

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

Petitioner:

Atrium Health, Inc.
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Contact:

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Request:

The Petitioner seeks to add a need determination or an additional heart-lung bypass (HLB) machine in Mecklenburg County to the *2026 State Medical Facilities Plan (SMFP or “Plan”)*.

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. *Policy AC-6: Heart-Lung Bypass Machines for Emergency Coverage*, which was introduced in the *2001 SMFP*, provides a pathway for hospitals with open-heart surgery programs that have only one HLB machine to acquire a second machine solely for emergency use and not for scheduled open-heart surgery procedures. Notably, machines approved under Policy AC-6 are exempt from the performance standards set forth in 10A NCAC 14C.1703.

Beginning with the *2012 SMFP*, the SHCC approved the removal of the HLB machine need methodology. As described in the *2025 SMFP*, facilities that have HLB machine and want to submit a CON application to acquire another machine – other than one approved under Policy AC-6 – must submit a summer petition. Machines approved pursuant to a summer petition are subject to the performance standards established in 10A NCAC 14C.1703.

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

- 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

Mecklenburg County currently has a total of 13 HLB machines: Atrium Health Pineville has three (“AH Pineville”; two adult with one emergency machine) Carolinas Medical Center has six (CMC; three adult with one emergency machine, and one pediatric with one emergency machine), and Novant Health Presbyterian has four (“Presbyterian”; three adult with one emergency machine).

Analysis/Implications:

Mecklenburg County is the second-largest county in North Carolina, and as shown in Table 1, its population is projected to grow at a faster rate than the state overall. Between 2025 and 2035 the county’s population change is expected to be about 16.0%, with an average annual compounded growth rate of 1.5%. In comparison, the state’s projected population change during that same period is 11.2%, with a 1.1% compounded annual growth rate.

Table 1: Projected Population Growth, 2020-2035

	2020	2025	2030	2035
Mecklenburg Population	1,118,967	1,198,460	1,293,761	1,390,256
Compound Annual Growth Rate (CAGR)		1.4%	1.5%	1.5%
Growth Rate		7.1%	8.0%	7.5%
State Population	10,472,893	11,107,246	11,743,841	12,355,144
Compound Annual Growth Rate (CAGR)		1.2%	1.1%	1.0%
Growth Rate		6.1%	5.7%	5.2%

Source: North Carolina Office of State Budget and Management

Mecklenburg County has also experienced an increase in open-heart surgery cases. As illustrated in Table 2, since 2020, Mecklenburg County has experienced a steady increase in open-heart surgery cases while the statewide totals have fluctuated. Between 2020 and 2024 the percent change for open-heart surgery cases utilizing HLB machines in Mecklenburg County’s was approximately 67% while the state’s percent change was about 14%.

Additionally, as shown in Table 2, Mecklenburg County’s share of the state’s total open heart surgery cases has steadily increased. In 2020, the county accounted for about 12% of all cases performed statewide. By 2024, that figure had risen to nearly 18%. According to the Petitioner, Atrium’s Mecklenburg facilities are also experiencing a rise in case complexity, with higher acuity patients and longer procedure times becoming more common.

Table 2: Open-Heart Surgery Cases Utilizing Heart-Lung Bypass Machines

License	Facility (HLB Machines)	2020	2021	2022	2023	2024
H0042	AH Pineville (3)	158	159	270	344	425
H0071	CMC (6)	580	729	777	803	876
H0010	Presbyterian (4)	339	434	360	450	500
Mecklenburg Total Cases		1,077	1,322	1,407	1,597	1,801
Mecklenburg County Annual % Change		-23.0%	22.8%	6.4%	13.5%	12.8%
State Total Cases		9,011	9,701	9,627	10,400	10,226
State Total Annual % Change		-13.8%	7.7%	-0.8%	8.0%	-1.7%
Mecklenburg Cases % of State Cases		12.0%	13.6%	14.6%	15.4%	17.6%

Source: *Proposed 2026 SMFP*

As highlighted in the Petition, HLB machines are also used as standby for cardiac procedures that are not traditional open-heart surgeries [e.g. transcatheter arterial valve replacement (TAVR); lead extractions; liver bypass; trauma]. These procedures are not captured in the LRA data. However, according to the Petitioner, they represent a substantial share of the HLB machine's workload. For example, the Petitioner notes that TAVR procedures and lead extractions require reserving one machine at the CMC campus every Monday and Wednesday for eight hours.

Because the Agency does not collect data on non-open-heart surgery procedures performed with HLB machines, it is not possible to fully assess overall machine utilization. Therefore, Agency staff have evaluated HLB machine utilization during the 2024 reporting year based only open-heart surgery cases. Pediatric cases typically require more time than adult cases. In the *2011 SMFP* – the last publication to include a need determination methodology for HLB machines – one pediatric procedure was weighted as equivalent to two adult open-heart surgeries. Applying this methodology, and as shown in Table 3 below, HLB machine utilization in Mecklenburg County for 2024 was calculated at 74.0%.

Table 3: 2024 HLB Machine Open-Heart Surgery Utilization

License	Facility Name	Total Cases	Total Cases (weighted)	Non-Emergency Machines	Capacity/Machine***	Total Capacity	Utilization
H0042	AH Pineville	425	425	2	312	624	68.1%
H0071	CMC	876*	1,152**	4	312	1,248	92.3%
H0010	Presbyterian	500	500	3	312	936	53.4%
Mecklenburg County		1,801	2,077	9	312	2,808	74.0%

* Pediatric procedures on HLB machines are not reported on the LRA. Atrium Health informed the Agency that CMC performed 276 pediatric procedures during the 2024 reporting year. The number of pediatric cases at Presbyterian is unknown.

** Total 2024 weighted cases equal the number of pediatric cases X 2 plus the number of adult cases.

*** Capacity assumes 1 procedure/machine/day for six out of seven working days a week for 52 weeks in a year.

Agency Recommendation:

The Petitioner seeks to add a need determination for an additional HLB machine in Mecklenburg County in the *2026 SMFP*. 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.