing and interested parties. If a health system is demonstrating good QBR performance, moderate margins under GBR, they should be entitled to an expedited process.

16. Should Maryland shift its regulatory focus to regulation of hospital and health systems merger and consolidation activity to preserve and strengthen competition for hospital services?

Isn't that the FTC's job? Of note is the recent Health Affairs article "The Challenging Transformation of Health Care Under Maryland's Global Budgets," December 19, 2017 (Galarraga & Pines). The authors included 3 suggestions, one of which was 'closely monitor hospital solvency and secure access to care through CON programs." Heed this advice. Evaluate the impact of market consolidation and lack of access due to hospital closures.

Scope of CON Regulation

17. Should the scope of hospital CON regulation be more closely aligned with the impact of hospital projects on charges?

    a. Should the use of a capital expenditure threshold in hospital CON regulation be eliminated? For example, should hospital capital projects or certain types of hospital project only require a CON if the hospital seeks an increase in its global budget to cover project-related capital cost (depreciation, interest and amortization) increases? Alternatively, should CON regulation be based on the overall impact of projects on hospital revenues (related to coverage of both capital and operating expenses, which could increase substantially even for low cost projects if new services are being introduced?)

No. It should not be eliminated but instead it should be revised waiving the threshold requirement if a hospital is not seeking an increase in its global budget.

    b. Should Maryland's system of hospital rate regulation include capital spending growth targets or capacity growth targets that shape the scope of CON regulation? If so, how would this work? For example, should CON regulation be redesigned to move away from single project review(s) for a multiple hospital system to a broader process of reviewing systems resource development needs and priorities? Such a process could resemble a periodic budget planning process with approval of a capital spending

plan that incorporates a set of capital projects for a given budget period.

No.

18. Should MHCC be given more flexibility in choosing which hospital projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the hospital to undergo CON review.

Yes. A pre-application process might be useful.
More staff resources are needed as well as subject matter experts (perhaps on a contract basis).

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

Establish criteria for eligible projects, adhere to timeframe, (maximum 150 days). See #14.

The Project Review Process

20. Are there specific steps that can be eliminated?

- ***Evaluate timeframe to docketing and other associated timeframes***
- ***Set limits on when project modifications can be made, site visits can be requested, when completeness questions must be finalized***
- ***Commissioners should be provided a list at each meeting of pending projects – both active and inactive and understand the status of the projects.***

21. Should post-CON approval processes be changed to accommodate easier project modifications?

Modifications should be streamlined if certain criteria are met. Can be a staff function.

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

See #14

23. Would greater use of technology including the submission of automated and form-based applications improve the application submission process?

Yes, automation would most likely improve the process

- ***Provide a scoring sheet that is automated that helps an applicant understand if the standards are being met before it is submitted.***
- ***Have available the potential and typical completeness questions in advance***

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

24. Are there areas of regulatory duplication in the hospital capital funding process that can be streamlined between HSCRC and MHCC, and between MHCC and the MDH?

There needs to be more coordination, not less.

25. Are there other areas of duplication among the three agencies that could benefit from streamlining?

See #24.

Thank you for the opportunity to participate in this important endeavor. We look forward to an improved process that helps us meet our mission: improving the health status of the people we serve.

Sincerely,

Paula S. Widerlite

Paula S. Widerlite
Chief Strategy Officer

cc: Brett McCone, Vice President, MHA

Bon Secours

January 15, 2018

Paul Parker
Director, Center for Health Care Facilities Planning & Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Mr. Parker:

On behalf of Bon Secours Baltimore Health System, we appreciate the opportunity to provide the Maryland Health Care Commission input on the potential reform of health planning and certificate of need (CON) programs. As outlined below, we recommend that the CON regulation of hospital capital projects be reformed to better align with the current healthcare landscape and the goals set forth in Maryland's new All Payer Model.

The Impact of CON Regulation on Hospital Competition and Innovation

The public and healthcare delivery system benefits from appropriate competition among hospitals. Generally, competition results in higher quality of services and lower costs. Additionally, it promotes innovation which results in advanced technologies and efficient methods of care delivery. Competition enables consumer choice and in conjunction with natural market forces, eliminates substandard services. The current CON program limits the abovementioned benefits through restrictive market entry.

In order to enhance competition, CON regulation should be reformed with consideration of deregulation where appropriate. However, a balance between state regulation and market forces should be maintained to achieve optimal performance in delivering and financing healthcare.

Although the aim is to control excessive capital investments that increase costs, CON regulation also limits investments in new medical technology. This is without necessity, as Maryland's financial structure functions as an effective method of cost containment.

Scope of CON Regulation

The scope of CON should be reformed to the extent that public need, cost effectiveness, and impact on smaller competing health systems are not negatively affected. There is opportunity to deregulate certain hospital projects and/or expand the categories of exemption review. Such projects should be identified and analyzed in the context of total healthcare spending, considering parity between HSCRC regulated and unregulated facilities. Furthermore, MHCC should study the potential impact of shifting the focus of CON regulation from capital expenditure thresholds to hospital revenues. To

maintain consistent with the aim of the All Payer Model, emphasis should include impact on operational expenditures as well.

Maryland's rate regulation should not include capital spending growth targets; such mandates could result in unintended consequences that contradict the goals of CON. Budgeting and planning are business decisions that should remain in the discretion of individual hospitals and health systems.

Project Review Process

The steps of the project review process should remain largely intact, including the letter of intent, completeness review, and the ability for interested and participating entities to comment. However the process should be streamlined to decrease the overall length of time to CON approval. This may be achieved in several ways such as simplifying the application form, reducing time cycles within individual steps, and adopting abbreviated reviews for specified projects.

Specifically, the application form should be re-evaluated and modified to only include the most pertinent information. Ideally, a condensed application should warrant a reduced timeline for completeness review. Moreover, the application process should be automated and posted online in real time. As a result, the cycle for commentary should also decrease. In terms of abbreviated review, MHCC should consider processes in states that have successfully implemented similar timelines for projects that are non-comparative or deemed to result in unsubstantial change.

As completion timelines vary by project, MHCC should maintain the flexibility in allowing for extension for good cause.

The State Health Plan for Facilities and Services

Overall, State Health Plan regulations for hospitals provide appropriate guidance for decision making. The strength in these regulations lie in the flexibility granted to MHCC to facilitate decision making on a case by case basis. On the other hand, improvements should be made to provide guidance that is more explicit, data driven, and consistent with current healthcare trends. For example, methodologies for volume capacity and criteria for CON review should align with population health efforts. Ultimately, examining need from a broader perspective also allows for a more comprehensive evaluation of CON projects.

When developing the State Health Plan, MHCC should increase efforts to solicit input from other industries.

Alternatives to CON Regulation for Capital Project

The benefits of CON, such as quality assurance can be achieved through alternative regulatory mechanisms and monitoring tools. MHCC should study the alternatives implemented by states

without CON, such as Pennsylvania and New Hampshire to understand the effectiveness of public reporting and expanded licensure requirements.

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

Charity and uncompensated care, as well as financial assistance policies are overseen by the HSCRC and therefore, it is unnecessary for the MHCC to duplicate regulation efforts in these areas.

Conclusion

In conclusion, CON regulation should be reformed to decrease the administrative burden on applicants, streamline the project review process, and better align with the evolving healthcare landscape. MHCC will benefit from utilizing other states' deregulation efforts and review processes as a model for CON reform. However, it is crucial for the state to consider the benefits of CON regulation and ensure that any modifications do not disproportionately affect smaller hospitals and providers.

We appreciate your consideration of our input and the agency's effort to enhance healthcare planning. Please reach out should you have further questions.

Sincerely,

Dr. Samuel L. Ross,
Chief Executive Officer

COMMENT GUIDANCE – HOSPITAL
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's adoption of global budgets for hospitals, its commitment to achieve the goals of the Triple Aim, and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of hospital CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of hospital CON regulation?

☐ CON regulation of hospital capital projects should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13 to 15.]

X CON regulation of hospital capital projects should be reformed.

☐ CON regulation of hospital capital projects should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on Hospital Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among hospitals?

   Carroll Hospital feels the CON process has served the state well in terms of ensuring quality and appropriate access to care and should continue to do so. Additionally, Carroll Hospital feels that the current infrastructure of hospitals and health systems in Maryland provide sufficient competition and scope of services, both general and specialty. While we view competition as essential and a driver of innovation and performance, under Maryland's payor system and the new CMS regulation that holds the state of Maryland and Maryland hospitals accountable for the total cost of care, the introduction of more service capacity that is likely to occur in the absence of a strong CON process, would not positively impact Maryland's ability to reach cost saving targets.

Carroll Hospital also believes patients in Maryland are well served by the high standards set forth by federal, licensing, regulatory and accrediting bodies including CMS and the Joint Commission as well as the numerous quality measures that are closely monitored and publically reported. Additionally, as they are challenged by increasingly stringent standards for improving the quality and experience of care and improving the overall health of populations, while reducing per capita costs of health care, hospitals continue to drive innovation that benefit their patients.

2. Does CON regulation impose substantial barriers to market entry for new hospitals or new hospital services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

   The schedule for submitting CONs is limiting. (More comments on these issues in the questions that follow.)

3. How does CON regulation stifle innovation in the delivery of hospital services under the current Maryland regulatory scheme in which hospital rate-setting plays such a pivotal role?

   While Carroll Hospital Health feels the CON process is essential and should stay in effect for services, especially those for open heart, in some cases, the CON regulation can stifle innovation in improving quality and the delivery of hospital services. In most cases, hospitals will not receive a rate adjustment for projects that improve the physical plant of a facility. We feel in these specific cases, much of the existing CON process unnecessarily prolongs projects most often designed to improve patient care, quality and safety. As hospital across the state look for "cost-effective approaches to meeting identified needs" LifeBridge Health feels that in some circumstances the CON process could be modified. In those isolated cases (covered in more detail below), licensing bodies can continue to adequately monitor quality.

Scope of CON Regulation

*Generally, Maryland Health Care Commission approval is required to establish or relocate a hospital, expand bed capacity or operating room capacity at ta hospital, introduce certain services at a hospital, or undertake capital projects that exceed a specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at: http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there hospital projects that require approval by the Maryland Health Care Commission that should be deregulated?

Carroll feels the CON process is a good one and should stay intact. Based on the premise stated above, however, LifeBridge Health would recommend deregulating or modifying the regulations for the following specific cases:

1) Renovation and replacement (new builds) projects that do not increase the physical bed count (over 10%), even if the cost exceeds the threshold established by the Maryland statute.

2) If you are going to keep the capital expenditure threshold, increase it to $16M.

3) For nursing homes that meet certain quality metrics (tbd), the addition of waiver beds should be modified to allow an increase of 20 or 20%; and the timeframe for adding those beds should be increased to every year, instead of every two years, again based on the facility meeting certain quality metrics.

B. Are there hospital projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

LifeBridge Health feels there should be a level playing field for hospitals and those offering ambulatory surgery services in free-standing facilities. If hospitals are required to submit a CON to increase surgical capacity, then free-standing ASCs should have to do the same, regardless of their size.

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

- **The schedule for CON review is somewhat restrictive. If you miss an application submission date, you have to wait at least six months to file a CON.**

- **Completeness questions traditionally add a significant amount of time to the process and involve substantial amount of time and resources by hospitals. The questions are most often unnecessarily detailed and often request an excessive volume of supporting documentation. That includes brochures, training manuals, etc. For example, when our most recent CON was filed, the Commission requested the entire volunteer training manual; promotional brochures and registration paperwork. That resulted in nearly 300 additional pages that needed to be copied, scanned and submitted. While we understand there will be additional questions or clarifications required, we do feel the Commission could ease the process and burden on hospitals by accepting a reference made to what's available and how it's used.**

Additionally, facilities have 10 business days to respond to the completeness questions, but while the Commission has similar time requirements for docketing; assigning a reviewer to complete CONs; or approving/reaching a decision on completed CONs, you do not always follow those timeline requirements. This significantly delays the progress of projects and has the potential to adversely impact capital costs, permitting, contracting, hiring and the health of a community. The Commission should have to be held to time requirements for processing CONs, for instance, no longer than 90 days. Or, if they do, the organization has some recourse to move forward with their project.

As an example, it has been more than a year since Carroll Hospital filed a CON for providing home-based hospice care in Baltimore City. It was presented in December 2016, docketed in July 2017 and a reviewer still has not been assigned to that application. While we understand that the Commission has experienced turnover, by any standards, for this and other important projects, more than 12 months is entirely too long to wait for a review and decision by the Commission.

6. Should the ability of competing hospitals or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Yes. We feel interested party comments should be limited to hospitals/providers physically located within a certain radius or your jurisdiction who provide the same care and should only be considered if the project has implications that adversely impact patient care or unreasonably limit patient choice.

7. Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

8. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)

   We would like the Commission to consider eliminating the requirement of submitting quarterly updates on the progress of construction projects. We feel that the construction schedule should suffice and that perhaps hospitals should only have to notify the Commission if the project completion date is prolonged by 60 or more days.

<u>The State Health Plan for Facilities and Services</u>

9. In general, do State Health Plan regulations for hospital facilities and services provide adequate and appropriate guidance for the Commission's decision-making? What are

the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

10. Do State Health Plan regulations focus attention on the most important aspects of hospital projects? Please provide specific recommendations if you believe that the regulations miss the mark,

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review
Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

    Carroll feels that much of this information is excessive and in some cases unknown and immaterial:

    Viability: Tables and financial information could be significantly pared down, especially the duplicative requests. Perhaps a brief business plan (1-2 pages) could be used.

    Impact on Others: This often is speculation by hospitals. Carroll Hospital questions what value this brings and if it should be considered at all in the CON process. As previously mentioned we feel competition is good and hospitals carefully consider every investment made, capital or otherwise, so it should not be the applying hospital's responsibility to explain how its project will impact others. Facilities should consider that there is competition for services and they should be able to freely invest in projects that most benefit patients and address safety and unmet needs, within the guidelines of the MHCC.

    Terms and Conditions of Previous CONs: This section in particular is one we feel could be removed altogether from the application. We feel the Commission should already know if the hospital has been compliant with its previous applications. Also, to ask for 17 years' worth of information seems disproportionate. Maybe the question could request hospitals to affirm

that it has been compliant with following CON guidelines and have submitted CONs appropriately. Or, significantly shorten the timeframe for which you're requesting information to no more than 24-36 months.

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

13. If you believe that CON regulation of hospital capital projects should be eliminated, what, if any, regulatory framework should govern hospital capital projects?

14. What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?

15. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of hospital licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain hospital facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care? Are there ways (other than those touched on in earlier questions) in which the regulation of hospital charges could be adapted as a substitute for CON regulation?

The Impact of CON Regulation on Hospital Competition and Innovation

16. Do you recommend changes in CON regulation to increase innovation in service delivery by existing hospitals and new market entrants? If so, please provide detailed recommendations.

17. Should Maryland shift its regulatory focus to regulation of hospital and health systems merger and consolidation activity to preserve and strengthen competition for hospital services?

Scope of CON Regulation

18. Should the scope of hospital CON regulation be more closely aligned with the impact of hospital projects on charges?
    A. Should the use of a capital expenditure threshold in hospital CON regulation be eliminated? For example, should hospital capital projects or certain types of hospital project only require a CON if the hospital seeks an increase in its global budget to cover project-related capital cost (depreciation, interest, and amortization) increases? Alternatively, should CON regulation be based on the overall impact of projects on hospital revenues (related to coverage of both capital and operating expenses, which could increase substantially even for low cost projects if new services are being introduced?)

B. Should Maryland's system of hospital rate regulation include capital spending growth targets or capacity growth targets that shape the scope of CON regulation? If so, how would this work? For example, should CON regulation be redesigned to move away from single project review(s) for a multiple hospital system to a broader process of reviewing systems resource development needs and priorities? Such a process could resemble a periodic budget planning process with approval of a capital spending plan that incorporates a set of capital projects for a given budget period.

No. LifeBridge Health and most hospitals and health systems have stringent budgeting processes already in place. We do not feel that the budgeting process should be expanded to include the Maryland Health Care Commission.

19. Should MHCC be given more flexibility in choosing which hospital projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the hospital to undergo CON review.

Carroll Hospital would prefer a more definitive approach any changes to the approval process, meaning specific changes should be made to the guidelines for what projects require a CON. We do feel strongly that hospitals and the MHCC should continue to have the flexibility in considering unique situations on a case by case basis via the existing determination process.

20. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

Yes. As outlined earlier, Carroll would fully support an abbreviated process for certain projects that includes a brief description of purpose, cost, funding, timeline and operational impact.

The Project Review Process

21. Are there specific steps that can be eliminated?
Yes, as partially outlined previously the Commission should consider:

- **Eliminating the LOI requirement.**
- **Revising or eliminating the schedule for CON submission.**
- **Limiting "Completeness Questions"**
- **Eliminating the requirement to deliver five hard copies of the application and ALL attachments to the Commission. Perhaps the Commission could go paperless and require only one hard copy.**
- **Eliminating the Quarterly Status Reporting requirement for open CON projects.**
- **Eliminating the requirement of hospitals having to send acknowledgment of receipt of the Commission's First Use Approval.**

22. Should post-CON approval processes be changed to accommodate easier project modifications?

    The modification process could be simplified and the thresholds modified so that fewer projects need to go through the official modification process. The Commission could consider changing the threshold to a fixed percentage of over the original total capital costs. Five percent may be a good target.

23. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

    Yes. See previous comments.

24. Would greater use of technology including the submission of automated and form-based applications ion improve the application submission process?

    Yes, see previous comments. Questions 22.

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

25. Are there areas of regulatory duplication in the hospital capital funding process that can be streamlined between HSCRC and MHCC, and between MHCC and the MDH?

26. Are there other areas of duplication among the three agencies that could benefit from streamlining?

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry.

Maryland
Hospital Association

January 22, 2018

Paul Parker
Director, Center for Health Care Facilities Planning & Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Mr. Parker:

On behalf of its 64 member hospitals and health systems, the Maryland Hospital Association appreciates the opportunity to respond to the Maryland Health Care Commission's (MHCC) request for comments on Maryland's Certificate of Need (CON) program. Our response includes several key overarching principles related to Maryland's current All-Payer Model and future Enhanced Total Cost of Care Model (collectively, the model), as well as direct answers to the questions posed in the MHCC's Comment Guidance questionnaire.

Background and All-Payer Model Performance
Since the beginning of Maryland's All-Payer Model in January 2014, Maryland's hospitals have outperformed the model's per capita spending targets. Statewide, hospital spending per capita is growing more slowly than the nation, while Maryland's hospitals continue to maintain a robust range of services that all Marylanders can access. Across the country, hundreds of rural hospitals are at risk of closing, while other hospitals require greater state and local subsidies to ensure access to health care for local communities.

Because hospitals are responsible for the total cost of health care statewide, the commission should recognize the unique position of Maryland's hospitals when revising CON statutes and regulations. As we provide feedback on Certificate of Need, Maryland's unique rate setting system and our All-Payer Model performance remain at the forefront of our positions.

Key Principles
There are key expectations that guide hospital positions on CON, the State Health Plan for Facilities and Services (State Health Plan) and related MHCC regulations. These include:

- Maryland will continue to operate under its unique waiver from Medicare's payment systems, transitioning from the current All-Payer Model to the Enhanced Total Cost of Care Model beginning in January 2019
- By 2023, Maryland must guarantee $300 million in annual savings, for both hospital and non-hospital services, through slower growth in total Medicare spending *per beneficiary* than the nation

- The Maryland Health Services Cost Review Commission (HSCRC) will continue to set hospital rates
- Other than normal Medicaid payment schedules, Maryland will not set rates for non-hospital health care providers; should the Centers for Medicare & Medicaid Services (CMS) grant Maryland the authority to apply a Medicare Performance Adjustment (MPA) to differentiate non-hospital payments, implementation for non-hospital providers would be voluntary
- Though delivery system incentives may influence provider behavior, only hospitals, through the HSCRC's authority, are being held responsible and accountable to deliver annual Medicare savings

Maryland's All-Payer Model and Enhanced Total Cost of Care Model
Maryland's hospitals strongly support Certificate of Need under both models. Securing the Enhanced Total Cost of Care Model is a priority for Maryland's regulators and elected officials, and is fully supported by Maryland's hospitals. The models provide unparalleled access to health care services and prevent the cost shifting among payers that occurs in other states.

Both Medicare spending growth per beneficiary and all-payer spending growth per capita, for all services, are bound by the models. The historical waiver (prior to January 2014) only required that Maryland's inpatient Medicare prices grow slower than the nation. The enhanced model that will begin in January 2019 limits *total Medicare* spending growth *per beneficiary*, including price and volume, for all health care services.

Hospital global budgets provide powerful incentives to reduce unnecessary and avoidable use, but this incentive only applies directly to hospitals. Hospitals can indirectly affect non-hospital service use through partnerships and alignment incentives. However, non-hospital service providers are not subject to rate setting or global budgets. **Unlike with Maryland's hospitals, non-hospital revenues grow when service use and volume increase**. Therefore, any unchecked volume growth increases Medicare spending, directly driving up the total spending per Maryland Medicare beneficiary.

The HSCRC can adjust hospital rates to make up for this increase in order to comply with the overall spending limit. Certificate of Need is one of the few tools to regulate the supply of health care services. Under Maryland's current All-Payer Model, significantly eroding or removing Certificate of Need barriers would not be appropriate. Maryland's hospitals, like all stakeholders, are willing to modernize CON and the State Health Plan, but the core principles of CON should remain in place.

MHCC plays an important role, issuing policies through the State Health Plan for Facilities and Services (State Health Plan). This policy role ensures Marylanders have access to quality, efficient health care. Determining the complement of available services throughout the state is the foundation of health care delivery, aligning with model incentives to provide the right care, at the right time, in the right setting, for every patient.

Comment Guidance Responses
Responses from the hospital field are attached to this letter. In several instances, the responses are based on our understanding of the question, but additional clarification may be needed. In those cases, we explicitly noted how we read the question.

In addition to this feedback, MHA's Certificate of Need and State Health Plan hospital work group is concurrently addressing these important issues. Further responses to the commission's questions are expected to be an outcome of the work group's review of these issues. For example, question 8 asks about the strengths and weaknesses of State Health Plan regulations. MHA's work group will first assess the overall purpose of the State Health Plan, and then review each chapter to suggest specific modifications.

Our initial responses are focused on hospitals and hospital services. However, through MHA's work group review process, we will provide feedback to the commission on State Health Plan chapters and other policies that affect non-hospital services. In some responses, we have provided general recommendations. MHA's work group will likely respond with specific, detailed recommendations as we complete our issue review.

We appreciate the commission's detailed and thorough approach to Certificate of Need review and Maryland's hospitals look forward to continuing to provide the commission with feedback on current considerations, potential changes and future impacts.

Thank you for your consideration.

Should you have any questions, please call me at 410-540-5060.

Sincerely,

Brett McCone
Vice President

cc: Robert Emmet Moffit, PhD., Chairman, MHCC
Ben Steffen, Executive Director, MHCC
Kevin McDonald, Chief, Certificate of Need, MHCC
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Enclosure

COMMENT GUIDANCE – HOSPITAL
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's adoption of global budgets for hospitals, its commitment to achieve the goals of the Triple Aim, and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of hospital CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON work group.

Need for CON Regulation

Which of these options best fits your view of hospital CON regulation?

☐ CON regulation of hospital capital projects should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13 to 15.]

☐ CON regulation of hospital capital projects should be reformed.

☐ CON regulation of hospital capital projects should, in general, be maintained in its current form.

The Maryland Hospital Association's (MHA) 2015 Certificate of Need Task Force, consisting of hospital CEOs and senior health planning and finance executives, concluded that a CON process is needed to determine the most efficient use of limited resources. The main reasons for this conclusion are that Maryland's hospitals are bound by the All-Payer Model and that Maryland's hospital payments are set by the Health Services Cost Review Commission (HSCRC).

As reflected in our cover letter, Maryland's hospitals strongly support CON as both appropriate and necessary under Maryland's unique All-Payer Model and the upcoming Enhanced Total Cost of Care Model (collectively, the model). Maryland's hospitals are the only health care providers accountable for achieving the financial and quality targets reflected in the agreement with the Centers for Medicare & Medicaid Services (CMS).

Though hospitals support CON, the task force recommended that MHA convene a second work group to assess appropriate statutes and regulations, and recommend specific revisions if needed. Certain aspects of CON require modernization. MHA's Certificate of Need and State Health Plan Work Group held its first meeting on November 8 to begin this work.

Because hospitals are responsible for the total cost of health care statewide, the commission should recognize the unique position of Maryland's hospitals when revising CON statutes

and regulations. MHA's work group is reviewing CON, the State Health Plan and other regulations, and will bring specific, consensus recommendations to the commission as the group finishes its issue review. Many recommendations will not be complete by the January 26, 2018, deadline, and some may not be complete until the middle of calendar year 2018.

ISSUES/PROBLEMS

The Impact of CON Regulation on Hospital Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among hospitals?

   In the existing CON environment, there is abundant, healthy hospital competition. Competition is just as visible as before the All-Payer Model and it exists with CON rules in place. In addition to hospitals competing with each other, hospitals compete with other providers for certain services, including outpatient surgery, diagnostic imaging, infusion, etc.

   At the same time, the model provides incentives for hospital collaboration in an attempt to reduce hospital costs, particularly for the chronically ill population. Hospital and regional partnerships have been formed to manage the health of the population, and large hospital systems drive collaboration among their subsidiaries. ***Since the beginning of the model, Medicare hospital spending per beneficiary has grown more slowly than all other health care market segments.*** *This trend has occurred without modifying CON rules.*

   Across the state, hospitals constantly compete with one another for services. Hospital competition is good. It can drive service innovation and efficiency, particularly since hospitals are accountable for Maryland's performance. Adding more hospitals or hospital services will not necessarily lower costs or improve quality, especially in areas with excess hospital capacity. Where there is excess capacity, regulatory efforts should incentivize appropriate access to care, while encouraging the repurposing or conversion of resources to address other health needs.

2. Does CON regulation impose substantial barriers to market entry for new hospitals or new hospital services?

   (We read "new hospitals" as a newly constructed hospital that did not previously exist, and hospital services as hospital services currently subject to CON.)

   Yes, CON imposes a barrier to unneeded market entry. We believe this barrier to market entry, either for a new hospital or a new hospital service, is appropriate. CON is appropriate to ensure access to services, and the quality of those services at the lowest possible cost.

A core tenet of CON is to prevent duplication of services, particularly for a new hospital. Certain specialized services – transplants, cardiac surgery, etc. – require CON because there are critical levels of volume needed to achieve quality standards. CON serves as an appropriate barrier to ensure a minimum level of volume is achieved. CON regulations should be based on what services are needed using an objective methodology.

Importantly, the All-Payer Model affects the demand for health care services, which in turn, affects the need for services. The model requires the CON barrier, and the CON barrier supports the desired outcome of the model to reduce total spending per capita. Assuming that HSCRC and hospital rate regulation remain, HSCRC will closely regulate capital funding in hospital rates to ensure that Maryland meets the model's targets.

Hospital and health system operating margins, and the current market environment – from competition for physician resources to the incentives to collaborate – provide additional, inherent barriers to prevent the development of unnecessary services. These barriers naturally apply before an organization considers developing a new service that requires CON approval.

If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

As reflected in the answer to question 1, there is abundant hospital competition in the current environment, and the model's incentives encourage hospitals to collaborate.

The work group is reviewing CON, the State Health Plan and other regulations, and will bring specific recommendations to the commission as the group finishes its review. Preliminarily, hospitals suggest reviewing regulations that are no longer required because they were implemented prior to specialized care standards being established (e.g., perinatal standards may replace the need for neo-national certificate of need approval). Any changes should not undermine the core principles of CON. The approach to CON, gathering market and regulatory information that has evolved over the years, should be modernized.

There is strong need for adequate behavioral health services to address access and quality. Any regulation assessment should begin with behavioral health services, given the current market dynamics and the dated state health plan regulations.

3. How does CON regulation stifle innovation in the delivery of hospital services under the current Maryland regulatory scheme in which hospital rate-setting plays such a pivotal role?

As reflected in our answer to question 1, there is abundant competition in the current environment, while the model's incentives also encourage hospitals to collaborate with each other. Further, Maryland's hospitals are some of the most innovative health care institutions in the United States. Maryland's All-Payer Model provides incentives for innovation designed to achieve the triple aim.

This question appears to be about how reimbursement encourages or discourages innovation. In certain cases, reimbursement hasn't caught up to innovation, but this is often a reality of the market. Certificate of Need neither stifles nor enhances innovation.

MHCC, HSCRC and the state need to think innovatively about how care can be provided more effectively in lower cost settings, delivered where people need the services. For example, the Freestanding Medical Facility statutory changes in 2016 were designed to make it easier to reduce capacity. In achieving this transformation, the perception is that state regulatory agencies should be much more responsive and flexible to achieve the intent. The statutes and policies have been changed, but the regulatory burden, either through process or interpretation, has not. More than just the commission, other state agencies are involved. This includes the Office of Health Care Quality and Maryland Institute for Emergency Medical Services Systems. MHCC, through statute or regulation, could play a leading role to shepherd innovation among all regulatory agencies.

The State Health Plan should be updated in accordance with the statute. This means more timely reviews of each chapter as innovation drives health care delivery system changes.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish or relocate a hospital, expand bed capacity or operating room capacity at a hospital, introduce certain services at a hospital, or undertake capital projects that exceed a specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?

The general scope of CON is appropriate and reasonable. There are adjustments that can and should be made, but these adjustments do not fundamentally alter the CON program.

The work group is reviewing CON, the State Health Plan and other regulations, and will bring specific recommendations to the commission as the group finishes its issue review. See responses to question 2 and question 3 for initial reactions. If other regulatory systems are in place, the commission might consider removing certain regulatory requirements.

A. Are there hospital projects that require approval by the Maryland Health Care Commission that should be deregulated?

The commission should consider eliminating, or significantly raising, the capital spending threshold for projects that do not change the number of a hospital's beds

or expand covered hospital services. Additionally, MHCC might consider limiting the scope of services required under CON (e.g., the perinatal example in the response to question 2.)

As reflected in the cover letter, our principles state that Maryland's All-Payer Model will continue, so the need to align CON and model incentives is critical. Ultimately, review of CON may require rethinking HSCRC regulatory approaches. Historically, CON approval was the "key to unlock the door" to potential capital rate relief. If the capital threshold is raised or eliminated, this may change the view of CON requirements for rate relief.

Hospital boards are stewards of community resources, and are not going to invest in capital projects they cannot afford. In our answer to question 2, operating margins and the health care market are natural barriers to unchecked service development. The availability and concentration of scarce clinical resources is another inherent barrier to service development, no matter what the community desires.

The MHCC guidance contemplates deregulating services and creating new review classes as ideas to improve the CON application process. Reducing unnecessary approval steps and enforcing the decision timeline, coupled with clear rules and consistent interpretation of those rules, will streamline reviews without changing CON requirements.

Though not an MHCC issue, an alternative is to potentially allow hospitals to deregulate outpatient services on an expedited basis. Alternatives might include moving services to unregulated space, or allowing services to be deregulated in place, within a hospital. The latter raises several issues, but all options should be identified. Our work group is still discussing this.

B. Are there hospital projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

Our work group is discussing this, and how CON statutes and regulations should address this consideration against the backdrop of the model's constraints.

Without recommending additions to the scope of CON regulation, we remind the commission that there are a range of services provided at hospitals that are not covered by CON, or can be exempt from CON, if provided outside of the hospital. Diagnostic imaging, infusion, and ambulatory surgery contribute significantly to covering the fixed costs and semi-fixed costs required to operate hospitals. Outside of hospitals, when Medicare volume increases, total Medicare spending per beneficiary increases.

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

   CON approval, unless contested, is supposed to be complete in 150 days. Maryland's hospitals identified potential areas for the commission to address:

   - *Before an application is even docketed, completeness questions can cause significant delays. We recommend that the commission limit MHCC staff to one round of completeness questions, and the completeness questions must be germane and essential to making a decision on the CON application.*
   - *From the hospital perspective, MHCC regulations governing charity and uncompensated care should be moved to the HSCRC's jurisdiction. This includes the timeline for determination of whether a patient is eligible for charity care. HSCRC governs hospital rates, including charity care and uncompensated care provisions. MHCC may continue to request this information from other providers to fulfill certain requirements for CON eligibility.*
   - *For hospital projects, financial feasibility and analysis should be the purview of HSCRC. This should eliminate the need to file two sets of financial projections – one to MHCC without inflation and one to HSCRC with inflation. Hospitals that assume a rate increase for financial feasibility will naturally require additional approval steps. They must concurrently file an HSCRC rate application requesting the rate increase reflected in the CON application.*
   - *Even with projects that include interested parties and/or involve comparative review, a delay in a single application step should not automatically delay deadlines throughout the whole project. Hospitals agree that if an applicant has delayed the process, then the applicant must recognize the consequences.*
   - *The submission forms can run in excess of 120 pages. The commission should review the submission forms and eliminate anything that is not required to determine CON approval.*
   - *For renovation-only projects that do not change the scope of hospital services, the commission should consider replacing the quantitative analysis with a simple narrative. Hospital margins and the hospital's board of directors should demonstrate adequate stewardship of resources.*
   - *Applicants should not have to submit pro-forma documentation if the documentation has already been filed with MHCC, the HSCRC or another state regulatory agency.*

   In general, the SHP must have clear and straightforward guidelines, and MHCC must follow those guidelines. The MHA work group plans to thoroughly review the general MHCC regulations and the SHP chapters. Recommendations from this review will aim to improve the application process by refining review steps.

The commission should also consider the number of CON subject-matter experts on staff. This number may need to increase, and/or the service experience complement may need to change (hospital, skilled nursing, etc.), to improve the process.

6. Should the ability of competing hospitals or other types of providers to formally oppose and appeal decisions on projects be more limited?

No, the commission should not consider limiting interested parties on projects. The commission already has statutes and regulations in place to determine interested and "adversely affected" parties. Those seeking to be interested parties must demonstrate impact from the proposed project. This impact should be demonstrated with well-organized, data-driven analyses and not a presumption of impact. This might include parties that have services in the applicant's service area, or parties that may be impacted if the applicant is seeking specialized regional or statewide services. Even with interested parties, the approval process should not be delayed.

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated?

This issue will be considered by the work group.

The CON exemption review process is arduous, requiring significant time and effort before the commission grants an exemption. The main difference between a CON exemption request and CON approval is the allowance of interested parties. However, a CON exemption request requires much of the same information and many of the same review steps.

The commission might simplify the requirements to grant CON exemptions. If the commission is concerned about quality of care, the licensure requirements could be reviewed and augmented.

Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

The exemption for merged asset systems should continue. The model creates incentives for cooperation and collaboration among hospitals, health systems, and community organizations. We should not erect barriers that prevent hospitals from operating efficiently, including efficiencies realized when resources are appropriately combined. To reduce the cost of health care, hospitals and health systems need to operate as efficiently as possible, often through the use of umbrella/overhead departments required to manage the back-end functions of the organization. Merged asset systems create efficiencies through economies of scale, particularly around functions like patient accounting, information technology, etc.

7. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)

Project completion timelines should be reviewed, particularly reporting compliance after project approval. Currently, the post-approval quarterly reporting forms are very complicated, especially for a large project. The forms should be simple and should only collect information that was relevant to the project approval decision.

Though largely an HSCRC issue, the commission might also consider an approved project's impact on spending per capita. After the project is approved and in service, for the primary service area, the commission could measure the service-specific spending per capita compared to a prior period.

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for hospital facilities and services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

The State Health Plan should begin with a clear purpose, accompanied by two to three key goals and objectives. The purpose and goals should align with the model because the state is collectively at risk to achieve the model's goals. In particular, the plans goals should take into account the model's influence on the demand for health care services, which in turn influences the "need" for services.

The chief strength of these regulations is the idea that there should be "standard" criteria to determine the need for a project. However, incentives in the Maryland model directly affect the demand for services. State Health Plan criteria deal with providing an adequate supply of services to meet the demand.

The regulations are static, and some haven't been updated in many years. The inpatient psychiatric services chapter has not been substantially updated in 20 years. Meanwhile, the state closed several state-owned psychiatric facilities. The State Health Plan needs to be updated, and flexible enough to account for changes in emerging technologies, like telehealth, as well as technologies that don't exist yet, but will shape future health care delivery.

As reflected in our cover letter, MHA's work group plans to discuss the purpose and goals of the State Health Plan. The work group then plans a chapter-by-chapter review to suggest revisions and modifications. We expect this process to take place concurrently with the commission's work group.

9. Do State Health Plan regulations focus attention on the most important aspects of hospital projects? Please provide specific recommendations if you believe the regulations miss the mark.

   See response to question 8, in particular the last paragraph.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

    The State Health Plan should be more regularly reviewed and updated, in accordance with the current legal requirements. MHA's work group acknowledged that a SHP chapter review involves a significant time commitment. Given the commitment, the commission, with input from the public, should prioritize the SHP chapters that are ripe for review and revision.

    When State Health Plan chapters are revised, commission staff create a stakeholder work group to provide input and feedback. This feedback is then synthesized by commission staff into a series of recommendations, and a revised chapter is drafted. The commission will solicit informal, then formal public comments. These comments receive written responses from staff that are shared with commissioners. However, oral comments are not considered at the public meetings. When ripe for commission action on a chapter of the State Health Plan, the commission should welcome comments at a public meeting.

    At a minimum, at the end of this review process, when the commissioner-led work group releases its final recommendations for commission action, the full commission should allow presentations and comments before voting.

General Review
Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

    In general, the criteria are appropriate but need to be applied consistently to all CON applications, particularly the "need" criteria. The criteria should be reviewed to determine the model's influence on the demand for services. This influence may require revising the need criteria, particularly the formulas to determine inpatient beds.

The MHA work group is reviewing the State Health Plan. Recommendations will be shared with the commission when the process is complete. At a minimum, ***hospital requirements*** *to report charity/uncompensated care are not needed, or should fall under HSCRC jurisdiction.*

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

12. If you believe that CON regulation of hospital capital projects should be eliminated, what, if any, regulatory framework should govern hospital capital projects?

    Maryland's hospitals strongly support the continuation of CON requirements. *CON is appropriately necessary to operate under Maryland's All-Payer Model. We are reviewing individual services to determine whether certain regulations are no longer required because other clinical or application standards have been established.*

    Absent another mechanism to hold non-hospital service providers accountable for achieving model targets, the commission must continue to regulate the supply of services.

13. What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?

    See the response to question 12.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of hospital licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain hospital facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care? Are there ways (other than those touched on in earlier questions) in which the regulation of hospital charges could be adapted as a substitute for CON regulation?

    Given the unique payment system in Maryland, CON is needed to determine the most efficient use of limited resources.

    From a financial perspective, the HSCRC serves as an important hospital regulatory body. HSCRC and the Maryland Department of Health are leading the negotiations to extend Maryland's All-Payer Model. HSCRC has imposed global budgets that create much different incentives to constrain avoidable and unnecessary health care service use. We do not propose that HSCRC set rates or otherwise regulate non-hospital providers, but we would remind the commission that hospitals are already heavily regulated.

Though hospitals support the overarching CON principles, other regulatory requirements might be leveraged to appropriately regulate other health care services. Licensing and/or certification requirements should be explored further.

Changes to regulatory mechanisms, particularly out of MHCC's scope, may require a reallocation of resources away from MHCC to other state agencies, with a corresponding reduction in MHCC user fees.

The Impact of CON Regulation on Hospital Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing hospitals and new market entrants? If so, please provide detailed recommendations.

See the response to question 3. CON is not an impediment to innovation. Changes in the hospital payment system have created incentives for Maryland's hospitals to serve as innovators. The hospital marketplace provides an appropriate balance of competition and collaboration. By adopting, supporting and extending the model, the state, through HSCRC, has given hospitals the implicit directive to collaborate and improve the health of the population. Global budgets are driving innovative alignments of hospitals, physicians and post-acute providers.

More timely updates of the SHP are needed as delivery system changes outpace the existing regulations. MHA's work group is reviewing CON, State Health Plan and other regulations to determine specific revisions.

16. Should Maryland shift its regulatory focus to regulation of hospital and health systems merger and consolidation activity to preserve and strengthen competition for hospital services?

Absolutely not**. Maryland should not focus on regulating mergers and consolidation activity. This question suggests that mergers and acquisitions reduce hospital competition. **Maryland's hospitals strongly disagree with this implied assertion.

In fact, hospital mergers, consolidations and affiliations have strengthened health care service delivery in Maryland. There are several examples of the benefits of mergers and consolidations having eliminated fixed costs and generated system savings. Three examples are: the consolidation of hospital services in Alleghany County, the proposed conversion of small acute care hospitals in Easton and Havre de Grace to emergent and outpatient facilities, and eventual redevelopment of hospital facilities in Prince George's County that previously required significant public subsidies (University of Maryland Capital Region Health.)

The merged asset exemption allows for health systems to better allocate/align services and avoid unnecessary duplication. This should continue and be encouraged across all providers. There are also substantial quality benefits from hospital mergers due to the

standardization of clinical protocols and concentration of complex services at a limited number of hospitals.

Other regulatory bodies already provide adequate oversight of hospital mergers – the Federal Trade Commission, the Department of Justice and the antitrust division of the Attorney General's office.

Scope of CON Regulation

17. Should the scope of hospital CON regulation be more closely aligned with the impact of hospital projects on charges?

No, there are sufficient incentives under the All-Payer model to control hospital charges. The model limits all-payer per capita growth and Medicare payment per beneficiary growth. Any rate increase to cover capital expenditures will affect these growth rates. Therefore, hospitals must reduce avoidable and unnecessary service use to generate additional savings, or the HSCRC must regulate hospital payment rates to maintain compliance with the model.

Non-hospital providers have the ability to grow volume to pay for capital and operating expansions. Unlike hospitals, these providers are not subject to global budgets, and therefore revenues will increase as volumes increase.

A. Should the use of a capital expenditure threshold in hospital CON regulation be eliminated? For example, should hospital capital projects or certain types of hospital project only require a CON if the hospital seeks an increase in its global budget to cover project-related capital cost (depreciation, interest, and amortization) increases? Alternatively, should CON regulation be based on the overall impact of projects on hospital revenues (related to coverage of both capital and operating expenses, which could increase substantially even for low cost projects if new services are being introduced?)

Please see the response to question 4A.

For projects that do not add hospital beds or change the hospital service portfolio, the commission should consider eliminating, or significantly raising, the capital threshold.

Unless HSCRC grants a hospital rate increase, no additional revenue is added to the system for approved hospital projects. The hospital provider, or parent health system, is at risk for having the resources to cover capital expenses. Operating revenue may increase from market shift, or the hospital has the ability to file a rate increase application. ***However, Maryland's all-payer per capita growth and Medicare spending per beneficiary growth are ultimately capped by the model and HSCRC regulates hospital revenue to ensure compliance.***

A different approach might be to estimate the impact of the project on total cost of care growth, particularly for non-hospital services. This could be done when evaluating a CON application, or by determining that services should be added or removed from the scope of CON regulations.

B. Should Maryland's system of hospital rate regulation include capital spending growth targets or capacity growth targets that shape the scope of CON regulation? If so, how would this work? For example, should CON regulation be redesigned to move away from single project review(s) for a multiple hospital system to a broader process of reviewing systems resource development needs and priorities? Such a process could resemble a periodic budget planning process with approval of a capital spending plan that incorporates a set of capital projects for a given budget period.

We do not support this approach. The hospital market encourages a balance of competition and collaboration. The commission should review each project on its individual merits and should not predetermine capital projects for a given period. This would stifle innovation and the ability of the market to determine the most efficient use of capital, conditions that exist under the current CON regulatory umbrella. We do not support deregulation of CON, and we do not support the commission usurping health system management and planning functions.

Maryland's rate regulation system should provide hospitals adequate capital funding. When the rate setting system was developed, funds were not placed in rates for replacement or renovation of aging facilities. Rather, HSCRC would review and approve hospital rate increases to cover the cost of capital at the time of replacement. Under a fixed revenue system, HSCRC might consider revising the historic Capital Facilities Allowance that provided hospitals with a benchmark for capital funding. MHA's work group may explore this issue further.

18. Should MHCC be given more flexibility in choosing which hospital projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the hospital to undergo CON review.

No, the MHCC should not be given more flexibility in choosing which projects require approval. This would likely result in greater uncertainty and the potential for arbitrary decisions. The commission should adopt policy principles and clear, unambiguous regulations to guide decision making. Decisions should be applied consistently. If the application process is too complicated, simplify the regulations that govern the process and eliminate unnecessary steps that will not affect decisions by the commission. The policy principles should be reviewed at regular intervals with respect to Maryland's

performance under the forthcoming Enhanced Total Cost of Care Model, and the regulations, including chapters of the SHP, should be updated on a regular basis. The policy principles may reference incentives to expand or contract types of service providers, steered by having the flexibility to determine which providers or projects require CON approval.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

    The previous MHA CON Task Force discussed a "fast track" approach for projects with no interested parties and a documented need in the State Health Plan. Other possibilities include no assumption of hospital rate increases or project that demonstrate significant cost savings.

The Project Review Process

20. Are there specific steps that can be eliminated?

    Completeness questions should be limited to one round, and they should be limited to only those issues that are essential to a commission decision.

21. Should post-CON approval processes be changed to accommodate easier project modifications?

    Yes, particularly for projects without new beds or services.

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

    See the response to question 19. Additionally, if the State Health Plan is updated on a regular basis, it will improve the process by eliminating certain requirements. Changing the state health plan should create room to expedite reviews for small delivery changes.

23. Would greater use of technology including the submission of automated and form-based applications ion improve the application submission process?

    Possibly, but if the form continues to exceed 120 pages, it will still be arduous. The commission should explore the potential to submit auto-generated forms for post CON follow up. The commission should review what is currently required in a CON application to determine if the information is critical to making a decision, or, whether the information is already publicly available.

    Questions 20 through 23 will continue to be discussed by the MHA work group.

In general, ***the commission should identify steps that add little or no value to the CON decision-making process and remove those steps.*** *Several areas should be considered, including the charity care policy, cost per square foot benchmarks, etc. The commission should investigate whether an incentive that created the CON requirement is still valid, or whether the incentive been superseded by other regulatory actions, innovation, and/or market forces.* ***Commissioners and the legislature should not hesitate to eliminate steps that are no longer necessary, but have not changed because there has been no real incentive to change.*** *We agree with commission staff that "rules matter." It's time to review the rules and eliminate those that are unneeded.*

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

24. Are there areas of regulatory duplication in the hospital capital funding process that can be streamlined between HSCRC and MHCC, and between MHCC and the MDH?

25. Are there other areas of duplication among the three agencies that could benefit from streamlining?

MHA's work group will discuss these questions and provide specific responses to the stakeholder work group.

Questions 24 and 25 are broader than CON and state health plan review. Responding to these questions provides MHA's work group the opportunity to comment more generally on MHCC and its mission. The MHCC has been an advocate for innovation, helping create pilot programs to improve access and reduce costs. The desire to modernize CON may require a broad look at the commission, including its "core missions" like CON, and the appropriate resources to complete these core missions.

In the response to question 11, the general standard for charity care for hospitals should be eliminated or moved to the HSCRC's authority.

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry.

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January 23, 2018

Paul E. Parker
Director, Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Parker:

Attached are MedStar Health's comments in response to the November 21, 2017 survey questions in preparation for the Commission's new Certificate of Need (CON) Workgroup.

Our comments represent our initial thoughts on the issues with the current health planning and CON programs. In response to the questions, we've also included a few general comments on possible solutions, with the understanding that the workgroup won't focus on solutions until in its second phase, where more detailed suggestions will be developed.

We appreciate the opportunity to contribute to the workgroup's efforts. If you have any questions regarding these comments, please do not hesitate to contact me.

Sincerely,

Pegeen A. Townsend

Pegeen A. Townsend
Vice President, Government Affairs

Attachment

MHCC QUESTIONS ON CON

General

Need for CON Regulation

- *MHA CON Task Force concluded CON is needed to determine the most efficient use of limited resources primarily because All-Payer model and hospital payments are set by the HSCRC.*
- *Under the new Total Cost of Care Model hospitals will be held accountable for achieving financial and quality targets required under the agreement with CMS.*
- *While it should be retained, the CON program needs to be modernized.*
- *Modernization needs to address more than just capital expenditures, e.g. scope and process as well.*

Impact on CON Regulation on Hospital Competition and Innovation

1. Would the public and health care delivery system benefit from more competition among hospitals?

   - *Adding more hospitals does not necessarily lower costs or improve quality especially where there are areas in the state that have excess hospital capacity.*
   - *Hospitals compete every day for market share under the new payment system.*
   - *Hospitals already face competition from other non-rate regulated providers that do not have the same fixed costs, not-for-profit missions, or responsibilities under the new Total Cost of Care model.*
   - *The hospital payment model encourages collaboration among hospitals and providers to drive care to the lowest cost, appropriate setting.*
   - *In parts of the state there are too many hospital beds and regulatory efforts should incentivize and encourage the rightsizing and/or conversion to other needed uses.*

2. Does CON impose substantial barriers to market entry for new hospitals or new hospital services?

   - *By definition CON is a barrier if need cannot be demonstrated – it is intended to keep out unneeded services and facilities.*
   - *Arguably, the larger barrier to hospital entry in Maryland is the historically slim hospital margins.*
   - *CON regulation should be based on what services are actually needed based on an objective methodology.*

- *There should be incentives created to encourage providers to meet unmet need, e.g. behavioral health, hospice.*

3. How does CON stifle innovation in the delivery of hospital services under the current Maryland regulatory scheme in which hospital rate-setting plays such a pivotal role?

   - *Maryland hospitals are among the most innovative in the nation.*
   - *Regulators need to think differently and be more responsive to a changing environment (FMF).*
   - *Failure to make timely updates to parts of the State Health Plan to keep pace with a changing environment.*

Scope of CON Regulation

4. Should the scope of CON regulation be changed?

   A. Are there capital projects that require approval by the MHCC that should be deregulated?

   - *Eliminate the capital threshold limit for hospital renovation projects that do not include new beds or services.*

   B. Are there projects that do not require approval by the MHCC that should be added to the scope of CON regulation?

   - *No but the process governing determinations of non-coverage and CON exemptions should be simpler and faster.*

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke points?

   - *Completeness questions should be limited to one-round and only include requests for information essential to making a decision on the application.*
   - *Complying with the time frames in statute should make the process more efficient.*
   - *Much of the pro forma information required to be included as part of the CON application could be eliminated, e.g. copy of the hospital license, charity care policy, shell space, square footage costs, etc.*

- *For straight hospital renovation projects, the quantitative analysis of alternative scenarios should be eliminated and replaced with a simplified narrative requirement (if CON for renovations is retained).*

6. Should the ability of competing hospitals or other types of providers to formally oppose and appeal decisions on projects be more limited?

   - *No because one hospital's project may have a financial impact on other hospitals under the new all payer model.*

   Are there existing categories of exemption review that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

   - *The merged asset exemption allows for health systems to better allocate/align services and avoid unnecessary duplication – this should be encouraged.*
   - *The exemption was intended to (and has) facilitated the reduction of excess capacity.*
   - *Hospital systems decrease costs as a result of the benefits of scale and reduced costs of capital.*
   - *There are substantial quality benefits from hospital mergers due to standardizing clinical protocols, investments made to upgrade services, deployment and recruitment of additional medical staff, and concentrating provision of complex services at a limited number of system hospitals to benefit from increased volume.*
   - *Other benefits include coordination of patient care, sharing information through electronic medical records, population health management, and risk-based contracting.*
   - *New value based payment models necessitate alignment of the financial and clinical incentives of an integrated team of providers – both vertical and horizontal.*

7. Are project completion timeframes, i.e., performance requirements for implementing and completing projects, realistic and appropriate?

State Health Plan for Facilities and Services

8. In general, do state health plan regulations for hospital facilities and services provide adequate and appropriate guidance for the Commission's decision making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

- *Lack of specific up to date need projections and need projections across all chapters*
- *Need projections should not be based entirely on historical data and other factors should be considered, e.g., new technologies, shift from inpatient to outpatient, new competitors, etc.*

9. Do State Health Plan regulations focus attention on the most important aspects of hospital projects? Please provide specific recommendations if you believe the regulations miss the mark.

   - *Eliminate CON for hospital renovation projects that do not increase beds or services*

10. Are the typical ways in which the MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

    - *The process is adequate but several chapters have not been undated in a timely manner, e.g. behavioral health.*

General Review

Criteria for all Project Reviews

11. Are the general criteria adequate and appropriate? Should other criteria be use? Should any of these criteria be eliminated or modified in some way?

    - *The criteria are appropriate but need to be applied consistently to all applications– particularly the "need" criteria.*
    - *There should be an in-depth review of what is currently required in a CON application to assess whether the information is critical to making a decision or whether it is already publically available.*

Alternatives to CON Regulation for Capital Project

12. If you believe that CON regulation of hospital capital projects should be eliminated, what, if any, regulatory framework should govern hospital capital projects?

- *CON for hospital renovation projects that do not add new beds or services should be eliminated.*
- *No additional regulatory framework is needed- the HSCRC control over hospital payment is more than adequate check.*

13. What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?

- *CON for hospital renovation projects that do not add beds or services should be eliminated.*
- *No additional regulatory framework is needed- the HSCRC control over hospital payment is more than an adequate check.*

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms?

- *Given the unique hospital payment system in Maryland CON is needed to determine the most efficient use of limited resources.*

The Impact of CON Regulation on Hospital Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing hospitals and new market entrants?

- *More timely updates of the state health plan chapters and need projections.*
- *CON is not an impediment to innovation and changes in the payment system creates sufficient incentives to innovate.*

16. Should Maryland shift its regulatory focus to regulation of hospital and health system merger and consolidation activity to preserve and strengthen competition for hospital services?

- *Other regulatory bodies already provide adequate oversight of hospital mergers – FTC and DOJ and the antitrust division of the Attorney General's office.*
- *The merged asset exemption allows for health systems to better allocate/align services and avoid unnecessary duplication – this should continue to be encouraged.*
- *Hospital systems decrease costs resulting from the benefits of scale and reduced costs of capital.*

- *There are substantial quality benefits from hospital mergers due to standardizing clinical protocols, investments made to upgrade services, deployment and recruitment of additional medical staff, and concentrating provision of complex services at a limited number of system hospitals to benefit from increased volume.*
- *Other benefits include coordination of patient care, sharing information through electronic medical records, population health management, and risk-based contracting.*
- *New value based payment models necessitate alignment of the financial and clinical incentives of an integrated team of providers both vertically and horizontally.*

Scope of CON Regulation

17. Should the scope of hospital CON regulation be more closely aligned with the impact of hospital projects on charges?

- *No there are sufficient incentives under the new all payer model to control hospital charges.*

A. Should the use of a capital expenditure threshold in hospital CON regulation be eliminated?

- *CON for hospital renovation projects that do not add beds or services should be eliminated.*

B. Should Maryland's system of hospital rate regulation include capital spending growth targets or capacity growth targets that shape the scope of CON regulation?

- No the hospital payment system is an adequate check.

18. Should MHCC be given more flexibility in choosing which hospital projects require approval and those that can move forward without approval, based on adopted regulations for making these decisions?

- *No this would result in uncertainty and has the potential for an arbitrary process and decisions.*

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

- *Perhaps for projects where there is a documented need in the State Health Plan and no interested parties.*
- *Limit the completeness question scope and process to one round of questions that are essential to making a decision.*
- *Expediting decisions relating to non coverage and exemptions from CON.*

The Project Review Process

20. Are there steps that can be eliminated?

    - *Keeping completeness review to one round limited to only those issues/questions that are essential to making a decision.*

21. Should post-CON approval processes be changed to accommodate easier project modifications?

    - *Yes particularly if the project does not include new beds or services.*

22. Should regulatory processes be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

    - *Perhaps for projects where there is a documented need in the State Health Plan and no interested parties.*

23. Would greater use of technology including the submission of automated and form-based applications improve the application submission process?

    - *There should be an in-depth review of what is currently required in a CON application to assess whether the information is critical to making a decision or whether it is already publically available.*

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

24. Are there areas of regulatory duplication in the hospital capital funding process that can be streamlined

25. Are there other areas of duplication among the three agencies that could benefit from streamlining?

Mercy
MEDICAL CENTER

A University Affiliated Center Conducted by the Sisters of Mercy

January 26, 2018

Mr. Paul Parker
Director, Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Parker:

Attached is Mercy Medical Center's response to the MHCC CON Study Comment Guidance – Hospital Survey. Mercy Medical Center is participating in the Maryland Hospital Association (MHA) Certificate of Need and State Health Plan Work Group to assess appropriate statutes and regulations, and recommend specific revisions if needed. Mercy Medical Center's responses to this survey closely mirror those provided by MHA.

Sincerely,

Ryan O'Doherty
VP, External Affairs & Marketing
Mercy Health Services

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COMMENT GUIDANCE - HOSPITAL
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's adoption of global budgets for hospitals, its commitment to achieve the goals of the Triple Aim, and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of hospital CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of hospital CON regulation?

- ☐ CON regulation of hospital capital projects should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13to 15.]
- ☒ **Certain aspects of CON regulation of hospital capital projects should be ~~reformed.~~ *Modernized***
- ☐ CON regulation of hospital capital projects should, in general, be maintained in its current form.

Mercy Medical Center is participating in the Maryland Hospital Association (MHA) Certificate of Need and State Health Plan Work Group to assess appropriate statutes and regulations, and recommend specific revisions if needed. Certain aspects of CON require modernization. Mercy Medical Center's responses to this survey closely mirror those provided by MHA.

A CON process is needed to determine the most efficient use of limited resources. *The main reasons for this is that Maryland's hospitals are bound by the All-Payer Model and that Maryland's hospital charges and global budgets are set by the Health Services Cost Review Commission (HSCRC). Maryland's hospitals, including Mercy, strongly support CON review as both appropriate and necessary under Maryland's unique All-Payer Model and the anticipated Enhanced Total Cost of Care Model (collectively, the Model). Maryland's hospitals are the only health care providers accountable for achieving the financial and quality targets reflected in the agreement with the Centers for Medicare & Medicaid Services (CMS). Though hospitals support CON,* ***Certain aspects of CON require modernization.*** *Because hospitals are responsible for the total cost of health care statewide, the Commission should recognize the unique position of Maryland's hospitals when considering revisions to CON statutes and regulations.*

ISSUES/PROBLEMS

The Impact of CON Regulation on Hospital Competition and Innovation

1. **In your view, would the public and the health care delivery system benefit from more competition among hospitals?**

In the existing CON environment, there is abundant, healthy hospital competition. Competition is just as visible as before the All-Payer Model and it exists with the CON statutes and regulations in place. In addition to hospitals competing with each other, hospitals compete with other providers for certain services, including outpatient surgery, diagnostic imaging, infusion, etc. At the same time, the Model provides incentives for hospital collaboration in an attempt to reduce hospital costs, particularly for the chronically ill population. Hospital and regional partnerships have been formed to manage population health and health systems drive collaboration among their subsidiaries. Since the beginning of the Model, Medicare hospital spending per beneficiary has grown more slowly than all other health care market segments. This trend has occurred without modifying CON statutes and regualtions.

Across the State, hospitals constantly compete with one another for services. Hospital competition is good. It can drive service innovation and efficiency, particularly since hospitals are accountable for Maryland's performance. Adding more hospitals or hospital services will not necessarily lower costs or improve quality, especially in areas with excess hospital capacity. Where there is excess capacity, regulatory efforts should incentivize appropriate access to care, while encouraging the repurposing or conversion of resources to address other health needs.

2. **Does CON regulation impose substantial barriers to market entry for new hospitals or new hospital services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?**

For purposes of this response, Mercy interprets "new hospitals" as a newly constructed hospital that did not previously exist, and hospital services as hospital services currently subject to CON review.

Yes, CON review imposes a barrier to unneeded market entry. Mercy believes this barrier to market entry is appropriate, either for a new hospital or a new hospital service. CON review is appropriate to ensure access to services and the quality of those services at the lowest possible cost.

A core tenet of CON review is to prevent duplication of services, particularly for a new hospital. Certain specialized services – transplants, cardiac surgery, etc. – require CON review because there are critical levels of volume needed to achieve quality standards. CON review serves as an appropriate barrier to ensure a minimum volume level is achieved. CON regulations should be based on what services are needed using an objective methodology.

Importantly, the All-Payer Model affects the demand for health care services, which in turn, affects the need for services. The Model requires a CON barrier for new hospitals, unnecessary services, and certain specialized services, and the CON barrier supports the desired outcome of the Model to reduce total spending per capita. Assuming that the HSCRC and hospital rate regulation remain, HSCRC will closely regulate capital funding in hospital rates to ensure that Maryland meets the model's targets.

Hospital and health system operating margins and the current market environment – from competition for physician resources to the incentives to collaborate – provide additional, inherent barriers to prevent the development of unnecessary services. These barriers naturally apply before an organization considers developing a new service that requires CON approval.

If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

As reflected in the answer to question 1, there is abundant hospital competition in the current environment, and the Model's incentives encourage hospitals to collaborate.

Mercy is participating with the MHA work group is reviewing CON statutes and regulations, the State Health Plan and other regulations, and will bring specific recommendations to the commission as the group finishes its review. Preliminarily, hospitals suggest reviewing regulations that are no longer required because they were implemented prior to specialized care standards being established (e.g., perinatal standards may replace the need for neo-national Certificate of Need approval). Any changes should not undermine the core principles of CON review. The approach to CON review, gathering market and regulatory information that has evolved over the years should be modernized.

There is strong need for adequate behavioral health services to address access and quality. Any regulation assessment should begin with behavioral health services, given the current market dynamics and the out-dated state health plan regulations.

3. How does CON regulation stifle innovation in the delivery of hospital services under the current Maryland regulatory scheme in which hospital rate-setting plays such a pivotal role?

Maryland's hospitals are some of the most innovative health care institutions in the United States. As reflected in our answer to question 1, there is abundant competition in the current environment, while the model's incentives also encourage hospitals to collaborate with each other. Maryland's All-Payer Model provides incentives for innovation designed to achieve the triple aim.

This question appears to be about how reimbursement encourages or discourages innovation. In certain cases, reimbursement hasn't caught up to innovation, but this is often a reality of the market. Certificate of Need neither stifles nor enhances innovation.

The MHCC, the HSCRC and other State agencies need to think innovatively about how care can be provided more effectively in lower cost settings, delivered where people need such services. More than just the Commission, other state agencies are involved. This includes the Office of Health Care Quality and Maryland Institute for Emergency Medical Services Systems. MHCC, through statute or regulation, could play a leading role to shepherd innovation among all regulatory agencies.

The State Health Plan should be updated in accordance with the statute. This means more timely reviews of each chapter as innovation drives health care delivery system changes.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish or relocate a hospital, expand bed capacity or operating room capacity at ta hospital, introduce certain services *at a hospital, or undertake capital projects that exceed a specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:*
*http :// www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=l0.24.01.**

4. Should the scope of CON regulation be changed?

The general scope of CON is appropriate and reasonable. There are adjustments that can and should be made, but these adjustments do not fundamentally alter the CON program.

The MHA work group is reviewing CON statutes and regulations, the State Health Plan and other regulations, and will bring specific recommendations to the commission as the group finishes its issue review. See Mercy's responses to question 2 and question 3 for initial reactions. If other regulatory systems are in place, the Commission might consider removing certain regulatory requirements.

A. Are there hospital projects that require approval by the Maryland Health Care Commission that should be deregulated?

The Commission should consider eliminating, or significantly raising, the capital spending threshold for projects that do not change the number of a hospital's beds or expand covered hospital services. Additionally, MHCC might consider limiting the scope of services required under CON (e.g., the perinatal example in the response to question 2.)

Maryland's All-Payer Model is expected to continue, so the need to align CON and Model incentives is critical. Ultimately, review of CON may require rethinking HSCRC regulatory approaches. Historically, CON approval was the "key to unlock the door" to potential capital rate relief. If the capital threshold is raised or eliminated, this may change the view of CON requirements for rate relief.

Hospital boards are stewards of community resources, and are not going to invest in capital projects they cannot afford. In our answer to question 2, operating margins and the health care market are natural barriers to unchecked service development. The availability and concentration of scarce clinical resources is another inherent barrier to service development, no matter what the community desires.

The MHCC guidance contemplates deregulating services and creating new review classes as ideas to improve the CON application process. Reducing unnecessary approval steps and enforcing the decision timeline, coupled with clear rules and consistent interpretation of those rules, will streamline reviews without changing CON requirements.

B. Are there hospital projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

Mercy is participating in the MHA work group that is discussing this issue, and how CON statutes and regulations should address this consideration against the backdrop of the Model's constraints.

Without recommending additions to the scope of CON regulation, we remind the Commission that there are a range of services provided at hospitals that are not covered by CON review, or can be exempt from CON review, if provided outside of the hospital. Diagnostic imaging, infusion, and ambulatory surgery contribute significantly to covering the fixed costs and semi-fixed costs required to operate hospitals. Outside of hospitals, when Medicare volume increases, total Medicare spending per beneficiary increases.

Though not an MHCC issue, an alternative under question 4A is to potentially allow hospitals to deregulate outpatient services on an expedited basis. Alternatives might include moving services to unregulated space or allowing certain services to be deregulated within a hospital. The latter raises several issues, but all options should be identified. The MHA work group is still discussing these topics.

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

CON approval, unless contested, is supposed to be complete within 150 days of docketing. Maryland's hospitals identified potential areas for the commission to address:

- ***Before an application is even docketed, completeness questions can cause significant delays. We recommend that the commission limit MHCC staff to one round of completeness questions, and the completeness questions must be germane and essential to making a decision on the CON application.***

- *From the hospital perspective, MHCC regulations governing charity and uncompensated care should be moved to the HSCRC's jurisdiction. This includes the timeline for determination of whether a patient is eligible for charity care. HSCRC governs hospital rates, including charity care and uncompensated care provisions. MHCC may continue to request this information from other providers to fulfill certain requirements for CON eligibility.*
- *For hospital projects, financial projections, including inflation, are reviewed by HSCRC to determine if the results are reasonable, while the projections submitted to MHCC exclude inflation. Hospitals that assume a rate increase for financial feasibility will naturally require additional approval steps. They must concurrently file an HSCRC rate application requesting the rate increase reflected in the CON application.*
- *Even with projects that include interested parties and/or involve comparative review, a delay in a single application step should not automatically delay deadlines throughout the whole project. Hospitals agree that if an applicant has delayed the process, then the applicant must recognize the consequences.*
- *The submission forms can run in excess of 120 pages. The commission should review the submission forms and eliminate anything that is not required to determine CON approval.*
- *For renovation-only projects that do not change the scope of hospital services, the commission should consider replacing the quantitative analysis with a simple narrative. Hospital margins and the hospital's board of directors should demonstrate adequate stewardship of resources.*
- *Applicants should not have to submit pro-forma documentation, such as quality metrics, if the documentation has already been filed with MHCC, the HSCRC or another state regulatory agency.*

In general, the SHP must have clear and straightforward guidelines, and MHCC must follow those guidelines. The MHA work group plans to thoroughly review the general MHCC regulations and the SHP chapters. Recommendations from this review will aim to improve the application process by refining review steps.

6. Should the ability of competing hospitals or other types of providers to formally oppose and appeal decisions on projects be more limited?

No, the Commission should not consider limiting interested parties on projects. The Commission already has statutes and regulations in place to determine interested and "adversely affected" parties. Those seeking to be interested parties must demonstrate impact from the proposed project. This impact should be demonstrated with well-organized, data-driven analyses and not a presumption of impact. This might include parties that have services in the applicant's service area, or parties that may be impacted if the applicant is seeking specialized regional or statewide services. Even with interested parties, the approval process should not be delayed. While the commission should not consider limiting provider interested parties on projects it should exclude insurance companies from having interested party status for hospital project.

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

Mercy is participating in the MHA work group that will consider this issue. The CON exemption review process is arduous, requiring significant time and effort before the Commission grants an exemption. The main difference between a CON exemption request and CON approval is the allowance of interested parties. However, a CON exemption request requires much of the same information and many of the same review steps.

The Commission might simplify the requirements to grant CON exemptions. If the Commission is concerned about quality of care, the licensure requirements could be reviewed and augmented.

Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

The exemption for merged asset systems should continue.

7. **Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)**

Project completion timelines should be reviewed, particularly reporting compliance after project approval. Currently, the post-approval quarterly reporting forms are very complicated, especially for a large project. The forms should be simple and should only collect information that was relevant to the project approval decision.

Though largely an HSCRC issue, the Commission might also consider an approved project's impact on spending per capita. After the project is approved and in service, for the primary service area, the Commission could measure the service-specific spending per capita compared to a prior period.

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for hospital facilities and services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

The State Health Plan should begin with a clear purpose, accompanied by two to three key goals and objectives. The purpose and goals should align with the Model because the State is collectively at risk to achieve the model's goals. In particular, the State Health Plans' goals should take into account the model's influence on the demand for health care services, which in turn influences the "need" for services.

The chief strength of these regulations is the idea that there should be "standard" criteria to determine the need for a project. However, incentives in the Maryland Model

directly affect the demand for services. State Health Plan criteria deal with providing an adequate supply of services to meet the demand.

The regulations are static, and some haven't been updated in many years. The inpatient psychiatric services chapter has not been substantially updated in 20 years. Meanwhile, the state closed several state-owned psychiatric facilities. The State Health Plan needs to be updated, and flexible enough to account for changes in emerging technologies, like telehealth, as well as technologies that do not yet exist, but will shape future health care delivery.

MHA's work group plans to discuss the purpose and goals of the State Health Plan. The work group then plans a chapter-by-chapter review to suggest revisions and modifications. We expect this process to take place concurrently with the Commission's work group.

9. Do State Health Plan regulations focus attention on the most important aspects of hospital projects? Please provide specific recommendations if you believe that the regulations miss the mark.

See Mercy's response to question 8, in particular the last paragraph.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

The State Health Plan should be more regularly reviewed and update, in accordance with the current legal requirements. The MHA's work group acknowledged that a SHP chapter review involves a significant time commitment. Given the commitment, the Commission, with input from the public, should prioritize the SHP chapters that are ripe for review and revision.

When State Health Plan chapters are revised, Commission staff often create a stakeholder work group to provide input and feedback. This feedback is then synthesized by Commission staff into a series of recommendations, and a revised chapter is drafted. The Commission will solicit informal, then formal public comments. These comments receive written responses from staff that are shared with Commissioners. However, oral comments are not considered at the public meetings. When ripe for Commission action on a chapter of the State Health Plan, the Commission should welcome comments at a public meeting.

At a minimum, at the end of this review process, when the Commissioner-led work group releases its final recommendations for commission action, the full Commission should allow presentations and comments before voting.

General Review
Criteria for all Project Reviews

COMAR 10.24.01.08G{3}(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

In general, the criteria are appropriate but need to be applied consistently to all CON applications, particularly the "need" criteria. The criteria should be reviewed to determine the model's influence on the demand for services. This influence may require revising the need criteria, particularly the formulas to determine inpatient beds. Mercy is participating with the MHA work group that is reviewing the State Health Plan. Recommendations will be shared with the commission when the process is complete. At a minimum, ***hospital requirements*** *to report charity/uncompensated care are not needed, or should fall under HSCRC jurisdiction.*

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

12. If you believe that CON regulation of hospital capital projects should be eliminated, what, if any, regulatory framework should govern hospital capital projects?

Mercy strongly support the continuation of CON requirements. *CON is appropriately necessary to operate under Maryland's All-Payer Model. Mercy is collaborating with the MHA work group to review individual services to determine whether certain regulations are no longer required because other clinical or application standards have been established.*

Absent another mechanism to hold non-hospital service providers accountable for achieving model targets, the commission must continue to regulate the supply of services.

13. What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?

See the response to question 12.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of hospital licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain hospital facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under- utilization or poor quality of care? Are there

ways (other than those touched on in earlier questions) in which the regulation of hospital charges could be adapted as a substitute for CON regulation?

Given the unique payment system in Maryland, CON review is needed to determine the most efficient use of limited resources.

From a financial perspective, the HSCRC serves as an important hospital regulatory body. HSCRC and the Maryland Department of Health are leading the negotiations to extend Maryland's All-Payer Model. The HSCRC has imposed global budgets that create much different incentives to constrain avoidable and unnecessary health care service use. Mercy does not propose that HSCRC set rates or otherwise regulate non-hospital providers, but reminds the Commission that hospitals are already heavily regulated.

Though hospitals support the overarching CON principles, other regulatory requirements might be leveraged to appropriately regulate other health care services. Licensing and/or certification requirements should be explored further.

Changes to regulatory mechanisms, particularly out of MHCC's scope, may require a reallocation of resources away from MHCC to other state agencies with a corresponding reduction in MHCC user fees.

The Impact of CON Regulation on Hospital Competition and Innovation

15. **Do you recommend changes in CON regulation to increase innovation in service delivery by existing hospitals and new market entrants? If so, please provide detailed recommendations.**

See the response to question 3. CON is not an impediment to innovation. Changes in the hospital payment system have created incentives for Maryland's hospitals to serve as innovators. The hospital marketplace provides an appropriate balance of competition and collaboration. By adopting, supporting and extending the model, the state, through HSCRC, has given hospitals the implicit directive to collaborate and improve the health of the population. Global budgets are driving innovative alignments of hospitals, physicians and post-acute providers.

More timely updates of the State Health Plan are needed as delivery system changes outpace the existing regulations. MHA's work group is reviewing CON, the State Health Plan and other regulations to make specific recommendations regarding revisions.

16. **Should Maryland shift its regulatory focus to regulation of hospital and health systems merger and consolidation activity to preserve and strengthen competition for hospital services?**

No; other regulatory bodies already provide adequate oversight of hospital mergers – the Federal Trade Commission, the Department of Justice, and the antitrust division of the Attorney General's office.

Scope of CON Regulation

17. Should the scope of hospital CON regulation be more closely aligned with the impact of hospital projects on charges?

No; there are sufficient incentives under the All-Payer model to control hospital charges. The Model limits all-payer per capita growth and Medicare payment per beneficiary growth. Any rate increase to cover capital expenditures will affect these growth rates. Therefore, hospitals must reduce avoidable and unnecessary service use to generate additional savings, or the HSCRC must regulate hospital payment rates to maintain compliance with the model.

Non-hospital providers have the ability to grow volume to pay for capital and operating expansions. Unlike hospitals, these providers are not subject to global budgets, and therefore, revenues will increase as volumes increase.

A. Should the use of a capital expenditure threshold in hospital CON regulation be eliminated? For example, should hospital capital projects or certain types of hospital project only require a CON if the hospital seeks an increase in its global budget to cover project-related capital cost (depreciation, interest, and amortization) increases? Alternatively, should CON regulation be based on the overall impact of projects on hospital revenues (related to coverage of both capital and operating expenses, which could increase substantially even for low cost projects if new services are being introduced?)

Please see the response to question 4A.

For projects that do not add hospital beds or change the hospital service portfolio, the Commission should consider eliminating, or significantly raising, the capital threshold.

Unless the HSCRC grants a hospital rate increase, no additional revenue is added to the system for approved hospital projects. The hospital provider, or parent health system, is at risk for having the resources to cover capital expenses. Operating revenue may increase from market shift, or the hospital has the ability to file a rate increase application. However, Maryland's all-payer per capita growth and Medicare spending per beneficiary growth are ultimately capped by the Model and HSCRC regulates hospital revenue to ensure compliance.

A different approach might be to estimate the impact of the project on total cost of care growth, particularly for non-hospital services. This could be done when evaluating a CON application or by determining that services should be added or removed from the scope of CON regulations.

B. Should Maryland's system of hospital rate regulation include capital spending

growth targets or capacity growth targets that shape the scope of CON regulation? If so, how would this work? For example, should CON regulation be redesigned to move away from single project review(s) for a multiple hospital system to a broader process of reviewing systems resource development needs and priorities?

Mercy does not support this approach. The hospital market encourages a balance of competition and collaboration. The Commission should review each project on its individual merits and should not predetermine capital projects for a given period. This would stifle innovation and the ability of the market to determine the most efficient use of capital, conditions that exist under the current CON regulatory umbrella. Mercy does not support deregulation of CON review, and it does not support the Commission usurping health system management and planning functions.

Maryland's rate regulation system should provide hospitals adequate capital funding. When the rate setting system was developed, funds were not placed in rates for replacement or renovation of aging facilities. Rather, the HSCRC would review and approve hospital rate increases to cover the cost of capital at the time of replacement. Under a fixed revenue system, the HSCRC might consider revising the historic Capital Facilities Allowance that provided hospitals with a benchmark for capital funding. The MHA's work group may explore this issue further.

18. **Should MHCC be given more flexibility in choosing which hospital projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the hospital to undergo ·CON review.**

No; the MHCC should not be given more flexibility in choosing which projects require approval. This would likely result in greater uncertainty and the potential for arbitrary decisions. The Commission should adopt policy principles and clear, unambiguous regulations to guide decision making. Decisions should be applied consistently. If the application process is too complicated, simplify the regulations that govern the process and eliminate unnecessary steps that will not affect decisions by the Commission. The policy principles should be reviewed at regular intervals with respect to Maryland's performance under the anticipated Enhanced Total Cost of Care Model, and the regulations, including chapters of the State Health Plan, should be updated on a regular basis. The policy principles may reference incentives to expand or contract types of service providers, steered by having the flexibility to determine which providers or projects require CON approval.

19. **Should a whole new process of expedited review for certain projects be created? If so,**

what should be the attributes of the process?

The previous MHA CON Task Force discussed a "fast track" approach for projects with no interested parties and a documented need in the State Health Plan. Other possibilities include no assumption of hospital rate increases or projects that demonstrate significant cost savings.

The Project Review Process

20. Are there specific steps that can be eliminated?

Completeness questions should be limited to one round, and they should be limited to only those issues that are essential to a Commission decision.

21. Should post-CON approval processes be changed to accommodate easier project modifications?

Yes, particularly for projects without new beds or services.

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

See the response to question 19. Additionally, if the State Health Plan is updated on a regular basis, it will improve the process by eliminating certain requirements. Changing the State Health Plan should create room to expedite reviews for small delivery changes.

23. Would greater use of techno logy including the submission of automated and form-based applications ion improve the application submission process?

Possibly, but if the form continues to exceed 120 pages, it will still be arduous. The Commission should explore the potential to submit auto-generated forms for post CON follow up. The Commission should review what is currently required in a CON application to determine if the information is critical to making a decision, or, whether the information is already publicly available.

Questions 20 through 23 will continue to be discussed by the MHA work group.

In general, ***the Commission should identify steps that add little or no value to the CON decision-making process and remove those steps.*** *Several areas should be considered, including the charity care policy, cost per square foot benchmarks, etc. The Commission should investigate whether an incentive that created the CON requirement is still valid, or whether the incentive been superseded by other regulatory actions, innovation, and/or market forces.* ***Commissioners and the legislature should not hesitate to eliminate steps that are no longer necessary, but have not changed because there has been no real incentive to change.*** *Mercy agrees with Commission staff that "rules matter." It is time*

to review the rules and eliminate those that are unneeded.

Duplication of Responsibilities by MHCC, HSCRC, and the MOH

24. **Are there areas of regulatory duplication in the hospital capital funding process that can be streamlined between HSCRC and MHCC, and between MHCC and the MOH?**

    No response.

25. **Are there other areas of duplication among the three agencies that could benefit from streamlining?**

    MHA's work group will discuss these questions and provide specific responses to the stakeholder work group.

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and/or recommendation(s) in each area of inquiry.

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January 26, 2018

VIA EMAIL

Paul.Parker@maryland.gov
Ruby.Potter@maryland.gov

Paul Parker, Director
Center for Health Care Facilities and Development
c/o Ms. Ruby Potter
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: ***Modernization of Certificate of Need Program***

Dear Mr. Parker,

I write on behalf of the University of Maryland Medical System ("UMMS") in response to the Maryland Health Care Commission's November 21st request for comment on the modernization of Maryland's Certificate of Need ("CON") system. As the Commission is aware, UMMS is a university-based health care system that delivers care at more than 150 locations, including the academic University of Maryland Medical Center, eleven community hospitals, and two specialty hospitals, to individuals in central and southern Maryland and the Eastern Shore.

UMMS appreciates the opportunity to comment on the evaluation of modernizing the CON program. The comments enclosed with this letter represent the joint collaboration and consensus of the fourteen hospitals within UMMS. As reflected in the comments, UMMS supports the continuation of a modernized CON program that is more narrowly tailored than existing regulation both in the scope of projects requiring a CON and standards for evaluating CON projects.

Maryland implemented the CON program at a time when less overall regulation of hospitals and hospital services existed and, in particular, the method of regulating hospital revenue was significantly different. The CON process has become, in some ways, an obstacle to hospital planning at a time when hospitals are incentivized under the All-Payer Model between Maryland and the Centers for Medicare & Medicaid Services to seek innovative ways to provide care in lower cost settings. The planning process is often impacted by the unpredictable length and broad scope of CON review. Some of the impediments imposed by the CON process do not come with a corresponding benefit given the existing breadth of regulation of hospitals and health-care spending that exists in Maryland today. A CON process that is narrower in both scope of projects that require review and standards applicable to a review, will allow Commission staff to conduct prompt, narrow, focused reviews of the most significant and impactful health planning projects, while allowing hospitals flexibility in planning as they seek to effect cost-saving changes in the health care delivery system.

As described in more detail in the enclosed comments, UMMS recommends elimination of a CON requirement for: (1) hospital capital projects, (2) the expansion of existing services within a hospital or hospital system, and (3) the establishment of most new services at an existing acute care hospital. UMMS recommends maintaining CON regulation for the establishment of a new general or special hospital, relocation of a hospital, and the establishment of some specialized services. For the remaining CON projects, UMMS recommends that the Commission, and the Maryland General Assembly, streamline the standards used to evaluate projects to standards focused narrowly on need, adverse impact on other providers, access, and, to a limited extent, volume, if volume is clearly correlated with quality for the regulated service.

The CON scope and review process changes that UMMS advocates are not aimed at changing the competitive landscape for hospitals in Maryland, but in making hospital planning more efficient, effective, timely, and less costly. UMMS believes that health care planning concerns addressed by the regulations that UMMS recommends modifying either already are or, with little change could be, more effectively regulated and managed by other agencies, including the Office of Health Care Quality within the Maryland Health Department, and the Maryland Health Services Cost Review Commission.

Thank you for your consideration of these comments.

Sincerely,

Donna L. Jacobs, Esq.
Senior Vice President
Government, Regulatory Affairs and Community Health

cc: Alison Brown

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University of Maryland Medical System Response to MHCC CON Study, 2017-2018, Comment Guidance – Hospital

The University of Maryland Medical System ("UMMS") submits these comments on behalf of itself and the fourteen hospitals within the system in response to the November 21, 2017 request of the Maryland Health Care Commission (the "Commission") for comment on the modernization of Maryland's Certificate of Need ("CON") program. The text of the Commission's survey is copied below in bold italics. UMMS responds under the headings "UMMS Comment."

COMMENT GUIDANCE – HOSPITAL
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's adoption of global budgets for hospitals, its commitment to achieve the goals of the Triple Aim, and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of hospital CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of hospital CON regulation?

☐ ***CON regulation of hospital capital projects should be eliminated.***

[If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13 to 15.]

☑ ***CON regulation of hospital capital projects should be reformed.***

☐ ***CON regulation of hospital capital projects should, in general, be maintained in its current form.***

UMMS Comment

[Note: This question refers to "capital projects," but given the surrounding context and comment that a recommendation to eliminate the Certificate of Need ("CON") requirement for capital projects will render many of the following questions moot, UMMS interprets the term hospital capital projects as used to refer to all hospital projects, not only those that require a CON solely because the project cost exceeds the Commission's capital expenditure threshold.]

Maryland adopted and implemented its CON program at a time when the method of regulating hospital rates and revenue differed significantly from the global budget revenue rate-setting methodology ("GBR") of the Maryland Health Services Cost and Review Commission ("HSCRC") that exists today, a response to the All-Payer Model between Maryland and the Centers for Medicare & Medicaid Services ("CMS"). Under the All-Payer Model and GBR rate-setting, hospitals are incentivized to seek innovative ways to provide care in lower cost settings. In addition, because GBR does not include any allowances for capital expenditures, hospitals must seek, and justify, rate changes to the HSCRC in order to have sufficient capital to engage in capital spending above the level of the existing CON capital threshold. In sum, today the HSCRC exercises strong regulatory oversight and control of hospital expenditures.

Considerable regulatory oversight of Maryland hospitals also exists in the arena of patient safety and quality of care. The Office of Health Care Quality ("OHCQ") and The Joint Commission appropriately monitor safety and quality issues, and certain specialized hospital services also adhere to national guidelines.

In light of the incentives of the All-Payer Model and the HSCRC's oversight of hospital budgets, the Commission's oversight of hospital capital expenditures and changes in beds and services is duplicitous and creates delays in the planning process. Of course, if the demonstration project does not meet the benchmarks for renewal and hospital rate-setting changes dramatically in the future, CON regulation of capital expenditures and bed and service changes may once again be an appropriate way to effect measured hospital spending that balances need with costs to payers and the healthcare system. If that should happen in the future, the Commission could recommend that the Maryland General Assembly renew regulation of capital expenditures and changes in beds and services. Under today's regulatory framework, however, the Commission's oversight of many of these hospital projects creates unnecessary procedures that restrict timely and innovative hospital planning.

ISSUES/PROBLEMS

The Impact of CON Regulation on Hospital Competition and Innovation

1. ***In your view, would the public and the health care delivery system benefit from more competition among hospitals?***

UMMS Comment

Maryland hospitals collaborate and compete in productive and beneficial ways today, in part because the All-Payer Model encourages collaboration as hospitals work collectively to reduce hospital spending. The scope and review process changes to the CON program that UMMS proposes in these comments are not aimed at changing the competitive landscape for hospitals in Maryland. Rather, UMMS seeks to make hospital planning more efficient, effective, timely, and less costly.

2. ***Does CON regulation impose substantial barriers to market entry for new hospitals or new hospital services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?***

UMMS Comment

The CON process does impose barriers to entry for new hospitals and services. As addressed more fully in UMMS' opening comment and in response to Question 4, UMMS posits that barriers for certain services are inappropriate, and stifle hospital planning without a commensurate benefit to the healthcare delivery system. As stated in response to Question 1, UMMS advocates for these changes to make hospital planning more efficient and timely.

3. ***How does CON regulation stifle innovation in the delivery of hospital services under the current Maryland regulatory scheme in which hospital rate-setting plays such a pivotal role?***

UMMS Comment

Some CON regulations are duplicitous and unnecessary in light of Maryland's current regulatory scheme for hospital rate-setting. The All-Payer Model and GBR system incentivize hospitals to encourage care in lower cost settings. Currently, however, Maryland's CON program restricts hospitals seeking to provide alternatives for hospital emergency or inpatient care, such as through the establishment of ambulatory surgical facilities and freestanding medical facilities. Strict regulation of such facilities and the length and uncertainty of the CON review process impose barriers and impede hospital innovation on how to most effectively reduce spending while improving care.

In addition, as addressed more fully in UMMS' opening comment and in response to Question 4, CON review of many hospital projects is duplicitous in light of hospital rate-setting. As addressed more fully in response to Question 9, concerning the State Health Plan chapters, and Question 11, concerning General Review Criteria, the Commission's review of criteria and standards involving the financial aspects of a regulated project, such as financial feasibility, viability, and cost-effectiveness, are also duplicitous and unnecessary in light of the strong role of the HSCRC in approving hospital rates and budgets.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish or relocate a hospital, expand bed capacity or operating room capacity at a hospital, introduce certain services at a hospital, or undertake capital projects that exceed a specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:

http :// www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.*

4. Should the scope of CON regulation be changed?

A. Are there hospital projects that require approval by the Maryland Health Care Commission that should be deregulated?

UMMS Comment

As described in response to Question 3, under the All-Payer Model, hospitals are incentivized to plan carefully and reduce the cost of care. Hospitals are also incentivized to consider lower-cost alternatives to inpatient and emergency care. In addition, the OHCQ and The Joint Commission monitor hospital quality. Certain specialized hospital services also adhere to national quality standards. As a result, for hospital services for which quality outcomes are not closely correlated with volume, CON regulation is not necessary.

UMMS urges the deregulation of most CON projects for existing providers, including deregulation of the following projects currently subject to CON review:

- Relocation of an existing health care facility to another site, COMAR § 10.24.01.02.A(2), if the new location is within the facility's existing primary service area;
- Change in the bed capacity of a health care facility, COMAR § 10.24.01.02.A(3), unless the change is for inpatient psychiatric services in a

special psychiatric hospital and the provider will no longer be eligible to receive Medicaid reimbursement or payment as a result of the change;

- Change in the type or scope of any health care service offered by a health care facility, COMAR § 10.24.01.02.A(4), and the change:
    - Establishes a new medical service, COMAR § 10.24.01.02.A(4)(a), defined by COMAR § 10.24.01.B(27) as:
        - Any of the following categories of health care services as they appear in the Commission's inventories of service capacity:
            - Medical/surgical/gynecological/addictions;
            - Obstetrics;
            - Pediatrics;
            - Psychiatry, unless the new service will not be eligible for Medicaid payment or reimbursement;
            - Rehabilitation;
            - Chronic care;
            - Comprehensive care;
            - Extended care;
            - Intermediate care; or
            - Residential treatment;
        - A subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of medical services for which the State Health Plan provides a need projection methodology or specific standards (subject to same comment above regarding psychiatric services);
    - Establishes a new neonatal intensive care program, COMAR § 10.24.01.02.A(4)(b) (in part, other programs excluded);
    - Establishes a new home health agency, general hospice care program, or freestanding ambulatory surgical facility, COMAR § 10.24.01.02.A(4)(c);
    - Builds or expands ambulatory surgical capacity in any setting owned or controlled by a hospital, COMAR § 10.24.01.02.A(4)(d);
    - Results in the establishment, expansion, or transfer of ownership of a home health agency or home health care service, COMAR § 10.24.01.02.A(4)(e);

- Closes or temporarily delicenses an existing medical service (and is not otherwise defined under the non-coverage regulation), COMAR § 10.24.01.02.A(4)(f); or
- Closes an existing health care facility or converts it to a non-health-related use COMAR § 10.24.01.02.A(4)(g);

- Capital expenditure by a hospital at any amount, COMAR § 10.24.01.02.A(5);

The proposed deregulation will also require legislative changes.

The deregulation proposed above would render the majority of the regulation under COMAR § 10.24.01.03, Non-Coverage by CON Review Requirements, and § 10.24.01.04, Exemption from CON requirements, moot. If the Commission and Maryland General Assembly do not fully deregulate each of the projects described above, UMMS recommends, in the alternative, that the Commission consider subjecting such projects to the less cumbersome review process of a CON exemption, determination of non-coverage, or some other new form of expedited review process.

UMMS does not recommend deregulation of the following projects currently subject to CON review:

- The establishment of hospital services by new market entrants, *i.e.*, the Commission should continue to regulate whether a "[a] new health care facility" may be "built, developed, or established" pursuant to COMAR § 10.24.01.02.A(1).

- The establishment of a new burn treatment, open heart surgery, or organ transplant surgery program (COMAR § 10.24.01.02.A(4)(b), in part), remain subject to CON review because the there is a recognized correlation between quality outcomes and volume for those services.

- The relocation of an existing health care facility to another site, COMAR § 10.24.01.02.A(2), if the new location is <u>not</u> within the facility's existing primary service area.

- The establishment of a new medical service for psychiatric services (COMAR § 10.24.01.02.A(4)(a); COMAR § 10.24.01.B(27)), or a change in beds of an existing facility providing psychiatric services, if the facility will not be eligible for Medicaid payment or reimbursement.

- The establishment of a freestanding medical facility ("FMF") by an existing acute care provider, where the provider is <u>not</u> establishing an FMF in its primary service

area or is not involved in a process of converting an existing acute care facility to a more limited scope of services.[1]

B. Are there hospital projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

UMMS Comment

UMMS does not believe new CON regulation of currently non-regulated hospital projects is necessary.

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

UMMS Comment

Some aspects of the CON review process pose significant barriers to hospital planning today because the current process does not allow hospitals to predict the timing, depth, or focus of an individual review. Three "choke-points" in the current process include (i) out-of-date review standards and criteria; (ii) review standards and criteria that are ambiguous or applied inconsistently; and (iii) a lack of clear timeline or enforcement mechanism.

(i) Out-of-date review standards and criteria

Outdated review standards can create a significant waste of resources and time in health care planning. By statute, the State Health Plan must be adopted every five years. Md. Code, Health General Article, § 19-118. Several State Health Plan chapters contain review standards and criteria or need methodologies that are outdated and have not been reviewed or revised in well more than five years. As a result, applicants sometimes must apply for a project without knowing what standards or criteria will be applied to it, or how the Commission will interpret out-of-date standards. The lack of clear standards is an impediment to the planning and application process because applicants may plan a project that the Commission will ultimately determine must be modified to meet the Commission's interpretation of an out-of-date standard – an interpretation that was unknowable to the applicant during the planning and application process. The Commission staff, in turn, spends significant time bringing out-of-date

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[1] Under current law, a general hospital may convert to an FMF pursuant to a CON exemption process. COMAR § 10.24.09.04C. UMMS proposes that such a conversion should be deregulated for an existing general hospital where the converted FMF would be located in the converting hospital's primary service area.

review criteria or standards up to date on an ad hoc basis, or creating alternatives, and then must review the project on these bases. This is a waste of resources for all parties.

As an example, applicants sometimes must apply for a project based on a need projection that is several years out of date. The applicant in such a scenario must advocate for a method to update the existing need projection methodology. The Commission staff will either accept the applicant's analysis, or will create their own update. If the applicant does not meet the updated need standard advocated by staff, staff will not recommend applicant's project. If instead the Commission timely updates need projections as required by statute, applicants will know in advance whether their applications are consistent with current need projections. If the projects they are considering exceed those projections, they will be able to direct their resources to other projects without costly and unnecessary delay.

The existence of outdated review standards and criteria may also result in a decision based on sound health care planning policy, but inconsistent with the applicable State Health Plan chapter. In an uncontested review, this may not pose a problem other than the increased uncertainty and potential additional planning costs described above. However, in a contested review, if the Commission grants a CON based on a State Health Plan chapter that includes a review standard that is impractical or impossible to apply because it is out of date, the decision will subject the Commission and the CON applicant to potential legal action by interested parties.

Examples of outdated standards include, but are not limited to:

- COMAR § 10.24.07 – Psychiatric Services – This chapter was last updated in October, 1996 for the five year term 1985-1990. The standards are significantly outdated and it should be replaced.

- COMAR § 10.24.18 – Specialized Health Care Services – Neonatal Intensive Care Services (Effective Feb. 9, 1998; Suppl. 1 Effective Dec. 14, 1998; Suppl. 2 Effective Oct. 23, 2006) – The Commission has not revised this chapter in more than a decade. The Commission should, at a minimum, consider whether the Minimum Volume standard reflects the current standard of care, and review the definitions for potential update based on advancements in the field.

- COMAR 10.24.10 – Acute Care Hospital Services (Effective Jan. 26, 2009) – Standard .04A(3)(b) requires an applicant hospital "with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospital's reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall

document each action it is take to improve performance for that Quality Measure." The Hospital Performance Evaluation Guide has evolved, and has not reported data in a method that would allow a hospital to determine its quartile ranking or compliance level since the measurement timeframe for January 2012 to December 2012. Commission staff has required hospitals instead to report on any quality measures now ranked as "below average" and provide a plan for correction. This is inconsistent with the plain reading of the standard, but strict compliance is also impractical. As a result, applicants are in regulatory limbo, and a decision under this chapter is subject to potential judicial action by an interested party for failure to comply with the State Health Plan.

- 10.24.17 – Specialized Health Care Services – Cardiac Surgery and PCI (Effective Nov. 9, 2015) – In the recent comparative CON review for the establishment of cardiac surgery services in the Upper Shore region, the Commission decision found that Standard .05A(7), Financial Feasibility, was not responsive to the current All-Payer Model and that if strictly interpreted, no applicant could meet the standard. While UMMS disagrees with that interpretation (UM Baltimore Washington Medical Center and UM Prince George's Hospital Center are parties in that case), if this standard remains a part of the Commission's CON review following modernization of the CON program, the Commission should revise the standard to consider the current rate-setting methodology.

(ii) Review standards and criteria that are ambiguous or applied inconsistently

Ambiguity in how compliance with certain standards and criteria will be evaluated and inconsistent evaluation by the Commission furthers the unpredictability of the CON review process. The Commission should publish regulations that make clear how compliance with review standards and criteria will be evaluated.

In addition, any methodologies that the Commission will use to evaluate compliance with a review standard should be published through rulemaking in a transparent process. The use of new methodologies not set forth in Commission regulations creates unpredictability in the planning process and wastes significant resources of applicants who would be better positioned to determine whether to apply for a CON if the Commission published clear guidance on what methodologies would govern a review in advance.

The recent comparative review of applications to establish cardiac surgery services in the Upper Shore region illustrates the inefficiency posed by the inconsistent application of ambiguous standards and the late revelation of methodologies to evaluate compliance with ambiguous standards. The Commission's inconsistent application of

the minimum volume standard in that cardiac surgery review as compared to prior reviews, the lack of clear instruction in the standard itself, and the late revelation of a new methodology to evaluate the standard at the close of the review left the parties without predictability in the process. This has cost the parties and the Commission significant time and resources, and has delayed the establishment of a cardiac surgery program in Anne Arundel County. These issues may have been avoided if review standards and criteria provided clear instruction as to how compliance would be evaluated.[2]

(iii) Lack of clear timeline or enforcement mechanism

CON reviews can take a significant and uncertain amount of time, which can impede efficient hospital planning. The table below depicts the average amount of time between the application date and Commission action for decisions from 2014 to 2017, based on type of review:

CON Service/Project Type	No. Reviews 2014-2017	Average Days from Application to Decision
Certificate of Need Reviews		
COMAR 10.24.07: Psychiatric Services	2	371
COMAR 10.24.08: Nursing Home Services	13	275
COMAR 10.24.10: Acute Care Hospital Services	5	608
COMAR 10.24.11: General Surgical Services	8	179
COMAR 10.24.13: Hospice Services	4	264
COMAR 10.24.14: Alcoholism and Drug Abuse, Intermediate Care Facility Treatment Services	4	562
COMAR 10.24.16: Home Health Agency Services	1	132
COMAR 10.24.17: Specialized Health Care Services - Cardiac Surgery & PCI	1	762
Total CON Reviews, Review Days	**38**	**341**
CON Modification	**10**	**120**
CON Exemption	**5**	**99**

A table containing more information for each review is attached as Appendix 1.

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[2] The cardiac surgery review is not the only example where the Commission applied a newly created methodology to evaluate compliance with review standards or criteria at the end of a review, putting the applicant(s) and interested parties in a position where they could not have known at the start of the review how compliance would be measured. The Commission revealed and relied upon new methodologies near the close of reviews in the recent CON projects involving the relocation of Washington Adventist Hospital, Sheppard Pratt at Elkridge, and Prince George's Hospital Center.

This history makes clear that there is little predictability in the timing of CON reviews, and most reviews take longer than the applicant expected. Improvement in both timeline predictability and overall length of time of CON reviews will enable hospitals to engage in more efficient and effective planning.

As discussed more fully in response to other questions, the Commission's review of many CON review standards and criteria is duplicitous with the regulatory control and oversight of OHCQ and HSCRC, as well as the quality monitoring provided by national bodies for certain specialized services. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 4, 11, 14, 17, 24, and 25). Reduction in the scope of projects that require a CON and of the review standards and criteria may allow staff to process applications in a prompt manner. Such changes will require legislative action.

In addition, UMMS recommends imposing more clear regulatory timelines regarding the length of each step of the CON process, and clear guidance as to what relief is available to applicants if the Commission has not met those timelines, such as deemed approvals. Such changes may be accomplished through the regulatory rulemaking process.

6. Should the ability of competing hospitals or other types of providers to formally oppose and appeal decisions on projects be more limited?

UMMS Comment

UMMS believes it would be appropriate to limit the criteria and standards that interested parties are permitted to address to issues directly involving the interested party, such as adverse impact. If volume is correlated with quality for a particular service, it would be appropriate for an interested party to comment on the need for the service. Competing hospital applicants in a comparative review should be permitted to comment on any criteria or standard to the extent that the competing hospital is commenting that its proposal better meets that criteria or standard.

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

UMMS Comment

UMMS advocates for deregulation of CON projects based solely on the project cost exceeding a capital expenditure threshold. However, should the Commission continue to regulate such projects, UMMS believes it would be appropriate to review them through a truncated CON exemption process.

The exemption review for merged asset systems makes good sense and encourages hospitals to collaborate on cost saving measures. The exemption process should continue to be an option for merged asset systems.

7. ***Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)***

UMMS Comment

UMMS believes current regulatory performance requirements should be modified to allow greater flexibility that currently exists where the applicant demonstrates good cause. For any project that remains subject to CON review, obstacles may arise in the course of implementing a project that were not foreseen or foreseeable by applicants. The current strict performance requirements do not allow flexibility for such situations. The imposition of inflexible performance requirements could result in a scenario where an applicant who has received a CON based on a determined need (and compliance with met all other criteria and standards) must reapply for a CON for purely procedural reasons, even where the continuance of performance requirements would be noncontroversial. This could impose additional cost and delay on both the applicant and Commission staff without any commensurate benefit.

The State Health Plan for Facilities and Services

8. ***In general, do State Health Plan regulations for hospital facilities and services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?***

UMMS Comment

As addressed throughout these comments, UMMS believes the Commission's review of any project that remains subject to the CON program should be more limited in scope to issues of need, access, and adverse impact, which would necessitate significant changes in each State Health Plan chapter. Many current regulations concern issues that are already effectively controlled through HSCRC rate-setting and adjustments to GBR, OHCQ licensing and other quality control, and The Joint Commission accreditation and regular survey process. If there is any concern that the removal of quality and financial issues from the CON program would result in insufficient oversight of those issues, adjustments should be made to the regulatory authority of OHCQ and the HSCRC.

In addition, as discussed more fully in response to Question 5, Certain State Health Plan regulations are outdated and should be updated. The paring down of the scope of CON

review would allow the Commission to devote additional resources to more timely updates of State Health Plan chapters and out-of-date need methodologies.

9. ***Do State Health Plan regulations focus attention on the most important aspects of hospital projects? Please provide specific recommendations if you believe that the regulations miss the mark.***

UMMS Comment

UMMS advocates changes to the CON program that would necessitate significant changes to each State Health Plan chapter and the procedural regulations. Even if the Commission does not seek to deregulate the projects identified in response to Question 4, UMMS recommends that the Commission seek to remove several topical areas currently considered by the Commission. UMMS believes that issues involving construction costs, charges, charity care, financial feasibility, and viability, should be within the exclusive regulatory authority of the HSCRC, and that issues involving quality of care, including compliance with quality measures and facility design elements responsive to quality of care issues, should be within the exclusive regulatory authority of OHCQ. UMMS comments below on the State Health Plan chapter for Acute Care Hospital Services for illustrative purposes, and recommends similar changes across all State Health Plan chapters. The deregulation UMMS proposes will require regulatory and legislative changes.

In addition, UMMS notes that different State Health Plan chapters identify standards that appear in all or most chapters, such as financial feasibility, yet these standards, and the method of compliance, are defined differently in different chapters. While some distinction may be necessary based on the different services addressed, some differences in the standards in different chapters do not appear related to the individual service but instead may result merely from the drafting of different chapters at different times. UMMS urges the Commission to define standards similarly across all chapters, such that any differences are for intentional, substantively meaningful purposes.

UMMS also urges the Commission to include guidance and instruction as to how compliance with any standard that remains part of the CON review process will be measured. This will increase the predictability of the CON review process, allowing hospitals to plan more effectively and efficiently, and will protect against the application of inconsistent compliance measures and methodologies in different reviews.

10.24.07 – Psychiatric services. As discussed more fully in response to question 5, this chapter is outdated and should be updated throughout or replaced entirely.

10.24.10 – Acute Care Hospital Services. Many of the review standards within this chapter address concerns that are either already effectively regulated by, or would be better suited for oversight by other agencies.

The HSCRC should exclusively regulate the concerns addressed by the following standards:

- .04A(1) Information regarding charges
- .04A(2) Charity care policy
- 04B(4)Adverse impact, subsection (b) only, concerning rate increase
- 04B(5) Cost Effectiveness
- .04B(7) Construction cost of hospital space
- .04B(8) Construction cost of non-hospital space
- .04B(11) Efficiency
- .04B(13) Financial feasibility.

The OHCQ, with The Joint Commission involvement, should exclusively regulate the concerns addressed by the following standards:

- .04A(3) Quality of care (Note that subsection (b) refers to Quality Measures that are no longer updated. At a minimum, if this issue remains under Commission review, this subsection should be removed or revised.)
- .04B(3) Minimum Average Daily Census for Establishment of Pediatric Unit.)
- .04B(12) Patient safety

The following standards should remain part of Commission's CON review process:

- .04B(1) Geographic Accessibility
- .04B(2) Identification of bed need (However, as noted in response to question 5, UMMS believes certain expansions of beds or new services in existing hospitals should be deregulated entirely.)
- 04B(4) Adverse impact, except that subsection (a) concerning rate increase should be under sole authority of HSCRC
- 04B(6) Burden of proof regarding need
- .04B(14) ED treatment capacity and space
- .04B(15) ED expansion
- .04B(16) Shell space

10.24.11 – General Surgical Services. Should the Commission continue to regulate the addition of surgical capacity at new or existing health care facilities, UMMS recommends, in addition to the general comments above, that the Commission revise the current regulations to employ a more flexible approach to the number of operating rooms that a facility may contain. The costs associated with an additional operating room have minimal impact on the healthcare delivery system. Thus, considerations of

volume and utilization should be balanced with other factors, such as scheduling and convenience, especially where operating costs are not significantly affected.

10. ***Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.***

UMMS Comment

The Commission should provide more opportunity for public comment, including opportunities for stakeholders to address Commissioners directly. For example, the Commission should provide the opportunity for stakeholders to address Commissioners directly at meetings when new regulations are being considered for adoption. Currently, stakeholders may only make comments on regulatory changes during drafting process, and are not permitted to directly address the Commission at the public meeting.

In addition, if the Commission determines that it is appropriate to modernize the CON program in response to this comment process, the Commission should continue to provide opportunities for stakeholders to comment on the scope and nature of proposed changes throughout each step of the process.

General Review
Criteria for all Project Reviews

COMAR 10.24.01.08G{3}(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. ***Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?***

UMMS Comment

Some of the general criteria are duplicative of the regulatory oversight of other agencies. As addressed in response to other questions, the HSCRC has specific expertise and broader regulatory control and enforcement capability over hospital spending than does the Commission. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 14, 17, and 24.)

As a result, UMMS recommends the removal of general criteria (2) Availability of More Cost-Effective Alternatives, and (3) Viability. The concerns that these standards address

are already appropriately met through the HSCRC's oversight. UMMS recommends maintaining the general criteria (1) Need, (4) Impact, and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded CON. This will require regulatory and legislative changes.

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

12. ***If you believe that CON regulation of hospital capital projects should be eliminated, what, if any, regulatory framework should govern hospital capital projects?***

UMMS Comment

As addressed in response to other questions, the current All-Payer Model and HSCRC's oversight and control of hospital budgets provides sufficient governance of hospital capital spending, and the OHCQ and The Joint Commission provide appropriate regulatory oversight of quality and patient safety issues. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 11, 4, 14, 17, and 24.)

13. ***What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?***

UMMS Comment

Deregulation of hospital capital projects will not require changes to the HSCRC's authority. As described in UMMS' initial comment, the HSCRC has sufficient authority to control hospital capital projects because hospitals must seek, and justify, rate changes in order to fund capital expenditures.

A minor legislative change would be needed to remove the reference to a CON in the definition of outpatient services provided in an FMF, Md. Code, Health General, § 19-201(d)(1)(iv).

14. ***Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of hospital licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain hospital facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under- utilization or poor quality of care? Are there ways (other than those touched on in earlier questions) in which the regulation of hospital charges could be adapted as a substitute for CON regulation?***

UMMS Comment

As addressed throughout these comments, the HSCRC and the OHCQ oversight that exists today adequately assures appropriate utilization and quality of hospital facilities and services. Specifically, the HSCRC's global budget revenue model carefully monitors utilization of hospital services and adjusts hospital budgets based on such utilization. Further regulation is not necessary.

Quality is an important consideration for every hospital. The OHCQ and The Joint Commission monitor hospital quality. Certain specialized hospital services also adhere to national guidelines. The Commission's lack of enforcement following first-use approval and the duplication of Commission and OHCQ review of quality issues make it preferable for quality issues to be within the exclusive control of the Maryland Department of Health.

The Impact of CON Regulation on Hospital Competition and Innovation

15. ***Do you recommend changes in CON regulation to increase innovation in service delivery by existing hospitals and new market entrants? If so, please provide detailed recommendations.***

UMMS Comment

Maryland hospitals are well positioned under the All-Payer Model and GBR to innovate in service delivery. In light of that model and the HSCRC's oversight, the current CON process can impede hospital planning without a commensurate benefit. As addressed more fully in response to question 4, UMMS recommends deregulating a number of hospital projects that currently require CON.

16. ***Should Maryland shift its regulatory focus to regulation of hospital and health systems merger and consolidation activity to preserve and strengthen competition for hospital services?***

UMMS Comment

Merger and consolidation activity in Maryland has not weakened competition for hospital services. Such consolidation has in fact proven to be an effective way for hospitals to decrease spending while maintaining access to critical services. In some cases, such as the recent affiliation of the former Dimensions Healthcare System within UMMS, merger and consolidation can result in bringing greater efficiency to the health care delivery system. Federal and state antitrust regulation also acts as an appropriate mechanism to promote competition.

Scope of CON Regulation

17. Should the scope of hospital CON regulation be more closely aligned with the impact of hospital projects on charges?

UMMS Comment

UMMS advocates against the adopting the measures suggested below. These questions recognize that under the regulatory landscape that exists in Maryland today, hospital planning is closely tied to each hospital's rates and GBR agreement. As discussed throughout these comments, there is regulatory duplication among the Commission and the HSCRC. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 11, 14, and 17). The HSCRC appropriately interacts with hospitals to make adjustments to a hospital's GBR for appropriate hospital spending. The Commission should not consider adding regulation that duplicates the HSCRC's oversight, but instead should focus on removing existing duplicative oversight and focus on health care planning that is not effectively regulated by the HSCRC. The measures suggested in the questions below would add greater cost and uncertainty to health care planning without a commensurate benefit.

A. Should the use of a capital expenditure threshold in hospital CON regulation be eliminated? For example, should hospital capital projects or certain types of hospital project only require a CON if the hospital seeks an increase in its global budget to cover project-related capital cost (depreciation, interest, and amortization) increases? Alternatively, should CON regulation be based on the overall impact of projects on hospital revenues (related to coverage of both capital and operating expenses, which could increase substantially even for low cost projects if new services are being introduced?)

B. Should Maryland's system of hospital rate regulation include capital spending growth targets or capacity growth targets that shape the scope of CON regulation? If so, how would this work? For example, should CON regulation be redesigned to move away from single project review(s) for a multiple hospital system to a broader process of reviewing systems resource development needs and priorities? ~~Such a process~~

C. [Such a process] [c]ould resemble a periodic budget planning process with approval of a capital spending plan that incorporates a set of capital projects for a given budget period.

18. Should MHCC be given more flexibility in choosing which hospital projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information

related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the hospital to undergo ·CON review.

UMMS Comment

UMMS does not advocate the process described in this question. CON review should be a predictable process based on clear standards. The imposition of a flexible approach to whether a CON review is required may cause unpredictability and could potentially impose inconsistent burdens on different hospitals seeking to add the same service. Such a process could also have the unintended consequence of prolonging certain reviews – applicants could be required to provide a significant amount of information just to reach a determination as to whether staff will recommend CON review, followed by a potential full review. This initial step could be complicated by interested parties, yet excluding them from the first step would seem inappropriate.

19. ***Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?***

UMMS Comment

UMMS advocates a significant reduction in the scope of hospital projects that require CON review. If this deregulation is not accomplished, UMMS recommends, in the alternative, that that the Commission consider an expedited review process for projects for which UMMS recommends deregulation that instead continue to require CON review. For example, if the capital expenditures over the threshold are not deregulated, the Commission should consider an expedited review process for such projects.

New Jersey, for example, mandates an expedited review process that requires a decision to be rendered no later than 90 days after an eligible application has been accepted. *See* N.J.A.C §8-33, Chapter 5. While New Jersey's express categories of projects eligible for expedited review are narrower than UMMS would recommend as an alternative to complete deregulation, the process itself may be an appropriate model to consider. In addition to the projects expressly identified for expedited review, the applicable regulation allows use of the expedited review process "when the project has minimal impact on the health care system as a whole." N.J.A.C. 8:33-5.1(b).

The Commission should also consider an expedited review process for any CON that does not involve interested parties.

The Project Review Process

20. Are there specific steps that can be eliminated?

UMMS Comment

The current procedural steps involved in review of a CON project are appropriate. The process would benefit, however, from clear rules regarding the timing and scope of each step in the process. As described more fully in response to Question 5, hospitals are unable to determine how long the CON process will take with any degree of certainty, which is a significant impediment to the planning process. While clear rules regarding timing would be helpful for each procedural steps, UMMS recommends two in particular.

First, the process for the Commission staff's completeness review should be subject to timing and procedural limitations. The current completeness review often involves several rounds of completeness questions from Commission staff. Sometimes questions asked in later rounds do not concern new information provided in an applicant's responses to completeness questions, but material from the application itself available at the time of the first round of questions. This process sometimes causes unnecessary delay.

UMMS recommends that completeness review be limited to only one round of questions from Commission staff, with additional rounds permitted only to the extent the applicant failed to respond adequately to the initial questions or to the extent that any new completeness questions address new material and could not have been raised previously. UMMS also encourages the Commission to limit the scope of staff review such that additional information may be requested only if it is material to determining whether an applicant complies with a review standard or criteria. UMMS further recommends that the Commission promulgate a rule that states a prescribed period of time after an applicant's response to completeness questions within which the Commission must either submit any follow-up completeness questions that respond directly to new material provided, or confirm that the application is complete and docket it.

Second, UMMS recommends that there be clear rules governing when the Commission will seek comment from the HSCRC. In recent reviews, such comment is often sought near the end of a review. This may cause delay, especially where the Commission determines a modification or additional information is necessary based on the HSCRC's comment. UMMS recommends that the Commission seek input from the HSCRC as soon as the application is docketed, similar to the timing for interested party comments.

21. ***Should post-CON approval processes be changed to accommodate easier project modifications?***

UMMS Comment

UMMS recommends that the Commission consider ways to allow for greater flexibility in both the changes permitted post-CON approval and the process for receiving approval. For example, the scope of impermissible changes should be reconsidered to allow for most changes where an applicant can demonstrate good cause. The Commission should also consider a speedy, staff-driven review process for certain changes, such as an increase in capital costs up to a certain percentage, subject to the right of CON holders to appeal to the full Commission.

22. ***Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.***

UMMS Comment

As described in response to Question 4, UMMS recommends significant deregulation of projects that currently require CON review. (*See also* UMMS response to Question 19.) If the Commission and the General Assembly do not fully deregulate each of the projects described in UMMS' response, UMMS would support in the alternative a more abbreviated form of review for those projects.

23. ***Would greater use of technology including the submission of automated and form-based applications improve the application submission process?***

UMMS Comment

Use of available technology would improve the CON application process.

For example, the process could be made more efficient and transparent through the electronic submission of applications and electronic docketing of other filings. Several states use electronic filing for docket management of their CON matters.[3] Federal

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[3] There is a range in how states use electronic filing, from optional to mandatory, use for only for certain steps (*e.g.*, electronic filing of application following paper submission of letter of intent), or use for only certain types of reviews (*e.g.*, paper filings required for comparative reviews). *See, e.g.*, Alabama State Health Planning & Development Agency, SHPDA Online Filing System, "intended to allow applicants and interested parties to file documents related to CON filings," http://www.shpda.state.al.us/OnlineFiling.aspx (Jan. 22, 2018); Michigan Department of Health e-Serve Application ("allows users to submit applications and view CON information....[via an] online application housed and maintained through the State of

courts have used an electronic filing system for more than 15 years. Under such a system, applicants, interested parties, and the MHCC would submit filings by uploading them through an online docketing interface. The materials would be available for public inspection immediately.

Duplication of Responsibilities by MHCC, HSCRC, and the MOH

24. Are there areas of regulatory duplication in the hospital capital funding process that can be streamlined between HSCRC and MHCC, and between MHCC and the MDH?

UMMS Comment

As discussed throughout these comments, there is regulatory duplication among the Commission, HSCRC and the Maryland Department of Health. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 11, 14, and 17).

In particular, under the All-Payer Model and likely future agreements between the State of Maryland and the Centers for Medicare & Medicaid Services, HSCRC regulation and processes impose appropriate checks on hospital capital spending without the need for the CON process to require additional review of projects based on a capital expenditure threshold. Moreover, in light of the HSCRC's regulatory authority over hospital revenue and expenditures, there is no need for the CON process to include duplicative analyses to assess the financial feasibility, viability, or cost effectiveness of any proposed CON project.

25. Are there other areas of duplication among the three agencies that could benefit from streamlining?

UMMS Comment

The OHCQ's authority over licensure and other quality and patient safety issues renders CON standards that assess those issues duplicative and unnecessary. (*See also* cover letter enclosing comments, and comments in response to Question 14.)

Michigan MILogin System," available at http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-165238--,00.html (Jan 22, 2018); and New York State Electronic Certificate of Need (NYSE-CON), "a web-based, electronic application system designed to streamline the processing of applications, while improving communication and transparency," available at https://www.health.ny.gov/facilities/cons/nysecon/ (Jan 22, 2018).

Add more Living to your Life®

January 12, 2018

Paul Parker
Director of the Center for Health Care Facilities
Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Parker:

On behalf of Erickson Living, I am writing to provide input on potential reforms of Maryland's Certificate of Need (CON) law for nursing homes as requested by Chairman Moffit in his November 21, 2017 letter. We very much appreciate the opportunity to share our views.

About Erickson Living

As you know, most Erickson communities, including Charlestown, Oak Crest and Riderwood in Maryland, average over 1,000 residents and 80+ acres, compared to a typical CCRC with 200-300 residents. Erickson also operates a Centers for Medicare and Medicaid Services (CMS)-approved Medicare Advantage plan, Erickson Advantage; assuming risk through the plan for the cost and quality of outcomes for the care of their seniors. This year CMS awarded Erickson Advantage a 5-star CMS rating. And, U.S. News & World Report named Erickson Advantage a "Best Medicare Advantage Plan."

The scale of our communities enables us to not only drive down healthcare and living costs for seniors, but also allows us to access the latest technologies and practices to deliver on a promise of providing unprecedented healthcare results. Our model of care has decreased hospital readmissions and hospital length of stay by over 50% among a population considered to be the costliest in health care: those over 85 years old and managing at least one or more chronic conditions. Our communities enable middle-income seniors to privately finance attractive, high quality, long-term care—dramatically reducing Medicaid utilization and cost.

General Comments on CON

We believe Maryland CON regulation of nursing home capital projects should be reformed and we support the comments provided under separate cover by LifeSpan to examine a number of areas, including: 1) increasing the capital threshold; 2) exempting certain projects from being included under the capital threshold if bed capacity is not being increased; 3) reviewing the performance requirements for after a CON is granted; 4) assessing whether an MOU for Medicaid residents continues to be necessary and/or whether standards should be adjusted;

5) reviewing which quality measures should be part of the CON process; and 6) considering the use of occupancy standards for an increase in bed capacity.

Direct Admission Limitations

The most problematic provisions of the CON law for Erickson Living are related to the restrictions on CCRCs' ability to directly admit non-community residents into our nursing homes. Current Maryland law only allows a direct admission to a CCRC from within the CCRC's resident community; if the subscriber has the potential for an eventual transfer to an independent living unit or an assisted living unit, and in the case of a spouse of a resident or long term relationships. The provisions also require (Section 19-114 (d)(2)(ii)3.A. and B.) that the number of comprehensive care nursing beds in the community does not exceed 24 percent of the number of independent living units in a community having less than 300 independent living units, or 20 percent of the number of independent living units in a community having 300 or more independent living units.

Further, in Section 19-124 (b) and (c), notwithstanding the provisions noted above in Section 19-114, the total number of comprehensive care nursing beds occupied by subscribers who have been directly admitted to a comprehensive care nursing bed may not exceed 20 percent of the total number of comprehensive care nursing beds that are available in the continuing care nursing facility, and a CCRC that qualifies for an exemption from CON under Section 19-114 may not admit a subscriber directly into a comprehensive care nursing bed if the direct admission would cause the occupancy of the comprehensive care nursing beds in the continuing care community to exceed 95 percent of full capacity.

Impact of Direct Admission Limitations

Because Maryland significantly limits a CCRC's ability to directly admit non-residents into nursing homes, Maryland CCRC consumers wind up paying more and/or have less access to skilled nursing and assisted living services, particularly at the end of the continuum of care, than many other consumers of CCRCs.
The result of this policy, created many years ago, means CCRCs have two unappealing choices: 1. Contract out nursing home and assisted living care, meaning people leave campus to receive those services, sometimes splitting couples at the end of life because building and staffing those facilities without the ability to market externally are too expensive until the community has aged in place for more than a decade, or 2. Offer the full continuum of services onsite in the early stages of the development without the ability to directly admit non-residents, and pass the cost of building, staffing and operating a less occupied building onto consumers. Neither choice is good for consumers: they either agree to leave for certain services, or, pay higher fees to have access to them today.

In an effort to address this issue and the already expensive fees related to privately affording one's long-term care, and given the clear policy benefit of people financing their own long-term care to the state, rather than divesting assets and enrolling in the state's Medicaid plan, Erickson Living proposes updating Maryland's policy to reflect a more modern approach to address the need for seniors' housing and healthcare that isn't financed by the state.

Proposed New Policy

We believe a more realistic policy would be to eliminate the current direct admission restrictions if a CCRC's comprehensive care nursing bed capacity is 10% or less of its independent living units.

Rationale

The purpose of the current restrictions is to ensure that providers are not creating CCRCs to circumvent the needs requirement of the CON process. However, in the market place, CCRCs are shrinking their SNF components due to market conditions and substitute products. As a result, the limitation on direct admissions is overly complex and burdensome for the provider and the consumer.

Maryland's current CCRC regulatory system makes more challenging the development of large, "all in one" campuses, and makes the development of skilled nursing facility beds and assisted living beds much more expensive. Such a modification would enable CCRCs that encourage seniors to privately finance their long-term care to develop more quickly, serving interests of Maryland residents who enter into continuing care contracts, and reducing Medicaid participation.

Because they encourage private financing of long term care, CCRCs have a significant and positive impact on state Medicaid budgets. Erickson Living's participation in a CMS approved Medicare Advantage plan enables meaningful care coordination, which results in better health outcomes for seniors and significant reductions in cost to state and federal budgets. In fact, as a result of federal legislation passed in 2005, every Erickson Living resident is obligated to fully spend down all available assets, including CCRC entrance deposits, prior to accessing Medicaid.

Again, we appreciate the opportunity to comment and would be happy to answer any questions.

Sincerely,

Lynn Gordon

Lynn Gordon
Director, Regulatory Affairs

HFAM
Health Facilities Association of Maryland
Partners in Quality Care

January 11, 2018

Robert E. Moffitt, Ph.D., Chair
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215-2299

Re: Reforms to the Health Planning and Certificate of Need Process

Dear Dr. Moffitt:

On behalf of the Health Facilities Association of Maryland ("HFAM"), we appreciate the opportunity to provide input as solicited by your November 21, 2017 letter concerning the health planning and certificate of need ("CON") process under the authority of the Maryland Health Care Commission (the "Commission"). We endorse this decision by the Commission to review the CON process.[1]

HFAM has been a leader and advocate for Maryland's long-term care provider community for nearly 70 years. HFAM has over 150 skilled nursing and rehabilitation center members who collectively employ 19,000 Marylanders who provide over 9 million days of care annually across all payer sources (Medicare, Medicaid, private pay). HFAM members provide quality care for 72 percent of all Maryland Medicaid long-term care beneficiaries.

HFAM represents every type of long-term care provider, including assisted living, sub-acute, rehabilitation and comprehensive care facilities ("CCFs"). HFAM's membership ranges from small, local, family-owned independent nursing facilities, to larger regional and national organizations to faith-based nonprofit organizations (including the largest nonprofit long-term care facilities in Maryland). HFAM facilities are found in every community, county and city across Maryland.

1. Need for reform of the CON process governing capital projects. Suggestions for deregulation.

[1] Since there is overlap between the questions posed, we have organized our response in this manner. If you need a cross-walk to link our suggestions to the questions we answer with them, please let me know.

HFAM believes the CON process governing capital projects should be maintained but reformed. There should be an exemption from CON review where a capital cost is being incurred that does not result in an increase in health care delivery system rates. At the time the CON process was established, both Medicare and Medicaid reimbursement was cost-based. Those forms of state and federal reimbursement are now prospective, and rates are not increased by such costs. Commercial insurance rates are set by a third party payer and private pay rates are constrained by market forces. Investment of providers in the repair, renovation and replacement of a CCF should not require prior CON approval.

Moreover, given that the acuity of CCF patients now mirrors patients who were formerly receiving care in hospitals when the CON thresholds for capital expenditure (the "Capital Threshold") were established, it is illogical for CCFs to be subject to the lower Capital Threshold applicable to providers such as home health agencies, and not the Capital Threshold applicable to hospitals. Given the role of CCFs in the health care delivery system and the benefits of facilitating the ability of CCFs to prevent hospitalizations and rehospitalizations, CCFs (a) should be subject to same Capital Threshold as hospitals and (b) should be entitled to the same exemption as is available to hospitals for capital expenditures that exceed the Capital Threshold but do not result in rate increases above a designated amount, under Health-General, Section 19-120(k)(1) and (6)(vii), and COMAR 10.24.01.01B(40) and .04A(5).

2. Would the public and health care delivery system benefit from more competition among CCFs?

There is already competition among CCFs. Costs of capital improvements and operations in delivering care that meets quality standards, health care innovation, consumer expectations and strictly enforced government oversight are very high. Medicare and Medicaid reimbursement is both underfunded and prospectively established. There is unchecked competition from assisted living facilities since they are not subject to the CON process. There are Medicaid waiver programs designed to provide alternatives to CCFs and discharge to the community. Occupancies are not increasing. There are state and federal ranking systems that engender competition for quality scores. There is already competition among CCFs. A change to the CON bed need process is not needed.

3. How does CON regulation stifle innovation among CCFs?

a. Our comments above concerning the Capital Threshold apply to this response. Innovations among CCFs should be fostered by either eliminating the Capital Threshold for innovative projects or those involving innovation, renovation, replacement and improvement of CCFs.

b. The Medicaid Memorandum of Understanding ("MOU") requirement under the Nursing Home Services Chapter of the State Health Plan under COMAR 10.24.08 should be eliminated (or substantially reduced). Policy 3.3, Sections .05A(2)(a) and (d), and B(4). Among

the innovation efforts are those that would avoid or reduce the need for utilization of CCF services by Medicaid beneficiaries. The MOU requirement threatens to penalize CCFs unless they foster Medicaid patient days in their facilities. There is not current data to support the view that Medicaid beneficiaries have any barrier to receiving CCF services. The MOU stifles innovation.

c. Recent changes to the waiver bed process should be returned to prior interpretations. Waiver beds are an important "safety valve" in the effective use of existing inventory.

i. Until relatively recently, when waiver beds under COMAR 10.24.01.03E(2) were available, fractional numbers up to 10 beds were "rounded up." Now, in a change of policy, the fractional numbers are only "rounded down." The longstanding prior interpretation should be reinstated.

ii. Sometimes a beneficial capital project is stymied or reduced because, unlike under past policy, space for available waiver beds is not permitted to be constructed. So, for example, if a facility has triple or quad rooms, or wishes to increase private rooms, and it is entitled to 10 or fewer waiver beds under this regulation, the Commission does not permit new space to be constructed for the waiver beds. Only if there is existing, pre-construction space available for the waiver beds are they available. This is can be a problem when the revenue from the incremental waiver beds can facilitate a capital project for all facility residents. Onsite use of waiver beds in new space should be permitted if the overall project does not require a CON.

4. Suggestions concerning the project review process

a. The completeness review aspect of the CON review regulations under COMAR 10.24.01.08C should be reformed. Under the current process, there is a 10 business day deadline for the Commission staff to issue completeness questions and the Staff sets a deadline for reply. However, once that information is provided to the Staff, there is no timeline or deadline for the Staff to reply to that additional information or find the application "complete" for docketing purposes. The entire CON review can be delayed as a result. There should be a deadline by which an application should be considered complete unless there is a problem with what was submitted.

b. There can be an unlimited number of Interested Parties and/or Participating entities, each of which can file up to 25 pages of comments on an application, up to 35 pages in a comparative review. Moreover, the Interested Parties and Participating entities will have access to the CON application through the months as soon as it is filed and through the completeness process, including at least 30 days from docketing. However, irrespective of the number, volume or content of any unlimited comments developed over weeks if not months, under COMAR 10.24.01.08F the applicant has only 15 days to develop a reply and only one 25

page reply to all of the comments collectively (35 pages in a comparative review), putting the applicant at a substantial disadvantage.

5. Changes to performance requirements.

There are a variety of ways the CON process should be reformed with respect to project review and performance requirements. Some of these are based on the language of the CON regulations and others are based on interpretations of the CON regulations as expressions of policy.

a. Currently, there are strict performance requirements with only one extension for up to 6 months each being permitted for whatever reason may arise. Failure to meet these deadlines requires a project under ongoing development to go back to the starting point of the CON process. This should be changed under COMAR 10.24.01.12E and F.

b. Each of the performance requirements should be reviewed. For example, under COMAR 10.24.01.12C(3)(a) and (b) a new health care facility is required to be constructed within 18 months after financing while renovations of existing facilities can have up to 24 months to be completed. This is illogical and inconsistent with the time it takes for a new facility to be developed.

c. Some of the performance requirements have implementation periods that are tied to capital amounts that have not changed over time and no longer make sense, such as under COMAR 10.24.01.12C(3)(b), (c) and (d). These should be eliminated, updated or tied to inflation.

d. There are restrictions on when a health care facility can propose to construct a project in phases to projects with a cost above $40 million under COMAR 10.24.01.01B(28) and .12C(3)(g). The ability to develop a project in phases should not be so constrained.

e. The Commission staff interprets the CON regulations so as to prohibit any change in the identity of owners within the legal entity that is the applicant, during the CON review, even if the change is less than the 25% threshold that would trigger notice to the Commission after the facility is constructed. There can be legitimate reasons why there should be additional or different minority owners in an applicant entity during a CON review, so long as this is disclosed.

f. Sometimes there is a judicial appeal of a CON decision or a related appeal such as through the zoning process. The regulations should state clearly that an applicant may, but is not required to, delay a project while the appeal is pending.

6. Changes to the requirements for when Commission review of project changes is required.

Under COMAR 10.24.01.17 there are regulations on when information about project changes is disclosed to and reviewed by Staff, when a change requires a vote of the Commission and those that are impermissible.

a. The Commission should not require a vote of the Commission for capital cost increases during the CON development process so long as notice to the staff is given and the applicant is going to absorb that cost and an increase in rates will not result.

b. The Commission has a policy that, after a CON is granted and during the implementation phase there can be no change whatsoever, however minor, to the composition of the ownership of the approved applicant, even below the 25% threshold that triggers review after the project is completed, even with Commission review or vote. This can stymie positive and routine changes that facilitate the development of an approved project.

7. In question 16, a response is requested to how the Commission can take into account an applicant's quality of care.

a. We would be concerned if the Commission were to consider a process akin to the process used in the Home Health chapter of the State Health Plan, to bar existing facilities from even filing a letter of intent unless preapproved by the Commission.

b. We have seen the Commission refer to the CMS Five Star process in CON reviews. This is a concern as anything other than an observation. There are both benefits and flaws to the Five Star system, which we can explain further. Moreover, rankings can be fixed for periods of time such as is being done as part of the new federal Requirements of Participation so they do not reflect current services. Moreover, periodically adjusts the Five Star scoring the effect of which is to cause a drop in star rankings until facilities adapt to the change. Over reliance on the Five Star rankings is a concern.

c. In this regard, in response to question 24, we do believe there is duplication between the MHCC and the MDH. We reviewed the Commission's enabling legislation under Health-General Article, Sections 19-103 and 115 related to the purpose of the Commission and its role in the health planning and development process. We do believe that, particularly as to the evaluation of whether an applicant renders quality care, there should be reliance on the Office of Health Care Quality's survey reports and plans of correction since that agency enforces the state and federal rules that apply in the delivery of day to day care. There should not be a different but overlapping set of standards that apply if CON review might be sought in the future.

8. Acquisition Determination Process

The Commission has regulations under COMAR 10.24.01.03A, implementing the process for obtaining a determination that a CON is not required for the acquisition of a health care facility, which is defined as including a change in 25% among the existing owners or a change in control. Also, via a helpful policy the Commission has determined that a simple change in tenant with no change in the ownership of the "bed rights" is not the acquisition of a health care facility and that only notice of the change in tenant is required.

In obtaining such determination that no CON is required for an acquisition, the Commission requires disclosure of information on a specific form, some of which is not relevant to the applicable regulation and the scope of which has changed over time. For example, purchase price information is required even though the amount is irrelevant to the determination that no CON is required. Also, "market share" information is required to be provided, even though there is no provision of the regulation that ties to this information. Patient day and operating revenue information is required. The process should be more simple. Moreover, we propose that the acquisition notice be informational and that an affirmative determination of noncoverage not be required. Or, so long as a timely notice is given, upon the expiration of the applicable time period the determination of noncoverage should be presumed. It is not a good use of Staff resources to gather this information and require formal determinations of exemption.

Thank you for the opportunity to comment.

Sincerely,

Joseph DeMattos, Jr.
President

cc: Mr. Eric Shope, Chair, HFAM
Mr. Ben Steffen
Mr. Paul Parker
Mr. Kevin McDonald

Charles E. Smith Life Communities

HEBREW HOME OF GREATER WASHINGTON • WASSERMAN & SMITH-KOGOD RESIDENCES
COHEN-ROSEN HOUSE • ELDERSAFE™ CENTER • HIRSH HEALTH CENTER
LANDOW HOUSE • REVITZ HOUSE • RING HOUSE

January 12, 2018

Robert E. Moffit, Ph.D., Chair
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Dr. Moffit:

I am writing in response to your letter seeking input on potential reforms to the health planning and certificate of need (CON) programs. As the owner/operator of the Hebrew Home of Greater Washington, we are very interested in the future of the CON program and the impact it has on our community and the long term care industry.

As members of Health Facilities Association of Maryland (HFAM), we support the position that they have outlined in their letter to you. We believe that the CON process governing capital projects should be maintained but reformed. HFAM has outlined numerous adjustments that would make the process more efficient and fair.

Charles E. Smith Life Communities is very pleased that the Commission has undertaken this review of the CON process.

Sincerely,

Beth DeLucenay
Vice President, Strategic Planning
delucenay@ceslc.org

6121 Montrose Road • Rockville, MD 20852
Tel 301.770.8331 • Fax 301.770.8512 • www.smithlifecommunities.org

LIFESPAN NETWORK

January 9, 2018

Paul Parker
Director
Health Care Facilities Planning and Development
4160 Patterson Avenue
Baltimore, Maryland 21215

RE: Certificate of Need Review Process

Dear Mr. Parker:

This letter is in response to the letter sent by the Maryland Health Care Commission on November 21, 2017 to nursing facility administrators seeking feedback on Maryland's current certificate of need (CON) process. In the letter, the Commission requested that associations submit "consensus responses." Below are LifeSpan's preliminary comments.

It is important to note that, at the same time the Commission is reviewing the CON process, the Commission will also begin its review of the Nursing Home Chapter of the State Health Plan. For the nursing facility industry, it is of utmost importance that there is overlap in the discussions of these workgroups with regular communication between the two as issues are discussed and recommendations determined.

First and foremost, LifeSpan strongly supports maintaining a CON requirement for nursing facilities. However, LifeSpan does believe that there are areas where changes are necessary to either update or streamline the process. These areas include:

1) Increasing the capital threshold;

2) Exempting certain projects from being included under the capital threshold if bed capacity is not being increased;

3) Reviewing the performance requirements for after a CON is granted to ensure that they are consistent with current practices and standards;

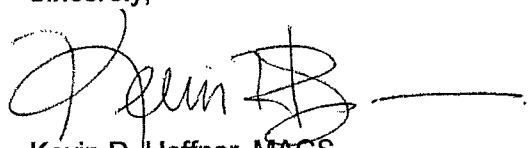
4) Examining whether there is a continued need to maintain a Memorandum of Understanding for Medicaid residents and/or whether standards should be adjusted; and

5) Reviewing occupancy standards of other nursing facilities in the jurisdiction where a CON is being requested where it will result in an increase in bed capacity.

Lastly, while LifeSpan believes that quality measures should be included in a CON review, there needs to be a more thorough discussion on appropriate measures. Given recent issues with the federal 5-Star rating system, there is strong consensus among the membership that a quality standard should not include this measurement.

Again, LifeSpan appreciates the opportunity to submit these preliminary comments and we look forward to working with the workgroup to discuss these comments and other issues more in-depth. On a side note, LifeSpan has formed an internal committee to monitor and provide feedback to the workgroup as issues are discussed. If there are any issues that you would like to get more specific information on in advance of an official workgroup meeting, we would be more than willing to assist you.

Sincerely,



Kevin D. Heffner, MAGS
President

LORIEN HEALTH SERVICES
Family caring for Families

January12, 2018

Mr. Paul E. Parker
Director, Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: Comments on Health Planning / CON Reform

Dear Mr. Parker:

On behalf of Lorien Health Services, I enclose our Comments concerning proposed health planning and CON Program reforms, as requested by Chairman Moffit's letter dated November 21, 2017. As you will note, our Comments are presented in the form of Responses to the MHCC document entitled "Comment Guidance – Nursing Home MHCC CON Study, 2017-18".

Thank you for this opportunity to present our views in this important undertaking.

Very truly yours,

LOUIS G. GRIMMEL, SR, CEO
Lorien Health Services

LGG/ds
Encl.

cc: Ben Steffen, Executive Director, MHCC
Kevin McDonald, Chief, CON

Scope of CON Regulation

COMMENT GUIDANCE - NURSING HOME MHCC
CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of nursing home CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of nursing home CON regulation?

- o CON regulation of nursing home capital projects should be eliminated. *Note: If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 to 13.*
- o CON regulation of nursing home capital projects should be reformed.
- **X** CON regulation of nursing home capital projects should, in general, be maintained in its current form.

ISSUES / PROBLEMS

The Impact of CON Regulation on Nursing Home Competition and Innovation

1. **In your view, would the public and the health care delivery system benefit from more competition among nursing homes?**

   Response: The current CON process provides an appropriate level of regulation of the supply and distribution of Nursing Facilities. It does not unduly stifle competition or innovation. Nursing Facilities already actively compete for residents and provide innovative services which reflect the demands of their customer base. Please refer to the responses to Questions 14 and 15, below.

2. **Does CON regulation impose substantial barriers to market entry for new nursing homes or new nursing home services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?**

   Response: CON regulation does not impose substantial barriers to new nursing home services because the comprehensive care licensure category is broad enough to authorize all potential nursing home services. While the process does impose

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health

impediments to the unfettered entry of new facilities, it acts as an efficient means of preventing the oversupply of beds / facilities and ensuring that sufficient resources are available to meet public need in a way which furthers important public policy objectives.

3. **How does CON regulation stifle innovation in the delivery of nursing home services under the current Maryland regulatory scheme?**

Response: See response to Question 2, above. See also response to Question 14, below. In addition, the imposition of the Medicaid MOU condition frustrates innovative undertakings because it forces facilities to maintain high Medicaid utilization despite the lack of evidence that Medicaid beneficiaries have an access problem in Maryland.

Generally, Maryland Health Care Commission approval is required to establish or relocate a nursing home, expand bed capacity at a nursing home, or undertake capital projects that exceed a specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01. *

4. Should the scope of CON regulation be changed? No.
   A. Are there nursing home projects that require approval by the Maryland Health Care Commission that should be deregulated?

Response: Yes. Under the HSCRC's All-Payer Model Progression Plan (Global Payments System), Hospitals and Nursing Facilities are encouraged to work closer together with the goal of reducing hospital admissions and re-admissions while improving patient outcomes at lower total system costs. Further, under CMS regulatory initiatives, Nursing Homes will face federal reimbursement deductions when such reductions are not achieved. Therefore, Nursing Homes should be exempted from having to obtain a CON in order to provide home health services to their post discharge patients. Nursing Facilities were allowed to offer such services in the past. By allowing facilities to again offer such post – discharge services to their discharged patients, Nursing Facilities will be able to improve quality of care and continuity of care, while maintaining control of patient care for an appropriate period of time. Since Nursing Facilities are being held accountable, they must have greater control over follow – up care.

   B. Are there nursing home projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?
   Response: No.

The Project Review Process

Scope of CON Regulation

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

   Response: The Docketing and Completeness Review process should be streamlined and simplified. They are also the primary choke points of the review process. Commission Staff seems to approach Completeness Review on an ad hoc basis. Completeness Review was originally intended simply to ensure that applications addressed all applicable review criteria and standards. As such, it was a "quantitative" review, as opposed to a "qualitative" review. However, in practice Completeness Review has become much more expansive and frequently involves Staff asking for additional substantive information beyond that requested by the review criteria. This results in delays and added expense in the review process since the statutory review tine limitations run from the date of docketing and not the date the application was filed. Adhering to the intended quantitative review would not deprive Staff of any information it might deems helpful, since such information can be requested as part of an "Additional Information" request during the course of the review (i.e. after the Application is docketed) as authorized by COMAR 10.24.01.08C(2). Finally, the regulations should be amended to impose a time limit on Staff's determination of "Completeness" following an Applicant's submission of the requested information.

6. Should the ability of competing nursing homes or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Response: No. It is critical that existing facilities which may be negatively impacted by Commission approvals of new facilities or expansions of existing facilities have standing to participate in CON reviews and to appeal adverse decisions. CON Staff are not sufficiently aware of Nursing Facility operational matters or the potential impact of new providers or expansions on manpower and utilization. Full participation in reviews by competing providers ensures that critical information is considered by the reviewer and that legal rights are protected.

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated?

   Response: No.

   Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

   Response: Yes.

7. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)

Scope of CON Regulation

Response: No. Construction of new Nursing Facilities involves lengthy land use and development approvals. Finding suitable sites near public transportation routes which neither warehouse seniors nor unacceptably encroach upon residential communities has become increasingly difficult. Local development approvals take time and can be adversely impacted by heavy volumes of other development proposals. New Nursing Facility projects should have 48 month performance requirements with the continued availability of 6 month extensions of each performance requirement. In addition, the regulations should be amended to explicitly state that the filing of administrative or judicial appeals of all zoning, permitting and other local approvals required in a project's development process should trigger an automatic stay of applicable performance requirements. Currently, such stays have been granted by the Executive Director upon the applicant's request.

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for nursing home facilities and services provide adequate and appropriate guidance for the Commission's decision-making?

   Response: Yes.

   What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

   Response: As a general matter, the review criteria provide a good basis for CON decision making. However, the analysis of building designs and specifications is not necessary in the CON process since Staff do not have expertise in building design issues. Further, design requirements are governed by applicable regulations of the Office of Health Care Quality (see COMAR 10.07.02).

9. Do State Health Plan regulations focus attention on the most important aspects of nursing home projects? Please provide specific recommendations if you believe that the current regulations miss the mark.

   Response: Yes. However, the SHP bed need methodology should be updated and revised to reflect the declining need for additional nursing beds in view of the growth of assisted living and community-based alternatives including in-home services.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate?

    Response: Yes. If you believe that changes should be made in the development

Scope of CON Regulation

process for State Health Plan regulations, please provide specific recommendations.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G{3}(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: {1} Need; {2} Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and {5} the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

Response: The 5th criterion should no longer be interpreted or applied so as to require Applicants to provide 20 years' worth of records concerning compliance with prior CONs. Many providers do not maintain CON records for lengthy periods of time. Commission Staff does, however maintain records of prior project approvals and Quarterly Reports. Moreover, as part of the Commission's 1st Use Approval process, Staff reviews all applicable project conditions and certifies that projects have indeed been constructed in accordance with all conditions imposed. Further, Staff has determined that any approved request for an extension of performance requirements, as authorized by the regulations and granted per the Executive Director's discretion, is a "black mark" against an Applicant. This practice should be discontinued since the CON regulations do not authorize this "sanction". Further, such an interpretation amounts to an 'after the fact' repudiation of the Executive Director's exercise of discretion to grant 6 months extensions under clearly applicable regulations. Finally, such a policy is poor public policy since it penalizes an applicant for extensions granted for circumstances completely beyond its control in prior projects, as determined by the Executive Director.

CHANGES / SOLUTIONS

Alternatives to CON Regulation for Capital Project

12. If you believe that CON regulation of nursing home capital projects should be eliminated, what, if any, regulatory framework should govern nursing home capital projects? N/A

13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of nursing home licensure requirements administered by the Maryland Department of Health serve as an alternative

Scope of CON Regulation

approach to assuring that certain nursing home facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

Response: No. CON regulation, as a pre-condition to licensure, is best administered by the same agency which undertakes the State's health planning function. MDH agencies such as OHCQ are already managing a substantial regulatory burden concerning operational issues of facilities already in place.

The Impact of CON Regulation on Nursing Home Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing nursing homes and new market entrants? If so, please provide detailed recommendations.

Response: No changes are necessary since CON Applicants are already empowered to propose innovative proposals and programs such as combined CCFs / ALFs, telemedicine units, informational technology, Wellness Centers, onsite Cafes / Grills, etc.

15. Should Maryland shift its regulatory focus to regulation of nursing home merger and consolidation activity to preserve and strengthen competition for nursing home services?

Response: No change in focus is required. However, mergers and consolidation should only be approved if in the public interest. Nursing service providers already compete for customers through quality of care, services, programmatic offerings, physical plants, and reputations.

The Impact of CON Regulation on Nursing Home Access to Care and Quality

16. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?

Response: Quality of care performance should be considered during the course of the CON Review so that all applicable information is considered including the unique aspects of the proposed project. Past incidences of quality of care deficiencies should **not** be used as a bar against even considering a proposed CON project which would

Scope of CON Regulation

occur if consideration of such incidents was employed as a docketing rule. This is particularly important to note since a proposed project may be the only reasonable way for an existing facility to correct physical plant deficiencies or other problems that prevent attracting qualified staffing resources. Quality of care and survey records are available for out of state providers who apply for CONs in Maryland. New entrants to the industry can be evaluated under existing regulations regarding their financial and resource availability to deliver quality care.

17. Should the use of a capital expenditure threshold in nursing home CON regulation be eliminated?

Response: No.

18. Should MHCC be given more flexibility in choosing which nursing home projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the nursing home to undergo CON review.

Response: No. The current CON Program is sufficient to allow the protection of the interests of all stakeholders.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

Response: No, the current process is sufficient provided the Commission Staff meets the statutory and regulatory deadlines.

The Project Review Process

20. Are there specific steps that can be eliminated?

Response: Completeness Review and docketing should be streamlined by eliminating the practice of requiring submission of "additional information requests" over and above information necessary for docketing applications. Current regulations already grant Staff the ability to request additional information after docketing and during the course of the CON review

21. Should post-CON approval processes be changed to accommodate easier project modifications?

Response: Yes. As long as total bed complements, proposed services, and the location

Scope of CON Regulation

remain the same; and nursing Unit sizes, total square footage, and Medicare / Medicaid rates remain substantially the same, post approval modifications should be allowed if proper notice is given to the MHCC.

22 **Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review?**

Response: No. The CON process as it pertains to Nursing Facility reviews is currently sufficient, provided the Commission adheres to the statutory and regulatory deadlines.

23 **If so, please identify the exemptions and describe alternative approaches that could be considered.** N/A

24 **Would greater use of technology, including the submission of automated and form-**

25 **based applications, improve the application submission process?**

Response: Yes. Form-based Applications should be able to be completed online and submitted electronically. Currently, Staff requires Applications to be submitted electronically in both Word and PDF formats, along with multiple hard copies.

Duplication of Responsibilities by MHCC and MOH

26 **Are there areas of regulatory duplication in nursing home regulation that can be streamlined between MHCC and MDH?**

Response: Yes. The CON process should eliminate the requirement of detailed drawings and specifications and consideration of technical building / design requirements regulated by OHCQ, local health departments, and the State Fire Marshal.

See also, response to Question 8, above.

Thank you for your responses.

Hearts for Home Care
A BAYADA program supporting quality home health care.

BAYADA®
Home Health Care

Mrs. JoAnn Saxby
Division Director, Camellia Home Health Division
BAYADA Home Health Care
8600 Lasalle Road, Suite 335
Towson, MD 21286

Mr. Paul Parker
Director, Commissioner's Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

January 2, 2018

Re: Proposed Regulations about Health Planning and Certificate of Need
Comments Requested by January 13, 2018

Mr. Parker:

Thank you for the opportunity to provide comments in response to the Maryland Health Care Commission's (MHCC) proposed regulations about Health Planning and Certificate of Need (CON). BAYADA Home Health Care (BAYADA) is very proud to provide home health care with an outstanding level of quality to more than 16,000 Marylanders annually, employing 775 skilled dedicated professionals. In 2017, we earned Home Health Care Compare ratings of 4.5 and 5 stars. We credit scores like this to our nationwide focus on continuous reflection, measurement and improvement and on professional development for our employees. BAYADA is a mission-driven organization. Central to the BAYADA Way is our collective belief that our clients and their families deserve home health care delivered with *compassion, excellence, and reliability*, our BAYADA core values. We look forward to 2018 with hopes to be able to serve even more Marylanders in a wider geographical area, with additional services. Home health care serves a vital role in our health care system - reducing health complications, readmissions and overall healthcare cost when used appropriately. BAYADA is proud to serve our clients and our state with consistently high quality.

In response to your questions regarding reform to the CON process for home health care, BAYADA suggests that the MHCC retain home health care CON, but take on certain reforms to improve the process and to increase the assurance of quality for home health care clients statewide.

BAYADA supports the continued use of CON for home health care in Maryland for the primary reason that the process has been proven to reduce the incidence of fraud. Fraud in home health care reduces the standing of all home health care providers by association and may have the impact of limiting the availability of high quality care to clients who need it. In other states that do not have a CON or home health care licensure process, major scandals have been seen in recent years. Massachusetts saw a dramatic increase in the number of new providers, coinciding with a

dramatic increase in investigations for fraudulent behavior in 2016.[1] New Jersey has seen the introduction of online, unlicensed caregiver registries that threaten the sustainability of tax-paying in-state provider organizations. As recently as December 2017, news from Illinois published findings that federal investigators estimate that home health agencies in the state have collected at least $104 million of public dollars through improper measures.[2] BAYADA knows how important high-quality home health care is to a clients' recovery or ongoing health. The home health care CON in Maryland safeguards the continued availability and quality of this care for Marylanders. Without the home health care CON, a rapidly increasing number of providers, undifferentiated in their compliance with state regulatory processes or quality scores, may become a race to the bottom-differentiating primarily in price instead. This diminishes provider incentive to focus on client quality, improvement and innovation. Indeed, there would be no ability to pursue value-based purchasing if there were no CON; a low-performing provider would be able to simply reorganize overnight with a different trade name and escape value-based contract penalties. BAYADA believes that this would not be in clients' best interest, and continued use of CON would be far superior in pursuing high-quality care for Marylanders.

High-quality home health care providers focus on recruiting highly skilled professionals, retaining them, constantly improving client care, and offering continuous training and professional development opportunities. These efforts require economies of scale to be economically feasible with limited reimbursement rates from state and private payers. The MHCC's periodic study of clients' access to home health care in various areas of the state and its considered release of additional home health care CONs safeguards the ability of providers to make investments into these essential programs to continuously improve the quality of home health care clients in Maryland receive, and enhances the opportunities for professionals to improve their skills and potentially step up to additional professional licenses. To this end as well, and recognizing the current trend toward consolidation, the MHCC should retain the exemption review for merged systems. Larger systems will have the benefit of these economies of scale and should be able to offer better care to more people. Encouraging fewer, larger providers will also decrease the administrative burden to the state in the number of providers needing annual state surveys.

With regard to the CON process itself, BAYADA supports an expedited review for providers who have proven to provide high quality care to Marylanders over the previous several years. We support the MHCC's continued use of Home Health Care Compare scores as a quantitative measure of quality, as well as reference to preventable hospital readmission percentages. For providers who are currently, actively providing care within the Maryland regulatory system, with proven quality, an expedited review makes sense. We should be encouraging good providers to care for more people who need this care. We would like to encourage the MHCC to continue its requirement that applicants consider their impact on a market during the application process as well. This is an especially useful portion of the process.

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[1] Nelson, Mary Kate, "Large-Scale Home Health Crackdown Begins in Massachusetts." Home Health Care News. https://homehealthcarenews.com/2016/02/large-scale-home-health-crackdown-begins-in-Massachusetts/

[2] Calma, Carlo, "Illinois Home Health Fraud Tops $100 Million." Home Health Care News. https://homehealthcarenews.com/2017/12/Illinois-home-health-fraud-tops-100-million/ 13December2017.

As to your question regarding the appropriateness of current timelines and deadlines within the CON process, we fully agree that provider-side deadlines are reasonable to collect all relevant requested data. There may be room for improvement in the timeline for review once the application is completed, as well as communication to providers throughout the review process. It would be wonderful to have better visibility into this process at the MHCC.

BAYADA agrees that (1) need, (2) availability of more cost-effective alternatives, (3) viability, (4) impact, (5) applicant's compliance with previously awarded CONs are good criteria to be used in the evaluation of CON applications. We suggest an additional criterion that relates to prevention of fraud or noncompliance with CMS regulations. As mentioned previously, bad actors within home health care reflect poorly on the industry, other providers and our regulators, as a team. The CON process offers the best opportunity for regulators to carefully choose providers who will serve Marylanders well over the long term. We want our peers to be the best they possibly can be.

As the MHCC examines the home health care CON process, BAYADA suggests that it also look into a process of reclaiming CONs from providers who are not using them to their fullest ability or who are wavering in their commitment to quality. Non-utilization of existing CONs does not benefit those who need access to this care; it makes it more difficult for the MHCC and other providers to recognize a new or increasing need for additional care when it arises, and delays the availability of care to clients in those areas. Non-utilization of existing CONs also encourages the unregulated secondary market for CONs which could lead to lower quality providers entering Maryland without the MHCC's review. For existing CONs that are being used, BAYADA suggests that the MHCC take a more involved stance in ensuring ongoing quality provided to Marylanders. To suggest a metric, maintaining an above-average Home Health Compare score (3.5) should be required to begin an application for a Maryland home health care CON. If a provider drops below a Home Health Compare score of 3.0, that provider should be required to work with the MHCC on a plan of correction, at the risk of having their CON revoked. Client care is of the utmost importance. It is what brings all of us to work each day and should be central to everyone who works in this profession. The MHCC is in the ideal position to ensure that home health care provided in Maryland is of high quality and that fraud is prevented. BAYADA supports the MHCC taking this opportunity to hold all providers to a high standard.

Finally, the MHCC has requested feedback on whether the CON stifles innovation. BAYADA believes it is quite the opposite. Innovation requires presence and scale. A provider organization, to have a real impact on innovation within the health care system, must know the current environment, trends, client needs and existing areas of opportunity. Home health care is more complicated and more complex than many in healthcare realize. BAYADA's recent invitations to engage in joint ventures with hospital systems is evidence of that. If home health care were simply sending nurses, therapists and other professionals who already work in hospital settings into the community, these hospitals would surely have chosen to do the work themselves over partnering with another organization. Our joint ventures have benefitted clients and have led to further conversations about value, organizational strengths and further potential partnerships with hospital-based providers.

Thank you, again, for the opportunity to provide feedback on these proposed regulations. BAYADA is happy to offer our perspectives and ideas in this process and looks forward to being an ongoing partner with the MHCC to improve the quality of home health care, sustainability of the

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A BAYADA program supporting quality home health care.

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Maryland's unique health care system, and provision of the best care to meet the needs of all Marylanders. If you'd like to discuss our comments further, please reach out to me. I would be happy to discuss them with you.

Sincerely,

JoAnn Saxby

JoAnn Saxby
Division Director, Camellia Home Health Division
BAYADA Home Health Care
Phone: (410) 823-0880
Email: jsaxby@bayada.com

KEVIN KAMENETZ
County Executive

GREGORY WM. BRANCH, M.D., MBA, CPE, FACP
Director, Department of Health and Human Services

January 12, 2018

Maryland Healthcare Commission
Mr. Paul Parker
Director of the Commission's Center for Health Care Facilities Planning and Development
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Mr. Parker:

Please consider this letter an official response to your request dated November 21, 2017 for comments regarding potential reforms of health planning and certificate of need (CON) programs.

Scope of CON Regulation

Maryland Health Care Commission approval is required to establish a home health agency or expand the service area of an existing home health agency into new jurisdictions.

Need for CON Regulation

Which of these options best fits your view of nursing home (is this supposed to say home health?) CON regulation?

☐ CON regulation of home health agencies should be eliminated.

☐ CON regulation of home health agencies should be reformed.

☐ CON regulation of home health agencies should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The impact of CON regulation on Home Health Agency Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among home health agencies?

   Yes.

2. Does CON regulation impose substantial barriers to market entry for new home health agencies or expansion of home health agency service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

   For profit agencies are too large.

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3. How does CON regulation stifle innovation in the delivery of home health agency services under the current Maryland regulatory scheme?

   Hospital referral patterns only use a few home health agencies.

4. Outline the benefits of CON given that home health services do not require major capital investment, do not induce unneeded demand, are not high costs and do not involve advanced or emerging medical technologies.

   Home Health services affect readmission rates so represent a cost savings measure that can improve population health. Home Health needs to keep abreast of all new technologies (e.g. wound vacs).

5. Should the scope of CON regulation be changes?

   A. Are there home health agency projects that require approval by the Maryland Health Care Commission that should be deregulated? *No.*

   B. Are there home health agency projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

      Residential Service Agencies that are acting as home care agencies.

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

   The volume of paperwork required.

7. Should the ability of competing home health agencies or other types of providers to formally oppose and appeal decisions on projects be more limited? *No.*

   Are there existing categories of exemption review that should be eliminated? *No.*

   Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems? *No, the Home health (as health facilities) are too large and exclusive and have a monopoly on the hospital referrals.*

8. Are project completion timelines realistic and appropriate?

   Yes.

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for home health agencies provide adequate and appropriate guidance for the commission's decision making? *Yes.*

What are the chief strengths and what do you perceive to be the chief weaknesses?

Weakness - lack of incorporate population health in terms of a continuum of care.

10 Do State Health Plan regulations focus attention on the most important aspects of home health agency projects? No.

Home Health agencies are too focused on Medicare reimbursement to embrace the environment of case management.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be make in the development process for State Health Plan regulations, please provide specific recommendations.

Input is adequate and appropriate, but partnerships within systems of care that provide health care should be examined for ways to influence population health. For instance, Social Services agencies should be required partners to address the social determinants of health.

General Review Criteria for all Project Reviews

12. Are these general criteria adequate and appropriate? *Yes.*

CHANGE/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of home health agencies should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

NA.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms?

Expansion of license requirements to assure quality of care.

Both MDH licensing, and CON regulation are required in terms of the quality of care and sanctions.

Hospital systems, rehabilitation, home health and residential service agencies should all work together.

The Impact of CON Regulation on Home Health Agency Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing home health agencies and new market entrants?

Yes, partnerships within systems.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of home health agencies to preserve and strengthen competition for home health agency services?

Yes, especially to include partnerships and share collaboration in the continuum of facilities.

The Impact of CON Regulation on Home Health Agency Access to Care and Quality

1. At what stage should MHSS take into consideration an applicant's quality of care performance? How should new applicants be evaluated?

Home Health Compare for quality of care; New applicants should provide history previous quality of care initiatives.

Scope of CON Regulation

2. Should MHCC be given more flexibility in choosing which home health agency projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions?

Yes, as long as the process retains integrity. For example, what are the proposed clinical pathways or best practices to be followed.

3. Should a whole new process of expedited review for certain projects be created? If so what are the attributes?

If the State Health Plan is working to improve population health, and a system improvement linking different partners together as a system to achieve that, expedited review could be granted. If another model of practice could be replicated that has good outcomes, for example.

The Project Review Process

4. Are there specific steps that can be eliminated? *No comment.*

5. Should post-CON approval processes be changed to accommodate easier project modification?

Yes.

6. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review?

   Not sure.

7. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

   Yes.

Duplication of Responsibilities by MHCC and MDH

8. Are there areas of regulatory duplication in home health agency regulation that can be streamlined?

   Somehow the State Health Plan and population health has to be a joint responsibility that makes sense. Residential Service agencies have to have more quality regulation.

Should you have additional questions, please contact Laura Culbertson; Chief, Quality Improvement at 410-887-3729

Sincerely,

Gregory Wm. Branch, M.D., MBA, CPE, FACP
Director, Health and Human Services
Health Officer

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HomeCentris
HEALTHCARE
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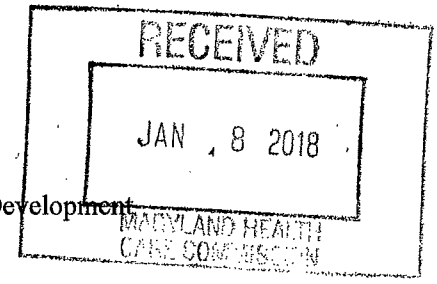

January 2, 2018

Mr. Paul Parker
Director of the Commission's Center for Health Care Facility Planning and Development
Maryland Healthcare Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Parker,

This letter is in response to your request for comment guidance on the MHCC CON Study. As context for my responses, HomeCentris Healthcare operates two home-based healthcare companies in Maryland licensed by the Office of Health Care Quality ("OHCQ"). The first, Personal Home Care, is a Residential Service Agency ("RSA") with over 1,100 clients. Nearly 95% of these clients are Medicaid Waiver clients. The second, HomeCentris Home Health, is a Medicare-certified home health agency, licensed in Baltimore County only.

Need for CON Regulation.

We believe the home health CON regulations should be eliminated or significantly reformed. In general, our view is that home health CONs are an outdated method of regulating home health entities that no longer contribute towards their initial intent. Further, although we do understand an argument to review the need for additional hospital or skilled nursing beds in a geography, because home health care is not limited by licensed beds or building size, it should not be viewed as a "needs based" health care business. In home health care, the concept of a geography being "full" with a "need" for more providers does not apply as there is no limit to the number of patients an agency can service. In theory, one agency could service the entire state given its ability to open branch locations and hire additional staff. In this example, there would never be a "need" for another agency as a single agency is infinitely expandable. Therefore, we believe the existing home health regulations should be revised away from a needs-based review and towards ensuring quality of care, financial viability, and a lower cost of care. A home health CON achieves neither of these goals.

In our view, the existing home health CON requirements protect and perpetuate low quality home health agencies with poor clinical and/or patient satisfaction outcomes by blocking high quality operators from entering the market. A good example occurs between Baltimore City and Baltimore County. Our company's circumstances further assert this example. There are approximately 21 licensed home health agencies in Baltimore City and additional agencies have not been licensed since at least 2010. However, nearly all the metropolitan area's hospitals are inside the city limits. Even though Baltimore City has several low-quality operators as evidenced by CMS Five Star ratings, current home health CON regulations prevent new high-quality agencies from serving Baltimore City patients. As we review competitive outcomes data, there are several agencies in Baltimore City with high rehospitalization rates and two stars for Clinical and Patient Satisfaction outcomes.

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In our case, HomeCentris is currently a Five-Star agency both for clinical outcomes and for patient satisfaction. Further, our rehospitalization rate is approximately half the Maryland average. However, due to CON restrictions, we are unable to provide our services to City patients. We believe this example shows why CON restrictions do not achieve the Triple Aim's goals. First, using HomeCentris as an example, a new high-quality agency cannot enter new markets and implement its rehospitalization prevention protocols. This would lower the total cost of care in Maryland. Second, the CON regulations restrict competition and access to good quality providers while protecting poor quality providers. This protection does not fulfill the CON's initial intent nor does it fulfill the triple aim goal of improving patient experience and improving health.

In addition, licensing additional home health providers may create downward pressure on the total cost of care by limiting a patient's time in a high cost setting like a hospital or skilled nursing facility and transferring the patient's care to the lowest-cost setting, home health care. In our view, the MHCC should consider the impact on total cost of care that would result from prioritizing low-cost settings and minimizing high cost settings.

The Impact of CON Regulation on Home Health Agency Competition and Innovation

1. In our view, the public and the health care delivery system would benefit from more competition among home health providers. When competition is introduced to a market, the outcome is generally better outcomes and lower costs. High quality providers will thrive while low quality providers will struggle and be replaced. However, we strongly believe that there should still be some pre-requisites to issuing new home health licenses. For example, to prevent inexperienced and non-serious providers from entering the market, Maryland could consider requiring operators to post a significant surety bond to be licensed (see our response to Question 13). This will prevent small RSAs who hope to service a few of their patients from becoming licensed. It should also prevent low quality or non-compliant providers from entering the market.
2. The CON regulation does not impose "substantial" barriers, it imposes "absolute" barriers to new home health agencies, when considering the 2010 moratorium on new licenses. At a minimum, we hope the MHCC would consider amendments to the home health CON regulations that would consider high quality providers, based on quality outcomes and financial qualifications rather than the concept of "need." For example, our Personal Home Care division services approximately 325 Medicaid Waiver clients in Baltimore City. Likewise, we have another 260 clients in Montgomery County. As those clients are hospitalized, HomeCentris Home Health has no ability to provide its Five-star home health services to them. Further, this interruption in care can cause transition issues between levels of care, confusion with the clients, poor care coordination between home health and home care agencies and potentially higher rehospitalizations and total cost of care.
3. If there was more market competition among home health providers vying for the same number of patients, Maryland would see a migration of patients towards the high quality and/or low-cost providers. These high quality, low cost providers are exactly the providers who are experimenting with innovative ways to increase quality and/or lower costs. With the current CON protections in place, the low-quality providers have little incentive to improve or innovate as their franchise is completely protected.
4. One of the benefits of the current CON regulations is that they prohibit new low-quality operators from entering the market. With limited barriers to entry as your question suggests, many, many

providers would apply for home health licensure. However, these same regulations also prevent high quality providers from entering the market which would drive up quality and drive down total cost of care. We believe there exists a way to provide for objective, appropriate barriers to entry without shutting out 100% of new operators. For example, as discussed previously and in Question 13, Maryland could create a significant financial barrier to entry by requiring a large bond to obtain licensure. This would not be a burden for reputable agencies, but a significant burden for un-serious providers. This would prohibit small, low quality RSAs and other operators from entering the market. We also believe there could be quality standards imposed upon agencies operating in Maryland.

Scope of CON Regulation

5. In general, we believe the home health CON regulations should be amended to reflect allowing high quality providers with the appropriate financial support to enter the market. We do not believe home health licensure should be approached on a project by project basis. Rather, we believe there should be strict licensing requirements to discourage low quality operators from entering the market.

The Project Review Process.

6. No opinion
7. In our view, competing home health agencies should have little say in opposing new agencies. As stated earlier, the CON provides absolute protection against other providers entering the market. It is difficult to imagine any circumstances when a protected, low quality agency would support bringing more competition to the market.
8. No opinion.

The State Health Plan for Facilities and Services.

9. No opinion.
10. If State Health Plan regulations focus on the "need" for additional home health agencies, then we believe they are not focusing on what is best for Maryland's patients nor its taxpayers. By focusing on need, which cannot exist in home health as there are no bed limitations, current regulations do not support competition nor do they lead to higher quality or lower cost of care.
11. No opinion.

General Review Criterial for all Project Reviews.

12. We believe that (1) Need and (2) Availability of More Cost-Effective Alternatives are not appropriate for home health licensure. As discussed, "need" is not a relevant consideration in home health given the lack of real estate or licensed bed restrictions. Likewise, as home health is generally the low-cost setting for health care, it seems inappropriate to evaluate this factor. Those restrictions are much more appropriate when evaluating the need for additional hospital or nursing facility beds. These two items should be replaced with quality measures.

Alternatives to CON Regulation

13. We believe the existing "need based" approval process should be eliminated or reformed in favor of quality and financial viability-based requirements for home health licensure. The existing framework at OHCQ could govern the licensing of new applicants and the oversight of existing providers if it were presented with clear licensing guidelines. Currently, Maryland uses a county by county basis for licensing new home health companies. We believe that framework would be eliminated if the CON requirement were meaningfully changed. In addition to the existing licensure requirements, below are some proposed recommendations to ensure the quality and financial viability of home health applicants.

    a. Require new applicants and existing providers to post a $250,000 surety bond to OHCQ upon application or re-application for licensure. In response to your question about low barriers to entry, this surety bond requirement would help ensure the financial viability of the applicant or continuing agency and would discourage unserious or underfunded agencies from applying. The bond would be held by OHCQ during the licensure period and would be returned when the licensee sells or closes the agency, assuming the agency is operating in good standing. Agencies that are forced to close due to poor quality, poor state surveys, etc. would forfeit all or a portion of the bond and the state would retain the funds. The bonding requirement for home health agencies is present in many other states and Maryland requires a surety bond for many other entities. The mechanism for enforcing this already exists.

    b. Home Health applicants must demonstrate experience in home health operations. This requirement would go beyond providing policy manuals which are easily purchased and customized by applicants. Rather, an applicant must demonstrate the agency will be run by an experienced and qualified home health Administrator and Director of Nursing. Without a requirement like this and appropriate verification, Maryland risks opening the market to inexperienced operators who could put patient safety at risk.

    c. Home Health Administrator must be credentialed and/or certification. Currently, there are no certifications required to be a home health administrator. Skilled nursing facilities require certain training, onsite apprenticeships, and education. However, home health administrators require no such training. We believe the requirements for home health administrators could be strengthened.

    d. Home Health providers must demonstrate a commitment to quality outcomes. Poor operators should be at risk of losing their licensure due to poor survey outcomes, poor five star ratings, etc. Maryland has many low-quality home health agencies that are protected by the current CON requirements and not truly at risk of losing their licensure. We would support meaningful quality standards to retain licensure.

14. Included in response above.

The Impact of CON Regulation on Home Health Agency Competition and Innovation.

15. HomeCentris vision is to "Empower people to remain in the community through innovative health solutions." However, requiring innovation by regulation may be difficult to achieve. Healthcare is already a very regulated business and necessarily so. It would be difficult to

mandate innovation as many innovations would run into conflicts with other regulations. Our view is that increased competition will force both better outcomes and lower costs as quality operators find ways to innovate without overarching regulations forcing innovation.

16. We see no opportunities within the existing regulations governing mergers and acquisitions of home health agencies that would increase quality. Currently, consolidation is the only possible way for home health providers to enter new markets and regulatory burdens are not overly oppressive in this regard. However, additional survey activity on home health agencies would ensure compliance with regulations and would lead to higher quality by focusing more scrutiny on lower quality providers. If consolidation means forcing out low quality providers, we would support this in conjunction with allowing high quality providers access to the market.

The Impact of CON Regulation on Home Health Agency Access to Care and Quality

1. Based on our recommendations in Question 13 above, we strongly believe that quality, financial viability, and specific home health experience should factor into new home health licensure. The size of a company or its institutional prestige should not be considered if outcomes and quality are low. Out of state applicants can be evaluated on quality outcomes for both clinical and satisfaction outcomes through the CMS Five Star program. As this program is nationally managed, it would be an objective measure. New applicants should be able to demonstrate past success in delivering home health services. We believe this requirement would preclude hundreds of RSA from becoming home health agencies. Although both business deliver home based care, home health is significantly more regulated and difficult to deliver than home care and MHCC should be careful in creating standards that do not allow any provider into the home health program.

   In combining this response with the question regarding redundancies and inefficiencies, we see no reason that OHCQ could not administer the licensing and oversight of new home health applicants based on Maryland regulations and licensure requirements. The OHCQ office already oversees licensure requirements and state surveys of both RSA and home health providers. Their staff is experienced in assessing the qualifications and outcomes of home health providers and we believe they would be appropriate to implement any revised licensure requirements. We view the MHCC as more of a strategic and long-range planning body and not a day-to-day licensing oversight entity.

Scope of CON Regulation

2. In our view, there should not be a project by project review process by the MHCC. We believe the MHCC, in conjunction with the Maryland legislature and other regulatory bodies, should establish a set of standard criteria and requirements such as those proposed in Question 13 and as already required by existing Maryland licensure regulations. All applicants meeting those standards, however strict the MHCC decides they should be, should be approved without a review panel by the MHCC to evaluate "need" or "alternative low cost of care." This will not only streamline the approval of high quality, low cost providers, but it will also ensure the approval process is consistently administered and not subject to political influence, institutional prestige, or other factors apart from the interests of the community.

3. Same answer as Question 2 above.

4. We believe all "need based" processes and steps should be eliminated and replaced with quality and financial viability based standards. As discussed, need based reviews serve to protect some low-quality operators which is not good for the triple aim goals. To truly get a competitive market in which high quality operators compete on quality, innovation, and low price, needs based reviews should be replaced with standards such as our proposals in Question 13. This would dramatically streamline the approval process and eliminate the tedious and expensive studies required to prove "need."

5. Same answer as Question 2 above. Project modifications should ensure compliance with the requirements of all home health agencies and can be administered by OHCQ.

6. We believe the regulatory process should be overhauled to create a set of quality and financial standards required to license a home health agency. We do not believe there should be exemptions, special favors, or panel review of specific projects. We believe in a standard set of licensure requirements that would favor high quality, low cost providers and gradually eliminate low quality providers and applicants.

7. Yes, always.

8. No opinion.

To summarize our position, we feel that Maryland's current home health Certificate of Need regulations do not work toward the "triple aim" objectives of improving care, improving health, and reducing the cost of health care. To the contrary, we believe they protect low quality and/or high cost providers, while excluding potential higher quality and/or lower cost providers and discouraging innovation. Further, they impose an unnecessary coordination of care hurdle when clients transition from home care to home health, and back again. We feel that Maryland can modernize its regulations to license reputable high-quality providers but still ensure high quality by requiring strict adherence to new quality and financial based barriers as we propose in Question 13. Thank you for taking a proactive view and soliciting the opinions of existing providers. Please contact me if you have any questions.

Sincerely,

Matthew F. Auman
CEO

Home Health Services
Pediatrics at Home
Pharmaquip
5901 Holabird Ave., Suite A
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410-288-8000 T

JOHNS HOPKINS
MEDICINE
JOHNS HOPKINS
HOME CARE GROUP

January 24, 2018

Dear Maryland Health Care Commission,

Thank you for the opportunity to comment on the CON regulation that is currently in place. Attached you will find our agency's response to the important questions you have asked. If you have any further questions or would like clarification please feel free to contact me.

Thank you,

Mary G. Myers
President/Chief Executive Officer
Johns Hopkins Home Care Group
5901 Holabird Avenue Suite A Baltimore, MD 21224

Paul Parker
Director, Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

January 25, 2018

Dear Mr. Parker:

Thank you for the opportunity to provide feedback on the Maryland Certificate of Need ("CON") regulatory process as it pertains to Home Health services. We feel strongly that **a Certificate of Need requirement should be maintained for Home Health Services in Maryland.**

If the CON requirement for Home Health Services were removed, and new agencies could enter the market without any assessment of need, experience, quality, or value to the health system, we worry in particular about the following:

1. Further escalation of current clinical workforce shortages, and
2. Potential degradation in the quality of services available in Maryland.

Johns Hopkins Home Care Group, along with many other agencies, struggles to fill key clinical positions that serve Marylanders in their homes due to the limited pool of qualified workers. The work demanded of home health clinicians requires a great deal of autonomy, resilience, and energy. Need for home health services is growing, while at the same time the average age of the workforce increases. Because of this, it has become increasingly challenging to attract qualified individuals, especially ones willing to work in a home-based setting rather than a facility-based one. Without the MHCC evaluating new agencies and allowing for gradual growth in capacity in the market, we fear that the existing workforce will be cannibalized by new agencies.

Furthermore, the CON process provides an initial check of quality and experience before an agency is allowed to enter the market. We believe the CON regulations play a vital role in ensuring that Home Health Services in Maryland are available, accessible, and of the highest quality.

Please find included here additional information and input in response to your specific questions. Thank you for the opportunity to comment on the CON regulations that we believe protect our community and the health of all Marylanders. We truly believe this is critical to ensuring the delivery of high quality care and that workforce resources are preserved. Please feel free to contact us for additional insight and questions so that we may better serve our state and communities together.

Sincerely,

Mary Myers

The Impact of CON Regulation on Home Health Agency Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among home health agencies?

   There is adequate competition to promote high quality, efficient and effective services in the existing system.

2. Does CON regulation impose substantial barriers to market entry for new home health agencies or expansion of home health agency service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

   The largest barrier to market entry for a home health agency is the ability to be financially viable and the ability to recruit a qualified workforce. The existing CON regulations impose a reasonable barrier to market entry for new home health agencies that helps ensure readiness to enter the market, a thoughtful approach, and adequate resources before entering the market. In this way the CON requirement for Home Health services promotes competition among qualified agencies.

3. How does CON regulation stifle innovation in the delivery of home health agency services under the current Maryland regulatory scheme?

   CON regulation does not stifle innovation in the delivery of home health services. Our experience with the regulation has actually allowed us to be more innovative in our approach to care for our population. By going through the CON process we feel we are more equipped to care for the communities we serve and better understand their needs through the process which allows us to create innovative solutions for care.

The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) improving the health of populations, and; (3) Reducing the per capita cost of health care.

4. Outline the benefits of CON given that home health services do not require major capital investment, do not induce unneeded demand, are not high costs and do not involve advanced or emerging medical technologies.

   Having recently undergone the CON process in another jurisdiction, we were reminded of the benefits the process provides for new agencies entering the market. It allowed us to review the population's unique needs and how our services could fulfill those needs as part of a larger health care continuum.

   Additionally, we disagree that home health "does not involve advanced or emerging medical technologies". As technologies evolve, they are becoming more portable and accessible. We are able to deliver more innovative, complex care in the home because of the immense gains in

technology. Although not covered by the Medicare home health benefit, agencies including our own are exploring new ways to deliver more complex care that is patient-centric and cost-effective by delivering it in the home setting. For example, our agency has developed a mobile vascular access program that places central lines within the home setting. Furthermore, telemedicine and remote patient monitoring are evolving and allow us to prevent unnecessary emergency department visits and avoid readmissions that are extremely costly to the system. Without understanding the needs of the population we serve, we would not have been able to invest or fulfill those needs with innovative solutions that are beneficial to the health system.

The biggest benefit of the CON requirement, though, is that it creates a more stable, predictable market by preventing an influx of unprepared and perhaps not qualified agencies.

Scope of CON Regulation

*Generally, Maryland Health Care Commission approval is required to establish a home health agency or expand the service area of an existing home health agency into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at: http://www.dsd. state.md.us/comar/Subtitle5earch.as px?search=10.24.01. **

5. Should the scope of CON regulation be changed?

    a. Are there home health agency projects that require approval by the Maryland Health Care Commission that should be deregulated?
    We believe the scope as it exists today is appropriate and addresses the needs of the state.

    b. Are there home health agency projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?
    No.

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

    None.

7. Should the ability of competing home- health agencies or other types of providers to formally oppose and appeal decisions on projects be more limited?

    No.

    Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

Regulations are sufficient as they are.

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

   Yes.

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for home health agencies provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

   Strengths of the State Health Plan regulations include:

   - Allowing high quality and high value agencies to grow as long as there are enough labor resources available to do so.
   - A well-thought process allowing the gradual entry of new agencies to prevent labor resource cannibalization.
   - The utilization of national benchmarks for quality and market competition.

   We recommend that more attention be paid to the workforce-related components of the CON application process. This is a critical issue in the delivery of home health services. Potential market entrants should demonstrate that they understand the challenges and have plans in place that are likely to result in an adequate workforce without undue cannibalization.

Under Maryland CON law, home health agencies are classified as "health care facilities."

10. Do State Health Plan regulations focus attention on the most important aspects of home health agency projects? Please provide specific recommendations if you believe that the regulations miss the mark.

    We believe the regulations sufficiently focus on the most important aspects.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

    We believe the MHCC's process for obtaining input is adequate.

General Review Criteria for all Project Reviews

COMAR 10.24.01.0BG(3]{b)-(J)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

    We believe the current criteria are appropriate.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of home health agencies should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

    We believe CON regulation should be preserved in its current form.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of home health agency licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that home health agencies are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under- utilization or poor quality of care?

    We do not believe additional licensure requirements can serve as a substitute for the CON regulation. Although additional quality metrics may be placed upon licensure, it would not maintain the thoughtful gradual entry of agencies based upon national standards that define market competition. This key aspect of the CON regulation helps prevent the cannibalization of the workforce and ensures that existing agencies can maintain their high quality services.

The Impact of CON Regulation on Home Health Agency Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing home health agencies and new market entrants? If so, please provide detailed recommendations.

    We have no recommendations at this time.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of home health agencies to preserve and strengthen competition for home health agency services?

    We believe the current CON criteria address this issue adequately.

The Impact of CON Regulation on Home Health Agency Access to Care and Quality

1. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?

   Quality should be considered after docketing.

Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

Scope of CON Regulation

2. Should MHCC be given more flexibility in choosing which home health agency projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff recommendation not to require CON approval or, based on significant project impact, to require the home health agency to undergo CON review.

   We do not believe this is necessary. Instead, we recommend that the application process be simplified, reducing the burden on applicants. Perhaps special consideration could be given to applicants proposing to serve geographic areas or populations that do not have adequate home health services.

3. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

   No.

The Project Review Process

4. Are there specific steps that can be eliminated?

   None known at this time.

5. Should post-CON approval processes be changed to accommodate easier project modifications?

   Not necessary especially for home health services applicants.

6. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

We are not aware of any changes that would be helpful specifically to the home health services category of applications.

7. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

   Yes.

Duplication of Responsibilities by MHCC and MOH

8. Are there areas of regulatory duplication in home health agency regulation that can be streamlined between MHCC and MOH?

   None that we know of.

January 12, 2018

Mr. Paul Parker, Director
Maryland Healthcare Commission
Center for Health Care Facilities Planning and Development
4160 Patterson Avenue
Baltimore, MD 21215

RE: Comments – Home Health Agencies MHCC CON Study 2017018

Dear Mr. Parker:

Please accept these comments on behalf of LHC Group, Inc. LHC is the preferred post-acute care partner for hospitals, physicians, and families nationwide. From home health and hospice care to long-term acute care and community-based services, LHC delivers high-quality, cost-effective care that empowers patients to manage their health at home. LHC provides services in over 450 locations in the 28 states in which it operates, including Maryland. In Maryland, LHC operates four licensed home health providers with 10 locations offering Medicare-certified home health services to residents spanning from Washington County to Worcester County. Throughout Maryland LHC offers state-of-the art home health services for a wide range of diseases and conditions with a *CMS star rating average of 4.5*.

Home health care helps patients recover from injury and illness in the comfort of home, reducing avoidable hospital readmissions and keeping healthcare costs down. As a result, the home health care industry in Maryland must maintain its economic viability and stability. LHC supports the Commission's Certificate of Need (CON) Program, which is necessary to ensure the continued provision of high quality care to patients in a cost-effective and efficient manner. Maintaining and improving the existing CON program is essential in a health care system that relies upon a strong and enduring post acute care system to succeed in the All-Payer Model today, and the Total Cost of Care Demonstration in the future. However, as long as the CMS Star Rating system is being used to determine eligibility for CON application, we believe the Commission has the obligation to update the eligibility of agencies with each update of the CMS Home Health Compare.

Our perspective on the CON issue comes from our experience across the country. In other states in which LHC operates where CON laws have been repealed or relaxed, the number of home health agencies has dramatically increased as a result. For a prime example one has to look no further than Texas and Florida. Florida in particular is the poster child for the untoward effects of deregulation of CON in the home health context. Florida eliminated CON for home health in 2003. In the first five years following deregulation, home health care charges submitted to Medicare *rose to twenty times the national average* prompting a Federal investigation of suspected fraudulent billing. Miami-Dade County experienced a 1,300% percent increase in <u>just the first five years</u> and recently has been identified as having the <u>highest Medicare expenditures for home health care services of any county in the country</u>.

These massive increases in cost and volume of home health services in Florida occurred at a time when the population increased only 10.2 percent.

South Florida also illustrates the consequences of eliminating CON oversight in home health. Historically, when CON regulation is relaxed or lifted, states quickly experience dramatic growth in the number of home health agencies; such growth inevitably leads to CMS and OIG fraud investigations. Because of the high rate of fraud cases in South Florida, Texas, and other states, CMS implemented a moratorium on new providers in those areas and has extended the moratorium several times. The experience in Florida, Texas and other states also shows that elimination of CON results in over capacity, which causes staffing shortages of healthcare professionals. This staffing shortage, in and of itself, lowers quality and fragments healthcare delivery networks. These are undesirable results for Maryland's health care system, but could be particularly devastating under global budgets and the Total Cost of Care Demonstration.

For the reasons expressed in this letter, LHC supports the Commission's continued oversight on home health CON regulation. Responses to the Commission's specific questions are provided in an attachment.

Thank you for your consideration of these comments. As always, please feel free to contact me for additional information regarding this matter.

Sincerely,

Margret S. Green RN BSN

Margaret (Peg) Green, RN, BSN
Area Vice President
HomeCall Maryland
Proud Member of LHC Group
4701 Mount Hope Dr., Suite A
Baltimore, MD 21215

COMMENT GUIDANCE – HOME HEALTH AGENCIES
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of home health agency CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of ~~nursing~~ home **health** CON regulation?

- ☐ CON regulation of home health agencies should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

- ☐ CON regulation of home health agencies should be reformed.

- **X CON regulation of home health agencies should, in general, be maintained in its current form.**

ISSUES/PROBLEMS

The Impact of CON Regulation on Home Health Agency Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among home health agencies? **Answer:** *Removing the CON requirement for home health is associated with increased fraud and abuse. We believe the MHCC has done a good job managing the CON process therefore keeping fraud and abuse low in Maryland. Furthermore, the patient population receiving home health services is a particularly vulnerable group – they deserve the protection and oversight of the Commission to ensure their safety and well being.*

2. Does CON regulation impose substantial barriers to market entry for new home health agencies or expansion of home health agency service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public? **Answer:** *We believe the public would benefit by considering expansion requests from long-standing, high-quality providers into contiguous counties.*

3. How does CON regulation stifle innovation in the delivery of home health agency services under the current Maryland regulatory scheme? **Answer:** *We do not believe CON regulation stifles innovation. It encourages innovation by preventing an overpopulation of providers. An overpopulation of providers is not in the best interest of the senior/Medicare or Medicaid*

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

population – groups that can be extremely vulnerable and deserve the protection and oversight of the state.

4. Outline the benefits of CON given that home health services do not require major capital investment, do not induce unneeded demand, are not high costs and do not involve advanced or emerging medical technologies. **Answer:** *Please see our accompanying letter outlining specific examples of fraud and abuse in non-CON states. We encourage the Commission to coordinate with other states such as Florida, Texas, and Pennsylvania to analyze the potential implications of removing the CON requirement in Maryland.*

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a home health agency or expand the service area of an existing home health agency into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

5. Should the scope of CON regulation be changed? **Answer:** *No*
   A. Are there home health agency projects that require approval by the Maryland Health Care Commission that should be deregulated? **Answer:** *No*
   B. Are there home health agency projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation? **Answer:** *No*

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process? **Answer:** *No comment.*

7. Should the ability of competing home health agencies or other types of providers to formally oppose and appeal decisions on projects be more limited? **Answer:** *No*

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems? **Answer:** *No comment.*

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.) **Answer:** *No comment.*

The State Health Plan for Facilities and Services

[2] Under Maryland CON law, home health agencies are classified as "health care facilities."

9. In general, do State Health Plan regulations for home health agencies provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses? **Answer:** *No comment.*

10. Do State Health Plan regulations focus attention on the most important aspects of home health agency projects? Please provide specific recommendations if you believe that the regulations miss the mark. **Answer:** *No comment.*

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations. **Answer:** *No comment.*

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? **Yes** Should other criteria be used? **No comment.** Should any of these criteria be eliminated or modified in some way? **No**

CHANGES/SOLUTIONS

Alternatives to CON Regulation

1. If you believe that CON regulation of home health agencies should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies? **Answer:** *No comment.*

2. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of home health agency licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that home health agencies are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care? **Answer:** *We do not believe that MDOH has the capacity at this time to serve in a similar function as MHCC in this regard.*

The Impact of CON Regulation on Home Health Agency Competition and Innovation

3. Do you recommend changes in CON regulation to increase innovation in service delivery by existing home health agencies and new market entrants? If so, please provide detailed recommendations. **Answer:** *No*

4. Should Maryland shift its regulatory focus to regulation of the consolidation of home health agencies to preserve and strengthen competition for home health agency services? **Answer:** *We believe this would be an over-reach of the Commission's authority. If the Commission believes there is inadequate competition, it can open up the county of concern to new CONs.*

The Impact of CON Regulation on Home Health Agency Access to Care and Quality

5. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry? **Answer:** *The current practice of using CMS Star Ratings to determine eligibility to apply for a CON could be improved to include an updated review of the Star Ratings prior to docketing since they are published regularly and reflect performance greater than 1 year ago.*

   Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

Scope of CON Regulation

1. Should MHCC be given more flexibility in choosing which home health agency projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the home health agency to undergo CON review. **Answer:** *No comment.*

2. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process? **Answer:** *No comment.*

The Project Review Process

3. Are there specific steps that can be eliminated? **Answer:** *No comment.*

4. Should post-CON approval processes be changed to accommodate easier project modifications? **Answer:** *No comment.*

5. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered. **Answer:** *No comment.*

6. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process? **Answer:** *Yes, automation to improve the submission process would be an improvement.*

Duplication of Responsibilities by MHCC and MDH

1. Are there areas of regulatory duplication in home health agency regulation that can be streamlined between MHCC and MDH? **Answer:** *We do not believe MDH has the capacity at this time to take on similar responsibilities as MHCC.*

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry. Please see accompanying letter.

mncha
Home Health • Private Duty
Home Medical Equipment

Mr. Paul Parker
Director, Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Mr. Parker,

I hope this letter greets you well. On behalf of the Maryland-National Homecare Association (MNCHA), I want to thank the Commission for the opportunity to comment on this very important issue. We also want to thank you for including Mrs. Ann Horton on the workgroup that will review the CON process in Maryland.

In discussing this with the home healthcare community, you can expect that several agencies will be submitting their responses to your survey. At this time, MNCHA is currently in the midst of a conversation on this complex issue with our membership. It is our hope to continue this dialogue with our membership and with the Commission as the discussion progresses.

MNCHA's Board of Directors and our members stand ready to work with the workgroup and the Commission while reviewing the CON process and any related issues.

Thank you again for taking the lead on reviewing this issue and for recognizing home healthcare's critical role in the state's healthcare delivery system in ensuring that Maryland's most vulnerable patient population receives the care they both need and deserve.

Sincerely,

Angelo Terrana

Angelo Terrana
Executive Director
Maryland-National Capital Homecare Association
11350 McCormick Road
Suite 1006
Hunt Valley, MD 21031
aterrana@mncha.org

January 10, 2018

Mr. Paul Parker
Director, MHCC Center for Health Care Facilities Planning and Development
4160 Patterson Avenue
Baltimore, MD 21215

Response to Comment Guidance - General Hospice Services
MHCC CON Study, 2017-18

Dear Mr. Parker,

Thank you for the opportunity to comment on the state of hospice CON regulation in Maryland. As the sole provider of hospice services in Calvert County, Maryland, Calvert Hospice has a 34 year history of providing expert and compassionate end-of-life care to our community. Our independent, non-profit hospice serves approximately 300 terminally ill patients and families per year, at an overall hospice utilization rate of 45% in our county for the year ending 2016.

Calvert Hospice is proud to work closely with the sole hospital and all three skilled nursing facilities within our jurisdiction, and we have contracts for general inpatient and respite care with each facility. In addition, our agency is an active member of both the Calvert County Chamber of Commerce and the Chamber Non-Profit Alliance. We serve as a Center for Continuum of Care at End of Life, and provide frequent community education on topics such as advance care planning, caregiver support, medication management, and grief and bereavement. Our quality indicators and accreditation survey results show that we consistently provide excellent care to our patients and families, and the support that we receive from the Calvert County Board of Commissioners serves as additional testimony to the role that we play in our community.

Thank you for considering our responses to the items below.

Need for CON Regulation

Which of these options best fits your view of general hospice CON regulation?

- ☐ CON regulation of general hospices should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

- ☐ CON regulation of general hospice services should be reformed.

- ✓ CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?

No. Current CON regulations provide necessary limits to entry into the market and limits on expansion into other jurisdictions, but does not prohibit competition outright. Each hospice's survival is determined by their ability to provide the needed services to the members of their jurisdiction. We are concerned that if the CON were eliminated, jurisdictions in Maryland may be overrun with new hospice providers. Such an influx would contribute to increased competition for already scarce resources such as qualified clinical staff and volunteers. In addition, hospice providers would be forced to dedicate more of their financial and human resources to marketing and sales, which in turn would limit the expenditures that they are able to put directly toward patient care, including charity care.

In addition, we believe that hospice is and should remain a tightly regulated benefit with close oversight by state and federal accreditation agencies. An influx of new hospice providers into the state, without a corresponding increase in surveyor staff, would result in a significant risk of hospices operating without sufficient oversight and providing potentially substandard care.

Further, demographic data on hospices nationwide shows that CON states maintain a higher proportion of non-profit, community-based hospices than state without CON regulation. It is to be expected that removing CON regulations in Maryland would lead to a substantial increase in the number of for-profit or multistate corporate hospices.

Finally, there is no reputable evidence to show that increasing the number of hospices in a jurisdiction can be credited with increasing hospice utilization in that area. In fact, in the Medicare Payment Advisory Commission (MedPAC) 2010 Report to Congress, it was determined that, nationally, there is no relationship between number of hospice agencies and hospice enrollment.

2. Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

The CON provides the barriers necessary to ensure that market entry and jurisdiction expansion are limited. While densely populated jurisdictions have multiple providers, rural jurisdictions are able to meet utilization needs without competition. More rural jurisdictions, which have a single (typically community non-profit) provider, likely could not sustain operations in the face of competition from a large multi-state hospice organization. The limited populations of rural communities would be unable to support competing hospices.

3. How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?

There is no evidence to suggest that CON regulation stifles innovation in the delivery of hospice services. In fact, because hospices in Maryland are not diverting resources to sales and marketing in an effort to compete with multiple hospices in each jurisdiction, they are able to dedicate financial and human resources toward attention to quality and innovation.

In the past two years, Calvert Hospice has expanded innovative offerings including:

- Implementation of a contract with CareFirst as a partner in the Total Care and Cost improvement (TCCI) initiative, allowing our agency to provide open access hospice care to CareFirst members in our jurisdiction
- Membership in the Alliance Kids partnership as well as the Children's National Medical Center PANDA program, which are both pediatric hospice partnerships that engage providers to collaborate on topics related to providing end-of-life care to children and their families
- Updated bereavement programs targeted specifically to the needs of our community, including specialized services for substance abuse loss and teenagers who have experienced losses
- Selection in two consecutive years as a partner agency for the Leadership Southern Maryland Executive Leadership Academy, ensuring exceptional professional development for hospice staff as well as an expanded quality assurance program
- Achievement of National Hospice and Palliative Care Organization (NHPCO) We Honor Veterans Level 4 Partner, the highest designation possible, which is a testament to the comprehensive and innovative care that we provide to terminally ill veterans in our county
- Partnership with Calvert Health Medical Center to embed palliative care professionals within the hospital system and ensure that patients in our community are offered critical conversations about end-of-life care options earlier in their disease trajectory

In addition, Calvert Hospice staff are active members in the Hospice and Palliative Care Network of Maryland committees and Board of Directors, and collaborate often with agencies such as the National Hospice and Palliative Care Organization (NHPCO). These close working relationships ensure that Calvert Hospice is continually at the forefront of new clinical innovations, models of care delivery, and compliance with quality measures.

4. Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.

It is not accurate to state that hospice services are not high cost and do not usually involve advanced medical technologies. The structure of the hospice benefit has not substantially changed since its inception in the 1980's. In that time, hospices have been tasked with developing methods of caring for increasingly acute patients with ever greater medical needs, without significant increases in our reimbursement structure. Hospices are now expected to

provide all medications and treatments associated with the terminal prognosis for patients with a wide variety of medical ailments and comorbidities. Along with the increased expense of providing medications and equipment for our patients, we must also ensure that our clinicians are capable of caring for acutely ill individuals in a home care setting. As hospitals are increasingly incentivized to prevent readmissions of seriously ill patients, hospices are tasked with developing methods to care for those patients who just a few years ago would have been considered so ill as to require hospitalization.

Finding clinical staff such as physicians, nurse practitioners, nurses, and social workers with expertise in hospice and palliative care is a significant challenge. This would become an almost insurmountable obstacle in the face of an open CON resulting in competition for experienced clinical resources, especially in rural areas. Again, the risk of forcing competing hospices to turn to less qualified staff to provide critical care to terminally ill patients in their homes is that hospices may provide care of a poor quality.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a general hospice, increase the bed capacity (general inpatient hospice care) of a general hospice, or expand the service area of an existing general hospice into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.2f 01.02 - .04, which can be accessed at:
http:// www.dsd.state.md.us/comar/Subtitle5earch.aspx?search=10.24.01. *

5. Should the scope of CON regulation be changed?

A. Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?

No, we are not aware of any.

B. Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

No, we are not aware of any.

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

We have not submitted a CON application for review and are thus unable to address this question.

7. Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

Competing providers should absolutely have a venue to appeal or formally oppose decisions on projects, especially as relates to their jurisdiction.

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

We have not submitted a CON application for review and are thus unable to address this question.

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

In general, yes, the State Health Plan regulations provide adequate guidance.

10. Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the regulations miss the mark.

The State Health Plan regulations are appropriate with regard to hospice, but may benefit by a further focus on quality measures. As Medicare increases quality scrutiny of hospices, the State Health Plan should continue to evolve to reflect a focus on the quality metrics that hospices are being asked to collect.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

There are no specific changes that we can recommend.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

We believe that hospices seeking to enter or expand hospice services in Maryland should also be reviewed in terms of quality. Performance on mandatory quality measures such as the Hospice Item Set, CAHPS Hospice survey should be reviewed by the Commission when making a determination about the CON application. In addition, data from the hospice PEPPER report should be reviewed in order to determine compliance on a number of factors. For existing hospices seeking to expand, this data would be readily available to the commission.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

Not applicable, we believe that CON regulation should continue.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland

Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

We do not believe that alternate regulatory mechanisms should be considered at this time.

The Impact of CON Regulation on General Hospice Program Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.

No. As stated previously, there is no evidence to suggest that CON regulation stifles innovation. Hospice providers will continue to innovate within the existing Medicare Benefit while functioning optimally under the CON system.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?

No. Hospice and Home Health serve different populations under a different model, and should not be consolidated in any way.

The Impact of CON Regulation on General Hospice Access to Care and Quality

17. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

The Commission should consider quality of care performance at the very beginning of the process. MHCC should use actual complaint and survey data of the existing providers, in addition to quality metrics stated above such as the Hospice Item Set, CAHPS Hospice survey, and hospice PEPPER report. Hospices will poor performance on quality metrics, multiple or serious complaints, significantly deficient surveys, or any sort of active investigation by the Department of Justice should be denied approval to enter or expand in Maryland markets.

Scope of CON Regulation

18. Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

No. The public, and other providers, should retain the ability to comment and formally oppose any CON applications, and giving the Commission the ability to expedite applications would seem to remove the ability for the public to comment or oppose.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

Existing hospice provider expansion within their licensed jurisdictions could be considered for expedited review. As an example, inpatient beds is an area for expedited review. In the interest of meeting patient needs in a timely manner, if an existing hospice provider has the capital, location and agreements to build and construct an inpatient center there should be an expedited process to move the project forward.

The Project Review Process

20. Are there specific steps that can be eliminated?
We have not submitted a CON application for review and are thus unable to address this question.

21. Should post-CON approval processes be changed to accommodate easier project modifications?
We have not submitted a CON application for review and are thus unable to address this question.

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.
Perhaps applications for inpatient beds within a jurisdiction, as discussed above.

23. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?
We have not submitted a CON application for review, but greater use of technology would seem to be beneficial.

Duplication of Responsibilities by MHCC and MOH

24. Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?

No. The departments serve different functions and at this time should maintain their existing areas of responsibility.

Thank you for your consideration of our responses.

Sincerely,

Jean E. A. Fleming, Ed.D, R.N.
Executive Director
Calvert Hospice
P.O. Box 838
Prince Frederick, MD 20678

Compass Regional Hospice Responses to MHCC request letter for reforms to health planning and CON programs

COMMENT GUIDANCE - GENERAL HOSPICE SERVICES MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of general hospice CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of general hospice CON regulation?

0 CON regulation of general hospices should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

0 CON regulation of general hospice services should be reformed.

☒ 0 CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?

No. The current CON regulation doesn't eliminate competition. It provides limits to entry into or expansion in the market, but the free market determines the provider's survival. Competition among existing hospice providers is adequate and sufficient to offer patients choice, removing the barriers to entry of new providers will not necessarily improve services. In fact, it may have a detrimental impact. Removal of the CON process will likely result in an influx of new hospice providers across the State. Primarily, more hospice providers would cause increased competition for limited clinical resources and diminishing return on realized economies of scale. Required components of the Medicare hospice benefit, like volunteer hours, would be compromised with more

providers competing for limited resources. Hospice providers, utilizing a greater percentage of budget resources for staff recruiting and sales and marketing with additional competition, would have fewer resources available to support those in the community needing financial assistance or charity care. Additional general hospice providers would drive up (redundant) fixed costs, which is one of the core benefits of a service based model. In addition, it would also drive up the cost of the health care delivery system by adding additional providers to oversee compliance and quality. The densely populated jurisdictions have significant competition presently, and utilization (delivery) trends are growing well alongside the new hospital reimbursement models. In addition, the careful selection of hospice providers into the market based upon need helps ensure that patients most in need receive quality services in their same geographic area. Without the CON process, more populous areas attract providers, less populated areas are ignored.

Research conducted by the Hospice and Palliative Network of Maryland indicates that Maryland might experience the following should CON be relaxed or removed:

Growth in Number of Hospices

If CON were removed in Maryland, some amount of growth in the number of providers is a certainty, based on the pace of growth in states without CON in recent years. For instance, between 2009 and 2014, the number of hospice agencies in California expanded from 231 to 501, a startling 117% increase. Non-CON states more comparable to Maryland in population and percentage of population over 65 have also experienced growth across a wide range: Over all 50 states, the total number of new agencies in CON states was 15; whereas non-CON states added 736. In general, more growth has occurred in southwestern and western states (average 36%) and in the for-profit sector (739 new for-profit agencies vs. 12 new non-profit). On average, the number of hospices in CON states has increased by one new agency over the five-year span. In non-CON states, the number of hospices has increased by an average of 21 new agencies.

Growth in For-Profit and Multistate or National Service Providers

Growth in the number of agencies is one issue; another is the kind of agency that would likely be added and how that might impact overall quality of care. In large part due to controlled growth in the number of agencies, CON states have maintained a higher percentage of community-based, freestanding and nonprofit agencies vs. corporate, multi-location for-profit agencies: On average nationally, nonprofit hospices are 32% of the total; in non-CON states, over 50. In Maryland, currently, of the 27 active hospices, 7 are for-profit and 6 of the 7 are branches of multistate or national corporate entities. Significant new growth in this class of agency is to be expected if CON is discontinued.

Growth from Outside Hospice

If Hospice CON were eliminated in Maryland, there may be extensive growth in the number of hospices from outside the hospice community by other provider types. Growth from this sector would likely contribute to a number of new agencies at the high end of the projected range and from providers not as thoroughly steeped in hospice philosophy or trained in specialized palliative skills. Growth in this sector is likely also to be for-profit and multistate or national.

Adding more hospices will not assure more hospice access. As the Medicare Payment Advisory Commission (Med PAC) wrote on page 148 in its 2010 Report to Congress, "Recognizing that the raw number of hospices may not be the best measure of provider capacity, we examined the relationship between the supply of hospices and the rate of hospice use among Medicare decedents across states." On page 149, in Figure 2E-1, MedPAC concluded, "Hospice enrollment rates are unrelated to the number of hospices in a state."

2. Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

The CON provides necessary barriers to market entry and jurisdiction expansion. The densely populated jurisdictions have appropriate competition. More rural jurisdictions, which have a single provider, likely could not sustain a business model and likely would not attract new market entrants, due to their low volume of need.

3. How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?

There has been NO negative impact on innovation and no experience or data to suggest that Maryland is less innovative regarding end of life care than non CON states. In fact, there is MORE attention to quality and innovation afforded from scale and avoided distraction due to questionable practices that arise with oversaturation, as well as, instability of staff caused by inflated supply of providers. As an example, hospice providers across Maryland invest in innovation with special programs that are not required by hospice regulation. Programs like Palliative Care Services, Pet Therapy, Massage Therapy, Music Therapy and utilization of telehealth technology are just a few examples of areas of innovation in Maryland. Additionally, the Hospice & Palliative Network provides a collaborative venue for hospices to share innovative solutions and this is accomplished through multiple venues such as General Membership Meetings, Annual Education Conference, Annual Regulatory Conference and other numerous collaborative opportunities.

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[1]The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1} Improving the patient experience of care (including quality and satisfaction);(2} Improving the health of populations, and; (3} Reducing the per capita cost of health care.

4. Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.

The key benefit of the CON process with regard to hospice care, and particularly care for the needy, is that it supports avoidance of unnecessary services and encourages more services where they are needed. The CON actually promotes innovation and the ability to scale to meet the demands of the market. Having a controlled number of licensed providers enables hospice to focus on key partnerships with hospital systems, skilled nursing homes and assisted living providers to keep readmission and mortality statistics minimized. Thus, supporting the significant savings achieved in the total cost of care model in Maryland. Post-acute ambulatory end of life care requires massive labor and infrastructure costs. Additional providers would add unnecessary competition for already competitive resources like Physicians (Board Certified), Nurses, Social Workers, Hospice Aide's, Chaplains, Volunteers, and clinical operations leadership. All of which are difficult to hire and could factor against existing hospice providers ability to scale and meet the needs of the market. The cumulative impact would be a reduction in the hospice providers ability to support the total cost of care initiative entering its second phase.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a general hospice, increase the bed capacity (general inpatient hospice care) of a general hospice, or expand the service area of an existing general hospice into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.2f 01.02 - .04, which can be accessed at:
http:// www.dsd.state.md.us/comar/Subtitle5earch.aspx?search=10.24.01.*

5. Should the scope of CON regulation be changed?
   A. Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?

The scope of the CON regulation appears sufficient at this time. We are not aware of any general hospice projects that should be deregulated.

   B. Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

We are not aware of any general hospice projects that do not require approval by the MCHH that should be added to the scope of the CON regulation.

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

The timeliness of the CON process is in the most need of reform. While there are existing regulations which set forth the timeline for review, they typically are neither followed nor upheld. In addition, for hospice providers, the need methodology and timeliness of data upon which the need methodology is determined should be re-examined. The addition of need methodology for inpatient beds also needs to be developed.

7. Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

A formal process to oppose and appeal is needed and should not be limited. Interested parties should have a venue and a platform to challenge and discuss competing hospice CON filings.

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

In general yes. The MHCC has demonstrated flexibility when needed to changing situations and unforeseen circumstances.

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

Overall the framework for the CON in the State Health Plan (SHP)is adequate and appropriate. The chief weakness of the SHP for hospice is the need to simplify and improve the current need methodology or projections. An area of opportunity to improve the current formula in which need is determined is a demographic weighting related to the underserved communities. As an example, African American hospice utilization is low nationally as reported by NHPCO. On a national level African American population as a percentage of total population is about 14% and in Maryland 29.4% of the total population is African American. Overall hospice

utilization in the state of Maryland is slightly lower than the national average, but this does not mean there is unmet need. The existing need calculation does not factor the impact of cultural diversity and the utilization of hospice. Our recommendation would be to compare "demographically" weighted utilization against those same demographically weighted national utilization rates.

The network would also recommend the SHP establish clarity and guidelines regarding the decision-making criteria as to the number of additional CON's to be awarded in a jurisdiction that has unmet need.

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2 Under Maryland CON law, home health agencies are classified as "health care facilities

10. Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the regulations miss the mark.

The State Health Plan would benefit by adding quality markers related to impacting the total payor model. The Network supports collaboration with the HSCRC and the State of Maryland in achieving meaningful and impactful outcomes that keep patients in place, avoid readmissions and drive down overall costs while improving quality. Establishment of key performance indicators (KPI's) related to Hospice and the State Health Plan should be considered. Hospice is most effective when the interdisciplinary team (IDG) has time to work with the patient and family. This takes time to build the trust and have the crucial conversations that provide the outcome of a high quality hospice experience. Nationally and similarly in Maryland our average length of stay (ALOS) is approximately 69 days while our median length of stay (MLOS) is 23 days and almost 30% of our admissions die within 7 days. Considering the baseline for hospice eligibility is a prognosis of 6 months or less, there is significant variance in the hospice benefit design and actual outcome. Earlier referrals would lead to greater hospice impact on the total cost of care model and provide enhanced end of life experiences in Maryland.

One productive change in the regulations occurred in 2013 when the need formula began using total deaths instead of cancer deaths. The accuracy regarding utilization was improved because, as recently reported in the annual report by the American Cancer Society, the cancer death rate has declined 26 percent since 1991 in the United States. Another possible change in the need methodology would be to lower the minimum age at death from 35 to 25 years old. Looking at hospice utilization broken down by race and ethnicity also would be meaningful as it would improve the relevance of the hospice utilization data. As the MHCC stated on page 4 in its 2013 **State Health Plan: Hospice Services**, "The use of hospice services nationally and within Maryland varies by population groups. It has been shown that some individuals and groups are reluctant to access hospice services based on religious, ethnic, cultural and other factors." On page 5 the **State Health Plan** also notes that "several factors affect future

hospice utilization. Differing views of health care, illness, and dying impact the use of end-of-life services by various ethnic and religious groups." It is well understood by hospice experts that minority communities tend to use hospice less than Caucasians.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

In general, summarized in previous questions. Regulation changes should be focused on need determination and Hospice Provider impact on the total cost of care model.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

The Hospice and Palliative Care Network of Maryland suggests that the following questions be considered as criteria for project review.

- Demonstrate and explain, as a new provider, your ability to establish timely and effective partnerships needed to achieve the State's goals for Global Budget Revenue and value based purchasing.
- The provision of charitable care, while already required data in a CON application submission, should be deemed an important element in the CON evaluation process.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to

address under-utilization or poor quality of care?

The Department of Health and Human Services (DHHS) should not be involved in the CON process. The DHHS serves a different purpose. It ensures existing providers meet the minimum regulatory requirements for the provision of services. As noted above, the CON process is and should remain a benchmark for entry into the market, not for continuation in the market.

The Impact of CON Regulation on General Hospice Program Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.

CON regulation does not stifle innovation. Hospice providers will continue to innovate within the existing Medicare Benefit.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?

We do not believe Maryland should shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve competition for home health services. The two services respond to different factors, treat different patients, and are paid under a different regulatory scheme.

The Impact of CON Regulation on General Hospice Access to Care and Quality

At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?

Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

MHCC should use actual complaint and survey data of the existing providers. *New applicants should be evaluated on like data from state or states in which they operate. Applicants or* ***corporate affiliated entities*** *with active DOJ investigations related to potential fraudulent practice should be disqualified.* Applicants should be evaluated with industry benchmarking standards such as Hospice Compare and the PEPPER report, which are indicators of quality, satisfaction and regulatory adherence.

Scope of CON Regulation

17. Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations

for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

This would appear to take away the ability of the public to oppose or comment on new projects and limit transparency.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

Existing hospice provider expansion within their licensed jurisdictions could be considered for expedited review. As an example, inpatient beds is an area for expedited review. In the interest of meeting patient needs in a timely manner, if an existing hospice provider has the capital, location and agreements to build and construct an inpatient center there should be an expedited process to move the project forward.

The Project Review Process

19. Are there specific steps that can be eliminated?

No specific steps to be eliminated other than previously noted in this document.

20. Should post-CON approval processes be changed to accommodate easier project modifications?

Post Con process is reasonable and adequate and the Commission has shown flexibility in working with providers on reasonable project modifications.

21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

As noted in the document.

22. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?
Yes.

Duplication of Responsibilities by MHCC and MOH

23. Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?

Not at this time, the departments serve different functions

Thank you for your responses.

gilchrist
INFORMED CHOICES. BETTER CARE.

January 11, 2018

VIA HAND DELIVERY AND
ELECTRONIC MAIL

Paul Parker, Director
Center for Health Care Facilities Planning and Development
MARYLAND HEALTH CARE COMMISSION
4160 Patterson Avenue
Baltimore, Maryland 21215-2229
paul.parker@maryland.gov

RE: *Comment Guidance – General Hospice Services*
MHCC CON Study – 2017-2018

Dear Mr. Parker:

On behalf of Gilchrist Hospice, please accept this response to Chairman Dr. Moffit's November 21, 2017 request for comments on potential reforms of the General Hospice Services certificate of need (CON) program. Enclosed you will find answers to the directed questionnaire, but I ask that you please also consider Gilchrist's additional comments below, which provide valuable context for our current CON program and purpose.

Maryland's decision to adopt the certificate of need process reflects the State's position that regulation of the size, scope, and location of health care facilities and services is preferable to unfettered competition in order to control accessibility and affordability of health care services, and that only facilities and services that respond to an unmet need in the affected community for the proposed service can be approved. We support this underlying concept – that need for a facility or service subject to CON review should remain the cornerstone of the CON process.

According to Maryland's State Health Plan, hospice is "a team-oriented approach to expert medical care, pain management, and emotional and spiritual support expressly tailored to the patient's needs and wishes. Support is provided to the patient's loved ones as well. Physical, social, spiritual, and emotional care is provided during the last stages of illness, during the dying process, and during bereavement, by a medically-directed interdisciplinary team consisting of patients, families, professionals, and volunteers. The focus is on caring, not curing and, in most cases, care is provided in the patient's home." (COMAR 10.24.13.03.) The most common type of hospice care is home-based care, which is a routine level of hospice care that is provided in the patient's residence (whether that is the patient's home or some other location, such as a nursing home). Hospice providers also must be able to provide general inpatient care – a higher level of hospice care – to their patients, either by themselves or through arrangements with other

providers, including hospitals. (*See* 42 C.F.R. § 418.108.) This level of care, however, is limited by Medicare law, which limitation should be recognized in the CON process.

The State Health Plan also recognizes that hospice utilization has increased in locations other than the patient's home. (COMAR 10.24.13.03.) Nursing homes and assisted living facilities more frequently utilize hospice, and residential hospices and inpatient units have increased in number. Furthermore, historically different population groups that, in the past, have been reluctant to utilize hospice, have increasingly turned to hospice providers. The cultural barriers that once prevented use have been increasingly addressed through public information and education and positive hospice experiences in those communities.

A hospice provider's size, scope, and location are critical elements to serving Maryland's hospice population. In the State of Maryland, the majority of hospice providers are not-for-profit entities. Non-profit hospice programs are the programs more often providing services to Maryland's more vulnerable populations, including children. These populations often seek inpatient services and have a shorter length of stay than for-profit entities.

As further detailed in the attached form, Gilchrist believes that the CON regulation of general hospice services should, in general, be maintained in its current form. If the Triple Aim framework is truly a goal, we believe that the CON regulations help achieve these goals of patient safety, access to quality care, and lower costs. But the process could be improved. It is noteworthy that "[h]ospice enrollment rates are unrelated to the number of hospices in a state." (MedPAC 2010 Report to Congress, p. 149, Figure 2E-1.) We recommend that the MHCC CON Workgroup consider our comments, which include suggestions to revisit the current need methodology for general hospice licensure and to establish a need basis for acute inpatient care facility beds.

Sincerely,

Catherine Y. Hamel
President

cc: Richard E. Moffitt, PhD (via email: robert.moffit@heritage.org)

COMMENT GUIDANCE – GENERAL HOSPICE SERVICES
MHCC CON STUDY
2017-2018

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of general hospice CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of general hospice CON regulation?

□ CON regulation of general hospices should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

□ CON regulation of general hospice services should be reformed.

■ CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?

Neither the public nor the health care delivery system would benefit from more competition. In Maryland's urban jurisdictions, there are six to seven current licensed providers. In the rural areas of the state, there are sole providers who by rights are protected from undue competition. These more rural areas would not support the fiscal requirements of additional hospice organizations.

It is also important to note that current CON regulation doesn't entirely eliminate competition. It provides limits to entry into or expansion in the market, but the free market determines the provider's survival. As competition among existing hospice providers is adequate and sufficient to offer patients choice, removing the barriers to entry will not necessarily improve services. In fact, it may have a detrimental impact. Removal of the CON process will likely result in an influx of new hospice providers all over the State. Each new provider would have to be

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes and approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimensions: 1) improving the patient experience of care (including quality and satisfaction); 2) improving the health of populations; and 3) reducing the per capital cost of health care.

reviewed and licensed. Each new provider would open and market heavily for new patients. But a truly free market anticipates that many providers will not survive, which is the case in many parts of the country. Hospice care is not a service well-suited for the whims of the free market. In hospice, one expects to be cared for until life expires. An oversaturated market would guaranty that providers may abruptly close, potentially creating trauma for hospice patients and their families. This also can cause patient confusion with facilities open one day and closed the next. In addition, the careful selection of hospice providers into the market based upon need helps ensure that patients most in need receive quality services in their same geographic area. Without the CON process, more populous areas attract providers, less populated areas are ignored. Utilization drives revenue, and more heavily populated areas drive more utilization;

The Hospice & Palliative Care Network of Maryland has performed research that indicates that Maryland might experience the following negative impacts should CON be relaxed or removed:

- **Growth in Number of Hospices.** If the CON process was removed in Maryland, some amount of growth in the number of providers is a certainty, based on the pace of growth in states without CON in recent years. For instance, between 2009 and 2014, the number of hospice agencies in California expanded from 231 to 501, a startling 117% increase. Non-CON states more comparable to Maryland in population and percentage of population over 65 have also experienced growth across a wide range. Over all 50 states, the total number of new agencies in CON states was 15; whereas non-CON states added 736. In general, more growth has occurred in southwestern and western states (average 36%) and in the for-profit sector (739 new for-profit agencies versus 12 new non-profit). On average, the number of hospices in CON states has increased by one new agency over the five-year span. In non-CON states, the number of hospices has increased by an average of 21 new agencies.

- **Growth in For-Profit and Multistate or National Service Providers.** Growth in the number of agencies is one issue; another is the kind of agency that would likely be added and how that might impact overall quality of care. In large part, due to controlled growth in the number of agencies, CON states have maintained a higher percentage of community-based, freestanding, and nonprofit agencies versus corporate, multi-location for-profit agencies. On average nationally, nonprofit hospices are 32% of the total; in non-CON states, over 50%. In general, and not as an absolute rule with respect to any one hospice agency, for-profit hospices tend to perform less well (i.e., divergent from national averages and industry norms) in currently available quality measures such as length of stay, percent patients discharged alive, average Medicare reimbursement per patient, etc. In Maryland, currently, of the 27 active hospices, seven are for-profit and six of the seven are branches of multistate or national corporate entities. Significant new growth in this class of agency is to be expected if CON is discontinued.

- **Growth from Outside Hospice.** If the hospice CON process was eliminated in Maryland, there may be extensive growth in the number of hospices from outside the hospice community by other provider types. Growth from this sector would likely contribute to a number of new agencies at the high end of the projected range and from providers not as thoroughly steeped in hospice philosophy or trained in specialized palliative skills. Growth in this sector is likely also to be for-profit and multistate or national.

Adding more hospices will not assure more hospice access. As the Medicare Payment Advisory Commission has noted, "recognizing that the raw number of hospices may not be the best measure of provider capacity, we examined the relationship between the supply of hospices and the rate of hospice use among Medicare decedents across states." (MedPAC 2010 Report to Congress, p. 148). MedPAC further concluded, "**Hospice enrollment rates are unrelated to the number of hospices in a state.**" (*Id*, p. 149, Figure 2E-1.)

2. Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

The CON regulations impose barriers to market entry, but that is part of the point of the CON process, and sufficient competition exists in the market with the existing CON process in place. The regulations impose barriers that regulate need and sufficiency of services, but the CON process does not regulate those providers once they enter the market. It is up to each provider to ensure its own survival once approved. The CON process does not eliminate market influences, it merely delays them a little. We are unaware in the markets served by Gilchrist of waiting lists that would indicate a need for more care.

Furthermore, CON regulation in and of itself, is not the answer. The entire health care community must engage to improve end of life. Given the penetration of academic teaching institutions, Maryland hospice ranks **42nd for its use and 37th for its length of stay,** out of all 50 states (with 1st being the highest). It would be in the best interest of Marylanders for the Commission to educate the medical community and the community at large about the benefits of high quality end of life care. While the hospices spend a fair amount of time and resources in these activities, Gilchrist alone spends over **$1 million** annually in these activities. The MHCC and other government entities should participate as well. Requiring other areas of the health system and physicians to engage in appropriate end of life discussions would be a welcome addition to our work. As noted, by MedPAC, enrollment rates are <u>not</u> related to the number of hospices.

3. How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?

The current CON regulations do not stifle innovation in the delivery of general hospice services. As noted above, the CON regulations restrict entry into the market, but do not restrict competition or innovation among existing providers. There is little need for additional market competition in the hospice industry. Gilchrist alone has engaged in the following innovations since 2010:

- Created a hospice program, Gilchrist Kids, serving children and those who love them. Together with seven other hospices in Maryland and Delaware, we now operate Alliance Kids a network of not-for-profit hospices providing care throughout most of the state of Maryland, DC and Delaware.

- Expanded our Towson inpatient unit by ten beds and opened a new facility, the first of its kind in Howard County.

- We acquired the Joseph Richey Hospice, **invested $6.1 million** in operating and capital investments for this operation to assure that Baltimore's Homeless have a safe, comfortable place to die.

- We now operate a music therapy program, (three full time employees) caring for hundreds of dying patients suffering from memory loss disorders who would otherwise die agitated and without a voice.

- We established an Elder Medical Program where we care for older adults who can no longer safely get to a medical office for care. On average these patients are 75 years of age or older, are suffering from a serious illness, need assistance with activities of daily living, and take 20-25 medications daily. We have 350 patients enrolled well in advance of hospice care. Our CRISP reports indicate that we save **$30,000 per enrollee** annually in avoidable healthcare utilization. Twenty of these enrollees have telehealth units in their homes through a grant with the MHCC. This is approximately **$10.5 million in savings** to the state. In addition, we have an additional 5,500 nursing facility patients under the Elder Medical Program.

- We are one of 70 hospices enrolled in the Medicare Choices innovation grant. This allows us to offer hospice eligible patients suffering from Cancer, CHF, COPD or HIV who want to pursue active treatment the option of continuing their traditional Medicare benefits, allowing them to pursue treatment while also receiving hospice care. Our program has over 70 current enrollees and is one of the largest programs in the country. 93% of the enrollees ultimately enroll in traditional hospice.

- We have established a partnership with a hospice in Tanzania. We raise their annual operating budget, which is just shy of $70K annually. We have provided access to morphine,

arranged for the purchase and delivery of an ambulance, providing training in wound care and drug therapy and hosted their team in the USA twice. We have sent two travel teams to Africa where we learn how to do more with less.

In addition to these highly innovative programs, Gilchrist has doubled its overall hospice census and maintained its reputation for providing the finest care through the end of life. We believe that an increase in providers would actually diminish our ability to innovate. Our colleagues in non CON states report spending much of their time "hunting" and competing for patients. We would contend that the CON regulation actually assure the highest level of innovation.

4. Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.

The key benefit of the CON process with regard to hospice care, and particularly care for the needy, is that it supports avoidance of unnecessary services and encourages more services where they are needed. Note that non-profits hospice providers rely on donations to fund high cost acute inpatient hospice care, care for the poor and homeless, and care for children.

Free-market competition among hospice providers would not leave room for non-profit hospice providers who largely care for patients who are not the focus of for-profit facilities: the poor and the homeless, even children. Nonprofit hospice programs would suffer the most without the CON process, and those programs are the ones that serve children, and the underserved populations, have a shorter length of stay, and tend to have more inpatients. In states without CON the amount of fraud is higher than what we see in Maryland. (*See* MedPAC Report to Congress: Medicare Payment Policy (March 2014), p. 221.) Additionally, the Hospice and Palliative Care Network, (our state association) provides a venue for all Maryland based hospices to share best practices. This collegial partnership assures that care is consistent throughout the state for all Marylanders.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a general hospice, increase the bed capacity (general inpatient hospice care) of a general hospice, or expand the service area of an existing general hospice into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.2f 01.02 - .04, which can be accessed at:
http:// www.dsd.state.md.us/comar/Subtitle5earch.aspx?search=10.24.01.

5. Should the scope of CON regulation be changed?
   A. Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?

The scope of the CON regulation appears sufficient at this time. We are not aware of any general hospice programs that should be deregulated.

B. Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

We are not aware of any general hospice projects that do not require approval by the MHCC that should be added to the scope of the CON regulation.

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

The timeliness of the CON process is in the most need of reform. While there are existing regulations which set forth the timeline for review, they typically are neither followed nor upheld. In addition, for hospice providers, the need methodology and timeliness of data upon which the need methodology is determined should be re-examined. While there is a current methodology for the addition of general hospice programs, the current methodology does not make adequate adjustments for the well-known and well-documented "under" utilization of hospice by minorities, specifically African Americans. To be held to a Caucasian standard when Maryland minority percentage is 30% when compared to 14% nationally, is inappropriate. In addition, when there is a bona fide need for additional hospice providers, there is no agreement on the number of providers that will be added at any given time. Adding a provision that defines this, making an adjustment for the number of providers to be granted CON's and establishing a "need" methodology for acute inpatient beds, would be welcome additions to the current regulations.

7. Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

Competing general hospice programs or other providers should continue to have an opportunity to contribute to and participate in the CON process. For one, this is statutorily mandated. In addition, the State's goal should be to continue to make health care transparent. Transparency would include giving other providers an opportunity to oppose or comment on proposed facilities. Currently, there is wide berth to who might participate in a CON discussion. Under

[2] Under Maryland CON law, home health agencies are classified as "health care facilities".

COMAR 10.24.01.01(20), an "Interested Party" means a person recognized by a reviewer as an interested party and may include: the applicant for a proposed project; the staff of the Commission; a third-party payor who can demonstrate substantial negative impact on overall costs to the health care system if the project is approved; a local health department in the jurisdiction, or, in the case of regional services, in the planning region in which the proposed service is to be offered; and a person who can demonstrate to the reviewer that the person would be adversely affected, in an issue area over which the Commission has jurisdiction, by the approval of a proposed project. This broad definition permits broad participation in the process and should be maintained.

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

Project timelines appear to be realistic and appropriate at this time.

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

The State Health Plan adopted by the Commission does not provide a specific need methodology for acute inpatient facility hospice beds, which is a problem. But the Commission still is required to consider whether the applicant has met its burden of persuasion that the applicant has demonstrated "unmet needs of the population to be served." The Commission's application form asks the applicant to "discuss the need of the population served or to be served by the Project" and notes that "[r]esponses should include a *quantitative analysis* that, at a minimum, *describes the Project's expected service area, population size, characteristics, and projected growth.*" It also adds, "For applications proposing to address the need of special population groups identified in this criterion, please specifically identify those populations that are underserved and describe how this Project will address their needs." *Id.* This is not the same thing as a market analysis to determine whether to enter a market, which focuses solely on profitability.

Other chief weaknesses of the SHP for hospice are the lack of projections and infrequent reviews. We note and agree with the comments of the Hospice Palliative Network with regard to their concerns and data supporting a reconsideration of the formula upon which need is determined.

10. Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the

regulations miss the mark.

SHP regulations seem sufficient for the most important aspects of general hospice projects. We agree with the Hospice Palliative Network, however, that the SHP would benefit by adding quality markers related to impacting the total payor model, and specifically, the establishment of KPI's related to hospice and the SHP.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

The manner in which MHCC obtains and uses industry and public input seems to be appropriate at this time.

General Review Criteria for All Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

Additional criteria that should be considered in the CON process:

- In what manner does the proposed project support the State's commitment to total cost of care restraint? Note that the only way the State of Maryland can survive in a total cost of care environment is to control and avoid unnecessary utilization. The Total Medicare Spend annually is estimated at $600 billion annually. A third of those expenses are attributed to care during the last year of life by 5% of the total Medicare beneficiaries. Only 15% of the $200 billion is spent on hospice care which means that 85% of these costs are likely "futile" treatments. Increasing the use of hospice care is critical to Maryland's success with Phase II of the CMS waiver. Lowering costs is irrelevant to any service other than a hospital because providers get paid the same under Medicare (except for modest differences due to location). Significant reductions in hospital expenditures are insufficient to make up for increased Part B expenditures and nonhospital Part A expenditures provided by nonhospital providers. Elimination of the CON process entirely will encourage additional providers which, in order to survive, have to attract additional patients. Total cost of care control is impossible in that setting.

- In what manner does the proposed project consider affordability to the patients?

  The provision of charitable care should be deemed an important element in the CON evaluation process.

CHANGES /SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

We do not believe the CON regulation of general hospices should be eliminated.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The Department of Health and Human Services should not be involved in the CON process. The DHHS serves a different purpose. It ensures existing providers meet the minimum regulatory requirements for the provision of services. As noted above, the CON process is and should remain a benchmark for entry into the market, not for continuation in the market.

The Impact of CON regulation on General Hospice Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.

We do not recommend changes in CON regulation to increase innovation in service delivery. We have discussed the innovation that the CON process promotes in some detail in question number three.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?

We do not believe Maryland should shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve competition for home health services. The two services

respond to different factors, treat different patients, and are paid under a different regulatory scheme.

The Impact of CON Regulation on General Hospice Access to Care and Quality

17. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

The MHCC should take into consideration the applicant's quality of care performance throughout the CON application process. The CMS PEPPER report, HIS and CAHPS data and accreditation survey information should be considered when evaluating new applicants.

Scope of CON Regulation

18. Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

The MHCC should not necessarily be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval. To do so would take away the ability of the public to oppose or comment on new projects, and puts more power in the hands of the Commission. We would suggest, however, that the Commission consider making the process to move a bed more streamlined. An existing provider should be able to move beds with a much more abbreviated review, simply because most of the requirements under consideration for the bed need already have been evaluated and determined.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

With the exception of moving a bed, as noted above, a whole new process of expedited review for certain projects should not be created for hospice projects.

The Project Review Process

20. Are there specific steps that can be eliminated?
21. Should post-CON approval processes be changed to accommodate easier project

modifications?

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered?
23. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Elimination of steps, easier project modifications, and abbreviated reviews each may contribute to improving the process, but these proposals are fact-specific. If there is a specific proposal related to any of these elements, it should be considered, but not simply approved for the sake of eliminating a step. It is recommended that the CON application process remain consistent with technological trends in general, once they have had an opportunity to be tested and proven useful. At this time, the technological use appears to be consistent with trend.

Duplication of Responsibilities by MHCC and MDH.

24. Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?

Not at this time, the departments serve different functions.

Thank you for your responses.

Hospice & Palliative Care Network
OF MARYLAND

January 12, 2018

Sent via email and USPS

Mr. Paul Parker
Director of the Commission's Center for Health Care Facilities
Planning and Development
Maryland Health Care Commission
4160 Patterson Ave.
Baltimore, Maryland21236

RE: COMMENT GUIDANCE - GENERAL HOSPICE SERVICES MHCC CON STUDY, 2017-18

Dear Mr. Parker:

The Hospice & Palliative Care Network of Maryland (HPCNM) has completed the Comment Guidance – General Hospice Services MHCC CON Study. Please see our response to the questions below which were formulated based on a consensus with our membership.

Need for CON Regulation

HPCNM strongly supports the idea that CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. **In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?**

No, HPCNM does not believe that the public and the health care delivery system benefit from more competition among general hospice programs. The current CON regulation doesn't eliminate competition. It provides limits to entry into or expansion in the market, but the free market determines the provider's survival. Competition among existing hospice providers is

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adequate and sufficient to offer patients choice. Removing the barriers to entry of new providers will not necessarily improve services. In fact, it may have a detrimental impact. Removal of the CON process will likely result in an influx of new hospice providers across the State. Primarily, more hospice providers would cause increased competition for limited clinical resources and diminishing return on realized economies of scale. Required components of the Medicare hospice benefit, like volunteer hours, would be compromised with more providers competing for limited resources. Hospice providers, utilizing a greater percentage of budget resources for staff recruiting and sales and marketing with additional competition, would have fewer resources available to support those in the community needing financial assistance or charity care. Additional general hospice providers would drive up (redundant) fixed costs, which is one of the core benefits of a service based model. In addition, it would also drive up the cost of the health care delivery system by adding additional providers to oversee compliance and quality. The densely populated jurisdictions have significant competition presently, and utilization (delivery) trends are growing well alongside the new hospital reimbursement models. In addition, the careful selection of hospice providers into the market based upon need helps ensure that patients most in need receive quality services in their same geographic area. Without the CON process, more populous areas attract providers, less populated areas are ignored.

Hospice & Palliative Care Network of Maryland research indicates that Maryland might experience the following should CON be relaxed or removed:

- Growth in Number of Hospices
  If CON were removed in Maryland, some amount of growth in the number of providers is a certainty, based on the pace of growth in states without CON in recent years. For instance, between 2009 and 2014, the number of hospice agencies in California expanded from 231 to 501, a startling 117% increase. Non-CON states more comparable to Maryland in population and percentage of population over 65 have also experienced growth across a wide range. Over all 50 states, the total number of new agencies in CON states was 15; whereas non-CON states added 736. In general, more growth has occurred in southwestern and western states (average 36%) and in the for-profit sector (739 new for-profit agencies vs. 12 new non-profit). On average, the number of hospices in CON states has increased by one new agency over the five-year span. In non-CON states, the number of hospices has increased by an average of 21 new agencies.

- Growth in For-Profit and Multistate or National Service Providers
  Growth in the number of agencies is one issue; another is the kind of agency that would likely be added and how that might impact overall quality of care. In large part due to

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controlled growth in the number of agencies, CON states have maintained a higher percentage of community-based, freestanding and nonprofit agencies vs. corporate, multi-location for-profit agencies: On average nationally, nonprofit hospices are 32% of the total; in non-CON states, over 50. In Maryland, currently, of the 27 active hospices, 7 are for-profit and 6 of the 7 are branches of multistate or national corporate entities. Significant new growth in this class of agency is to be expected if CON is discontinued.

- Growth from Outside Hospice
  If Hospice CON were eliminated in Maryland, there may be extensive growth in the number of hospices from outside the hospice community by other provider types. Growth from this sector would likely contribute to a number of new agencies at the high end of the projected range and from providers not as thoroughly steeped in hospice philosophy or trained in specialized palliative skills. Growth in this sector is likely also to be for-profit and multistate or national.

Adding more hospices will not assure more hospice access. As the Medicare Payment Advisory Commission (MedPAC) wrote on page 148 in its 2010 Report to Congress, "Recognizing that the raw number of hospices may not be the best measure of provider capacity, we examined the relationship between the supply of hospices and the rate of hospice use among Medicare decedents across states." On page 149, in Figure 2E-1, MedPAC concluded, "Hospice enrollment rates are unrelated to the number of hospices in a state."

2. **Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?**

The CON provides necessary barriers to market entry and jurisdiction expansion. The densely populated jurisdictions have appropriate competition. More rural jurisdictions, which have a single provider, likely could not sustain a business model and likely would not attract new market entrants, due to their low volume of need.

3. **How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?**

There has been NO negative impact on innovation and no experience or data to suggest that Maryland is less innovative regarding end of life care than non CON states. In fact, there is MORE attention to quality and innovation afforded from scale and avoided distraction due to questionable practices that arise with oversaturation, as well as, instability of staff caused by

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inflated supply of providers. As an example, hospice providers across Maryland invest in innovation with special programs that are not required by hospice regulation. Programs like Palliative Care Services, Pet Therapy, Massage Therapy, Music Therapy and utilization of telehealth technology are just a few examples of areas of innovation in Maryland. Additionally, HPCNM provides a collaborative venue for hospices to share innovative solutions and this is accomplished through multiple venues such as General Membership Meetings, Annual Education Conferences, an Annual Quality/Regulatory Conference and other numerous collaborative opportunities.

[1]The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is the Institute for Health's belief that new designs must be developed to simultaneously pursue three dimensions: 1) Improving the patient experience of care (including quality and satisfaction); 2) Improving the health of populations, and; 3) Reducing the per capita cost of health care.

4. **Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.**

The key benefit of the CON process with regard to hospice care, and particularly care for the needy, is that it supports avoidance of unnecessary services and encourages more services where they are needed. The CON actually promotes innovation and the ability to scale to meet the demands of the market. Having a controlled number of licensed providers enables hospice to focus on key partnerships with hospital systems, skilled nursing homes and assisted living providers to keep readmission and mortality statistics minimized. Thus, supporting the significant savings achieved in the total cost of care model in Maryland. Post-acute ambulatory end of life care requires massive labor and infrastructure costs. Additional providers would add unnecessary competition for already competitive resources like Physicians (Board Certified), Nurses, Social Workers, Hospice Aide's, Chaplains, Volunteers, and clinical operations leadership. All of which are difficult to hire and could factor against existing hospice providers ability to scale and meet the needs of the market. The cumulative impact would be a reduction in the hospice providers ability to support the total cost of care initiative entering its second phase.

Scope of CON Regulation

5. **Should the scope of CON regulation be changed?**

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A. Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?

The scope of the CON regulation appears sufficient at this time. HPCNM is not aware of any general hospice projects that should be deregulated.

B. Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

HPCNM is not aware of any general hospice projects that do not require approval by the MHCC that should be added to the scope of the CON regulation.

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

The timeliness of the CON process is in the most need of reform. While there are existing regulations which set forth the timeline for review, they typically are neither followed nor upheld. In addition, for hospice providers, the need methodology and timeliness of data upon which the need methodology is determined should be re-examined. The addition of need methodology for inpatient beds also needs to be developed.

7. Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities2 be encouraged by maintaining exemption review for merged asset systems?

A formal process to oppose and appeal is needed and should not be limited. Interested parties should have a venue and a platform to challenge and discuss competing hospice CON filings.

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8. **Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)**

In general yes, the project completion timelines, i.e. performance requirement for implementing and completing projects is realistic and appropriate. The MHCC has demonstrated flexibility when needed to changing situations and unforeseen circumstances.

The State Health Plan for Facilities and Services

9. **In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?**

Overall the framework for the CON in the State Health Plan (SHP) is adequate and appropriate. The chief weakness of the SHP for hospice is the need to simplify and improve the current need methodology or projections. An area of opportunity to improve the current formula in which need is determined is a demographic weighting related to the underserved communities. As an example, African American hospice utilization is low nationally as reported by the National Hospice and Palliative Care Organization (NHPCO). On a national level African American population as a percentage of total population is about 14% and in Maryland 29.4% of the total population is African American. Overall hospice utilization in the state of Maryland is slightly lower than the national average, but this does not mean there is unmet need. The existing need calculation does not factor the impact of cultural diversity and the utilization of hospice. HPCNM's recommendation would be to compare "demographically" weighted utilization against those same demographically weighted national utilization rates.
The network would also recommend the SHP establish clarity and guidelines regarding the decision-making criteria as to the number of additional CON's to be awarded in a jurisdiction that has unmet need.

The answer to the second part of this questions is that, under Maryland CON law, home health agencies are classified as "health care facilities"

10. **Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the regulations miss the mark.**

The State Health Plan would benefit by adding quality markers related to impacting the total payor model. The Network supports collaboration with the HSCRC and the State of Maryland in

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achieving meaningful and impactful outcomes that keep patients in place, avoid readmissions and drive down overall costs while improving quality. Establishment of key performance indicators (KPI's) related to Hospice and the State Health Plan should be considered. Hospice is most effective when the interdisciplinary team (IDG) has time to work with the patient and family. This takes time to build the trust and have the crucial conversations that provide the outcome of a high-quality hospice experience. Nationally and similarly in Maryland our average length of stay (ALOS) is approximately 69 days while our median length of stay (MLOS) is 23 days and almost 30% of our admissions die within 7 days. Considering the baseline for hospice eligibility is a prognosis of 6 months or less, there is significant variance in the hospice benefit design and actual outcome. Earlier referrals would lead to greater hospice impact on the total cost of care model and provide enhanced end of life experiences in Maryland.
One productive change in the regulations occurred in 2013 when the need formula began using total deaths instead of cancer deaths. The accuracy regarding utilization was improved because, as recently reported in the annual report by the American Cancer Society, the cancer death rate has declined 26 percent since 1991 in the United States. Another possible change in the need methodology would be to lower the minimum age at death from 35 to 25 years old. Looking at hospice utilization broken down by race and ethnicity also would be meaningful as it would improve the relevance of the hospice utilization data. As the MHCC stated on page 4 in its 2013 State Health Plan: Hospice Services, "The use of hospice services nationally and within Maryland varies by population groups. It has been shown that some individuals and groups are reluctant to access hospice services based on religious, ethnic, cultural and other factors." On page 5 the State Health Plan also notes that "several factors affect future hospice utilization. Differing views of health care, illness, and dying impact the use of end-of-life services by various ethnic and religious groups." It is well understood by hospice experts that minority communities tend to use hospice less than Caucasians.

11. **Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.**

In general, summarized in previous questions. Regulation changes should be focused on need determination and Hospice Provider impact on the total cost of care model.

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General Review Criteria for all Project Reviews

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

HPCNM suggests that the following questions be considered as criteria for project review:

- Demonstrate and explain, as a new provider, your ability to establish timely and effective partnerships needed to achieve the State's goals for Global Budget Revenue and value based purchasing.
- The provision of charitable care, while already required data in a CON application submission, should be deemed an important element in the CON evaluation process.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

HPCNM does not believe that CON regulation of general hospice should be eliminated.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The Maryland Department of Health (MDH) should not be involved in the CON process. The MDH serves a different purpose. It ensures existing providers meet the minimum regulatory requirements for the provision of services. As noted above, the CON process is and should remain a benchmark for entry into the market, not for continuation in the market.

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Hospice & Palliative Care Network
OF MARYLAND

The Impact of CON Regulation on General Hospice Program Competition and Innovation

15. **Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.**

CON regulation does not stifle innovation. Hospice providers will continue to innovate within the existing Medicare Benefit.

16. **Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?**

We do not believe Maryland should shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve competition for home health services. The two services respond to different factors, treat different patients, and are paid under a different regulatory scheme.

The Impact of CON Regulation on General Hospice Access to Care and Quality

17. **At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?**
Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

MHCC should use actual complaint and survey data of the existing providers. New applicants should be evaluated on like data from state or states in which they operate. Applicants or corporate affiliated entities with active DOJ investigations related to potential fraudulent practice should be disqualified. Applicants should be evaluated with industry benchmarking standards such as Hospice Compare and the PEPPER report, which are indicators of quality, satisfaction, and regulatory adherence.

Scope of CON Regulation

18. **Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require**

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notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

HPCNM believes that this action would appear to take away the ability of the public to oppose or comment on new projects and limit transparency.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

Existing hospice provider expansion within their licensed jurisdictions could be considered for expedited review. As an example, inpatient beds is an area for expedited review. In the interest of meeting patient needs in a timely manner, if an existing hospice provider has the capital, location and agreements to build and construct an inpatient center there should be an expedited process to move the project forward.

The Project Review Process

20. Are there specific steps that can be eliminated?

No specific steps to be eliminated other than previously noted in this document.

21. Should post-CON approval processes be changed to accommodate easier project modifications?

Post Con process is reasonable and adequate and the MHCC has demonstrated flexibility in working with providers on reasonable project modifications.

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

As noted in the document.

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23. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Yes, greater use of technology, including the submission of automated and for-based applications would improve the CON application submission process.

Duplication of Responsibilities by MHCC and MDH

24. Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?

Not at this time. These departments serve different functions

Thank you for the opportunity for HPCNM to provide our comments on this very important issue. We look forward to hearing the results of this survey in the near future.

Sincerely,

Peggy Funk
Executive Director
Hospice & Palliative Care Network of Maryland

cc: Ben Steffen, Executive Director, MHCC
Dean Forman, HPCNM Treasurer
Reggie Bodnar – HPCNM Past President and Workgroup Representative
Heather Guerieri, HPCNM President
Alane Capen, HPCNM Public Policy Committee Chair
Danna Kauffman, HPCNM Lobbyist

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HOSPICE
Of Garrett County, Inc.

January 8, 2018

Maryland Health Care Commission
Paul Parker, Director Commission's Center For Health Care
Facilities Planning & Development
4160 Patterson Ave.
Baltimore, MD 21215

Dear Mr. Parker:

I am writing on behalf of Hospice of Garrett County, Inc. and in response to the questionnaire regarding the Maryland Health Commission certificate of need (CON) programs. We would like to inform the Maryland Health Care Commission that we feel that current regulation of hospice service should be maintained in its current form. We feel there would be no benefit to the public or health care delivery from more competition.

Realizing that our hospice is quite unique compared to any other in Maryland, Hospice of Garrett County, Inc. provides excellent care for the terminally ill in Garrett County. Comparably we are small and must receive a great deal of public support to survive financially. Last year over 25% of our budget was from public support such as fundraising, memorials and donations. Since there is little to no market incentive for hospice providers to offer services in remote or sparsely populated areas such as Garrett County and since we survive by virtue of strong community and financial support, any growth in additional hospice agencies would dilute the resources available to our existing programs and adversely impact our ability to provide high quality service.

We continue to maintain a professional staff no matter how many patients we serve. We are the only hospice in Garrett County; being incorporated in 1983, serving the patients and their families as a volunteer hospice until October 1995. At that time we became Medicare Certified and began doing total home health care for our terminally ill patients.

Although Garrett County is the second largest county in Maryland with land mass (662 square miles) we are quite small in population:

2017 Estimated Population:	29,425
2010 Census Population:	30,097
2000 Census Population:	29,840

Mailing Address: P. O. Box 271 ♦ Oakland, Maryland 21550
Office Location: 203 South Second Street ♦ Oakland, Maryland 21550
Phone 301.334.5151 ♦ Fax 301.334.5800
www.hospiceofgarrettcounty.org ♦ email hospiceofgc@gmail.com

We operate with three full-time nurses, one part-time nurse, two full-time certified nursing aides and one part-time aide-serving the county 24/7. In addition, we have great resources to hire from, including a new nursing program at Garrett College and we have been teamed up with the nursing program at Allegany College for years, working with their internship program. We pull additional resources from the National Hospice & Palliative Care Organization and our Relias training programs. Our bereavement services reach out to the community for 13 months after the death of a loved one. We support both hospice families and community referrals. Our devoted patient volunteers serve along with other auxiliary and office volunteers logging hundreds of hours.

Our current daily census is twenty- two patients and we have the flexibility to take on an increased patient level or scale back to less than ten patients, as we are accustomed to from time to time. In 2017 our yearly census was 105 patients. Our county also maintains a large Amish community, from which we get no reimbursement whatsoever. In addition, with the new local cancer center at Garrett Regional Medical Center, patients are engaging in treatment longer, making for reduced days on our program.

We feel that the CON regulation of general hospice services, should, in general, be maintained in its current form.

At the last State inspection, the Maryland State surveyors that performed our evaluations were impressed with our agency and stated "This is the way hospices should operate!" We feel that we provide the needs of Garrett County citizens and saturating the county with additional agencies would only weaken the strongest of organizations to the point when services would be diminished.

We are proud to say since our inception in 1983 no family has received a bill for services or supplies rendered by Hospice of Garrett County, Inc.

Please do not hesitate to contact me if you require additional information.

Sincerely,

Donna Brenneman
Hospice of Garrett Co., Inc.

hospice of the chesapeake
JOHN & CATHY BELCHER CAMPUS

90 Ritchie Highway • Pasadena, MD 21122
phone: 410.987.2003 • fax: 443.837.1558
hospicechesapeake.org

December 11, 2018

Mr. Paul Parker
Director of the Commission's Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Parker:

Thank you for the opportunity to provide input on the potential reforms of health planning and certificate of need (CON) programs. Attached is Hospice of the Chesapeake's responses to the questions posed by the Maryland Health Care Commission.

We have tried to be as thorough as possible, while being succinct and clear in our responses. If you have need of any additional information or needs points of clarification related to any of our responses, please do not hesitate to contact me directly.

Sincerely,

Ben Marcantonio
President and CEO
Hospice of the Chesapeake

COMMENT GUIDANCE - GENERAL HOSPICE SERVICES MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of general hospice CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of general hospice CON regulation?

O CON regulation of general hospices should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

O CON regulation of general hospice services should be reformed.

X O CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. ***In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?***

   Hospice of the Chesapeake does not view CON regulation as eliminating or overly restricting competition. While it limits entry into or expansion in the market, healthy competition among providers exists and promotes quality of care, development of services appropriate to those with advanced complex illness, i.e., palliative, end of life and bereavement. There is no infringement on the free market which determines the provider's survival. The competition that exists among hospice providers is adequate and sufficient to offer patients choice and would not necessarily improve services.

   It is actually equally, if not more, important to consider the detrimental impact opening the market to increased competition would likely have. Competition for already limited

clinical staffing resources would have a direct and negative impact on existing programs' ability to have the critical professional resources to support quality care into the future. In addition, required components of the Medicare hospice benefit, like volunteer hours, would be compromised with more providers competing for these limited resources. Hospice providers, utilizing a greater percentage of budget resources for staff recruiting and sales and marketing with additional competition, would have fewer resources available to support those in the community needing financial assistance or charity care.
It is also important to note that the careful selection of hospice providers into the market based upon need helps ensure that patients most in need receive quality services in their same geographic area. Without the CON process, more populous areas attract providers, less populated areas are ignored.

Many of us in hospice leadership have provided hospice and palliative care services in both CON and Non-CON states. This experience does not confirm that a completely open market provides any increased benefit in terms of access to or quality of care for those needing palliative and/or end of life care.

Opening up the CON further or completely also creates the potential for those who have not developed the expertise in palliative and/or end of life care to enter the market without vetting or constraint. This not only harms existing providers who have devoted decades of resource to advancing skill and development of services to meet the needs of those living and dying with advanced complex illness, but also is a disservice to patients and families who are challenged with making difficult choices and decisions at a critical time in their life.

2. ***Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?***

The CON provides appropriate barriers to market entry and jurisdiction expansion. The densely populated jurisdictions have the needed competition to provide access to care. More rural jurisdictions likely could not sustain a viable business model with increased competition. In addition, these areas likely would not attract new market entrants, due to their low volume of need.

3. ***How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?***

This question makes an invalid presumption. CON regulation does **not** stifle innovation. There is no negative impact on innovation, and nothing to suggest that Maryland is less

innovative regarding end of life care than programs in Non-CON states. Hospice of the Chesapeake has been, historically and progressively, innovative in its program design and delivery of services. While existing competition is compelling and requires attention to creativity and innovation, it is our long-standing commitment to our mission that drives innovation and best practice as a provider in our field. Competition is only one driver and increasing it would be more of a distraction from than a catalyst for innovation.

4. ***Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.***

While hospice services do not require major capital investment, the existing reimbursement structure makes it extremely challenging to be effective stewards in a fully open market. Unfortunately there have been hospices that have practiced in such a way to induce unneeded demand; most frequently in open market, Non-CON states. And while our practice has not required advanced or emerging medical technologies, our costs related to advances in pharmacological treatments that are most effective for managing pain and other end of life symptoms continue to increase.

CON benefits hospice providers, as it does other for health care services. The benefits of CON are in managing competition to the degree that it allows hospices to be good stewards of our limited resources and providing open access to care, while competing effectively with other providers.

Also, Hospice of the Chesapeake has established excellent partnerships with other healthcare service providers. In a time when Maryland is promoting greater collaboration between hospital systems and post-acute providers, CON will support these relationships and allow us to work together, without distraction, to achieve the Triple Aim goals we have already made great strides in together.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a general hospice, increase the bed capacity (general inpatient hospice care) of a general hospice, or expand the service area of an existing general hospice into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.2f 01.02 - .04, which can be accessed at:
http:// www.dsd.state.md.us/comar/Subtitle5earch.aspx?search=10.24.01.*

5. ***Should the scope of CON regulation be changed?***
   A. ***Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?***

We are not aware of any general hospice projects that should be deregulated.

B. ***Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?***

No, we are not aware of any general hospice projects that do not require approval by the MHCC that should be added to the scope of the CON regulation.

The Project Review Process

6. ***What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?***

The timeliness of the CON process is the aspect most in need of reform. We would also support an opportunity to revisit the formula for establishing need—there may be other states' models that could help us establish a better formula given our current needs and goals in Maryland.

7. ***Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?***

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

A formal process to oppose and appeal is needed and should not be limited. Interested parties should have a venue and a platform to challenge and discuss competing hospice CON filings.

Existing guidelines seem appropriate and adequate for guiding the process of those systems that want to pursue merger.

8. ***Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)***

Yes. The MHCC has demonstrated flexibility when needed.

The State Health Plan for Facilities and Services

9. ***In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?***

We find the framework for the CON in the State Health Plan (SHP) to be adequate and appropriate. We do believe, however, as noted above that the current need determination could be updated and simplified.

In the most recent hospice CON application process, there has been unclear and conflicting information as to the number of providers that would be approved. It would seem that the SHP should identify the projected number of providers needed before or early on in the process.

10. ***Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the regulations miss the mark.***

Key performance indicators (KPI's) related to Hospice and the State Health Plan should be considered along with additional quality indicators captured in Hospice Compare and in PEPPER reports.

Hospices' ability to identify patients' needs for palliative care and intervention at the right time, for the right level of care, in the right setting is a critical component of the healthcare continuum and helps achieve the State's goals for population health. Timely provision of palliative care (>6 months prognosis) and hospice services (<6 months prognosis) allows the interdisciplinary team (IDG) time to work with the patient and family in ways that help reduce hospitalizations, and avoid unnecessary and costly interventions. Goals of care conversations initiated in the earlier stages of advanced complex illness lay the groundwork for the more challenging conversations related to choosing the hospice benefit in a timely manner. Earlier referrals would lead to greater hospice impact on the total cost of care model and provide enhanced end of life experiences in Maryland. Hospice providers seeking to establish services in a new market should have to demonstrate the ability and expertise in this regard.

11. ***Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.***
Regulation changes should be focused on need determination and Hospice Provider impact on the total cost of care model.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. ***Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?***

We believe that new applicants for CON need to be required to demonstrate and explain how they, as a new provider, would be able to establish timely and effective partnerships needed to achieve the State's goals for Global Budget Revenue and value based purchasing.

They also should be able to address the provision of charitable care. While already required data in a CON application submission, should be deemed an important element in the CON evaluation process.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. ***If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?***

Not applicable

14. ***Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?***

The Department of Health and Human Services (DHHS) should not be involved in the CON process. The DHHS serves a different purpose. It ensures existing providers meet the minimum regulatory requirements for the provision of services. The CON process is, and should remain, a benchmark for entry into the market, not for continuation in the market.

The Impact of CON Regulation on General Hospice Program Competition and Innovation

15. ***Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.***

CON regulation does not stifle innovation. Hospice providers will continue to innovate within the existing Medicare Benefit.

16. ***Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?***

We do not believe Maryland should shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve competition for home health services. The two services respond to different factors, treat different patients, and are paid under a different regulatory scheme.

The Impact of CON Regulation on General Hospice Access to Care and Quality

At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?

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MHCC should use actual complaint and survey data of the existing providers. *New applicants should be evaluated on like data from state or states in which they operate. Applicants or* ***corporate affiliated entities*** *with active DOJ investigations related to potential fraudulent practice should be disqualified.*

Applicants should be evaluated with industry benchmarking standards such as Hospice Compare and the PEPPER report, which are indicators of quality, satisfaction and regulatory adherence.

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17. ***Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of***

service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

No.

18. ***Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?***

No.

The Project Review Process

19. ***Are there specific steps that can be eliminated?***

No specific steps to be eliminated other than any noted above that help to streamline and improve on timeliness of the process.

20. ***Should post-CON approval processes be changed to accommodate easier project modifications?***

Post Con process is reasonable and adequate and the Commission has shown flexibility in working with providers on reasonable project modifications.

21. ***Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.***

No.

22. ***Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?***

Yes.

Duplication of Responsibilities by MHCC and MOH

23. ***Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?***

Not at this time, the departments serve different functions

Thank you for your responses.

1/11/2018

Jewish Social Service Agency (JSSA) Hospice
1390 Piccard Drive
Rockville, MD 20850

Maryland Health Care Commission
41360 Patterson Avenue
Baltimore, MD 21215-2299

RE: GENERAL HOSPICE SERVICES MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of general hospice CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of general hospice CON regulation?

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0 CON regulation of general hospice services should be reformed.

X CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. **In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?**

No. Current CON regulations do not eliminate competition. They provide limits to entry into or expansion in the jurisdiction, but ultimately innovation, quality of patient care and regulatory compliance determines a hospice programs success. Competition among existing hospice providers is adequate as there are more than five CON's in Montgomery County (JSSA Hospice, Montgomery Hospice Society, Hospice of Frederick County, Washington Home and Hospice, Seasons Hospice, Holy Cross Home Care and Hospice, as well as others that are less active) and as a result, patients have a sufficient number from which to choose. Removal of CON process will likely have a negative impact on the existing providers, as this will result in an influx of new hospice providers across the state and obviously include Montgomery County as well. Increased competition will result in competition for limited clinical resources (hospice nurses, social workers, chaplains, and trained hospice aides) thereby diminishing return on realized economies of scale. Required components of the Medicare hospice benefit, like volunteer hours (for which there is a Medicare requirement that 5% of total patient care hours by all disciplines be provided by volunteers, and bereavement support for 13 months following the death of a patient, that is unreimbursed-would be compromised with new non-community based providers competing for volunteer and trained bereavement support . Hospices would be forced to spend a larger percentage of their budgets on recruiting scarce staff as well as dollars spent on sales and marketing with the additional competition of more providers in a jurisdiction. These budget impacts would translate to being forced to provide fewer dollars on serving the uninsured and historically underserved populations. Additionally, more hospice providers would drive up (redundant) fixed costs, which is one of the core benefits of a service-based model. It would also drive up the cost and strain on our overtaxed health care delivery system by requiring the department of health care quality to hire additional surveyors and administrative staff to ensure compliance, quality and licensing. Montgomery County's densely populated jurisdiction has significant competition and utilization (delivery) trends are growing well alongside the new hospital reimbursement models. In addition, the careful selection of hospice providers into the market based upon need helps ensure that patients most in need receive quality services. Without the CON process, areas that are more populous

attract providers, and less populated areas ignored.

Hospice & Palliative Care Network of Maryland and JSSA Hospice research indicates that Maryland might experience the following should CON be relaxed or removed:

Growth in Number of Hospices

If CON were removed in Maryland, some amount of growth in the number of providers is a certainty, based on the pace of growth in states without CON in recent years. For instance, between 2009 and 2014, the number of hospice agencies in California expanded from 231 to 501, a startling 117% increase. Non-CON states more comparable to Maryland in population and percentage of population over 65 have also experienced growth across a wide range:

Over all 50 states, the total number of new agencies in CON states was 15; whereas non-CON states added 736. In general, more growth has occurred in southwestern and western states (average 36%) and in the for-profit sector (739 new for-profit agencies vs. 12 new non-profit). On average, the number of hospices in CON states has increased by one new agency over the five-year span. In non-CON states, the number of hospices has increased by an average of 21 new agencies.

Growth in For-Profit and Multistate or National Service Providers

Growth in the number of agencies is one issue; another is the kind of agency that would likely be added and how that might affect overall quality of care. In large part due to controlled growth in the number of agencies, CON states have maintained a higher percentage of community-based, freestanding and nonprofit agencies vs. corporate, multi-location for-profit agencies: On average nationally, nonprofit hospices are 32% of the total; in non-CON states, over 50%. In Maryland, of the 27 current active hospices, seven are for-profit and six of the seven are branches of multistate or national corporate entities. Significant new growth in this class of agency is to be expected if CON is eliminated.

Growth from Outside Hospice

If Hospice CON were eliminated in Maryland, there may be extensive growth in the number of hospices from outside the hospice community by other provider types. Growth from this sector would likely contribute to a number of new agencies at the high end of the projected range and from providers not as thoroughly steeped in hospice philosophy or trained in

specialized palliative skills. Growth in this sector is likely also to be for-profit and multistate or national.

Adding more hospices will not assure more hospice access. As the Medicare Payment Advisory Commission (MedPAC) wrote on page 148 in its 2010 Report to Congress, "Recognizing that the raw number of hospices *may not* be the best measure of provider capacity, we examined the relationship between the supply of hospices and the rate of hospice use among Medicare decedents across states." On page 149, in Figure 2E-1, MedPAC concluded, **"Hospice enrollment rates are unrelated to the number of hospices in a state."**

2. **Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?**

The CON serves the purpose for which it was intended; it provides necessary barriers to market entry and jurisdiction expansion. The densely populated jurisdictions have appropriate competition. Jurisdictions that are more rural i.e. - less densely populated areas who have a single providers, would likely could not be able to sustain a viable business model and would be unlikely to attract new market entrants, due to their low volume of need because of this low population density.

3. **How does CON regulation stifle innovation in the delivery of general hospice services underthe current Maryland regulatory scheme?**

There has been NO negative impact on innovation and no experience or data to suggest that Maryland is less innovative regarding end of life care than non-CON states. In fact, there is MORE attention to quality and innovation afforded from scale and avoided distraction due to questionable practices that arise with oversaturation, as well as, instability of staff caused by inflated supply of providers. As an example, hospice providers across Maryland invest in innovation with special programs that are not required by hospice regulation. Programs like Palliative Care Services, Pet Therapy, Massage Therapy, Music Therapy and utilization of telehealth technology are just a few examples of areas of innovation in Maryland. JSSA Hospice currently provides a free program called "Transitions". This program provides regular visits by a nurse and the support of a hospice trained volunteer. Generally, this program admits patients who have a year to live, vs. the 6-month prognosis required by the Medicare Hospice. The aim of the program is to identify potentially terminally ill individuals in need of support and low level oversight an avenue to the more comprehensive care that

hospice provides. All patients in this program are offered a choice of hospice provider when it is clear that hospice is indicated. Currently this program is providing service to 90 individuals and transfers 40-50 patients a year to hospice providers. Some patients elect to stay with JSSA Hospice, while others will choose other providers. For patients who elect JSSA Hospice as their provider, they continue to receive support and attention from their volunteer.

The Hospice & Palliative Network provides a collaborative venue for hospices to share innovative solutions and this is accomplished through multiple venues such as General Membership Meetings, Annual Education Conference, Annual Regulatory Conference and other numerous collaborative opportunities. Existing providers enjoy a sense of collaboration and sharing of best practices that would surely be lost if many other providers entered the market.

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[1]The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1} Improving the patient experience of care (including quality and satisfaction);(2} Improving the health of populations, and; (3} Reducing the per capita cost of health care.

4. **Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.**

The key benefit of the CON process with regard to hospice care, and particularly care for those who are financially compromised, is that it supports avoidance of unnecessary services such as Emergency Room visits and hospital admissions, and encourages care in the home where services are most needed. The CON facilitates and encourages innovation and the ability to scale up to meet the demands of the market. JSSA Hospice has grown every year by an average of 10-15%. We have done this by being innovative in hiring practices, in the processes of our work, in becoming efficient in orienting and mentoring new staff. In addition, having a controlled number of licensed providers enables hospice to focus on key partnerships with hospital systems, skilled nursing homes and assisted living providers to keep hospital readmission rates and mortality statistics minimized. In 2016, less than 2% of JSSA Hospice's patients were readmitted to area hospitals. Thus, contributing to and supporting the significant savings achieved in the total cost of care model in

Maryland. Post-acute ambulatory end of life care requires massive labor and infrastructure costs. Additional providers would add unnecessary competition for already competitive resources like Physicians (Board Certified), Nurses, Social Workers, Hospice Aide's, Chaplains, Volunteers, and clinical operations leadership. All of which are difficult to hire and could factor against existing hospice providers ability to scale and meet the needs of the market. The cumulative impact would be a reduction in the hospice providers' ability to support the total cost of care initiative entering its anticipated second phase.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a general hospice, increase the bed capacity (general inpatient hospice care) of a general hospice, or expand the service area of an existing general hospice into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.2f 01.02 - .04, which can be accessed at:

http:// www.dsd.state.md.us/comar/Subtitle5earch.aspx?search=10.24.01.*

5. **Should the scope of CON regulation be changed?**

   A. **Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?**

The scope of the CON regulation appears sufficient at this time. We are not aware of any general hospice projects that should be deregulated.

   B. **Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?**

We are not aware of any general hospice projects that do not require approval by the MCHH that should be added to the scope of the CON regulation.

The Project Review Process

6. **What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?**

The timeliness of the CON process is in need of significant reform. While there are existing

regulations that set forth the timeline for review, they typically are neither followed nor upheld by the MHCC. In addition, for hospice providers, the need methodology and timeliness of data upon which the need methodology is determined should be re-examined. The addition of need methodology for inpatient beds for existing providers needs to be developed.

7. **Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?**

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

A formal process to oppose and appeal decisions is needed and should not be limited. Interested parties should have a venue and a platform to challenge and discuss competing hospice CON filings. Periods for this should be developed and maintained.

8. **Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)**

In general yes. The MHCC has demonstrated flexibility when needed to changing situations and unforeseen circumstances.

The State Health Plan for Facilities and Services

9. **In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?**

Overall the framework for the CON in the State Health Plan (SHP) is adequate and appropriate. The chief weakness of the SHP for hospice is the need to simplify and improve the current need methodology or projections. An area of opportunity to improve the current formula in which need is determined is a demographic weighting related to the underserved communities. As an example, African American hospice utilization is low nationally as reported by NHPCO. On a national level African American population as a percentage of total population is about 14% and in Maryland 29.4% of the total population is African American.

Overall hospice utilization in the state of Maryland is slightly lower than the national average, but this does not mean there is unmet need. The existing need calculation does not factor the impact of cultural diversity and the utilization of hospice. Our recommendation would be to compare "demographically" weighted utilization against those same demographically weighted national utilization rates.
We would also recommend the SHP establish clarity and guidelines regarding the decision-making criteria as to the number of additional CON's to be awarded in a jurisdiction that has unmet need.

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[2] Under Maryland CON law, home health agencies are classified as "health care facilities

10. **Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the regulations miss the mark.**

The State Health Plan would benefit by adding quality markers related to affecting the total payor model. We support collaboration with the HSCRC and the State of Maryland in achieving meaningful and impactful outcomes that keep patients in place, avoid readmissions and drive down overall costs while improving quality. Establishment of key performance indicators (KPI's) related to Hospice and the State Health Plan should be considered. Hospice is most effective when the interdisciplinary team (IDG) has time to work with the patient and family. It takes time to build this trust that enable the crucial (and often difficult) conversations to take place. This contributes to the outcome of a high quality hospice experience. Nationally and similarly in Maryland our average length of stay (ALOS) is approximately 84 days while our median length of stay (MLOS) is 39 days and 30% of our admissions die within 7 days. Considering the baseline for hospice eligibility is a prognosis of 6 months or less, there is significant variance in the hospice benefit design and actual utilization. Earlier referrals would lead to greater hospice impact on the total cost of care model, and provide enhanced end of life experiences in Maryland. Without hospice access and acceptance, one must consider, however, the impact of the total cost of care model for patients who would then utilize expensive inpatient services of emergency rooms and ICU beds

One productive change in the regulations occurred in 2013 when the need formula began

using total deaths instead of just cancer deaths, given that only 20% of hospice admissions are comprised of patients with cancer diagnoses. The accuracy regarding utilization was improved because, as recently reported in the annual report by the American Cancer Society, the cancer death rate has declined 26 percent since 1991 in the United States. Another possible change in the need methodology would be to lower the minimum age at death from 35 to 25 years old. Looking at hospice utilization broken down by race and ethnicity also would be meaningful as it would improve the relevance of the hospice utilization data. As the MHCC stated on page 4 in its 2013 **State Health Plan: Hospice Services**, "The use of hospice services nationally and within Maryland varies by population groups. It has been shown that some individuals and groups are reluctant to access hospice services based on religious, ethnic, cultural and other factors." On page 5 the **State Health Plan** also notes that "several factors affect future hospice utilization. Differing views of health care, illness, and dying impact the use of end-of-life services by various ethnic and religious groups." It is well understood by hospice experts that minority communities tend to use hospice less than Caucasians.

11. **Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.**

In general, summarized in previous questions. Regulation changes should be focused on need determination and Hospice Provider impact on the total cost of care model.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. **Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?**

JSSA Hospice and The Hospice and Palliative Care Network of Maryland suggest the following questions be considered as criteria for project review.

- Demonstrate and explain, as a new provider, your ability to establish timely and

effective partnerships needed to achieve the State's goals for Global Budget Revenue and value based purchasing.

- The provision of charitable care, while already required data in a CON application submission, should be deemed an important element in the CON evaluation process.
- Commitment to providing care to underserved populations.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. **If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?**

14. **Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?**

The Department of Health and Human Services (DHHS) should not be involved in the CON process. The DHHS serves a different purpose. It ensures existing providers meet the minimum regulatory requirements for the provision of services. As noted above, the CON process is and should remain a benchmark for entry into the market, not for continuation in the market.

The Impact of CON Regulation on General Hospice Program Competition and Innovation

15. **Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.**

CON regulation does not stifle innovation. Hospice providers will continue, as they have- and innovate within the existing Medicare Benefit.

16. **Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?**

We do not believe Maryland should shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve competition for home health services. The two services respond to different factors, treat different patients, and are paid under a different regulatory scheme.

The Impact of CON Regulation on General Hospice Access to Care and Quality

At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?

Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

MHCC should use actual complaint and survey data of the existing providers. *New applicants should be evaluated on like data from state or states in which they operate. JSSA Hospice firmly believes that applicants or corporate affiliated entities with active DOJ investigations related to potential fraudulent practice be disqualified from applying.* Applicants should be evaluated with industry benchmarking standards such as Hospice Compare and the PEPPER report, which are indicators of quality, satisfaction and regulatory adherence. \

Scope of CON Regulation

17. **Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.**

This would appear to take away the ability of the public to oppose or comment on new projects and limit transparency and we do not support this.

18. **Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?**

Existing hospice provider expansion within their licensed jurisdictions or expansion of GIP beds to meet patient demand should be considered for expedited review. In the interest of meeting patient needs in a timely manner, if an existing hospice provider

has the capital, location and agreements to build and construct an inpatient center there should be an expedited process to move the project forward.

The Project Review Process

19. **Are there specific steps that can be eliminated?**

No specific steps to be eliminated other than previously noted in this document.

20. **Should post-CON approval processes be changed to accommodate easier project modifications?**

Post Con process is reasonable and adequate and the Commission has shown flexibility in working with providers on reasonable project modifications.

21. **Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.**

As noted in the document.

22. **Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?**

Yes-JSSA Hospice is in agreement with this suggestion. Measures to expedite and clarify the process are needed improvements.

Duplication of Responsibilities by MHCC and MOH

23. **Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?**

Not at this time, the departments serve different functions

We thank you for the opportunity to respond and share our ideas for improvement.

Sincerely,

Joyce Sexton, RN
Hospice Director,
Jewish Social Services Agency Hospice

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January 11, 2018

Sent via email and USPS

Mr. Paul Parker
Director of the Commission's Center for Health Care Facilities
Planning and Development
Maryland Health Care Commission
4160 Patterson Ave.
Baltimore, MD 21236

RE: COMMENT GUIDANCE - GENERAL HOSPICE SERVICES MHCC CON STUDY, 2017-18

Dear Mr. Parker:

Montgomery Hospice has completed the Comment Guidance – General Hospice Services MHCC CON Study. Please see our response to the questions below.

Need for CON Regulation

Montgomery Hospice strongly supports the idea that CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. **In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?**

Adding more hospices will not assure more hospice access. As the Medicare Payment Advisory Commission (MedPAC) wrote on page 148 in its 2010 Report to Congress, "Recognizing that the raw number of hospices may not be the best measure of provider capacity, we examined the relationship between the supply of hospices and the rate of hospice use among Medicare

decedents across states." On page 149, in Figure 2E-1, MedPAC concluded, "Hospice enrollment rates are unrelated to the number of hospices in a state."
Hospice is an interdisciplinary medical model that cares for extremely fragile and sick patients in their homes with resources available on a 24 hour basis. Small hospices cannot provide this comprehensive care because the insurance payment level is inadequate to support a high level of fixed costs (labor and overhead) unless the average daily census is well above 100 patients. Therefore, adding more small hospices does not increase utilization since the small hospices are incapable of providing the level of care that is needed.
One area where the public and health care delivery system benefit is when fewer terminally ill patients die in hospitals.

2. **Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?**

CON regulation should be concerned with good consumer access to quality hospice care. Competition and market entry are not the primary concern for terminally ill Marylanders. Ensuring an adequate number of larger hospices delivering quality patient care is.

3. **How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?**

CON regulation does not stifle innovation. Inadequate reimbursement stifles innovation.

4. **Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.**

CON ensures that Maryland does not have dozens of small, ineffectual hospices that are incapable of keeping dying patients out of hospitals. When a small hospice does not have a nurse available to visit a home in the middle of the night, the patient with uncontrolled symptoms will be sent by ambulance to the hospital. This is a common occurrence with small hospices.

Hospice care is delivered in patient homes which improves the patient and family experience of care; improves the health and well-being of the family members; and reduces the per capita cost of caring for dying patients who would be admitted to an ICU if they were not cared for at home. Hospice patients, by definition, are the sickest patients in the healthcare system. Many futile medical interventions could be used in a hospital (intubation, respirators, etc.)

Inpatient hospice is the one service where hospices resemble hospitals. Inpatient hospices, like Casey House, require major capital investment. The financial viability of the free-standing inpatient hospices can be compromised when hospitals or nursing homes convert unused beds

to inpatient hospice beds. The MHCC, through the CON process, should develop a targeted need methodology and a separate projection for hospice inpatient beds in order to analyze whether new inpatient hospice beds are necessary in a jurisdiction that has a free-standing inpatient hospice.

5. Should the scope of CON regulation be changed?

A. Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?

No

B. Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

No

<u>The Project Review Process</u>

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

A chokepoint occurs when an applicant is given extra time even though it did not meet the timeliness or CON content requirements. This creates an unnecessary delay in the CON process for the applicants who know how to follow rules and regulations.
By allowing noncompliant applicants extra time, the MHCC appears to want to issue more CON's. The MHCC should be concerned mainly with the ability of applicants to provide quality hospice care. There should be no regard for the quantity of applicants. Hospices can grow to be as large as needed in order to meet the hospice demand. Maryland should want larger hospices since they are more financially viable and sustainable.

7. Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

It depends on whether the state wants to hear from the existing hospices. Existing hospices will object to the applicants because, given the low reimbursement rate for patients who truly have a short-term prognosis, losing any referrals to a new hospice results in financial hardship for the existing hospices.

When hospices merge, it tends to produce a stronger, more robust hospice; therefore, it is advisable that hospices should be able to merge without CON review. However, if each hospice has a CON, the merged asset system should only retain one. The other CON(s) should be null and void.

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The CON process can be lengthy; therefore, economic conditions may have changed once CON approval is given. Since project completion depends on the current economic and medical environment, adequate time should be given in order for the applicant to maximize its business model before finalizing the project.

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

A chief weakness is that the State Health Plan does not have a specific need methodology or projections for inpatient hospice beds. Freestanding inpatient hospices are important medical providers in several Maryland jurisdictions. Adding inpatient hospice beds without regard to need or demand puts the existing inpatient hospices in financial jeopardy.

10. Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the regulations miss the mark.

One productive change in the regulations occurred in 2013 when the need formula began using total deaths instead of cancer deaths. The accuracy regarding utilization was improved because, as recently reported in the annual report by the American Cancer Society, the cancer death rate has declined 26 percent since 1991 in the United States. Another possible change in the need methodology would be to lower the minimum age at death from 35 to 25 years old. Looking at hospice utilization broken down by race and ethnicity also would be meaningful as it would improve the relevance of the hospice utilization data. As the MHCC stated on page 4 in its 2013 **State Health Plan: Hospice Services**, "The use of hospice services nationally and within Maryland varies by population groups. It has been shown that some individuals and groups are reluctant to access hospice services based on religious, ethnic, cultural and other factors." On page 5 the **State Health Plan** also notes that "several factors affect future hospice utilization. Differing views of health care, illness, and dying impact the use of end-of-life services by various ethnic and religious groups." It is well understood by hospice experts that minority communities tend to use hospice less than Caucasians.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

In general, this has been summarized in previous questions. Regulation changes should be focused on need determination and hospice's helpful impact on the total cost of care model.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

"Availability of more cost-effective alternatives that deliver quality hospice service" should be eliminated, and the following expanded criteria could be implemented:

- Demonstrate and explain, as a new provider, your ability to establish timely and effective partnerships needed to achieve the State's goals for Global Budget Revenue and value based purchasing.

- The provision of charitable care, while already required data in a CON application submission, should be deemed an important element in the CON evaluation process.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

I do not believe that CON regulation of hospice should be eliminated.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope

and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The federal government has demonstrated that the public sector does not adequately police low quality providers. Medicare certification requirements are more rigorous that Maryland licensure, yet few hospices have been sanctioned. When the federal government finds a very serious problem, it usually only asks for a plan of correction. Recently, VITAS was fined $75 million after having provided plans for stopping its fraudulent behavior.

Using the Maryland Department of Health is not a viable alternative.

The Impact of CON Regulation on General Hospice Program Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.

CON regulation does not restrict innovative hospice behavior.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?

I do not understand this question. Home health agencies do not provide complex, interdisciplinary palliative care for patients AND families. Home health agencies and hospices are not similar.

The Impact of CON Regulation on General Hospice Access to Care and Quality

17. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

MHCC should consider the applicant's history of quality care performance in the very beginning of the process. An applicant should be eliminated if it cannot demonstrate its commitment to quality.

Scope of CON Regulation

18. Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

Hospices are currently able to initiate major projects and services without CON review. For example, Montgomery Hospice started a pediatric service, as well as a specialty team for patients who have only a week to live at the time of referral. Montgomery Hospice strongly believes that adding inpatient hospice beds to a jurisdiction, where free-standing inpatient hospices have been built, should be subject to a full CON process, with carefully constructed need methodology. The CON regulation should be maintained.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

There is no need for a whole new regulatory process.

The Project Review Process

20. Are there specific steps that can be eliminated?

No specific steps should be eliminated other than previously noted in this document.

21. Should post-CON approval processes be changed to accommodate easier project modifications?

Post Con process is reasonable and adequate and the Commission has shown flexibility in working with providers on reasonable project modifications.

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

This was addressed in the response to question 18.

23. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Yes

Duplication of Responsibilities by MHCC and MOH

24. Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?

Not at this time, the departments serve different functions

Thank you for the opportunity for Montgomery Hospice to provide our comments on this very important issue. We look forward to hearing the results of this survey in the near future.

Sincerely,

Ann Mitchell

Ann Mitchell, MPH
President & CEO

January 11, 2018

Paul Parker
Director of the Commission's Center for Health Care
Facilities Planning and Development
4160 Patterson Avenue
Baltimore, MD 21215

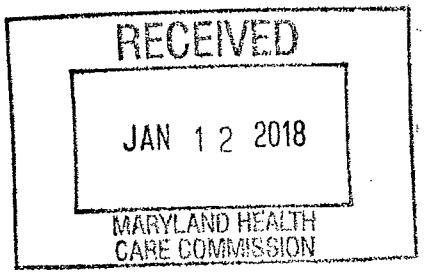
Dear Paul,

Please see attached for Seasons' response to the comment guidance related to the MHCC CON study. Please let me know if you'd like this electronically.

My e-mail address is: DForman@Seasons.org.

Sincerely,

Dean Forman, MBA
Executive Director
Vice President Operations



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COMMENT GUIDANCE - GENERAL HOSPICE SERVICES MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of general hospice CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of general hospice CON regulation?

O CON regulation of general hospices should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

O CON regulation of general hospice services should be reformed.

X O CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?

No. Primarily, more hospice providers would cause increased competition for limited clinical resources and diminishing return on the achieved and to be realized economies of scale. Additional general hospice providers would drive up (redundant) fixed costs, which is one of the core benefits of a service based model. In addition, it would also drive up the cost of the health care oversight system by adding additional regulatory resources to oversee compliance and quality. In Maryland, the densely populated jurisdictions have significant competition presently, and utilization (delivery) trends are growing well alongside the new HSCRC reimbursement models. There has never been a

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time our agency, and to our knowledge of other agencies, has not been able to meet the need of an eligible hospice patient/family who desired hospice enrollment.

2. Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

The CON provides necessary barriers to market entry and jurisdiction expansion. The densely populated jurisdictions have appropriate competition. More Rural jurisdictions which have a single provider, likely could not sustain a business model for new market entrants, due to the volume of need and the population sizes of their geographic areas. The rural sole provider reality, is not unique to Maryland, for the same population size/need reasons found here. It is something we see in many rural communities across the country, in both CON and non-CON environments.

3. How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?

As a national provider that operates in CON and non-CON states (19 states in total) there has been NO negative impact on innovation and NO experience to suggest that Maryland is less innovative regarding end of life care than non-CON states. In fact, there is MORE attention to quality and innovation afforded from scale and avoided distraction due to questionable practices that arise with oversaturation, as well as, instability of staff caused by inflated supply of providers. As an example, Seasons employs Board Certified Music Therapist as part of the IDG to add to quality and comfort at end of life. This is not a requirement of the Medicare Hospice Conditions of Participation. We also have dedicated resources to community education and deliver over 425 hours of education to over 4100 attendees. Seasons also contracts with hospitals, as well as, skilled nursing facilities to provide palliative care services in an innovation driven model. This model is leading to reduced readmissions and hospital mortality, complimenting the goals of the new total payer model in Maryland. In 2018 Seasons will be expanding its telehealth initiatives, bringing additional clinical assessments and physician interaction directly to the patient and caregiver on a more frequent and high-quality basis.

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[1]The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is this belief that new designs must be developed to simultaneously pursue three dimension: (1} Improving the patient experience of care (including quality and satisfaction) ;(2} Improving the health of populations, and; (3} Reducing the per capita cost of health care.

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4. Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.

The CON promotes innovation and the ability to scale to meet the demands of the community. Having a controlled number of licensed providers enables hospice to focus on key partnerships with hospital systems, skilled nursing homes, and assisted living providers to keep readmission and mortality statistics minimized. Thus, supporting the significant savings achieved in the all payor model in Maryland. Post-acute ambulatory end of life care requires massive labor, logistics investments, and infrastructure costs. Additional providers would add unnecessary competition for already competitive resources like Physicians (Board Certified), Nurses, Social Workers, HHA's, Volunteers, Chaplains and clinical operations leadership. All of which are difficult to hire and could factor against existing hospice providers ability to innovate, scale, and meet the needs of the community. It would also, as mentioned, create redundant fixed costs, adding to the overall delivery of care costs for payors. Here in Maryland, we are also seeing the demand and therefore expansion of Inpatient Hospice Services. Those services are far more capital intensive, in the traditional capital sense (brick/mortar), which is moving hospice further into of the capital investment arena.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a general hospice, increase the bed capacity (general inpatient hospice care) of a general hospice, or expand the service area of an existing general hospice into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.2f 01.02 - .04, which can be accessed at:
http:// www.dsd.state.md.us/comar/Subtitle5earch.aspx?search=10.24.01.*

5. Should the scope of CON regulation be changed?
   A. Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?

The modern interpretation of the regulation, calls for a separate Certificate of Need for Inpatient Beds to be developed, in all settings. If any change is to be considered given that a CON is required for a general hospice license, as well as for hospitals and skilled nursing facilities, we would simply suggest that an already licensed general hospice provider (with a CON), should be able to develop inpatient beds within its existing CON geography using the structure which Medicare regulation considers "direct/shared". Direct/shared is where the hospice and an already licensed hospital or skilled nursing facility may enter into an arrangement, where the

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hospice provides some services direct (staffing most common) and some services are purchased (shared), including the use of the facilities licensed beds. This is a structure that allows the hospice to repurpose existing capacity (that is already overseen by the state regulatory agencies on each side of the arrangement, as both the hospice and facility are licensed and surveyed) and adjust more quickly to changes in need both up./down with limited capital risk, and is very different than developing a freestanding inpatient facility (which Medicare refers to as "direct"). At present, there is an equal CON requirement for both structures.

B. Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

Current regulated scope is inclusive

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

The process at present has been fine for our needs

7. Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited? Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

A formal process to oppose and appeal is needed and should not be limited. Interested parties should have a venue and a platform to challenge and discuss competing hospice CON filings.

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

Yes, from our experience, they have not posed any problems

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What

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are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

Chief weakness is primarily the formula in which need is determined. A demographic weighting related to the underserved communities should be considered. As an example African American hospice utilization is low nationally, as reported by the National Hospice and Palliative Care Organization (NHPCO). On a national level, the African American community, as a percentage of total population, is about 14% and in Maryland is 29.4%. Overall hospice utilization in the state of Maryland is slightly lower than the national average, but this does not mean there is unmet need, because Maryland's demographic makeup isn't a pure compliment to the national demographic makeup. The existing need calculation does not factor in the impact of cultural diversity and their utilization of hospice. Our recommendation would be to compare "demographically" weighted utilization against those same demographically weighted national utilization rates.

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2 Under Maryland CON law, home health agencies are classified as "health care facilities."

10. Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the regulations miss the mark.

The State Health Plan would benefit by adding quality markers related to hospice length of stay. Hospice is most effective when the interdisciplinary team (IDG) has time to work with the patient and family. This takes time to build the trust and have the crucial conversations that provide the outcome of a high-quality hospice experience. Today our length of stay is approximately 60 days but more than a third of our admissions die within 7 days. Considering the baseline for hospice eligibility is a prognosis of 6 months or less, there is significant variance in the hospice benefit design and actual outcome. The quality markers should be physician education focused. Increased physician knowledge and comfort with prognostic indicators will provide enhanced end of life experiences in Maryland.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

The process is generally a good one, the issue we highlight in our response to #9, relates to the demographic issue that impacts the comparative data used to evaluate provider performance captured through successful industry and public input.

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General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

Very appropriate, we wouldn't suggest modifications in any way.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

We do not believe CON regulation should be eliminated.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

We do not believe any alternative would provide the governance necessary for continued sustained quality and service, which has kept pace with need.

The Impact of CON Regulation on General Hospice Program Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.

No. As an experienced provider in the state, we are having NO challenges in deploying innovation and unique service models, and developing collaborative relationships with the health care continuum. The only item as mentioned under #5, which is a bit stricter than in most other environments and recognized by Medicare, would be the "direct/shared" structure for inpatient services, to be considered permitted without a separate CON.

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16. Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?

Hospice is extremely different than home health care. The goals of care, coverage from a capitation perspective (24/7, etc...), and locations of service are not always overlapping (i.e. SNF's, hospitals, etc...). The largest and most successful hospice organizations, nationally, are not integrated with home health care. Even, the few that do have both service lines, do not operationally integrate them. The cultures, due to the reimbursement model and care goals, have proven to compete within integrated agencies. Hospice focus, being the harder conversation and harder to operate (given scope and capitation) usually is diminished and therefore so are the outcomes which hospice delivers.

The Impact of CON Regulation on General Hospice Access to Care and Quality

17. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

MHCC should use actual complaint and survey data of the existing providers. New applicants should be evaluated on like data from the state or states in which they operate. Applicants with active DOJ investigations related to potential fraudulent practice should be disqualified. Industry tools like Hospice Compare and the Pepper report, which are indicators of quality, satisfaction and regulatory adherence should also be reviewed and compared.

Scope of CON Regulation

18. Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

No. The only change we would propose is the response we provided under #5.

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19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

If "direct/shared" would continue to require the same CON process as a freestanding ("direct") inpatient unit, then an expedited process for hospital or skilled nursing facility based hospice inpatient beds/units, would be an area for expedited review. General criteria could be established regarding the size of the hospital/community, LOS, Mortality, and financial impact. As the global budget model expands and hospital utilization decreases space will become available in which hospitals may want to consider hospice inpatient units.

The Project Review Process

20. Are there specific steps that can be eliminated?

None at this time.

21. Should post-CON approval processes be changed to accommodate easier project modifications?

None at this time.

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

Nothing beyond our response to #19.

23. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Yes.

Duplication of Responsibilities by MHCC and MDH

24. Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?

None that we have identified at this time.

Thank you for your responses.

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Mr. Paul Parker
Director of the Commission's Center for Health Care Facilities
Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

RE: Certificate of Need (CON) for Hospices

January 10, 2018

Dear Mr. Parker:

In response to letter received from the Maryland Health Care Commission, I wish to express my views regarding the continuation of the general hospice CON regulation.

I am in favor of maintaining the Hospice CON regulation and support revisions or refinement in the CON process.

I do not believe the residents of Maryland would benefit from removing the CON regulation. The current process may be a bit burdensome for the hospice seeking licensure, and yes, some refinement to the CON process may be warranted.

I believe the CON process is a positive structure in the state. The MHHC has done a good job at looking at demographics in a region, mortality rates, and other vital statistics and has a broad overview of the health and welfare of the state. The CON process prevents an influx of agencies/entities converging in an area for increased competition.

- Removing the CON regulation will negatively impact smaller sized hospices or hospices that provide services in a less densely populated county or only in one county.
- It is my belief it will cause an influx of many hospices to flood an area causing greater difficulty for any one hospice to stay viable.
- For small hospices and in a small region (i.e. one county) additional competition and deregulation of the CON process would be a detriment to small hospices, especially like hospices on the Eastern Shore.

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- Talbot Hospice has been fully licensed as a general hospice for just three (3) years and our organization continues to work on building our census and program. The county has 39,000 residents, which will not support another hospice in this county. I am very concerned that Talbot Hospice would cease to exist with additional competition. We focus on exceeding the state regulations, Medicare Conditions of Participation and take pride that the quality of care we provide is exemplary.

- De-regulation will allow any entity to advertise (falsely) they provide hospice services without much oversight. There are a few home health agencies and Skilled Nursing Facilities that unfortunately advertise hospice services when in fact are not licensed as such.

I support a restructuring and revisions to the CON process if it aids reducing workload and paperwork for both the MHHC and the hospices applying for licensure. Review of any hospice's licensure survey and quality metrics may be an area for which to include when applying for licensure. Whatever the state determines broadly, the MHHC must take in to account the small hospices in rural areas and at a minimum consider the continuation of a rural distinction.

Palliative Care programs are currently not under the CON process and as a small hospice working to establish a new Palliative Care Program, we are experiencing increased competition from other hospices not licensed in Talbot County and from other entities. This makes the development of and expansion of our services more difficult.
As with Palliative Care, deregulation of the hospice CON will dilute hospice services throughout the state of Maryland.

I support efforts to open up eligibility requirements for currently licensed hospices. This allows hospices to serve patients further upstream, reducing costs by Medicare and the state.

Sincerely,

Vivian Dodge, MBA, BSN, RN
Executive Director

Ambulatory Plastic Surgery Associates

COMMENT GUIDANCE – FREESTANDING AMBULATORY SURGICAL FACILITIES (FASFs)
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of FASF CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of FASF CON regulation?

- ☐ CON regulation of FASFs should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]
- ☑ CON regulation of FASFs should be reformed.
- ☐ CON regulation of FASFs should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on FASFs Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among FASFs? YES
2. Does CON regulation impose substantial barriers to market entry for new FASFs or expansion of FASFs? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?
YES. LOWER THE BAR FOR NEED + RAISE BAR FOR APPEALS FROM COMPETING FASFS
3. How does CON regulation stifle innovation in the delivery of ambulatory surgical services under the current Maryland regulatory scheme?
NEEDING PREAPPROVAL FOR LARGE CAPITAL EXPENDITURES

Scope of CON Regulation

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

Generally, Maryland Health Care Commission approval is required to establish an FASF, which is an outpatient surgical center with two or more sterile operating rooms, to relocate an FASF, to expand the operating room capacity of an FASF, or to undertake a capital expenditure that exceeds a specified expenditure threshold.[2] For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there FASF projects that require approval by the Maryland Health Care Commission that should be deregulated? YES (CAPITAL EXPENDITURE THRESHOLD)
   B. Are there FASF projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?
      NO

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?
   PREAPPROVAL OF CON
6. Should the ability of competing FASFs or other types of providers to formally oppose and appeal decisions on projects be more limited?
   YES. THEY SHOULD STILL BE ALLOWED TO MAKE THEIR CASE BUT LESS WEIGHT GIVEN
   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?
   YES - ELIMINATE CAPITAL EXPENDITURE THRESHOLD APPROVAL
7. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)
   GREATER FLEXIBILITY WOULD BE REASONABLE

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for FASFs provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?
   YES
9. Do State Health Plan regulations focus attention on the most important aspects of FASF projects? Please provide specific recommendations if you believe that the regulations miss the mark.
   SUGGEST 1) LOWERING THE BAR FOR NEED (#1)
   2) ELIMINATE ~~GOOD~~ APPLICANT'S PRIOR COMPLIANCE (#5)

[2] Most outpatient surgical centers established in Maryland have no more than one sterile operating room and were not required to obtain CON approval for their establishment. Only a determination of coverage issued by MHCC staff is required for such centers, which are called "physician outpatient surgical centers" in Maryland.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

① ELIMINATE #5 ② LOWER BAR FOR #1

CHANGES/SOLUTIONS

Alternatives to CON Regulation

12. If you believe that CON regulation of FASFs should be eliminated, what, if any, regulatory framework should govern establishment, relocation, and expansion of FASFs?

RECOMMEND CONTINUED CON REGULATION BUT GREATER FLEXIBILITY WOULD BE DESIRABLE

13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of FASF licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that FASFs are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

CURRENT SYSTEM SEEMS TO WORK

The Impact of CON Regulation on FASF Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing FASFs and new market entrants? If so, please provide detailed recommendations.

YES: ① ELIMINATE NEED FOR APPROVAL CAPITAL EXPENDITURE ② LOWER REQUIREMENTS FOR NEED

15. Should Maryland shift its regulatory focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition for these services?

NO

Scope of CON Regulation

16. Should the use of a capital expenditure threshold in FASF CON regulation be eliminated?

YES

17. Should MHCC be given more flexibility in choosing which FASF projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider

YES. GREATER FLEXIBILITY WOULD BE BENEFICIAL

staff's recommendation not to require CON approval or, based on significant project impact, to require the FASF project to undergo CON review.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?
NO NOT NEEDED. CURRENT SYSTEM IS WORKING

The Project Review Process

19. Are there specific steps that can be eliminated?
NO BUT EASING OF REQUIREMENTS WOULD BE WORTHY OF CONSIDERATION
20. Should post-CON approval processes be changed to accommodate easier project modifications?
YES EASING OF REQUIREMENTS
21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.
NO
22. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?
POSSIBLY

Duplication of Responsibilities by MHCC and MDH

23. Are there areas of regulatory duplication in FASF regulation that can be streamlined between MHCC and MDH? NOT SURE

Thank you for your responses.

Baltimore Washington Eye Center

COMMENT GUIDANCE – FREESTANDING AMBULATORY SURGICAL FACILITIES (FASFs)
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of FASF CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of FASF CON regulation?

- ☒ CON regulation of FASFs should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]
- ☐ CON regulation of FASFs should be reformed.
- ☐ CON regulation of FASFs should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on FASFs Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among FASFs?
2. Does CON regulation impose substantial barriers to market entry for new FASFs or expansion of FASFs? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?
3. How does CON regulation stifle innovation in the delivery of ambulatory surgical services under the current Maryland regulatory scheme?

Scope of CON Regulation

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

Generally, Maryland Health Care Commission approval is required to establish an FASF, which is an outpatient surgical center with two or more sterile operating rooms, to relocate an FASF, to expand the operating room capacity of an FASF, or to undertake a capital expenditure that exceeds a specified expenditure threshold.[2] For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there FASF projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there FASF projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

6. Should the ability of competing FASFs or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

7. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for FASFs provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

9. Do State Health Plan regulations focus attention on the most important aspects of FASF projects? Please provide specific recommendations if you believe that the regulations miss the mark.

[2] Most outpatient surgical centers established in Maryland have no more than one sterile operating room and were not required to obtain CON approval for their establishment. Only a determination of coverage issued by MHCC staff is required for such centers, which are called "physician outpatient surgical centers" in Maryland.

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General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation

12. If you believe that CON regulation of FASFs should be eliminated, what, if any, regulatory framework should govern establishment, relocation, and expansion of FASFs? None. The free market would dictate whether CON is needed
13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of FASF licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that FASFs are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care? No

The Impact of CON Regulation on FASF Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing FASFs and new market entrants? If so, please provide detailed recommendations.

15. Should Maryland shift its regulatory focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition for these services?

Scope of CON Regulation

16. Should the use of a capital expenditure threshold in FASF CON regulation be eliminated?

17. Should MHCC be given more flexibility in choosing which FASF projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider

staff's recommendation not to require CON approval or, based on significant project impact, to require the FASF project to undergo CON review.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

19. Are there specific steps that can be eliminated?

20. Should post-CON approval processes be changed to accommodate easier project modifications?

21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

22. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Duplication of Responsibilities by MHCC and MDH

23. Are there areas of regulatory duplication in FASF regulation that can be streamlined between MHCC and MDH?

Thank you for your responses.

Chesapeake Eye Surgery

January 2, 2018
2002 Medical Parkway, Suite 330
Annapolis, MD

Dear Paul Parker:
Director of the Commissions Center for Health Care Facilities and Planning and Development

In response to your letter on potential reforms of health planning and certificate of need (CON) programs we feel that it should be eliminated.

Sincerely,

Jennifer Knopp RN

Jennifer Knopp, RN.
Nurse Administrator

ALTERNATIVES TO CON REGULATION

12. We believe that CON regulation of FASFs should be eliminated.

- MHCC should be responsible to govern establishment, relocation and expansion of FASFs, but without a formal CON approval.
- We believe that the need for new health care facilities should not be determined solely by the MCHH, but by the physicians involved in building the centers.
- Shared responsibility for CON approval should also depend on other factors such as, cost effective approach, geographical locations, finical feasibility and will not create finical burden on any other centers in the proposed area.

13. We believe that deregulation of the CON process can still provide important benefits to FASFs.

- Existing centers can have flexibility for their projects.
- Centers will still need Dept. of Health approval thru surveys to maintain quality of care.
- Guide for the public to access FASF information online.
- Applying for a new center should be accessible online to facilitate an expeditious process.
- There should be a process for important documentation to be uploaded directly to MHCC website for timely review by officials.
- The public can be served better by FASFs when the process is less demanding and centers can be built in a timely manner.

- If there is a need in a community for a FASFs. The community would be better served by a more expedited approach for delivery of service.
- A more streamlined process will be more cost effective to both FASFs and the state of Maryland.

Robert E. Moffitt, PhD
CHAIR

STATE OF MARYLAND

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

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

November 21, 2017

Dear Administrator:

I write to seek your input on potential reforms of health planning and certificate of need (CON) programs, This input will be used to identify issues and problems and develop recommendations for modernizing Maryland's approach to health facility planning.

The Chairs of the Senate Finance Committee and the Health and Government Operations Committee have asked the Maryland Health Care Commission (MHCC) to develop recommendations for modernizing Maryland's health facility planning and CON programs in light of Maryland's implementation of the global budgets under the All-Payer Model and the proposed migration to the Total Cost of Care Demonstration in 2019. The Committees have asked MHCC to submit an interim report in May and a final report in December of next year. The Commission supports this review and further believes that we should consider changes in our health planning and Certificate of Need (CON") authority across all categories of services at the same time.

Over the past several months, the MHCC has developed a comprehensive, constructive, and inclusive plan for responding to the Chairs' request. The Commission will develop recommendations for the Committees through a two-step review process using a Commissioner-led workgroup. In the first step, the workgroup will focus on the examination of issues and problems with existing health planning and CON programs. The interim report in May will identify issues and problems, and also highlight the range of potential solutions.

In step two, the workgroup will focus on assessing potential solutions in detail and developing recommendations that the General Assembly Committees may consider. The final report will provide a roadmap for aligning the health planning and the CON programs with the All-Payer Model and the Total Cost of Care Demonstration planned for launch in 2019. Both the interim and final reports will be developed by the workgroup and then submitted to the full MHCC for approval and transmission to the Committees.

The initial workgroup will consist of five Commissioners and eight stakeholder members. Representatives from the Maryland Department of Health and the Health Services Cost Review Commission will be designated by those respective organizations. Commissioners Fran Phillips and Randolph Sergent will serve as co-chairs. Commissioners Hafey, Metz, and O'Grady have also agreed to serve on the workgroup.

COMMENT GUIDANCE – FREESTANDING AMBULATORY SURGICAL FACILITIES (FASFs)
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of FASF CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of FASF CON regulation?

☒ CON regulation of FASFs should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

☐ CON regulation of FASFs should be reformed.

☐ CON regulation of FASFs should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on FASFs Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among FASFs?

2. Does CON regulation impose substantial barriers to market entry for new FASFs or expansion of FASFs? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

3. How does CON regulation stifle innovation in the delivery of ambulatory surgical services under the current Maryland regulatory scheme?

Scope of CON Regulation

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

Generally, Maryland Health Care Commission approval is required to establish an FASF, which is an outpatient surgical center with two or more sterile operating rooms, to relocate an FASF, to expand the operating room capacity of an FASF, or to undertake a capital expenditure that exceeds a specified expenditure threshold.[2] For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there FASF projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there FASF projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

6. Should the ability of competing FASFs or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

7. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for FASFs provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

9. Do State Health Plan regulations focus attention on the most important aspects of FASF projects? Please provide specific recommendations if you believe that the regulations miss the mark.

[2] Most outpatient surgical centers established in Maryland have no more than one sterile operating room and were not required to obtain CON approval for their establishment. Only a determination of coverage issued by MHCC staff is required for such centers, which are called "physician outpatient surgical centers" in Maryland.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation

12. If you believe that CON regulation of FASFs should be eliminated, what, if any, regulatory framework should govern establishment, relocation, and expansion of FASFs?

13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of FASF licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that FASFs are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The Impact of CON Regulation on FASF Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing FASFs and new market entrants? If so, please provide detailed recommendations.

15. Should Maryland shift its regulatory focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition for these services?

Scope of CON Regulation

16. Should the use of a capital expenditure threshold in FASF CON regulation be eliminated?

17. Should MHCC be given more flexibility in choosing which FASF projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider

staff's recommendation not to require CON approval or, based on significant project impact, to require the FASF project to undergo CON review.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

19. Are there specific steps that can be eliminated?

20. Should post-CON approval processes be changed to accommodate easier project modifications?

21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

22. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Duplication of Responsibilities by MHCC and MDH

23. Are there areas of regulatory duplication in FASF regulation that can be streamlined between MHCC and MDH?

Thank you for your responses.

Jonathan E. Efron, MD, FACS, FASCRS
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JOHNS HOPKINS
MEDICINE

January 29, 2018

Paul Parker
Director, Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Parker:

Thank you for the opportunity to provide feedback on the Maryland Certificate of Need ("CON") regulatory process as it pertains to Freestanding Ambulatory Surgery Facilities. I offer these comments on behalf of Johns Hopkins Medicine and the following entities: White Marsh Surgery Center (one operating room); Knoll North Endoscopy Center (two non-sterile procedure rooms); Ophthalmology Associates at Greenspring (one operating room); Ophthalmology Associates at Bel Air (two operating rooms); and the Greenspring Station Surgery Center (a five-operating room facility that received CON approval in September 2016 and is under development).

Attached are detailed responses to the survey questions. Johns Hopkins Medicine supports a modification of the Certificate of Need ("CON") requirement that applies to freestanding ambulatory surgery facilities ("FASFs"). One operating room FASFs should, at minimum, be required to receive a CON exemption similar to the requirements enacted in the most recent revision of the Chapter for the addition of a second room to a one-room facility. Currently, there is no review required to open one OR, the significant burden of an exemption request to add a second OR, and even more of a burden to obtain a CON for a two-OR facility or larger. This creates a perverse incentive to develop one OR FASFs, which runs counter to the MHCC's stated preference and also counter to what we believe will result in the best possible care for patients.

In addition, we suggest that quality and safety, potential to reduce overall health care costs, and patient preferences and needs should be meaningful factors in the consideration of exemption and CON requests.

Finally, we recommend that the CON criterion "Availability of more cost-effective alternatives" should be eliminated for FASFs. A proposal to create or expand an FASF is must be financially feasible, and that should continue to be a standard for review. Because financing is not linked to the rate-setting system and instead is at the risk of the developer or owner, there should not be an obligation for applicants to provide a detailed analysis of the alternatives considered and their relative cost-effectiveness. It is a burdensome requirement with no benefit.

Again, thank you for the opportunity to provide input. Please feel free to contact me if you have any questions or would like additional information about our responses.

Sincerely,

Jonathan E. Efron, MD

Jonathan E. Efron, MD, FACS, FASCRS
Mark M. Ravitch Professor of Surgery
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Johns Hopkins Medicine
Responses to MHCC Survey
January 29, 2018

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim, and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of FASF CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON work group.

Need for CON Regulation

Which of these options best fits your view of FASF CON regulation?

☐ CON regulation of FASFs should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13 to 15.]

XX CON regulation of FASFs should be reformed.

☐ CON regulation of FASFs should, in general, be maintained in its current form.

Johns Hopkins Medicine recommends maintaining a CON requirement for the establishment or expansion of FASFs in Maryland but advocates for a regulatory framework that no longer incentivizes the creation of one operating room FASFs, that reduces unnecessary administrative burden, and that promotes quality and safety.

ISSUES/PROBLEMS

The Impact of CON Regulation on FASFs Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among FASFs?

There is adequate competition among FASFs—indeed, Maryland has more FASFs than any other state. The lack of regulation of one OR FASFs creates a perverse incentive for the creation of these FASFs over larger centers. The biggest impediment to fair competition is the lack of regulation of one OR facilities.

2. Does CON regulation impose substantial barriers to market entry for new FASFs or expansion of FASFs? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

The CON requirement provides an appropriate barrier to entry, often resulting in changes to a project that strengthen it and help ensure success. The lack of any barrier to one OR facilities is unfair and creates an uneven competitive environment.

3. How does CON regulation stifle innovation in the delivery of ambulatory surgical services under the current Maryland regulatory scheme?

The plan's focus on a rigid, outdated measure of "minimum utilization" overlooks other potential efficiencies and quality benefits of new facilities or expansions. Minimum utilization has been a threshold requirement that must be met before an FASF can apply to expand, precluding consideration of projects that bring other benefits and are more cost-effective, despite not meeting the utilization threshold.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish an FASF, which is an outpatient surgical center with two or more sterile operating rooms, or relocate an FASF, to expand the operating room capacity of an FASF, or undertake a capital expenditure that exceeds a specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at: http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.*

4. Should the scope of CON regulation be changed?

   A. Are there FASF projects that require approval by the Maryland Health Care Commission that should be deregulated?

      No.

   B. Are there FASF projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

      Yes. One operating room FASFs should, at minimum, be required to receive a CON exemption similar to the requirements enacted in the most recent revision of the Chapter for the addition of a second room to a one-room facility. Under the current Chapter, there is no review required to open one OR, a significant burden of an exemption request to add a second OR, and even more of a burden to obtain a CON for a 2-OR facility or larger. This creates a perverse incentive to develop one OR FASFs, which runs counter to the MHCC's stated preference and also counter to what we believe will result in the best possible care for patients.

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

   Completeness questions should be limited to one round and should be limited to information that is essential under the regulations in order to make a ruling on the project.

6. Should the ability of competing FASFs or other types of providers to formally oppose and appeal decisions on projects be more limited?

   No—the existing rules are adequate. However, the determination of "qualified for interested party status" should be more rigorous, which is possible under the existing rules.

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? *No.*

   Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems? *Yes.*

7. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)

   Greater flexibility could be built into the performance requirements without undermining the purpose of ensuring that projects move forward in a timely manner.

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for FASFs provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

   Addressed elsewhere in the survey—in general, the SHP regulations provide adequate guidance with consideration for the suggested changes offered here.

9. Do State Health Plan regulations focus attention on the most important aspects of FASFs? Please provide specific recommendations if you believe the regulations miss the mark.

   The current regulations do not adequately consider safety and quality performance, the role of FASFs in reducing health care costs, or the ways in which FASFs are in some instances able to provide a better patient experience and better meet patient needs.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State

Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

We appreciate the efforts the MHCC makes during chapter reviews to involve stakeholders and receive broad input. Unfortunately, that input does not always receive full consideration or vetting. There are instances where stakeholders around the table have opposing views. MHCC staff, rather than confronting those issues or guiding the discussion, simply avoids the challenging issues and in this way misses opportunities for real reform and improvement. We would like for there to be more robust conversation throughout the process, not just initially, and to discuss issues with the full commission rather than have staff present a final product that then is subject to a yes or no vote.

General Review
Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

Availability of more cost-effective alternatives should be eliminated for FASFs. A proposal to create or expand an FASF is limited by the financial feasibility of the project, and that should continue to be a standard for review. Because financing is not linked to the rate-setting system and instead is at the risk of the developer or owner, there should not be an obligation for applicants to present alternatives and their relative cost-effectiveness. It is a burdensome requirement with no benefit.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

12. If you believe that CON regulation of FASFs should be eliminated, what, if any, regulatory framework should govern FASFs?

Not applicable.

13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of FASF licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that FASFs are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization

or poor quality of care?

CON regulation plays an important role distinct from licensure and should be maintained.

The Impact of CON Regulation on FASF Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing FASFs and new market entrants? If so, please provide detailed recommendations.

See our recommendation above regarding regulation of one OR FASFs. The imbalance created under the current system may inhibit innovation.

15. Should Maryland shift its regulatory focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition for these services?

No.

Scope of CON Regulation

16. Should the use of a capital expenditure threshold in FASF CON regulation be eliminated?

Yes. For the reasons cited in response to question 11 above.

17. Should MHCC be given more flexibility in choosing which FASF projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the FASF project to undergo CON review.

While flexibility is important and additional flexibility could reduce the burden on applicants, it runs the risk of creating a system that is arbitrary and unpredictable. We are not in favor of this.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

A new process is unnecessary and would be burdensome and tax the already limited resources of the regulator. The existing process can be reformed to meet the need for a more efficient and sometimes streamlined process.

The Project Review Process

19. Are there specific steps that can be eliminated?

Completeness questions should be limited to one round, and they should be limited to only those issues that are essential to the decision—meaning there are applicable regulations related to that aspect of the project.

20. Should post-CON approval processes be changed to accommodate easier project modifications?

    Yes. For an FASF project, if the modification is related only to an increase in cost, there should be minimal review and an expedited process. As noted in response to question 11, the developer/owner is at risk for construction costs, and all other requirements were reviewed and ruled upon in the initial review.

21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

    The recent addition of an exemption process to the surgical services chapter was helpful.

22. Would greater use of technology including the submission of automated and form-based applications ion improve the application submission process?

    Electronic submission of quarterly reports would be helpful but it is not a major obstacle.

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

23. Are there areas of regulatory duplication in FASF regulation that can be streamlined between MHCC and the MDH?

    None known.

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry.

Kahn Center for Pain Managment

COMMENT GUIDANCE – FREESTANDING AMBULATORY SURGICAL FACILITIES (FASFs)
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of FASF CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of FASF CON regulation?

☑ CON regulation of FASFs should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

☐ CON regulation of FASFs should be reformed.

☐ CON regulation of FASFs should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on FASFs Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among FASFs?

2. Does CON regulation impose substantial barriers to market entry for new FASFs or expansion of FASFs? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

3. How does CON regulation stifle innovation in the delivery of ambulatory surgical services under the current Maryland regulatory scheme?

Scope of CON Regulation

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

Generally, Maryland Health Care Commission approval is required to establish an FASF, which is an outpatient surgical center with two or more sterile operating rooms, to relocate an FASF, to expand the operating room capacity of an FASF, or to undertake a capital expenditure that exceeds a specified expenditure threshold.[2] For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:
*http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.24.01.**

4. Should the scope of CON regulation be changed?
   A. Are there FASF projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there FASF projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

6. Should the ability of competing FASFs or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

7. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for FASFs provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

9. Do State Health Plan regulations focus attention on the most important aspects of FASF projects? Please provide specific recommendations if you believe that the regulations miss the mark.

[2] Most outpatient surgical centers established in Maryland have no more than one sterile operating room and were not required to obtain CON approval for their establishment. Only a determination of coverage issued by MHCC staff is required for such centers, which are called "physician outpatient surgical centers" in Maryland.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

General Review Criteria for all Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

CHANGES/SOLUTIONS

Alternatives to CON Regulation

12. If you believe that CON regulation of FASFs should be eliminated, what, if any, regulatory framework should govern establishment, relocation, and expansion of FASFs? community needs, access to care in reasonable time frame, cost
13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of FASF licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that FASFs are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care? yes

The Impact of CON Regulation on FASF Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing FASFs and new market entrants? If so, please provide detailed recommendations.

15. Should Maryland shift its regulatory focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition for these services?

Scope of CON Regulation

16. Should the use of a capital expenditure threshold in FASF CON regulation be eliminated?

17. Should MHCC be given more flexibility in choosing which FASF projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider

staff's recommendation not to require CON approval or, based on significant project impact, to require the FASF project to undergo CON review.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

The Project Review Process

19. Are there specific steps that can be eliminated?

20. Should post-CON approval processes be changed to accommodate easier project modifications?

21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

22. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Duplication of Responsibilities by MHCC and MDH

23. Are there areas of regulatory duplication in FASF regulation that can be streamlined between MHCC and MDH?

Thank you for your responses.

MPCAC

MARYLAND PATIENT CARE AND ACCESS COALITION

January 12, 2018

VIA ELECTRONIC MAIL & OVERNIGHT DELIVERY
Mr. Paul Parker
Director, Center for Health Care Facilities Planning & Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Freestanding Ambulatory Surgical Facilities – MHCC CON Study, 2017-2018

Dear Mr. Parker:

On behalf of the more than 300 physicians whose medical practices are members of the Maryland Patient Care and Access Coalitions (MPCAC), I want to thank you for the opportunity to provide input on potential reform of the State's Certificate of Need (CON) program. This is a critically important issue, as the Chairs of the Senate Finance Committee and the House Health and Government Operations Committee recognized in asking the Maryland Health Care Commission (MHCC) to develop recommendations for "modernizing" the CON program. As we explain below, CON regulation of freestanding ambulatory surgical facilities (FASFs) is an anachronism that prevents Maryland from achieving the goals of the Triple Aim—improving the patient experience, improving the health of populations, and reducing the per capita cost of health care. Accordingly, **MPCAC believes that CON regulation of FASFs should be eliminated.**

In response to MHCC's Comment Guidance, we divide our remarks into three sections. First, we discuss the ways in which the State's CON regulatory framework stifles innovation and competition and is at odds with health care delivery in the 21st century. Second, we highlight key takeaways from recent academic studies and government reports about the quality of care delivered in—and cost savings achieved by—FASFs. We believe those findings call into question the value of continuing the State's CON program. Third, we offer a proposal for regulating FASFs that is more consistent with the goals of the Triple Aim than the State's existing CON program.

The Maryland Patient Care and Access Coalition

For nearly 15 years, MPCAC has been the voice of independent physician specialty practices in the State that deliver integrated, high quality, cost-efficient care to patients in the medical office and ambulatory surgery center settings. With more than 300 physicians drawn from the fields of gastroenterology, orthopaedic surgery, urology, pathology, radiation oncology and anesthesiology, MPCAC works to promote and protect the integrated model of health care delivery for the benefit of all patients in Maryland. The physicians in MPCAC's member medical practices treat more than 500,000 Marylanders each year in over 1,000,000 patient encounters. In addition, and of greatest relevance here, the physicians in MPCAC's member practices perform tens of thousands of procedures in FASFs and endoscopy centers each year.

The Current CON Regulatory Framework Is at Odds with the Goals of the Triple Aim

We believe a statement in MHCC's October 19, 2017 "Study of Maryland's Certificate of Need Program" captures the perspective of the physicians in our MPCAC member practices with respect to the State's CON program:

> By restricting market entry and making it more expensive, CON regulation limits competition and the potential for more competitive markets to enhance value [and] limits potential innovations in service delivery.

We also agree with the characterization set forth in the MHCC study that the CON "regulatory process is slow, burdensome & overly legalistic."

We fail to see how—in 2018—the continuation of CON regulation of FASFs will advance the Triple Aim's goals of (1) improving the patient experience of care (including quality and satisfaction); (2) improving the health of populations; and (3) reducing the per capita cost of health care. In fact, we believe that continuing the State's CON program as applied to FASFs will undermine Maryland's ability to achieve these goals and, accordingly, we applaud the General Assembly and MHCC for undertaking a reexamination of CON.

Our MPCAC member practices report that the CON process is incredibly burdensome—both in terms of the time it takes as well as the associated costs—and there can be little doubt that the process increases overall health care costs and does not contribute positively to the patient experience. For that matter, the CON program operates as a barrier to entry for independent medical practices seeking to design innovative, cutting edge health care delivery models that would move care out of the more expensive hospital setting. And, the elimination of competition and the associated restraint of trade created by CON programs drives up the cost of care even further. We do not believe that it is worth the time, money and effort to preserve an antiquated CON program, particularly given the absence of data demonstrating that Maryland's CON program is making a meaningful contribution to the containment of health care costs.

We are also concerned that the CON program is at odds with the goal of providing Maryland patients with convenient access to the highest quality and most innovative care. Not only is CON a barrier to entry for health care providers, but it is an impediment to patient choice. Our member practices report a continuing evolution in the preferences of their patients—particularly "millennials" and other young patients—to have procedures done in the non-hospital, community setting offered by FASFs.[1] The evolution in patient preference with respect to *where* their care is delivered should not be ignored as the MHCC Taskforce considers whether CON regulation of FASFs should be eliminated.

State Health Policy Should Be Revised to Encourage the Migration of Care to FASFs

Academic and government studies consistently show that FASFs provide higher-quality care at a lower cost than hospitals. We believe this data provides compelling support for the elimination of CON regulation of FASFs. We highlight some of the key takeaways from recent literature:

- Using data on procedure length, a study found significant time savings for ASC treatment suggesting that ASCs are substantially faster than hospitals at performing outpatient procedures, after controlling for procedure type and observed patient characteristics;[2]

- Physicians who perform a higher volume of particular types of surgery at surgery centers have better surgical outcomes;[3]

[1] In the "Issues and Policies" discussion of the Proposed Permanent Regulation COMAR 10.24.11, MHCC provided extensive statistical support for the migration of care from the hospital to the FASF setting for surgical cases. COMAR 10.24.11.03 (Proposed Permanent Regulation, 2017), *available at* https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/documents/surgical%20services/COMAR%2010.24.11_Proposed_Permanent_%20Regulation_20171027.pdf. Between calendar years 2010 and 2015, the total number of outpatient surgical cases in operating rooms at Maryland hospitals decreased by 2.9% and the total number of inpatient surgical cases decreased by 15.5 percent. *Id.* During that same time period, surgeries at surgery centers in the State increased by 7.5 percent. *Id.*

[2] Munnich, Elizabeth L., Parente, Stephen T., "Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability To Meet Demand Up." Health Affairs. 2014 May; 33(5): 764-769, 768 (finding that, on average, patients who were treated in ASCs spent 31.8 fewer minutes undergoing procedures than patients who were treated in hospitals—a difference of 25% relative to the mean procedure time of 125 minutes).

[3] See, *e.g.*, Borowski, D.W., Bradburn, D.M., Mills, S.J., Bharathan, B., Wilson, R.G., Ratcliffe, A.A., Kelly, S.B., "Volume-outcome analysis of colorectal cancer-related outcomes." Abstract. British Journal of Surgery Ltd. 2010 Sep; 97(9): 1416-1430; Murphy, M.M., Ng, S.C., Simons, J.P., Csikesz, N.G., Shah, S.A., Tseng, J.F., "Predictors of Major Complications After Laparoscopic Cholecystectomy: Surgeon, Hospital, or Patient?" Abstract. Journal of the American College of Surgeons. 2010 Jul; 211(1): 73-80; Wilson, A., Marlow, N.E., Maddern, G.J., Barraclough, B., Collier, N.A., Dickinson, I.C., Fawcett, J., Graham, J.C., "Radical Prostatectomy: A Systematic Review of the Impact of Hospital and Surgeon Volume on Patient Outcome." Abstract. ANZ Journal of Surgery. 2010 Jan; 80(1-2): 24-29.

- ASCs are consistently praised for their potential to provide less expensive, faster services for low-risk procedures and more convenient locations for patients and physicians compared to outpatient departments;[4]

- A study conducted by the University of California at Berkeley found that during the four-year period 2008 to 2011, ASCs saved the Medicare program and its beneficiaries $7.5 billion and were projected, as of publication in 2013, to save the Medicare program and its beneficiaries nearly $60 billion over the next decade;[5]

- A study conducted by the United States Department of Health and Human Services estimated cost savings at $12 billion between calendar years 2012 and 2017 because the rates for surgery centers are lower for performing the same procedures as their hospital outpatient department counterparts;[6] and

- A review of commercial medical claims data found that health care costs are reduced by more than $38 billion annually due to availability of ASCs as an alternative to hospital outpatient departments, with more than $5 billion of the cost reduction accruing to the patient through lower deductible and coinsurance payments.[7]

The overarching conclusion is that FASFs are a high-quality, lower-cost substitute for hospitals as venues for outpatient surgery. Maryland's regulatory framework should be modified to encourage the proliferation of FASFs, not to inhibit their creation.

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[4] See, *e.g.*, Paquette IM, Smink D, Finlayson SR. Outpatient cholecystectomy at hospitals versus freestanding ambulatory surgical centers. J Am Coll Surg. 2008; 206 (2):301-05; Grisel J, Arjmand E. Comparing quality at an ambulatory surgery center and a hospital-based facility: preliminary findings. Otolaryngol Head Neck Surg. 2009; 141 (6):701-09.

[5] University of California Berkeley, "Medicare Cost Savings Tied to Ambulatory Surgery Centers, (2013) available at http://www.ascaconnect.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=7b33b916-f3f1-42e5-a646-35cc2f38fe4d&forceDialog=0 (last accessed Jan. 5, 2018).

[6] HHS OIG, "Medicare and Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates," Report # A-05-12-00020, (April 2014), *available at* https://oig.hhs.gov/oas/reports/region5/51200020.pdf (last accessed Jan. 5, 2018).

[7] Healthcare Bluebook and HealthSmart Analysis, "Commercial Insurance Cost Savings in Ambulatory Surgery Centers," (2016) available at http://www.ascassociation.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=829b1dd6-0b5d-9686-e57c-3e2ed4ab42ca&forceDialog=0 (last accessed Jan. 5, 2018).

CON Regulation of FASFs Should Be Eliminated and Replaced with an Alternative Regulatory Framework

It is time for Maryland to replace its CON program with an alternative approach that ensures patient access to high quality health care without setting up barriers to market entry. In short, we believe that CON regulation of FASFs should be eliminated, regardless of the number of sterile operating rooms. Instead, all FASFs should be subject to the "determination of coverage" process MHCC currently uses to evaluate prospective FASFs with only one sterilized operating room. Beyond the "determination of coverage" process, we believe that oversight of FASFs should continue through existing regulations promulgated by the Department of Health[8] and through quality assessment accreditation (e.g., the Accreditation Association for Ambulatory Health Care, Inc. the Joint Commission, the American Association for Accreditation of Ambulatory Surgery Facilities).

* * *

As Chairpersons Middleton and Pendergrass noted in their June 23, 2017 letter to MHCC's Executive Director, Ben Steffen, the All-Payer Model "[c]alls for dramatic changes in health care delivery and spending, and the Certificate of Need (CON) program must also recognize these changes." It is the view of the more than 300 physicians in MPCAC's member medical practices that the kind of "dramatic changes" needed will not happen by modifying the CON program around the edges. CON regulation of FASFs should be eliminated. The State's "determination of coverage" process, coupled with mandatory national accreditation, is an appropriate regulatory framework that will promote access to the highest quality, cost-efficient and convenient care while eliminating artificial barriers to competition and innovation.

We look forward to serving as a resource to MHCC—and to the Senate Finance and House HGO Committees—on the important work ahead.

Sincerely,

Nicholas P. Grosso, M.D.
Chairman of the Board & President, MPCAC

cc: Joe Bryce, Manis Canning & Associates

[8] COMAR 10.05.01, et seq. The existing regulatory system requires FASFs to renew their licenses every three years (COMAR 10.05.01.03(A)-(B)), to be available for surveys by the Centers for Medicare and Medicaid Services to determine continued compliance and investigate complaints (COMAR 10.05.01.05(A)), and to monitor their own personnel and the quality of services provided at the surgery center (COMAR 10.05.01.07 & 10.05.01.08).

January 8, 2018

VIA FEDERAL EXPRESS

Paul Parker
Director of the Commission's Center for Health care Facilities Planning and Development
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Mr. Parker,

I write in on behalf of SurgCenter Development and the facilities in Maryland in which SurgCenter Development has an ownership interest in response to Robert E. Moffit, Ph.D.'s November 21, 2017 letter and the accompanying questionarre. SurgCenter Development is a national outpatient surgery center development company that has developed over 180 ambulatory surgery centers across the country. In Maryland, SurgCenter is affiliated with 29 facilities performing outpatient surgeries. Of those facilities, 26 of the facilities are state licensed/Medicare certified and accrediated as one sterile operating room faciltieis that are exempt from the CON process. SurgCenter is affiliated with 3 facilities that have successfully obtained approval under the CON FASF progrm to run a facilities with two sterile operating rooms.

Based upon SurgCenter's expreince across the country and having recently worked with two of our facilities to secure a CON to expand from one sterile operating room to two (2), our view of the CON FASF regulation would be that it should either be reformed or eliminated. We make this recommendation because we believe that expanding patients access to FASFs will help Maryland to achieve the goals of the Triple Aim. Specifically, for patients who are capable of having surgery performed at a FASF it is inarguably a better and more affordable patient expreince than having surgery performed at a hospital. As compared to having surgery at a hospital, patients that have surgeries at FASFs are given much more freedom in choosing the time of their surgery, infection risks are substantailly lower, and costs are typically 40% less than hospitals.

With the above in mind and based on our expreience in other markets across the country, we would recommend that the CON regulation either be revised to allow for an exemption from the CON Program for outpatient surgical facilities with up to two sterile operating rooms or to eliminate the FASF CON requiremnet all together. In other markets without CON restrictions, SurgCenter typically opens two sterile operating room facilties and we are confident that exempting such facilities from the CON requirement would have no deterimental impact on health care in Maryland. Further, having facilities in many states without CON restrictions for ambulatory surgery centers we are of the belief that removing the FASF CON requirement would not harm health care in Maryland and may in fact improve it.

Set forth below are answers to the specific questions that you posed.

The Impact of CON Regulation on FASFs Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among FASFs?

Answer: Yes, as set forth above, we believe that for patients capable of having surgeries performed in an outpatient setting, FASFs almost always are a superior choice for both patient experience and cost.

2. Does CON regulation impose substantial barriers to market entry for new FASFs or expansion of FASFs? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

Answer: Yes. Having recently gone through the CON process twice, it is a time consuming and expensive process. If the Commission is not inclined to eliminate the CON requirement, our recommendation would be to modify the requirement to allow 2 operating room facilties without having to secure a CON.

3. How does CON regulation stifle innovation in the delivery of ambulatory surgical services under the current Maryland regulatory scheme?

Answer: There are several ways in which the current framework stifles innovation and they all generally revolve around preventing people from being able to choose the facility that best fits their needs. For example, if someone is looking to develop a new facility, they cannot focus solely on the type of facility that would best serve their needs. Rather they have to decide if having two or more operating rooms warrants the cost and delay of going through the CON process. Similarly, if an operator of an existing facility, wishes to expand that facility, that operator is faced with the significant time commitment and cost of going through the CON process. We think that the Commission would see an uptick in the innovation of the delivery of ambulatory surgical services in Maryland if the CONs regulatory scheme was either revised or removed.

Scope of CON Regulation

4. Should the scope of CON regulation be changed?

Answer: Yes

4A. Are there FASF projects that require approval by the Maryland Health Care Commission that should be deregulated?

Answer: As stated above, at a minimum, FASF's wishing to build 2 operating room facilities should be exempted from the CON review process.

4B. Are there FASF projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

Answer: No

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

Answer: We believe that it would be helpful to simplify the application and review process. As the process currently is setup, we have been required to engage consultants and attorneys each time we have sought a CON. It would be helpful if there was a streamlined and simplified process where FASFs could easily establish that they should be granted a CON.

6. Should the ability of competing FASFs or other types of providers to formally oppose and appeal decisions on projects be more limited?

Answer: For small FASFs, those with under four operating rooms we see little need for providing competitors the opportunity to oppose. We would recommend that the Commission consider a monetary or number of operating room floor that must be exceeded before comments from competitors are solicited.

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated?

Answer: No.

Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

Answer: We have no input on this question.

7. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.}

Answer: In our experience, yes, the timeline requirements of the FASF are appropriate and realistic.

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for FASFs provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

Answer: Yes, we believe the State Health Plan regulations for FASFs provide adequate and appropriate guidance for the Commission's decision-making. We believe the chief strength is that the Commission is given a fair amount of discretion. As far as weaknesses, we believe that the impact to existing providers criteria is not as important as the other factors to be considered.

9. Do State Health Plan regulations focus attention on the most important aspects of FASF projects? Please provide specific recommendations if you believe that the regulations miss the mark.

Answer: Yes, we feel that the Health Plan regulations do focus attention on the key aspects of FASF projects.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

Answer: We are not informed enough to opine on this question.

General Review Criteria for all Project Reviews

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

Answer: We believe these criteria are adequate.

Alternatives to CON Regulation

12. If you believe that CON regulation of FASFs should be eliminated, what, if any, regulatory framework should govern establishment, relocation, and expansion of FASFs?

Answer: We believe that the licensure and Medicare certification requirements that one operating room outpatient surgical facilities currently go through would be sufficient.

13. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of FASF licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that FASFs are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

Answer: We actually believe that the current licensure requirements are sufficient, but if the Commission disagrees than we do feel that an alternative regulatory mechanism could meet the benefits currently served by CON regulation.

The Impact of CON Regulation on FASF Competition and Innovation

14. Do you recommend changes in CON regulation to increase innovation in service delivery by existing FASFs and new market entrants? If so, please provide detailed recommendations.

Answer: Again, our key recommendation would be to exempt two operating room facilities from having to go through the CON process.

15. Should Maryland shift its regulatory focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition for these services?

Answer: We do not believe that a shift is necessary as there is currently plenty of competition for ambulatory surgical services in Maryland.

Scope of CON Regulation

16. Should the use of a capital expenditure thresholds in FASF CON regulation be eliminated?

Answer: It may not need to be eliminated, but the threshold should increase to allow FASF's greater flexibility in their construction.

17. Should MHCC be given more flexibility in choosing which FASF projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the FASF project to undergo CON review.

Answer: So long as this flexibility would not be used to expand the projects requiring approval, we would be in favor of granting the MHCC more flexibility in managing the process.

18. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

Answer: Expedited review is available in many states for the CON process and it may be something worthy of MHCC consideration. We would note that in our experience an additional fee is often associated with expedited review. As far as attributes, we believe that the expedited review should have a set of clear standards that FASFs can easily note their compliance with. We would recommend that expedited review only be allowed for smaller FASF projects or expansions.

The Project Review Process

19. Are there specific steps that can be eliminated?

Answer: We believe that the application for the CON process could be simplified by not digging so far into the minutiae of the proposed facility or facility expansion. Completing a CON Application currently takes many hours and requires consultant assistance. We would recommend a more straightforward application that focuses only on the most critical items at a high level.

20. Should post-CON approval processes be changed to accommodate easier project modifications?

Answer: Yes, in our experience, with build-outs and renovations there are often unforeseen issues that come up and having to come back to the Commission if these issues arise can be problematic. We would recommend that the thresholds that would require one to return to the Commission for a modification be increased.

21. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

Answer: Yes, as already stated, we believe that two operating facilities should not be subject to CON review. We would recommend that two operating room facilities be treated the same way as one operating room facilities are currently treated.

22. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Answer: Yes, we believe that is a possible means of improvement.

Duplication of Responsibilities by MHCC and MDH

23. Are there areas of regulatory duplication in FASF regulation that can be streamlined between MHCC and MOH?

Answer: Nothing jumps to mind.

Thank you for this opportunity to respond and provide comments on this process. Please feel free to reach out to me if I can be of any further assistance.

Sincerely,

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January 2, 2018

Paul Parker
Director, Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

RE: MHCC CON Study: 2017-2018

Dear Dr. Moffit,

Ashley Addiction Treatment received the request for comments on the Certificate of Need program and respectfully submits the following for consideration:

Need for CON Regulation:

Choice number 2: CON Regulation of hospital capital projects should be reformed.

Issues/Problems

The Impact of CON Regulation on Hospital Competition and Innovation:

1. *In your view, would the public and the health care delivery system benefit from more competition among health care facilities?*
   We believe that all Caveat: needs to be highly qualified participants that would all meet a standard criteria.

2. *Does CON regulation impose substantial barriers to market entry for new health care facilities or new health care services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?*
   The CON regulation does impose barriers to new health care services. The CON should ensure a consistent standard of quality in health care, but by imposing substantial barriers to market entry for new and existing health care providers it prevents the public from benefiting from a range of services and price choices in healthcare.

3. *How does CON regulation stifle innovation in the delivery of health care services under the current Maryland regulatory scheme?*
   The CON regulation stifles innovation by regulating what the health care provider does. New treatment modalities and criteria need to be considered during the CON process. We feel strongly that the Health Care Commissioners and Health Commission staff were not

educated about the latest substance use disorder treatment methods and was biased against the treatment model of Ashley.

Scope of CON Regulation

4. *Should the scope of CON regulation be changed?*
   a. Are there health care facility project that require approval by the Maryland Health Care Commission that should be deregulated?
   Yes, the scope of the CON regulation should be changed to account for current costs. The minimum financial requirement that triggers the need for a CON is too low and does not account for current costs. Additionally, if an organization has already successfully completed the CON process there should be a streamlined/fast track approach to allow organizations to make additions/expansions in a timely manner.
   b. Are there health care facility projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?
   We are unsure on this issue.

The Project Review Process

5. *What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?*
   The extended time it takes to go through the CON process is the primary choke-point. The follow up process takes too long; the requirement that an organization must wait until the Commission meets in order to proceed with the project delays completion and drives up costs. Regulators should not have preconceived opinions of how an organization delivers care when that organization has met the COMAR regulations.

6. *Should the ability of competing health care facilities or other types of providers to formally oppose and appeal decisions on projects be more limited?*
   Interested parties should always have a say in order to ensure a level playing field. Transparency needs to be ensured.

7. *Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate?*
   The project completion timelines require modification. The formula for budget calculation is outdated and does not meet current construction criteria. Organizations should have flexibility to report to commission staff when projects are delayed by environment, budget, etc. while continuing the project. Currently, organizations are forced to delay projects while waiting on the Commission staff schedule, increasing costs.

The State Health Plan for Facilities and Services

8. *In general, do State Health Plan regulations for health care facility and service projects provide adequate and appropriate guidance for the Commission's decision-*

making? What are the chief strengths of these regulations and what do you perceive to be the chief weakness?
The chief weaknesses are the timelines; meeting dates; and the need for better communication between commissioners and commission staff.

9. *Do State Health Plan regulations focus attention on the most important aspects of health care facility projects? Please provide specific recommendations if you believe that the regulations miss the mark.*
We believe that the regulations did not focus on the most important aspects of healthcare. For example, Ashley Addiction Services wanted to provide services to more people, but it seemed like the Commission did not focus on the need for more health care access points.

10. *Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.*
The methodology for developing the capital project budget is outdated.

General Review
Criteria for all Project Reviews

11. *Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?*
COMAR contains 5 general criteria; we would add a sixth criteria: "Quality of Care".

CHANGES/SOLUTIONS
Alternatives to CON Regulation for Capital Project

12. *If you believe that CON regulation of health care facility capital projects should be eliminated, what, if any, regulatory framework should govern health care facility capital projects?*
N/A

13. *What modifications would be needed in HSCRC's authority if any, if the General Assembly eliminated CON regulation of hospital capital projects.*
N/A

14. *Are there important benefits served by CON regulation that could only be fully or adequately met with alternative regulatory mechanisms?*
N/A (Ashley is not regulated by these charges.)

The Impact of CON Regulations on Hospital Competition and Innovation

15. *Do you recommend changes in CON regulations to increase innovation in service delivery by existing health care facilities and new market entrants? If so, please provide detailed recommendations.*
N/A

16. *Should Maryland shift its regulatory focus to regulation of health care facility and health systems merger and consolidation activity to preserve and strengthen competition for hospital service?*
N/A

Scope of CON Regulations

17. *Should MHCC be given more flexibility in choosing which health care facility projects require approval and which can go forward without approval, based on adopted regulations for making these decisions?*
Yes, there should be more flexibility. Those organizations that are already qualified should be fast tracked for future projects, not be made to repeat the entire process again.

18. *Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?*
Yes. Organizations who have successfully completed the CON process should be recognized as certified and in a different category from organizations who need to begin the process.

The Project Review Process

19. *Are there specific steps that can be eliminated?*
The process should not be beholden to the HCSC; the budget should not be a stumbling block in the review process.

20. *Should post-CON approval processes be changed to accommodate easier project modifications?*
Absolutely. A more streamlined response from staff should be created. Not everything should hinge on the meeting schedule of the Commission.

21. *Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.*
Yes. Details above.

22. *Would greater use of technology, including the submission of automated and form-based applications ion, improve the application submission process?*
Yes.

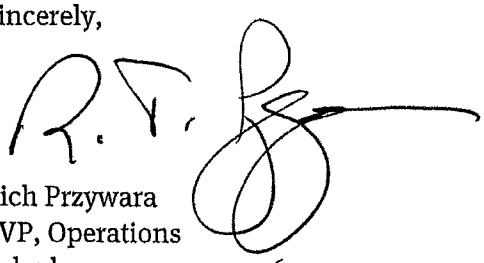
Duplication of Responsibilities by MHCC, HSCRC, and the MDH

23. Are there areas of regulatory duplication in health care facility regulatory processes that can be streamlined between HSCRC, MHCC, and MDH?
N/A

24. Are there other areas of duplication among the three agencies that could benefit from streamlining?
N/A

We are happy to discuss our responses with you at your convenience.

Sincerely,



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Garrett County Health Department

Office of Administration

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January 12, 2018

Paul Parker, Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: Certificate of Need Regulation for Health Heath Agencies

Dear Workgroup Members,

As the Health Officer for Garrett County I believe that our citizens would be best served if the Certificate of Need regulation be maintained in its current form. While relaxing the regulation may result in competition which could lead to improved services and innovation in some jurisdictions, it could have a deleterious effect on small, rural communities. In Garrett County, the Health Department has served as a provider of last resort for services that are critical to the overall health of the community and where the private sector has not been able or willing to provide service. Currently, the Garret County Health Department not only is the only provider of Home Health services in the County, it is also the only substance abuse treatment provider and operates the only outpatient mental health clinic. I include this information to demonstrate that the private sector has not stepped up to provide these critical services due to their inability to have a sound business model and also provide the level of service needed to meet the critical needs of the community. While it could be argued that other home health providers could operate in the community, our experience has been that if providers do choose to locate and develop services in the community, it will be for a carve out of those patients who allow them to maximize profits. They will not have the ability to serve all patients due to the high overhead of providing the services to a low density rural county. Our experience in other health services, such as mental health, is that there have been numerous providers over the years that open a practice only to close after it is determined that the number of patients needed to maintain a vibrant practice cannot be achieved, but also after carving out a sub group of clients who will maximize profit and mitigate risk, thus weakening the overall array of services. For substance abuse treatment, there have been no outside organizations that have located in the community despite the opportunity that exists.

While it is impossible to fully predict what will occur if home health agencies are allowed to operate in the community without first obtaining a CON, we believe the risk of jeopardizing the existing safety net great. For home health services, the Garrett County Health Department has been able to maintain a high quality service that guarantees all citizens of the county a full range of services, including skilled nursing, in-home aids, nutritional services, in-home social services, telehealth, OT, PT, etc. With the elimination of the Certificate of Need regulation, competing home health providers could operate in the community and "cherry pick" patients who are geographically concentrated in areas where a competitive business model would maximize profits. This would most likely have disastrous results for those patients who are located in outlying and hard to reach areas where providers would deny service. Garrett County has only 46

persons per square mile and a total land mass of 647 square miles. Patients' homes are often located 50 miles or more from the next patient. While it is a challenge for one home health agency in the community to serve the in-home needs of the entire county, the problem would be exacerbated if several home health agencies to operate in the County.

Another concern is that the Garrett County Commissioners contribute funds to the Garrett County Health Department in order to assure that home health services are available. While there are years when the program operates in the black, there have been years that the opposite has been true. If competing organizations were to operate in the County, it is less likely that the Board of Garrett County Commissioners will provide the stop-gap funding that assures services in all areas of the County.

In summary, I urge the workgroup to proceed cautiously in its review of the CON process. I am certain that there will be some advantages to relaxing or eliminating the CON requirement for home health services, however, I believe that the risk of increasing the health service disparity across the State is outweighed by the need to relax and/or eliminate the regulations.

In the letter we received we were asked to address questions related to the impact of the CON. Those answers as they relate to Garrett County are contained on the attachment.

Sincerely,

Robert Stephens, MS
Health Officer

Enclosures

COMMENT GUIDANCE - HOME HEALTH AGENCIES
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area
of inquiry beginning with the overarching question regarding continuation of home health agency CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of nursing home CON regulation?

D CON regulation of home health agencies should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

D CON regulation of home health agencies should be reformed.

D CON regulation of home health agencies should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on Home Health Agency Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among home health agencies?

In theory there is a benefit to more competition, but specifically for Garrett County, competition may have an adverse effect on home health services.

2. Does CON regulation impose substantial barriers to market entry for new home health agencies or expansion of home health agency service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

Yes, there is a barrier but in the case of our community, I must argue for the continuation of the Certificate of Need process.

3. How does CON regulation stifle innovation in the delivery of home health agency services under the current Maryland regulatory scheme?

Without competition there is not an external motivation to innovate. However, for public health, there is always a motivation to improve community outcomes and population health.

---

1 The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimension: (1) Improving the patient experience of care (including quality and satisfaction); (2) Improving the health of populations, and; (3) Reducing the per capita cost of health care.

4. Outline the benefits of CON given that home health services do not require major capital investment, do not induce unneeded demand, are not high costs and do not involve advanced or emerging medical technologies.

The specific benefit of the CON process in Garrett County is that it assures all residents of the community have access to high quality home health services. With "de-regulation" there is the possibility that services for "high cost/low profit" will not be adequately served.

Scope of CON Regulation

*Generally, Maryland Health Care Commission approval is required to establish a home health agency or expand the service area of an existing home health agency into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at: htt p:// www.dsd.state.md.us/comar/SubtitleSearch.aspx?search:::10.24.01.**

5. Should the scope of CON regulation be changed? *No*
   A. Are there home health agency projects that require approval by the Maryland Health Care Commission that should be deregulated?
   B. Are there home health agency projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

The **Project Review Process**

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process? *No comment*

7. Should the ability of competing home health agencies or other types of providers to formally oppose and appeal decisions on projects be more limited? *No*

   Are there existing categories of exemption review {see COMAR 10.24 .01. 04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

Yes. The timelines and performance requirements are appropriate.

---

2 Under Maryland CON law, home health agencies are classified as "healthcare facilities."

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for home health agencies provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

Yes, but I would defer to the Commission members' opinion on this point.

10. Do State Health Plan regulations focus attention on the most important aspects of home health agency projects? Please provide specific recommendations if you believe that the regulations miss the mark. *Yes*

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations. *No comment*

General Review Criteria for all Project Reviews

COMAR 10.24.01.0BG(3}(b)-(f)) containsfive general criteriafor review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

Yes. The criteria are adequate and appropriate

CHANGES/SOLUTION S

Alternatives to CON Regulation

13. If you believe that CON regulation of home health agencies should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies? *Not applicable*

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of home health agency licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that home health agencies are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under- utilization or poor quality of care?

There are possible benefits that could be addressed through licensure or an accreditation process

The Impact of CON Regulation on Home Health Agency Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing home health agencies and new market entrants? If so, please provide detailed recommendations.

The relaxing of CON regulation will increase innovation by driving down cost and improving patient experiences in communities where several vibrant home health agencies are competing for patients. However, in small communities like Garrett County, the relaxing of the regulation may lead to confusion in the "market" and undermine the quality of care.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of home health agencies to preserve and strengthen competition for home health agency services?

The Impact of CON Regulation on Home Health Agency Access to Care and Quality

1. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
   Note: docketing is the determination by the MHCC when an application is judged complete and Ready for review.

There is a need to assure that quality care measures are in place prior to the docketing.

Scope of CON Regulation

2. Should MHCC be given more flexibility in choosing which home health agency projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the home health agency to undergo CON review. *Yes*

3. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

Not certain. The Commission has better insight regarding this question.

The Project Review Process

4. Are there specific steps that can be eliminated? *No*

5. Should post-CON approval processes be changed to accommodate easier project modifications? *Yes*

6. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

No experience with the process. No opinion.

7. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process? *Yes*

Duplication of Responsibilities by MHCC and MOH

8. Are there areas of regulatory duplication in home health agency regulation that can be streamlined between MHCC and MDH?

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry.

HEALTH CARE for All
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MARYLAND CITIZENS' HEALTH INITIATIVE

January 12, 2018

Paul Parker
Maryland Health Care Commission
Center for Health Care Facilities Planning and Development
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Parker:

Thank you for this opportunity to provide comments to inform MHCC's recommendations on reforming the health planning and certificate of need (CON) program. We commend MHCC on examining this important issue, and are delighted to see that MHCC has committed to including a consumer representative on the upcoming workgroup. Examining potential reforms is a prime opportunity to further Maryland's goals of achieving the Triple Aim of delivering the right care in the right place at the right time.

To your question about the need for CON regulation, we think that CON regulation should be reformed and not eliminated. Our vision of a patient centered health care system is one in which everyone has access to quality, affordable healthcare. We believe that a strong CON program could enable health care facilities to make capital improvements that help them compete in ways that serve population health goals, promote innovative health delivery methods, achieve equitable health care access, and contain costs. From a consumer perspective, the state's CON program should be reformed to:

1. ensure that quality, affordable, health care services are equitably provided to residents and be delivered in a way that improves health outcomes;
2. maximize use of high cost devices, technology, services, and facilities so as to contain health care costs and increase efficiency;
3. ensure that approved projects are financially feasible and deliver on promised service delivery;
4. protect consumers from abrupt service interruption or withdrawal; and
5. be more transparent to consumers and taxpayers, more generally.

Maryland is one of 35 states that currently have a CON program. In one national rating of CON programs across different states, Maryland scores a B-.[1] We recommend that MHCC examine the practices of the six states that received scores of A or A- to continue to make improvements[2], including Massachusetts

[1] http://whenhospitalsmerge.org/maryland
[2] https://static1.squarespace.com/static/568ad532cbced6b473f20732/t/57962bcc414fb5c7c3766775/1469459434906/MergerWatch_CON_report_June2016.pdf

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which recently adopted strong policies requiring community engagement and investment in community health initiatives.[3,4]

More specifically, we recommend that the workgroup consider strengthening the CON program with the suggestions provided by the MergerWatch Program including:

- [Q. 5] Require that the MHCC or any separate CON review board include at least one consumer representative.
- [Q. 11] CON review should consider whether the project has an impact on underserved populations (e.g., whether the facility or service will deliver equitable care to communities of color and lower-income populations).
- [Q. 5] The public that lives nearby the CON project should be notified about CON applications via newspaper, the internet, or another widely circulated local platform and have a chance to submit testimony that will be considered by the Commissioner-Reviewer.

Thank you again for this opportunity to submit comments, and for MHCC's commitment to promoting strong health delivery models that serve as models for the nation.

Sincerely,

Vincent DeMarco, President
Maryland Citizens' Health Initiative

[3] https://www.mass.gov/determination-of-need-don
[4] https://www.mass.gov/files/documents/2017/01/vr/guidelines-community-engagement.pdf

Appendix F

Fact Sheets

Hospital Fact Sheet
CON Modernization Task Force
2018

Inventory:

There are 47 general hospitals and 32 special hospitals currently operating in Maryland.

There are 9,611 licensed acute care beds in general hospitals in FY 2018. This number is determined by a formula based on 140% of observed average daily census (i.e., the licensed bed capacity has an allowance for approximately 29% of beds at each hospital to be empty on an average day, based on the observed average daily census used in the formula). General hospitals reported total physical bed capacity for 11,635 acute care beds in 2016.

There are 17 freestanding special hospitals currently operating in Maryland.

- Nine are psychiatric hospitals. Five of these are operated by the state and are licensed to operate 1,658 beds. They reported staffing 957 beds in 2016. Four are private psychiatric hospitals. These four have 586 licensed beds. They reported staffing 508 beds in 2016.

- Two are medical rehabilitation hospitals with 146 licensed beds.

- Three are chronic care hospitals operated by the state with 226 licensed beds and 140 beds reported as staffed in 2016.

- Three are pediatric hospitals with 100 licensed beds and 91 beds reported as staffed in 2016.

There are four additional chronic care hospitals (238 licensed beds/141 staffed beds) and 11 medical rehabilitation hospitals (362 licensed beds) operated on general hospital campuses. There is one facility in Maryland that has a chronic hospital (100 beds) and a medical rehabilitation hospital (20 beds) that does not function as a general acute care hospital.

Use:

The formula used for licensing acute care bed capacity means that the overall average annual occupancy rate of licensed beds for most general hospitals, that have the ability to set up and staff beds equal to their licensed capacity if sufficient demand warrants, will typically be around 70 to 72%. Statewide, the average daily census used to establish licensed acute care bed capacity for FY 2018 is equivalent to 59% of the physical bed capacity reported in 2016. Staffed bed occupancy can be higher for particular categories of acute care bed (e.g., staffed bed occupancy statewide for acute psychiatric beds licensed as part of general hospital bed complements was reported to be 81% in 2015.)

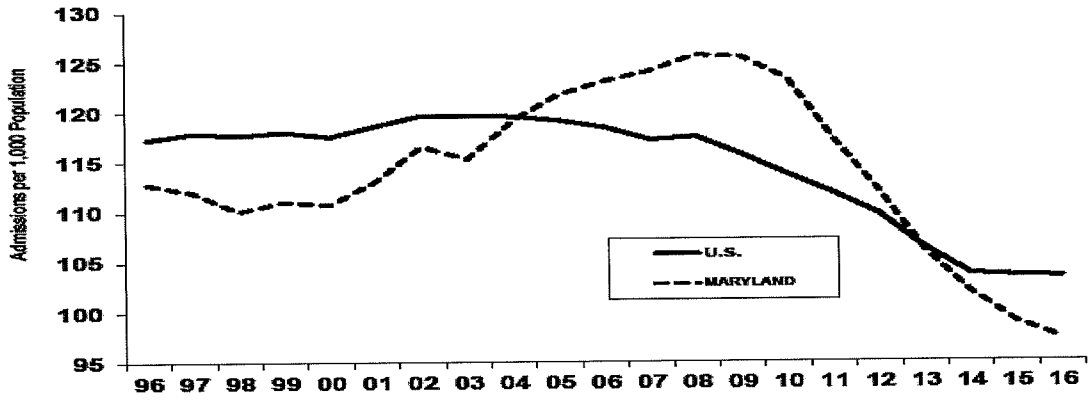
Six general hospitals reported having more licensed bed capacity than physical bed capacity in 2016.

The average occupancy rate of licensed bed capacity in state psychiatric and chronic care hospitals is low (as evidenced by the disparity reported between licensed bed capacity and staffed bed capacity).

Special rehabilitation hospital bed capacity (freestanding and on general hospital campuses) is estimated to have experienced an average annual occupancy rate of 67% in CY 2016.

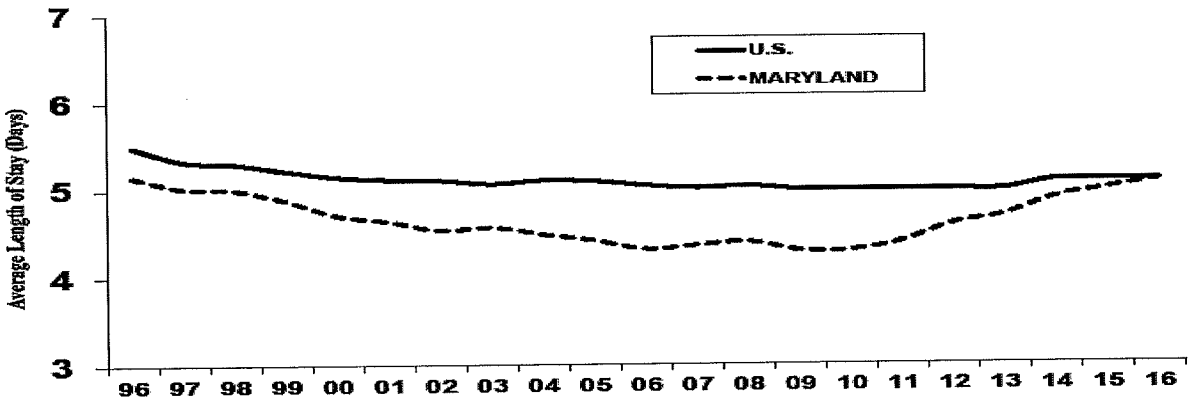
Population Use and Average Length of Stay (General Hospitals)

Chart 6: Hospital Admissions per 1,000 Population
All Hospital Unit Admissions (Excludes NH Unit Admissions)
U.S. and Maryland
1996-2016



Source: AHA Hospital Statistics

Chart 7: Hospital Average Length of Stay
All Hospital Unit Admissions (Excludes NH Unit Admissions)
U.S. and Maryland
1996-2016



SOURCE: AHA HOSPITAL STATISTICS

2

Regulatory Scope:

- CON approval is required to establish, relocate, or change the bed capacity of a hospital.

- CON approval is required to change the type of scope of services provided by a hospital in certain ways. These include adding medical/surgical, obstetric, pediatric, or psychiatric services. It also includes introducing cardiac surgery, PCI, neonatal intensive care, rehabilitation, or burn intensive care.

- In most cases, CON approval is required to add operating rooms to a hospital.

- Most general hospitals are now part of multi-hospital systems. This means that some redistribution of resources can be accomplished though approval of exemptions from CON.

Maryland vs. the U.S. [Source: AHA Hospital Statistics]
These supply and use comparisons are for general hospitals only.

Supply – 2015

Hospitals per 100,000 population
- Maryland – 0.8
- U.S. – 1.5

Average Beds per Hospital (excludes separate nursing home units)
- Maryland – 229
- U.S. – 152

Hospital Beds per 1,000 Population (excludes separate nursing home units)
- Maryland – 1.9
- U.S. – 2.3

Use -2015

Average Annual Occupancy Rate of Hospital Beds (excludes separate nursing home units)
- Maryland – 70.5%
- U.S. – 62.4%

Average Length of Stay (excludes separate nursing home units)
- Maryland – 5.0 days
- U.S. – 5.1 days

Nursing Home Fact Sheet

CON Modernization Task Force

March 23, 2018

Facilities, Quality, Innovation:

- 229 licensed comprehensive care facilities (CCFs) with 28,452 beds
- Average bed occupancy statewide: 89% in 2015
- CCF use rates have been trending down for all age groups, except <65, for many years
- Number of licensed CCF beds has declined 3.3% between 2007 and 2015
- Payor Mix (2015): Medicaid (61%), Medicare (19%), private pay (14%), other (6%)
- Nursing Home Compare Star Ratings: Maryland (30% facilities rated as below or much below average) compared to 32% nationally - Maryland (48%) above or much above average compared to 49% nationally
- Innovations: Erickson has formed a Medicare Advantage plan; 16 Maryland facilities participate in MedStar's MSSP ACO; 21 Maryland facilities are participating in Accountable Care Coalition of the Chesapeake, a CMS Next Gen Accountable Care Organization; one facility is in the CMS's Bundled Payments for Care Improvement Model 3 program; several nursing home are partnering with hospitals on telehealth projects.

Regulatory Scope:

- CON approval required to establish a CCF, relocate a CCF, add beds to a CCF, make a capital expenditure of $6+ million
- Current CCF State Health Plan adopted in 2007 – update anticipated in 2018
- Bed need projection is primary approach in SHP for regulating supply of CCF beds – bed supply regulated on a jurisdictional basis.
- Continuing care retirement communities have exception to CON approval requirements for a limited number of CCF beds to exclusively serve continuing care contract holders
- CCFs obtaining CONs must agree to serve Medicaid patients with required minimum participation levels based on geographic location

Supply – 2014

Nursing Homes
- Maryland – 3.8 per 100,000 population
- U.S. – 4.9 per 100,000 population

Nursing Home Beds
- Maryland – 4.6 per 1,000 population
- U.S. – 5.4 per 1,000 population

Average Beds per Facility
- Maryland – 122
- U.S. – 109

Average Annual Bed Occupancy Rate
- Maryland – 89.7%
- U.S. – 82.3%

Home Health Agency Fact Sheet

CON Modernization Task Force

March 23, 2018

Agencies, Quality, Innovation

- 55 licensed home health agencies (HHAs) – most are authorized to serve multiple jurisdictions – some do not serve all authorized jurisdictions
- In 2014, HHAs reported 111,378 clients (unduplicated count) and 1,813,878 home visits - overall average of 16.3 visits per client
- Payor Mix: Medicare (72%); Private insurance (22%), Medicaid (5%).
- CMS Home Health Compare dataset (January 2018): Quality of Patient Care Star Rating (Maryland average = 4.0 Stars; National average = 3.5 Stars); HHCAHPS Survey Summary Star Rating (Maryland average = 3.0 Stars; National average = 4.0 Stars).
- Recent Innovations: CMS imposed Value-Based Purchasing and joint ventures with hospital systems.

Regulatory Scope and CON Activities

- HHAs are the only type of home care provider required to obtain a CON to be established or to expand into new jurisdictions – Only HHAs serve Medicare patients
- Residential Service Agencies (1,187 licensed) are unregulated and provide services for private payment and some limited Medicaid reimbursement
- 21 HHAs entered Maryland through acquisition of an existing HHA.
- Current HHA State Health Plan was adopted in April 2016 – Established new CON review process: (1) determining jurisdictional need; (2) qualifying an applicant; and (3) determining preference in a comparative review.
- SHP does not project need for HHA or HHA capacity – jurisdictions are opened for new HHAs to enter the market based on insufficient consumer choice of HHAs; a highly concentrated HHA service market; or an insufficient choice of high performing HHAs.
- Quality measures and performance thresholds are approved by the Commission for use in opening up jurisdictions and qualifying applicants.
- SHP allows for use of multi-jurisdictional regions in CON review.
- In 2017, 15 jurisdictions were opened up and configured into 4 regions.

Supply in 2014

- Maryland – 0.9 HHAs per 100,000 population
- USA – 3.9 HHAs per 100,000 population

Hospice Fact Sheet

CON Modernization Task Force

March 23, 2018

Programs, Quality, Innovation:

- 27 licensed general hospice programs - many serve multiple jurisdictions
- 14 jurisdictions are served by a single general hospice
- Some hospices provide inpatient hospice care directly – most arrange for inpatient care provision through an existing hospital or nursing home
- Use rates for hospice are trending higher - utilization is lower for minority populations
- Major payer is Medicare (86% of patient days in 2016)
- Collection and reporting of hospice quality measures in early stages: Hospice Item Set began 2014; Hospice CAHPS 2015. Hospice Compare launched August 16, 2017
- Innovations: community education; telehealth initiatives; pet therapy, massage therapy, music therapy; specialized pediatric programs; elder medical program; Medicare Choice grant (permits patients to pursue active treatment while using hospice)

Regulatory Scope:

- CON approval is needed to establish a general hospice, expand an existing hospice's services into a new jurisdiction, change the bed capacity of a hospice, or make a capital expenditure of $6+ million for any purpose
- Current hospice State Health Plan adopted in 2013; not implemented until 2016
- SHP does not project need for hospices or hospice capacity – jurisdictions are opened for application review based on relatively low use rate of hospice services
- Hospice provides end of life care and pain management, primarily in the home; the effect is reduction in the use of hospital services and ICUs
- Baltimore City and Prince George's Counties currently opened for review
- MHCC facilitated meetings on hospice outreach and educating the public on hospice services in 2013 - 2015

Supply - 2014

- Maryland – 0.5 per 100,000 population
- USA – 1.3 per 100,000 population

Residential Treatment Center Fact Sheet
CON Modernization Task Force
2018

Residential treatment centers (RTCs) provide "campus-based intensive and extensive evaluation and treatment of children and adolescents with severe and chronic emotional disturbance or mental illness who require a self-contained therapeutic, educational, and recreational program in a residential setting whose length of stay averages between 12 and 18 months. RTCs typically also offer outpatient day treatment services and schooling for children and adolescents who are unable to live at home.

Residents admitted to RTCs are primarily referred from state juvenile justice and service agencies.

Supply:

- There are seven residential treatment centers currently operating in Maryland with a total of 382 beds. The facilities are located in four jurisdictions; Baltimore County has three centers, Baltimore City has two centers, and Frederick and Montgomery County each have one center.

- The demand for and supply of RTC facilities has been steadily dwindling. In 2001, there were 14 RTCs with 765 licensed and approved beds operating in eight jurisdictions of Maryland. Anne Arundel, Dorchester, Howard, and Prince George's Counties had RTC facilities in 2001 that no longer exist.

- In the past two years alone, two RTCs have ceased operation and been permanently delicensed and a third is currently out of operation and its temporarily delicensed status will expire in mid-2018. MHCC currently has one CON application to establish an RTC in Prince George's County under review.

Use:

- Sources for consistent and accurate reporting of utilization data for RTC services do not exist.

- Information developed by MHCC in the course of a CON application review indicates that in CY 2016, licensed RTC beds in Maryland were used at an average annual occupancy rate of approximately 68% and that staffed RTC beds were used at an average annual occupancy rate of approximately 84%.

Regulatory Scope:

- CON approval is required to establish, relocate, or change the bed capacity of an RTC.

- Some RTCs are part of multi-facility systems. This means that some redistribution of resources can be accomplished though approval of exemptions from CON.

Alcohol and Drug Abuse Treatment Intermediate Care Facilities Fact Sheet
CON Modernization Task Force
2018

"Alcohol and drug abuse treatment intermediate care facilities (ICFs)" is a term that is no longer in common usage. "Intermediate care facilities" are a regulated category of health care facility in the CON statute. Historically, with respect to addictions treatment, this term has been used to describe substance abuse detoxification and treatment programs operating at the American Society of Addictions Medicine (ASAM) Level 3.7. This level of care is medically-monitored intensive inpatient detoxification and/or treatment services that involve 24-hour nursing care with a physician's availability for significant problems. The Maryland Department of Health uses the ASAM level of care classification system in its licensing and certification program for addictions treatment service providers.

Supply

- There are 18 Level 3.7 programs in Maryland with approximately 770 beds and three additional programs have been authorized but are not yet operational. Less than four percent of the substance abuse programs identified by the Behavioral Health Administration in its *Maryland Certified Treatment Directory* provide this level of treatment.

- Across the full continuum of substance abuse treatment facilities and programs in Maryland, the CON program only regulates this specific category of treatment facility and these facilities comprise a very small segment of the treatment universe.

Use

- Sources for consistent and accurate reporting of utilization data for these facilities do not exist.

Scope of CON Regulation

- CON approval is required to establish, relocate, or change the bed capacity of an alcohol and drug abuse treatment ICF.

- CON approval is required for a capital expenditure by or on behalf of an alcohol and drug abuse treatment ICF that exceeds the statutory capital expenditure threshold (currently $6 million).

- The State Health Plan regulations for this category of health care facility recognizes two types of facility based on the source of payment. Track 1 facilities primarily serve patients whose treatment is paid for from private payers. The SHP has a quantitative limit on the number of Track 1 beds that can be approved in a region. Track 2 facilities primarily serve patients whose treatment is paid for from public payment programs. The SHP has no quantitative limit on the number of Track 2 beds that can be established.

Appendix G

The Time Required for CON Project Review

APPENDIX G: Projects Filed in July 2011 or Later for which Final Action by MHCC or Withdrawal by the Applicant has Occurred
Length of Project Review CORRECTED MAY 2018

Type of Project (Basis for Review)	Date of Application Filing	Date of Docketing of Application	Date of Final Action or Withdrawal	Type of Review	Project Cost Estimate	Application Filing to Docketing (Days)	Docketing to Action or Withdrawal (Days)	Application Filing to Action or Withdrawal (Days)
Change in bed capacity of a general hospice	7/28/2011	10/7/2011	7/18/2013	Contested	$1,075,211	71	649	720
Introduce acute rehabilitation services at a general hospital	4/6/2012	6/15/2012	8/29/13*	Uncontested	$7,557,170	70	440	510
Capital expenditure by a general hospital	7/6/2012	10/5/2012	2/21/2013	Uncontested	$23,539,350	91	139	230
Change in bed capacity of an alcohol and drug abuse ICF	1/25/2013	5/17/2013	9/19/2013	Uncontested	$20,928,056	112	125	237
Change in bed capacity of a general hospice	6/21/2013	10/4/2013	6/19/2014	Uncontested	$458,343	105	258	363
Relocation of an ambulatory surgery center and addition of an operating room	7/5/2013	9/20/2013	11/21/2013	Uncontested	$891,000	77	62	139
Change in bed capacity of a general hospice	9/30/2013	3/21/2014	12/18/2014	Contested	$1,388,372	172	272	444
Relocation of a general hospital	10/4/2013	12/12/2014	12/17/2015	Contested	$400,198,988	69	370	439
Establishment of a comprehensive care facility	10/4/2013	2/7/2014	9/3/15*	Contested	$13,013,500	126	573	699
Establishment of a comprehensive care facility	10/4/2013	2/7/2014	4/17/2014	Uncontested	$30,995,328	126	69	195
Relocation of a general hospital	10/4/2013	4/3/2015	10/20/2016	Contested	$543,000,000	546	565	1,111
Relocation of an ambulatory surgery center and addition of two operating rooms	1/31/2014	4/4/2014	7/17/2014	Uncontested	$3,637,265	63	104	167
Establishment of a general hospice	6/2/2014	8/8/2014	9/18/2014	Uncontested	$225,100	67	41	108
Change in bed capacity of a comprehensive care facility	9/12/2014	11/14/2014	2/19/2015	Uncontested	$25,025,000	63	97	160
Change in bed capacity of a comprehensive care facility	9/12/2014	1/23/2015	3/19/15*	Uncontested	$160,000	133	55	188
Change in bed capacity of a general hospice	10/29/2014	1/23/2015	3/19/2015	Uncontested	$7,015,000	86	55	141
Establishment of a residential treatment center	10/29/2014	10/16/2015	4/7/17*	Contested	$3,693,760	352	539	891
Change in bed capacity of a comprehensive care facility	2/6/2015	4/3/2015	7/16/2015	Uncontested	$5,807,345	56	104	160
Establishment of a comprehensive care facility	2/6/2015	4/3/2015	6/18/2015	Uncontested	$12,215,376	56	76	132
Introduce cardiac surgery at a general hospital	2/20/2015	6/26/2015	3/23/2017	Contested	$2,500,381	126	608	734
Introduce cardiac surgery at a general hospital	2/20/2015	6/26/2015	3/23/2017	Contested	$1,259,117	126	608	734
Establish an alcohol and drug abuse ICF	3/27/2015	10/16/2015	1/26/2017	Contested	$16,783,294	203	468	671
Establish an alcohol and drug abuse ICF	3/27/2015	10/16/2015	12/15/2016	Contested	$7,388,582	203	436	639

Establish an alcohol and drug abuse ICF	3/27/2015	10/16/2015	1/26/2016	Contested	$12,239,219	203	468	671
Change in bed capacity of a comprehensive care facility	4/10/2015	6/12/2015	9/17/2015	Uncontested	$3,680,000	63	97	160
Relocation of a special psychiatric hospital	4/10/2015	9/18/2015	9/20/2016	Uncontested	$96,532,907	161	368	529
Capital expenditure by a general hospital	4/10/2015	9/4/2015	5/19/2016	Uncontested	$207,251,608	147	258	405
Establish an ambulatory surgery center	8/7/2015	12/11/2015	9/20/2016	Uncontested	$16,340,840	128	283	411
Capital expenditure by a general hospital	10/9/2015	3/4/2016	11/17/2016	Uncontested	$51,654,138	147	258	405
Change in condition of operation of a residential treatment center	12/22/2015	5/13/2016	7/21/2016	Uncontested	$80,000	143	69	212
Addition of an operating room by an ambulatory surgical facility	2/5/2016	5/13/2016	6/17/2016	Uncontested	$2,253,239	98	35	133
Establish an alcohol and drug abuse ICF	3/21/2016	6/10/2016	12/15/2016	Uncontested	$1,936,275	81	188	269
Capital expenditure by a comprehensive care facility	4/8/2016	1/16/2017	5/18/2017	Uncontested	$29,691,826	283	122	405
Change in bed capacity of a comprehensive care facility	5/6/2016	7/8/2016	10/20/2016	Uncontested	$10,195,736	63	104	167
Addition of an operating room by an ambulatory surgical facility	7/8/2016	9/16/2016	12/15/2016	Uncontested	$266,397	70	91	161
Change in bed capacity of a comprehensive care facility	8/5/2016	10/28/2016	2/16/2017	Uncontested	$5,457,500	84	111	195
Capital expenditure by a general hospital	8/5/2016	12/9/2016	6/15/2017	Uncontested	$70,000,000	126	188	314
Addition of an operating room by an ambulatory surgical facility	1/6/2017	3/3/2017	4/20/2017	Uncontested	$1,998,352	56	48	104
Addition of jurisdictions to the service area of a home health agency	3/10/2017	6/9/2017	7/20/2017	Uncontested	$34,000	91	406	497
Addition of an operating room by an ambulatory surgical facility	2/3/2017	4/28/2017	6/15/2017	Uncontested	$216,925	84	48	132
Addition of an operating room by an ambulatory surgical facility	2/3/2017	4/28/2017	7/20/2017	Uncontested	$741,499	84	83	167
Establishment of a special psychiatric hospital	3/28/2016	10/14/2016	4/19/2018	Contested	$24,984,795	200	552	752
Capital expenditure by a comprehensive care facility	4/7/2017	12/8/2017	2/15/2018	Uncontested	$14,273,000	245	69	314
Change in bed capacity of a comprehensive care facility	4/7/2017	7/7/2017	9/19/2017	Uncontested	$6,799,182	91	74	165
Change in bed capacity of a comprehensive care facility	4/7/2017	9/1/2017	10/19/2017	Uncontested	$138,000	147	48	195
Addition of an operating room by an ambulatory surgical facility	7/7/2017	9/29/2017	11/16/2017	Uncontested	$1,759,618	84	48	132
Capital expenditure exceeding threshold by a general hospice	8/14/2017	10/13/2017	12/21/2017	Uncontested	$7,998,114	60	69	129
Addition of an operating room by an ambulatory surgical facility	10/6/2017	1/19/2018	3/15/2018	Uncontested	$183,031	105	55	160
Capital expenditure by a comprehensive care facility	11/13/2017	3/16/2018	4/19/2018	Uncontested	$19,219,869	123	34	157

*Application withdrawn following negative recommendation by staff or Commissioner/Reviewer

49 Projects Filed between July 2011 and November 2017 that obtained final action by MHCC or were withdrawn

Average number of days from application filing to docketing of application:	**128 (4.2 months)**
Average number of days from docketing to final action or withdrawal:	**222 (7.3 months)**
Average number of days from application filing to final action or withdrawal:	**350 (11.5 months)**
Median number of days from application filing to docketing of application:	**105 (3.5 months)**
Median number of days from docketing to final action or withdrawal	**117 (3.8 months)**
Median number of days from application filing to final action or withdrawal:	**222 (7.3 months)**