

Acute Care Committee Agency Report
Petition for the Addition of a Need Determination for
One Heart-Lung Bypass Machine in the Orange County Service Area
in the 2026 State Medical Facilities Plan

Petitioner:

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Request:

The Petitioner seeks to add a need determination in the *2026 State Medical Facilities Plan (SMFP* or “*Plan*”) for one heart-lung bypass (HLB) machine in Orange County. The request is for the machine to be designated for an academic medical center and exempt from the performance standards set forth in 10A NCAC 14C.1703.

Background Information:

Chapter Two of the *SMFP* notes that during the summer, the Agency accepts petitions that “involve requests for adjustments to need determinations in the *Proposed SMFP*. Petitioners may submit a written petition requesting an adjustment to the need determination in the *Proposed SMFP* if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies.” Any person may submit a certificate of need (CON) application for a need determination in the *Plan*. The CON review could be competitive and there is no guarantee that the Petitioner would be the approved applicant.

In 1993, the North Carolina General Assembly amended the CON statutes to include open-heart surgery programs. As a result, the State Health Coordinating Council (SHCC) developed an HLB need methodology, and the acquisition of an HLB machine required 1) a need determination in the current year’s *SMFP*, and 2) CON approval. The *SMFP* now includes *Policy AC-6: Heart-Lung Bypass Machines for Emergency Coverage*. This policy allows hospitals with open-heart surgery programs that have only one HLB machine to acquire a second machine exclusively for emergency use – not for scheduled procedures. Machines approved under Policy AC-6 are exempt the performance standards outlined in 10A NCAC 14C.1703, which include utilization thresholds.

Beginning with the *2012 SMFP*, the SHCC approved the removal of the HLB machine need determination methodology. As described in the *2025 SMFP*, facilities seeking to acquire an

additional HLB machine – other than one approved under Policy AC-6 – must submit a summer petition. Machines approved through this process are subject to the performance standards established in 10A NCAC 14C.1703.

Providers of open-heart surgery services annually report the following information about HLB machines to the Agency via Hospital License Renewal Applications (LRAs):

- 1) the number of heart-lung bypass machines
- 2) the total number of open-heart surgery procedures using these machines
- 3) the total number of open-heart surgery procedures done without these machines

UNCH is the only provider of open-heart surgery services in Orange County. Although UNCH already had an HLB machine for emergency purposes, the Agency subsequently approved UNCH's CON application to acquire a second emergency machine to be dedicated to pediatric cases. In total, it operates five HLB machines: three adult machines, including one for emergencies; and two pediatric machines, which includes one for emergencies.

Analysis/Implications:

UNCH recently relocated its surgical services and equipment - including all three of its adult HLB machines - to its new surgical tower. However, certain non-open-heart procedures, such as transcatheter aortic valve replacements (TAVRs), continue to be performed in the main hospital building. While these procedures do not require the routine use of HLB machines, the Petitioner asserts that an HLB machine must be on standby and immediately available in the event of an interoperative emergency.

According to the Petitioner, when an HLB machine is needed in the main hospital for these types of cardiac services, it must be transported from the surgical tower. This process involves moving the equipment between separate buildings and across different floors, requiring elevator use. Even under ideal conditions, this transport takes a minimum of 15 minutes – not including the additional time needed for equipment disconnection, reinstallation, and any unforeseen delays. While scheduled procedures allow for advance planning to mitigate these issues, true emergencies do not, and the resulting delays could compromise patient safety.

Agency staff note that if the emergency-designated HLB machine were permanently relocated back to the main hospital to provide emergency coverage for other cardiac services, only two HLB machines would remain in the surgical tower for open-heart surgery cases. Under this scenario, UNCH could apply to convert one of the two remaining machines to an emergency-use machine under Policy AC-6. However, as shown in Table 1 below, this hypothetical configuration would result in utilization of the single remaining non-emergency HLB machine exceeding 100% of capacity. Additionally, access to an emergency machine in the surgical tower would be severely limited, potentially compromising timely response during critical situations.

Table 1: 2024 HLB Machine Open-Heart Surgery Utilization*

	Total Adult Open-Heart Surgery Cases	Non- Emergency Machines	Capacity/ Machine	Total Capacity	Utilization
UNCH	378	2	312	624	61%
Adjusted UNCH	378	1	312	312	121%

*UNCH told the Agency that of the 451 total cases reported on their 2025 LRA, 73 were pediatric cases and 378 were adult cases.

Agency Recommendation:

The Petitioner requests the addition of a need determination for one HLB machine in the Orange County service area that would be designated for an academic medical center and exempt from the performance standards set forth in 10A NCAC 14C.1703. Given the available information submitted by the August 6, 2025 deadline, and in consideration of factors discussed above, the Agency recommends approval of the Petition. However, Agency staff did not find justification to limit CON applications for this need determination solely to academic medical centers or to stipulate that applications submitted in response to this need determination will be exempt from meeting the HLB performance standards.