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**VIA FEDERAL EXPRESS**

Paul Parker  
Director of the Commission's Center for Health care Facilities Planning and Development  
4160 Patterson Avenue  
Baltimore, Maryland 21215

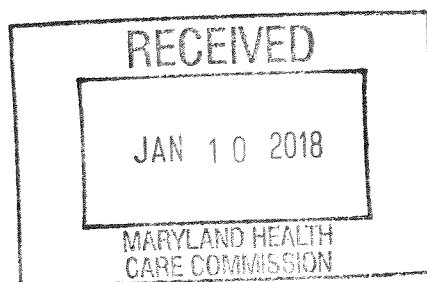
Dear Mr. Parker,

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 questionnaire. 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 accredited as one sterile operating room facilities that are exempt from the CON process. SurgCenter is affiliated with 3 facilities that have successfully obtained approval under the CON FASF program to run a facilities with two sterile operating rooms.

Based upon SurgCenter's experience 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 experience 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 substantially lower, and costs are typically 40% less than hospitals.

With the above in mind and based on our experience 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 requirement all together. In other markets without CON restrictions, SurgCenter typically opens two sterile operating room facilities and we are confident that exempting such facilities from the CON requirement would have no detrimental 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 facilities 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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