

TO: North Carolina Division of Health Service Regulation
Medical Facilities Planning Section
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Raleigh, NC 27699-2714

PETITIONERS: North Carolina Orthopaedic Association
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DATE: July 31, 2009

RE: Petition for Adjustment to the Proposed Need Determination for
Demonstration Projects for Single Specialty Ambulatory Surgery Centers

I. Introduction

The North Carolina Orthopaedic Association and the above-listed petitioners represent approximately 400 orthopaedic surgeons from across North Carolina who performed over 100,000 ambulatory orthopaedic surgeries during the past year. These physicians strongly support the development of single specialty ambulatory surgery centers. Fundamental benefits of ambulatory surgery centers (ASCs) include quality of care and cost savings:

“ASCs provide a benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost-effective manner. ASCs can improve the quality of care received by the patient and delivered by the physician.¹”

¹ Excerpt from American Academy of Orthopaedic Surgeons Position Statement

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Medical Facilities
PLANNING SECTION

The Proposed 2010 State Medical Facilities Plan includes a special need determination for three new separately licensed single specialty ambulatory surgical facilities with two operating rooms each; the need is that one new ambulatory surgical facility be in each of the three following service areas:

Mecklenburg, Cabarrus, Union counties (Charlotte Area)

Guilford, Forsyth counties (Triad)

Wake, Durham, Orange counties (Triangle)

As seen in Attachment 1, the Single Specialty Ambulatory Surgery Demonstration Project also includes the proposed special criteria that relate to the need determination.

The purpose of this petition is to: 1) clarify the special need determination and criteria for the single specialty ASC demonstration projects; 2) emphasize the importance of potential ASC cost savings; and 3) request definition of the annual reporting requirements.

<p>II. Requested Changes</p> <p>The petitioners request the following changes to the need determination criteria for Single Specialty Ambulatory Surgery Demonstration Project:</p> <p>A. Add the following language to the need determination, <u>“Each single specialty ambulatory surgery demonstration project facility shall include two surgical operating rooms and no more than two non-gastrointestinal procedure rooms.”</u></p>	<p>III. Rationale for the Proposed Changes</p> <p>The rationale for the proposed change is outlined:</p> <ul style="list-style-type: none"> • The development of non-gastrointestinal procedure rooms in a licensed ambulatory surgical facility are not limited by the need determination in the State Medical Facilities Plan.² • ASCs with non-gastrointestinal procedure rooms have greater capacity schedule to provide cost effective service. • Of the 15 existing licensed ASCs in NC with two or less operating rooms, 67 percent have non-gastrointestinal procedure rooms. None of the 2-OR ASCs have more than two non-gastrointestinal procedure rooms. • It is less disruptive and more cost effective to construct procedure rooms with the initial ASC building as opposed to adding procedure rooms later. • Setting the upper limit of two non-gastrointestinal procedure rooms per single specialty ASC is reasonable because including more than two procedure rooms could significantly increase the capital cost. • CON applications that include procedure rooms in addition to the surgical operating rooms must demonstrate the need for the proposed procedure rooms as separate health service components and in accordance with the CON review criteria.
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² Based on previous CON letters of no review for proposals to add procedure rooms to existing licensed hospitals and ambulatory surgery centers

B. Change the criteria "Demonstration projects are encouraged to provide open access to physicians." Replace this with "Applicants are required to provide the proposed medical staff bylaws and the written criteria for extending medical staff privileges at the facility."

Justification for the requested change relates to the single specialty ambulatory surgery centers having only two surgical operating rooms at each facility. Physician access is limited by the capacity of the facility. The operating room regulatory criteria 10A NCAC 14C .2105 (b) directs the CON applicants to estimate the number of physicians expected to utilize the facility and provide the criteria to be used by the facility in extending surgical and anesthesia privileges. In addition, some proposed single specialty ASC facilities may have legitimate reasons to exclude access by specific physicians.

C. Add the following criteria, "Applications for the demonstration projects shall provide a calculation of projected savings based on the difference between the Medicare reimbursement ASC (ambulatory surgical center) rates and the HOPD (Hospital Outpatient Department) rates using the specific procedure codes and projected volumes for the proposed project. Projects with the higher projected per case savings are more cost-effective than projects with less cost savings."

The rationale for the requested change is that the projected cost savings for the single specialty ASC is an important comparative factor that drives patient choice. Patients deserve improved access to the most cost effective healthcare facilities. Competing CON applications should be evaluated based on cost savings related to the ASC vs. HOPD reimbursement rates. Priority consideration should be given to the facilities that propose to greatly reduce healthcare expenditures.

The comparative analyses in previous CON decisions have examined gross and net revenue per case and cost per case. These comparative factors by themselves may be inappropriate when comparing single specialty ASCs of different specialties.

D. The special criteria include the following: "Facilities will provide annual reports to the Agency showing the facility's compliance with the demonstration project criteria in the State Medical Facilities Plan. The Agency may specify the reporting requirements and reporting format. The Agency will perform an evaluation of each facility..."

Add the following statement, "The annual report form for the demonstration project single specialty ASCs will either be included in the 2010 State Medical Facilities Plan or contained in the administrative rules that will be promulgated prior to 2010 CON reviews for the demonstration projects."

If special reporting requirements are included in the list of criteria for the demonstration project, then the report form and information requirements should be made available prior to the CON reviews. The specific information that will be required to evaluate the performance of the demonstration project will be very useful in determining the policies and procedures that may be included in the CON application exhibits.

The State Health Coordinating Council and the Division of Health Service regulation may request that existing licensed ambulatory surgery centers and hospitals voluntarily provide the same information. In this way the performance measures of the demonstration project ASCs can be compared to data for existing facilities.

The petitioners also agree that the Agency shall rely on existing CON law to enforce compliance with the conditions of the CON. The conditions could include reporting requirements for a specified time period.

IV. Adverse Effects if the Changes Are Not Made

- A. The requested change that specifies two surgical operating rooms and no more than two non-gastrointestinal procedure rooms is intended to define the maximum size and capacity of the demonstration project single specialty ASC facilities. If the requested change is not made then applications could be submitted for any number of non-gastrointestinal procedure rooms because no performance standards exist that pertain to procedure rooms. In addition, proposals that choose to include procedure rooms need to justify the proposed procedure rooms in addition to the proposed single specialty operating rooms.
- B. Instead of encouraging “open access to physicians for the demonstration projects”, the requested change simply requires applicants to provide the medical staff bylaws and the written criteria for extending medical staff privileges. The adverse effect of promoting “open access” is that this concept could work against the implementation of stringent medical staff criteria to promote quality and high levels of productivity. For example, an ASC that requires board certification and specific training should be favored for being purposely selective to promote high quality of care. Setting high standards for physician qualifications is more important than promoting the notion of “open access to physicians”.
- C. The third requested change involves adding a criterion for calculating the potential cost savings by comparing ASC to HOPD reimbursement rates for the project using the proposed volumes and procedure codes. This is a way to objectively measure the potential healthcare savings benefit of the project. If this change is not made, then the traditional CON comparative analysis will simply examine gross revenue per case, net revenue per case and cost per case. As stated in the Basic Principles, “Cost per unit of service is an appropriate metric when comparing providers of like services to like populations.” However, the demonstration project for single specialty operating rooms will be comparing different specialties, different procedures and different populations. Therefore the cost savings criterion is needed.
- D. The requested change for the annual reporting is a request to provide the information requirements prior to the CON review. If this change is not adopted then CON applicants will not know how the performance of their proposed facilities will be assessed. Unless the annual reporting requirements are defined, it is difficult to predict the success of the demonstration project for single specialty ASCs.

V. Alternatives Considered

The alternatives that were considered regarding the petition are outlined as follows:

Maintaining the status quo is not an acceptable alternative because the State Health Coordinating Council has specifically requested comments and petitions regarding the proposed need determination for demonstration projects for single specialty ambulatory surgery facilities.

Petitioning for additional operating rooms in each of the single specialty ambulatory surgery centers does not seem feasible because that would be contrary to the recommendation of the Operating Room Work Group's recommendations to the State Health Coordinating Council.

VI. Evidence That the Proposed Changes Would Not Result in Unnecessary Duplication of Health Resources

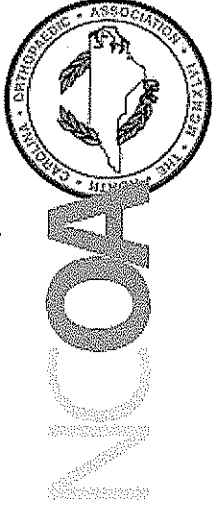
The following evidence is provided that the requested changes will not result in unnecessary duplication of health resources:

- ◆ The proposed changes to the need determination for single specialty ambulatory surgery facilities include the non-regulated procedure rooms and changes to the demonstration project criteria. Approval of this petition will not increase the number of single specialty operating rooms in the need determination.
- ◆ The requested changes will have no impact on the standard operating room methodology or the operating room need determinations that are derived.
- ◆ No new service areas or changes in the service areas are proposed in this petition. Therefore the proposed changes would not impact existing providers in other counties.

VII. Conclusion

The demand for specialized ambulatory surgery is expected to rise with the aging of the population combined with continued advances in surgical technology and anesthesia. Of all the surgical specialties, orthopaedic ambulatory surgery centers probably offer the greatest advantages in terms of potential cost savings and improved patient satisfaction based on the large volume of procedures that can be safely performed at a single specialty ASC.

Although the changes requested in this petition are not specialty specific, the North Carolina Orthopaedic Association endorses the development of orthopaedic ambulatory surgery centers that offer state-of-the art facilities, highly trained staff and substantial cost savings.



- ▶ The American Academy of Orthopaedic Surgeons states:

“ASCs provide a benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost-effective manner. ASCs can improve the quality of care received by the patient and delivered by the physician.”

- ▶ The Proposed 2010 State Medical Facilities Plan includes:
 - special need determination for three new separately licensed single specialty ambulatory surgical facilities in each of the three following service areas
 - Mecklenburg, Cabarrus, Union counties (Charlotte Area)
 - Guilford, Forsyth counties (Triad)
 - Wake, Durham, Orange counties (Triangle)

Purpose

The purpose of this petition is to:

1. Clarify the special need determination and criteria for the single specialty ASC demonstration projects
2. Emphasize the importance of potential ASC cost savings
3. Request definition of the annual reporting requirements

Requested Changes

Change	Rationale
<ul style="list-style-type: none">▶ Add the following sentence to the need determination, <u>“Each single specialty ambulatory surgery demonstration project facility shall include two surgical operating rooms and no more than two non-gastrointestinal procedure rooms.”</u>	<ul style="list-style-type: none">▶ There is no need determination for procedure rooms▶ A facility with two procedure rooms and two operating rooms would provide cost effective service▶ CON applications that include procedure rooms in addition to the surgical operating rooms must demonstrate their need

Change

- ▶ Change the criteria “Demonstration projects are encouraged to provide open access to physicians.”
- ▶ Replace this with “Applicants are required to provide the proposed medical staff bylaws and the written criteria for extending medical staff privileges at the facility.”

Rationale

- ▶ Physician access is limited by the capacity of the facility
- ▶ Allows CON applicants to determine the criteria of the facility
- ▶ Applicants may have legitimate reasons to exclude access by specific physicians

Change

- ▶ Add the following criteria, “Applications for the demonstration projects shall provide a calculation of projected savings based on the difference between the Medicare reimbursement ASC rates and the HOPD rates using the specific projected codes and projected volumes for the proposed project. Projects with the higher projected per case savings are more cost-effective than projects with less cost savings.”

Rationale

- ▶ Patients deserve improved access to the most cost effective healthcare facilities.
- ▶ The comparative analyses in previous CON decisions have examined gross and net revenue per case and cost per case.

Change

- ▶ Add the following statement, "The annual report form for the demonstration project single specialty ASCs will either be included in the 2010 State Medical Facilities Plan or contained in the administrative rules that will be promulgated prior to 2010 CON reviews for the demonstration projects."

Rationale

- ▶ The report form and information requirements should be made available prior to the CON reviews
- ▶ Performance measures can be compared to data for existing facilities
- ▶ The Agency shall rely on existing CON law to enforce compliance with the conditions, including reporting requirements, of the CON