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Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Petition for Adjustment to Step 4(m)/Criteria for Identification of "Chronically Underutilized ORs in Licensed Facilities" as Set Forth in Chapter 6, "Operating Rooms," of the *Proposed 2010 SMFP*

I. Name, address, and telephone number of Petitioner

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II. Requested Adjustment

The petitioner requests an adjustment to the definition and criteria for "Chronically Underutilized ORs in Licensed Facilities" as Set Forth in Step 4(m), Chapter 6, "Operating Rooms," of the *Proposed 2010 SMF*, so that at least 36 full months of actual OR case volume data from the provider's Hospital and Ambulatory Licensure Renewal Applications is considered in determining whether the ORs are "operating in licensed facilities at less than 40% utilization." Currently, the standard defined in Chapter 6, Step 4(m) for "chronically underutilized Licensed Facilities states: "licensed facilities operating at less than 40% utilization for the past two fiscal years, which have been licensed long enough to submit at least two License Renewal Applications to the Division of Health Service Regulation."

III. Reasons for the Proposed Adjustment

Currently, the performance standard established in the majority of the CON Criteria and Standards (the "CON Regulations"), including the CON OR regulations, is that the

provider/applicant, must demonstrate that they will meet the performance standard with projected volumes that achieve the targets set forth in the relevant CON regulations by the end of the third year of operation. See, for example the following performance standards set forth in existing CON regulations:

- Surgical Services and Operating Rooms at 10A NCAC.14C.2103(c)
- New Acute Beds at 10A NCAC.14C.3803
- MRI Scanner at 10A NCAC.14C.2703(b)
- CT Scanner at MRI Scanner at 10A NCAC.14C.2303
- Cardiac Catheterization & Cardiac Angiography Equipment at 10A NCAC.14C.1603
- PET Scanner at MRI Scanner at 10A NCAC.14C.3703
- Lithotripter Equipment at 10A NCAC.14C.3203
- ICU Beds at 10A NCAC.14C.1203
- Pediatric Intensive Care Beds at 10A NCAC.14C.1303
- Neonatal Beds at 10A NCAC.14C.1403
- Radiation Therapy Equipment at 10A NCAC.14C.1903
- Gamma Knife at 10A NCAC.14C.3603
- Substance Abuse/Chemical Dependency Treatment Beds at 10A NCAC.14C.2503

Thus, it is inconsistent to have language in SMFP Chapter 6/Operating Rooms, in Step 4(m) of the "Method for Projecting OR Need" that requires a provider to achieve target OR utilization within two years, when the OR CON regulation standard establishes a three-year time horizon to grow into the new OR capacity. In other words, the provider/applicant may have succeeded in their CON application in demonstrating the need for a new OR(s) in a new licensed facility by the end of the third year of operation, while the language in the *Proposed 2010 SMFP,* Chapter 6, Step 4(m) penalizes that provider by tagging those ORs as "chronically underutilized" in Year 2. The consequence, in the SMFP, of the "chronically underutilized" label is that those ORs are excluded from the *2010 SMFP* Table 6A "Operating Room Inventory." But it is premature in year 2 to make a determination of whether the OR(s) is/are underutilized, as the CON performance standard contemplates that ORs will be underutilized in operational year 2, as the target for OR volumes must be met at the end of operating year 3. See Surgical Services and Operating Room Standards at 10A NCAC.14C.2103(c). The early exclusion of ORs from the

SMFP Chapter 6, "Methodology for Projecting Operating Room Need," in Year 2 rather than in Year 3, may lead to the under-statement of surplus ORs in a given County in given SMFP year.

For example, Presbyterian Same Day Surgery Center Ballantyne, with 3 ambulatory ORs, is identified at the end of Table 6A, "Operating Room Inventory" based on well less than 2 full years of data in the SDSC Ballantyne annual ASC Licensure Renewal Application. This occurred because the first year's ASC LRA data reporting for SDSC Ballantyne only included reporting of 1-2 months within the 12-month data reporting year, due to when licensure and certification was finalized. It took 8-9 months from the time that construction on SDSC Ballantyne was complete until licensure and certification was complete. Providers cannot offer services to patients prior to licensure and often providers do not ramp up volumes until after the Medicare/Medicaid certification process is complete, in order to minimize start-up reimbursement issues from those two government payors. The timing of the DHSR Licensure Section required licensure and certification is completely within the discretion and authority of the state's Licensure Section, and outside the control of the providers seeking to be licensed.

Thus, it makes sense and creates more consistency if the "chronically underutilized ORs" are identified in Chapter 6 of the *Proposed 2010 SMFP* using 3 full years of OR case volume data rather by the taking of that measurement in the second year of operation.

Statement of Adverse Effects On The Population

See the discussion directly above in the Section III above, Reasons for the Proposed Adjustment. The surgical providers seeking licensure and certification are not able to completely ramp up their capacity until the licensure and certification processes are complete and all of the state's follow-up questions are addressed. This impacts the accessibility of the surgical services for potential patients, as well as the surgeons who care for them.

Statement of Alternatives Considered

The only alternatives considered were the status quo or time-periods one year or four years to measure "chronically under-utilized" OR status. This status quo is not acceptable for the reasons articulated in Section III above, Reasons for the Proposed Adjustment. The one year time period would be too short for the reasons discussed above in Section III above, Reasons for the Proposed Adjustment. Likewise, the four-year time period would be too long, as it would be longer that the 3-years of operation typically defined in the applicable OR CON regulations for the applicant/provider to demonstrate that the target utilization defined in the performance standards of the CON regulations had been met.

IV. The Adjustment Would Not Cause Unnecessary Duplication of Surgical Services

For the reasons discussed above in Section III, Reasons for the Proposed Adjustment, the proposed change in the criteria to identify "chronically underutilized ORs" by county in Chapter 6 of the *Proposed 2010 SFMP* would not create unnecessary duplication of surgical services. The early exclusion of ORs from the SMFP Chapter 6, "Methodology for Projecting Operating Room Need," in Year 2 rather than in Year of operations, may lead to the under-statement of surplus ORs in a given County in given SMFP year. If the OR surplus is under-stated, then there may be excess OR need, which may lead to unnecessary duplication of surgical services in a given SMFP OR service area.

V. The Proposed Change is Consistent With the SMFP Three Basic Principles: Safety, Quality, Access and Value

For the reasons discussed above in Section III, Reasons for the Proposed Adjustment, the proposed change will promote quality, access, and value. It is imperative that all new or expanded surgical providers go through the licensure and certification process as a baseline confirmation by an independent third party of quality of care and access to services. Licensure and Certification is also very necessary if the surgical provider is going to be successful at contracting with a wide variety of payors/insurance companies, as it is required by insurers for network participation. Provider contracts with health insurance companies also manage the pricing/charges/reimbursement for surgical services and thus are related to the SMFP "value" proposition. Thus, since these certification and licensure processes are mandatory and necessary, the timeframe used to define "chronically underutilized" ORs in Chapter 6 of the 2010, SMFP should be adjusted to 3-full years (36 months) of data to accommodate this process. In addition, the three year timeframe would be consistent with many of the performance standards in the CON regulations, including the CON OR regulations that require a provider to project volumes to achieve a regulatory target by the end of the third year of operation.