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.

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[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? 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.