

**Home Health Services  
Pediatrics at Home  
Pharmaquip**  
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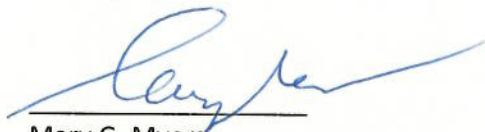


January 24, 2018

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.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?  
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.OBG(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.