

COMMENT SUMMARY- CERTIFICATE OF NEED REGULATION OF AMBULATORY SURGICAL FACILITIES

Comments were received from:

- Ambulatory Plastic Surgery Associates**
- Baltimore Washington Eye**
- Chesapeake Eye Surgery**
- Johns Hopkins Medicine**
- Kahn Center for Pain Management**
- Maryland Patient Care and Access Coalition**
- SurgCenter Development**

Need for CON Regulation

Among the seven facilities that provided comments, four facilities believed that CON regulation of ambulatory surgical facilities (ASFs) should be eliminated. Two facilities commented that ASFs should continue to be regulated but that CON regulation should be reformed. One facility believes that CON should either be eliminated or reformed.

Facility	Eliminate CON	Reform CON	Eliminate or Reform CON
Ambulatory Plastic Surgery Associates		X	
Baltimore Washington Eye	X		
Chesapeake Eye Surgery	X		
Johns Hopkins Medicine		X	
Kahn Center for Pain Management	X		
Maryland Patient Care and Access Coalition	X		
SurgCenter Development			X

Issues/Problems

The Impact of CON Regulation on Competition and Innovation

Ambulatory Plastic Surgery Associates

- The public and health care delivery system will benefit from more competition among ASFs.
- CON regulation imposes substantial barriers to market entry for new ASFs. The bar should be lower for need and higher for appeals from competing ASFs.
- CON stifles innovation by requiring pre-approval for capital expenditure.

Maryland Patient Care and Access Coalition

- Quoted MHCC’s October 2017 statement: “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.”

Freestanding Ambulatory Surgery Facilities Comment Summary

- The regulatory process is slow, burdensome and overly legalistic. The process is burdensome both in terms of time and associated costs.
- 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.
- Elimination of competition and the associated restraint of trade created by CON drives up the cost of care even further.
- The CON program as applied to ASFs will undermine Maryland's ability to achieve the Triple Aim goals. Applaud the General Assembly and MHCC for undertaking a reexamination of CON.
- CON program is at odds with the goal of providing Maryland patients with convenient access to the highest quality and the most innovative care. It's a barrier to entry for providers but also an impediment to patient choice.

SurgCenter Development

- The public and health care delivery system will benefit from more competition among ASFs.
- CON regulation imposes substantial barriers to market entry for new ASFs or expansion of ASFs. If the Commission is not inclined to eliminate the CON requirement, it should modify requirement to allow the development of two operating room facilities without having to secure a CON.
- CON stifles innovation by preventing people from being able to choose the facility that best fits their needs. When it comes to developing new facilities, applicants need to consider if having two or more operating rooms warrants the cost and delay of going through the CON process, which takes away from focusing truly on what the community needs.

Johns Hopkins Medicine

- There is adequate competition among ASFs in Maryland. There are more ASFs in Maryland than any other state.¹ The lack of regulation of one operating room ASFs create a perverse incentive for the creation of these FASFs over larger centers.
- CON provides an appropriate barrier to entry.
- The focus on rigid, outdated measures of "minimum utilization" for operating rooms overlooks other potential efficiencies and quality benefits of new facilities or expansions.

Scope of CON Regulation

Ambulatory Plastic Surgery Associates

- Capital expenditure threshold of ASF projects should be deregulated.
- No ASF project that currently does not require approval by MHCC should be added to the scope of CON regulation.

¹ Some clarification is needed here. The commenter is correct in noting that there are more Medicare-certified ambulatory surgery centers (ASCs) in Maryland than in any other state. But most of these ASCs are not regulated under the CON law in Maryland. Maryland law defines a CON-regulated ambulatory surgical facility as a non-hospital outpatient surgical provider operating two or more operating rooms. All non-hospital outpatient surgical providers are licensed as ambulatory surgical facilities by the Maryland Dept. of Health and are Medicare-certified ASCs.

Freestanding Ambulatory Surgery Facilities Comment Summary

SurgCenter Development

- ASFs wishing to build two operating room facilities should be exempted from CON review.
- No ASF that currently does not require approval by the MHCC should be added to the scope of CON regulation.

Johns Hopkins Medicine

- No ASF projects that currently require approval should be deregulated.
- One operating room ASFs should, at a 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. Current Chapter creates perverse incentive to develop one operating room ASFs.

Project Review Process

Ambulatory Plastic Surgery Associates

- Preapproval of CON requirement is primary choke-point in the review process.
- Competing ASFs or other types of providers should still be able to speak their case, but less weight should be given to these comments.
- Capital expenditure threshold approval should be eliminated.
- Greater flexibility should be given for project completion timelines, performance requirements, etc.
- In general, the State Health Plan (SHP) provides adequate and appropriate guidance for the Commission's decision making. The SHP should focus more attention on lowering the bar for need and eliminating capital expenditure threshold.

SurgCenter Development

- The review process should be simplified. Consultant and attorney engagements are required with the current process each time that SurgCenter has sought a CON.
- For small FASFs, i.e. those with under four operating rooms, there's little need for providing competitors the opportunity to oppose. Recommend the Commission consider a monetary or number of operating room floor that must be exceeded before comments from competitors are solicited.
- No existing categories of exemption review should be eliminated.
- The project completion timelines and performance requirements for ASF are appropriate and realistic.
- In general, SHP provides adequate and appropriate guidance for the Commission's decision making. The impact of existing providers criteria is not as important as other factors to be considered.

Johns Hopkins Medicine

- Completeness questions should be limited to one round and should be limited to information that is essential under the regulations.
- The determination of "qualified for interested party status" should be more rigorous when it comes to opposing and appealing decisions.

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- No existing categories of exemption review should be eliminated.
- Further consolidation of health care facilities should be encouraged by maintaining exemption review of merged asset systems.
- Greater flexibility should be built into the performance requirements without undermining the purpose of ensuring that projects move forward in a timely manner.
- The SHP provides adequate guidance for decision making. But current regulations do not adequately consider safety and quality performance, the role of ASFs in reducing health care costs, or the ways in which ASFs are in some instances able to provide a better patient experience and better meet patient needs.
- Appreciate MHCC involving stakeholders and receiving broad input, but the input does not always receive full consideration or vetting. There should be more robust conversation throughout the process, not just initially, and to have discussion of issues with the full commission rather than just having staff present a final product that is then subject to a yes or no vote.

General Review Criteria for all Project Reviews

Ambulatory Plastic Surgery Associates

- Lower the bar for need and eliminate capital expenditure threshold.

SurgCenter Development

- Criteria for all project reviews are adequate.

Johns Hopkins Medicine

- Availability of more cost-effective alternatives should be eliminated for ASFs. Financial feasibility of the project should continue to be standard for review. Because financing is not linked to the rate-setting system but at the risk of the developer, there should not be an obligation for applicants to present alternatives and their relative cost-effectiveness. This is burdensome with no benefit.

Changes/Solutions

Alternatives to CON Regulation

Chesapeake Eye Surgery

- MHCC should be responsible to govern establishment, relocation and expansion of ASFs, but without a formal CON approval.
- The need for new health care facilities should not be determined solely by MHCC, but by the physicians involved in building the centers.
- Shared responsibility for CON approval should also be dependent on factors like cost effectiveness of approach, geographical locations, financial feasibility, and whether a facility will create financial burden on any other centers in the proposed area.
- Deregulation of the CON process can still provide important benefits to ASFs. Existing centers will still need Department of Health approval through surveys to maintain quality of care. The public will be guided to ASF information online, applying for a new center should

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be accessible on-line to facilitate an expeditious process. There should be a process in place for convenient upload of documentation directly to MHCC website that will be reviewed by officials timely. The public can be served better by ASFs when the process is less demanding and centers can be built in a timely manner. A more streamlined process will be more cost effective to both ASFs and the state of Maryland.

Ambulatory Plastic Surgery Associates

- Current system seems to work, recommends continued CON regulation. But greater flexibility would be desirable.

Baltimore Washington Eye

- No regulatory framework should govern establishment, relocation, and expansion of ASFs. The free market should dictate whether a CON is needed.
- There are no important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms.

Kahn Center for Pain Management

- Important benefits served by CON regulation could be fully or adequately met with alternative regulatory mechanisms. Community needs, access to care in reasonable time frame, and cost are regulatory framework that should govern the establishment, relocation, and expansion of FASFs.

Maryland Patient Care and Access Coalition

- Provided multiple research conclusions indicating that ASFs are high-quality, lower cost substitute for hospitals as venues for outpatient surgery. The framework should be modified to encourage the proliferation of ASFs, not to inhibit their creation.
- An alternative regulatory framework should be able to ensure patient access to high quality health care without setting up barriers to market entry. ASFs should be subject to the “determination of coverage” process MHCC currently uses to evaluate prospective ASFs with only one sterilized operating room. Oversight of ASFs should continue through existing regulations promulgated by the Department of Health and through quality assessment accreditation.

SurgCenter Development

- The licensure and Medicare certification requirement that one operating room outpatient surgical facilities currently go through is sufficient.
- The current licensure requirements are sufficient, but if the Commission disagrees, then an alternative regulatory mechanism could meet the benefits currently served by CON regulation.

Johns Hopkins Medicine

- CON regulation of FASFs plays important role distinct from licensure and should be maintained.

The Impact of CON Regulation on FASF Competition and Innovation

Ambulatory Plastic Surgery Associates

- Changes recommended: lower the bar for need and eliminate need for approval of capital expenditure.
- Maryland should not shift focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition.

SurgCenter Development

- Key recommendation would be to exempt two operating room facilities from having to go through the CON process.
- Maryland should not shift regulatory focus to regulation of consolidation of ambulatory surgical services to preserve and strengthen competition for these services.

Johns Hopkins Medicine

- The regulation of one operating room ASFs causes imbalance under the current system and may inhibit innovation.
- Maryland shouldn't 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

Ambulatory Plastic Surgery Associates

- Capital expenditure threshold in ASF CON regulation should be eliminated.
- Greater flexibility in choosing which ASF projects require approval and those that can go forward without approval would be beneficial.
- The current process of expedited review for certain projects is working, no change is needed.

SurgCenter Development

- Flexibility in choosing which ASF projects require approval and those that can go forward without approval would be beneficial so long as the flexibility is not used to expand the projects requiring approval.
- Expedited review is worthy of MHCC's consideration. Expedited review should have a set of clear standards that ASFs can easily note their compliance with. Expedited review should only be allowed for smaller ASF projects or expansions.

Johns Hopkins Medicine

- The capital expenditure threshold in ASF CON regulation should be eliminated.
- 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. Not in favor of MHCC being given more flexibility in choosing which ASF projects require approval and those that can go forward without approval based on adopted regulations for making these decisions.
- A new process for expedited review for certain projects is unnecessary, would be burdensome, and would tax the already limited resources of the regulator. The existing

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process can be reformed to meet the need for a more efficient and sometimes streamlined process.

The Project Review Process

Ambulatory Plastic Surgery Associates

- No specific steps need to be eliminated but easing of requirements would be worthy of consideration.
- Regulatory process shouldn't be overhauled.
- Greater technology, including the submission of automated and form-based applications may possibly improve the application submission process.

SurgCenter Development

- CON process could be simplified by not digging so far into the minutiae of proposed facility or facility expansions.
- Post-CON approval processes should be changed to accommodate easier project modifications. Recommend that the thresholds that would require one to return to the Commission for modification be increased.
- The regulatory process should be overhauled to permit two operating room facilities be treated the same way as one operating room facilities are currently treated.
- Greater use of technology, including the submission of automated and form-based application will be a possible means of improvement.

Johns Hopkins Medicine

- Completeness questions should be limited to one round, and only those issues that are essential to the decision – there are applicable regulations related to that aspect of the project.
- The post-CON approval processes can be changed to accommodate easier project modifications.
- The recent addition of an exemption process to the surgical services chapter was helpful regarding permitting more abbreviated form of review.
- Greater use of technology such as electronic submission would be helpful but technology is not a major obstacle.

Duplication of Responsibilities by MHCC and MDH

Ambulatory Plastic Surgery Associates

- Not sure if there are areas of regulatory duplication between MHCC and MDH.

Johns Hopkins Medicine

- No known duplication between MHCC and the MDH.