Petition to the State Health Coordinating Council Regarding Special Need for a Demonstration Dental Operating Room for Cumberland County 2016 State Medical Facilities Plan

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STATEMENT OF REQUESTED ADJUSTMENT

Knowles, Smith and Associates, LLP (KSA), requests the following change to the 2016 State Medical Facilities Plan (SMFP) to address a special need for a demonstration dental ambulatory surgery operating room with supporting procedure rooms in Cumberland County. This would represent a modification to Chapter 6 and read as follows:

"In response to a petition from Knowles Smith and Associates on behalf of Village Family Dental, the State Health Coordinating Council approved an adjusted need determination for one operating room in Cumberland County to be included in a demonstration dentalonly ambulatory surgical center."

Table 6F: Operating Room Need Determination for Dental-Only Single Specialty Ambulatory Surgery Demonstration Project (Scheduled for Certificate of Need Review Commencing in 2016)

It is determined that the service areas listed in the table below needs additional operating rooms in accordance with the demonstration project criteria:

- 1. Operating Rooms must be located in a licensed ambulatory surgery facility dedicated to the scope of pediatric dentistry.
- 2. Applicant must provide evidence of having performed dental procedures in a surgical setting on at least 900 Medicaid patients in the past 12 months.
- 3. Facility must provide for general anesthesia coverage by certified anesthesia professionals.
- 4. Facility must provide three percent of services to persons with limited ability to pay, as determined by a formal charity care policy.
- 5. Facility must offer surgery privileges to qualified professionals who are not owners.
- 6. Facility must become Medicaid certified.
- 7. Facility must demonstrate that it will serve a minimum payor mix of 60 percent Medicaid and three percent Charity care.
- 8. Facility must become licensed as an ambulatory surgery facility in the State of North Carolina.
- 9. Facility must become accredited by an agency that maintains CMS deemed status for ambulatory surgery.
- 10. Facility operating rooms must be available for service eight hours a day.
- 11. Facility must comply with performance criteria in NCAC 14C .2103 (b) (1), with the exception that case length for outpatient cases shall be considered 2.5 hours rather than the assumed 1.5 in the existing rule.
- 12. Facility must provide a report to the Agency by third year of operations identifying: the number of patients served, cases by diagnosis, age, county of residence, and payor; and number of persons with surgical privileges by ownership status.

Service Areas	Operating Rooms	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Cumberland County	1	TBD	TBD

Need determination shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).

OVERVIEW

Access to dental care, particularly pediatric dental care that requires general anesthesia, is a major problem. In 2013, CMS reported that, of children eligible for Medicaid for 90 days or more, **only half** had seen a dentist for preventive service within a year; and a quarter had received dental treatment.¹ The service deficiency stems from many factors including insufficient number of providers, lack of proper facilities, and inadequate financial resources on the part of patients, their families and the state. A recent report from the UNC Cecil G. Sheps Center for Health Policy Research, which is included in Attachment A to this petition, provides excellent documentation for North Carolina's dental care access problem.

Among the 100 pediatric patients that Knowles, Smith and Associates (KSA) pediatric dentists see daily, 17 percent need surgery, yet only three percent receive it. The problem is limitations on operating room availability. The result is that that only 17.6 percent of KSA pediatric patients in need of surgery actually receive service. <u>Ninety percent</u> of KSA pediatric patients are Medicaid beneficiaries.

This petition proposes that dedicated ambulatory dental operating rooms would expand patient access to services, improve provider recruitment and retention, reduce the state cost of providing dental surgery and/or expand the capacity of the Medicaid dental surgery expenditures.

Data on need are difficult to find. To estimate need for ambulatory dental operating rooms, KSA created a model for statewide need for dental surgical procedures by Medicaid children and projected the number of dental operating rooms required to serve just Medicaid pediatric cases. A model that assumes half of the eligible children receive screening, 17 percent of those screened need surgery, and, 15 percent of those in need of surgery receive it in a dedicated dental ambulatory surgery center, would require three full time dental operating / procedure rooms for the Medicaid children in Health Service Area V. If none of the cases represent a shift away from hospitals, this could almost double current access (17 in need * 15 % = 2.55 more persons served per day). For additional details and sourcing of this model, see Attachment K.

Calculations aside, need for this service is widely understood by providers across the state. On June 3rd, 2015, NC DHSR held a stakeholders meeting to discuss issues surrounding access to operating rooms. Among the issues discussed was lack convenient access to hospital ORs, safety of procedures completed in-office, lack of proper dental equipment in multi-specialty ORs. Providers across the state voiced concerns. The NC Dental Society supports a demonstration project for a dental-only ambulatory surgery center. See Attachment C for a copy of this letter.

KSA is particularly concerned about access problems for its pediatric patients. Division of Medical Assistance Dental Director, Mark Casey, DDS, MD, requested that dental operating rooms be available to patients of all ages. Serving adult Medicaid patients would require a one third increase in capacity. The analysis shows that a facility with four rooms designed to operating room specifications is reasonable for HSA V, where Village Family Dental is located.

¹ CMS -416 Report, FFY 2013.

North Carolina requires a CON for an operating room but permits an ambulatory surgery center or hospital to have unrestricted numbers of procedure rooms built to operating room specifications. North Carolina practice requires at least one operating room to license a facility as ambulatory surgical facility unless the facility provides GI endoscopy procedures. Thus, the petition requests one operating room with supporting procedure rooms. North Carolina does not regulate the number of procedure rooms in hospitals or ambulatory surgery centers.

A mandatory <u>eight-hour operating room schedule</u>, rather than the nine required of multi-specialty operating rooms will enable a facility with four operating or procedures rooms to operate with a single shift of trained operating room staff. A longer, nine-hour schedule would require part-time staffing and could dilute staff quality and focus. As demand grows, the facility, on its own, may decide to expand hours of operation.

BACKGROUND

Pediatric dentistry requires a special level of training above and beyond that of general dentists. They are equipped to handle specific issues that developing children face. For children requiring dental procedures, pediatric dentists must consider the type of sedation/anesthetic appropriate for each individual.

Pediatric dentists often do procedures on patients under general anesthesia. Hospital outpatient surgery departments and ambulatory surgery centers (ASC) provide the setting for most North Carolina dental surgical cases.

While not all need general anesthesia, children that require dental surgery under general anesthesia are generally persons who have challenges in development, behavior, cooperation, age or physical condition. This includes:

- Extensive dental needs that cannot be safely treated in office.
- Multiple dental caries and acute stress reaction.
- Very young patients, typically under the age of 3.5 years.
- Too many office visits required to complete treatment.
- Patient does not respond adequately to oral sedation protocols.
- Protecting them from life -long psychological trauma and/or reducing medical risks.
- Patient is mentally / physically handicapped and requires general anaesthesia for proper management of behaviour or movement.
- Patient has a medical condition requiring medical supervision.
- Patient suffers from acute dental fear or anxiety.

Treating children with extensive dental caries often requires intensive clinical, technology and anesthesia support that is not typically available in a dentist office. Cases are complex, sometimes because of the extensive repair. Many of the required procedures are long, requiring operating room level preparation and recovery support.

A pediatric dentist performs comprehensive dental rehabilitation under general anesthesia when conventional dental treatment is not an option. As noted in a recent publication in *Pediatric Dentistry*:

The American Academy of Pediatric Dentistry (**AAPD**) endorses GA[general anesthesia] for pediatric dental patients who: are unable to cooperate; experience ineffective local anesthesia; are extremely fearful, anxious, or uncommunicative; require significant surgical procedures; can benefit from GA protecting them from psychological trauma and/or reducing medical risks; and require immediate, comprehensive oral care.^{1,3}Furthermore, many medical conditions present with oral disease that must be managed in an inpatient setting, and the operating room (**OR**) is often the best place to provide such care. Pediatric dentists are trained to recognize the need for hospital-based dental treatment and to work with an anesthesia team to provide optimal care for their patients.⁴ The AAPD definition of medically necessary care includes services of GA and use of surgery facilities.⁵

The American Society of Anesthesiology (**ASA**) classifies patients according to their physical status as follows: (I) a normal healthy patient; (II) a patient with mild systemic disease; (III) a patient with severe systemic disease; (IV) a patient with severe systemic disease that is a constant threat to life; (V) a moribund patient who is not expected to survive without the operation; and (VI) a patient declared brain-dead whose organs are being removed for donor purposes.⁶ Patients with an ASA classification of III or higher are usually not suitable candidates for moderate sedation and are more safely treated under GA supervised by a licensed, trained, and credentialed medical and dental team in an appropriately equipped facility.^{1.4}

The same report noted that patients with higher medical risk during sedation often receive more safe treatment in an operating room setting.²

The American Academy of Pediatric Dentistry supports provision of general anesthesia outside the hospital in controlled circumstances. In the AAPD study, the average operating time was for pediatric dental cases is 110 minutes, with a standard deviation of 28 minutes (1.8 to 2.3 hours). This excluded room turnover time.

American Academy of Pediatric Dentistry (AAPD) endorses in-office use of deep sedation or general anesthesia administered by a trained, credentialed, and licensed pediatric dentist, dental or medical anesthesiologist, nurse anesthetist, or anesthesia assistant on select pediatric dentistry training programs treat patients under deep sedation / general anesthesia, with 69 percent of these cases occurring in an operating room environment only; 29 percent of training programs provide treatment under deep sedation/general anesthesia in both clinic-based and operating room settings.³ Three-quarters of graduating pediatric dental residents have equal or more experience with deep sedation than with minimal / moderate sedation cases.⁴

² Forsyth, Anna, General Anesthesia Time for Pediatric Dental Cases, Pediatric Dent 34(5)129-135, 2012

³ American Academy of Pediatric Dentistry. Guidelines on use of anesthesia personnel in the administration of office-based deep sedation/general anesthesia to the pediatric dental patient. Reference Manual. 2009–10; 31(6):169–171. ⁴ Ibid

In North Carolina, dentists are required to obtain a permit from the state Board of Dental Examiners prior to administering sedation. The Board has five permit applications for Anesthesia, Moderate Pediatric Conscious Sedation, Moderate Conscious Sedation, Limited Moderate Conscious Sedation and Minimal Conscious Sedation. The training and experience requirements are available on the Board website, http://www.ncdentalboard.org/anesthesia.htm. Most dentists do not have these permits. Proposed North Carolina rule changes regarding anesthesia and sedation will be open or a public hearing scheduled for August 6, 2015.

REASONS FOR THE PROPOSED ADJUSTMENT

DENTAL PROVIDER SHORTAGE

In April 2014, the Kaiser Family Foundation summary of DHHS Health Resources and Services Administration data showed that **North Carolina ranked 32nd among the United States and its territories for percent of needed dentists available.**⁵ Last year, NC was short 270 dentists and had only 43 percent of the needed supply in the Health Professional Shortage Areas (HPSA). South Carolina, Mississippi, Kentucky and West Virginia ranked better than North Carolina in this report. The PEW Charitable Trust scores states on preventive dental care initiatives. In 2010, PEW gave North Carolina a "D" rating for children's dental care.⁶

In March 2013, the UNC Cecil G. Sheps Center for Health Services Research (Sheps) published detailed report on the status of the North Carolina dental workforce. The entire report is available in Attachment A. Sheps Center data rank North Carolina lower than Kaiser Family in supply of dentists. Key findings are relevant to this petition. According to the Sheps report, North Carolina has fewer dentists per capita than the United States as a whole. In 2011, there were 6.0 dentists per 10,000 population in the US, while in NC there were 4.4, 26 percent less than that of the nation. The report indicates that in 2007 **NC ranked 47th in the nation** in its ratio of active dentists per civilian population, the same rank it had in 1996. There is a disparity between the metropolitan and the non-metropolitan NC counties. Metropolitan counties have a rate of 3.1.

The Sheps report also shows the increase in the rate of North Carolina ED visits for dental disorders from 2008 to 2010 exceed that of the US and surrounding states. According to a study by the American Dental Association Emergency room visits for dental pain nationwide increased from 1.06 percent of all visits to 1.65 percent between 2000 and 2010, a 55 percent increase over that period and a 4.5 percent annual increase.⁷

The result is that many North Carolina children, particularly those in low-income communities, lack access to providers and therefore lack good dental hygiene. Many have multiple untreated caries in their baby teeth and frequently show up in emergency rooms. Most emergency departments are prepared to provide only temporary relief in the way of pain medicines and antibiotics. Treating the problem must involve care in dental offices and, in many cases, operating rooms.

⁵ Kaiser Family Foundation Dental Shortage areas website <u>http://kff.org/other/state-indicator/dental-care-health-professional-shortage-areas-hpsas/#</u>, accessed February 24, 2015.

⁶ Children's Dental Health: North Carolina, Making Coverage Matter May 2011 <u>http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2011/05/11/childrens-dental-health-north-carolina</u>

⁷ http://healthjournalism.org/blog/2014/04/lack-of-access-to-dental-care-leads-to-expensive-emergency-room-care/

PEDIATRIC DENTAL SURGERY DEMAND

A high percentage of young dental patients require surgical procedures, many of which require general anesthesia.

In KSA and other practices, most of these children are Medicaid beneficiaries and likely to be affected by cultural practices, lack of preventive care knowledge, and malnutrition. Many also struggle with housing and transportation issues. Collectively, these factors work against compliance with recommended dental hygiene and drive up need for surgical intervention. However, only a few have co-morbidities that would preclude them from medical clearance for ambulatory surgery.

Data for dental surgical cases are difficult to track. Medical codes used on hospital and ASC billing forms are generic, for example, a complex case will be coded as "CPT 521.00, Dental Caries." This is because Hospital and Ambulatory Surgery billing forms use ICD and American Medical Association CPT or CMS HCPCS codes, rather than American Dental Association Dental (CDT) codes. The CDT have more detailed procedure descriptions.

North Carolina DMA claims data for Medicaid dental cases, which are included in Attachment D provide a better picture. Though hospital data are still a bit inconsistent, the DMA report shows fewer than 50 of the 22,000+ Medicaid Dental surgery claims in 2014 were inpatient cases. This report showed only five percent of the outpatient cases occurred in ambulatory surgery centers; 95 percent were in hospitals.

This petition proposes that North Carolina have dedicated dental surgical facilities in high need areas to ensure that all pediatric dental surgery patients have timely and flexible access to a dental-specific operating room. Based on the petitioner's experience, in Southeastern North Carolina, a significant number of patients' needs, particularly children, cannot be met. This is generally, HSA V, but may include additional counties in HSA VI that are distant from the dental ambulatory surgery program at the Vidant/ECU surgery center in Greenville. Similarly, the petitioner identified a surgery center in Wilmington that accommodates dental cases in a dedicated procedure room. These are not the norm, and address the access for only certain counties.

KSA consulted with NC Division of Medical Assistance (DMA) Dental Director Mark W. Casey, DDS, MPH, regarding inpatient dental surgery. Neither KSA nor Dr. Casey expects any shift of cases from inpatient hospital operating rooms to ambulatory surgery operating rooms; nor do they have reason to believe that inpatient dental rehabilitation would be appropriate for any other type of facility.

SPECIAL NEED FOR MEDICAID PEDIATRIC DENTAL OPERATING ROOMS

Using conservative assumptions, the petitioner calculated need for at least three Medicaid Pediatric Dental Operating Rooms in <u>each</u> of North Carolina's six HSAs. The model uses data NC DMA for all beneficiaries in July 2014. Total Medicaid-covered children include the following:

- Children enrolled in AFDC 21 under 21
- Other Child
- Infants and Children
- MCHiP
- Half of children enrolled in CHiP and CHiP extended coverage⁸

The petitioner then made conservative assumptions about the number of Medicaid children who will require dental surgery and be appropriate for care in a dedicated dental ambulatory surgery facility. Results are in the following table.

Total Medicaid Children	170,849
Number in Largest County	36,925
Name of Largest County	Cumberland
Percent of Eligible Patients Screened	50%
Percent Screened in of Need Dental Surgery	17%
Percent of Need Treated Per Year	15%
Annual Dental Surgery Cases	2,178
Hours Per Case	2.5
Operating Room Hours Per Year	5,446
Hours Per Room Per Year	1,872
Number of OR's Needed for Pediatric Medicaid	3

Note: See Attachment K for sources, calculations, and assumptions for each HSA and all of North Carolina.

The projections above are for Medicaid children alone. Experience at Village Family Dental indicates that 10 percent more capacity would be absorbed by additional pediatric patients sponsored by private payors, military programs and self-pay. The need is approximately consistent with what the state's 157 pediatric dentists could do working one day a week, 48 weeks a year, doing three surgical cases each operating room day (157*3*48= 21,357 cases). February 2015 data from DMA list 22 pediatric dentists who are taking new Medicaid patients.

⁸ The petitioner reduced CHiP counts by one-half to avoid duplication.

LOW REIMBURSEMENT

North Carolina Medicaid (DMA) pays a professional fee for children's dental procedures. Fees are low and billing is more cumbersome than small dental offices can handle. As a result, not all pediatric dentists accept Medicaid patients and Medicaid reimbursement. In addition to the professional fee, DMA also pays both a technical fee of \$300 to \$580 for procedures done in hospitals and ambulatory surgery facilities, and a very low anesthesia professional fee for the same procedures. The dental anesthesia fee, approximately \$113 for a case that could last 2.5 hours makes the Medicaid dental cases unattractive to anesthesiologists. (See Attachment E) DMA is aware that fees are low, but budget constraints prohibit it from making changes. Fees have not changed for a decade.

Published Dental Reimbursement Rates provide basis for Ambulatory surgery facility (ASC) Medicaid technical fee payments. Attachment D contains a copy of the current schedule. ASC facilities bill charges as a bundled rate, - one set payment of a predetermined amount, regardless of the amount or complexity of services performed. Time is the only variable. These services include observation, supplies, medication, operating room time, recovery, intravenous solution, etc. According to data provided by Mark W. Casey, DDS, MPH, Dental Director, DMA Clinical Policy and Programs, the average payment for a dental procedure in an ASC in 2014 was \$375.

The ASC reimbursement is approximately 22 percent of the hospital outpatient dental procedure reimbursement Hospital outpatient technical fees are the same, but charges are itemized and Medicaid reimbursement is based on a collection of services actually rendered. The average amount DMA paid for a 2014 dental case done in a hospital outpatient operating room was \$1,701. If a hospital outpatient cases were shifted to an appropriate ASC, the Medicaid savings would be \$1,326 per case. If 50 percent of all of North Carolina hospital outpatient dental surgery cases shifted to an ASC, the savings to the State would \$7.6 million, enough to provide DMA funds to serve more patients, improve provider and facility reimbursement, and to provide DMA savings as well. Copies of the DMA data are in Attachment E.

Although ASC's are more economical, less than six percent of North Carolina Medicaid cases occur in ambulatory surgery facilities. With the ambulatory surgery setting far more desirable for dentist and patient, the disproportion in location suggests an access limitation in the ASCs.

Moreover, while Medicaid pays hospitals more than surgery centers, the hospitals' dental case reimbursement is low relative to other surgeries and dental cases are the first to lose block time when hospital surgical caseloads grow.

HOSPITAL VERSUS ASC ADMITTING PRIVILEGES

Contributing to dental operating room access limitations, North Carolina hospital statutes (NCGS 131E-76 and NCGS 90-9) and licensure rules do not recognize dentists as providers who can admit independently.⁹ Consequently, a physician credentialed at the hospital must "sponsor" each patient. In addition, to meet CMS and Joint Commission requirements, hospitals must require that a physician who meets the hospital's medical staff by-law requirements, independently recertify the patients' histories and physicals (H&P) within 24 hours prior to surgery.¹⁰ In an ambulatory surgery center, on the other hand, North Carolina statute and regulations permit a pediatric dentist to admit directly and to recertify the H&P. Frequently, the family pediatrician performs the initial H&P. A shift of cases to an ASC may produce additional savings by not requiring a hospital medical staff member to sponsor the physician and recertify their patients. State ASC licensure rules are in Attachment F.

DENTAL AMBULATORY SURGERY CENTER

Dental cases are highly specialized. Sedating children for dental surgery requires skill, precision, trained staff, and specialized equipment. Multi-specialty ORs are inefficient for dental procedures and do not adequately meet the specialized need. Minimizing time under general anesthesia is critical to good post-surgical outcomes. A dedicated facility would support the high volume and specialization needed for optimal outcomes.

North Carolina has no dedicated dental ambulatory surgery center; and, the Proposed 2016 SMFP offers no way for areas in need to acquire one. The proposed 2016 SMFP and related CON Special Rules favor multi-specialty facilities. The exceptions are the six operating rooms associated with the 2010 SMFP Single Specialty Ambulatory Surgery Demonstration Project, and grandfathered eye and women's surgical centers. The Single Specialty Demonstration is collecting data to support earlier petitions that provided considerable information that implied potential improved outcomes in provider owned specialty operating rooms. The criteria for the Single Specialty demonstration are in Attachment G and could be adapted for the current proposed demonstration. <u>The Single Specialty Demonstration excluded</u> <u>the Cumberland County Metro area from participation</u>.

The proposed Demonstration project would be innovative for North Carolina, but not a first. The proposed demonstration is very similar to others across the county. Any approved pediatric dental ambulatory surgery center should have enough cases for pediatric dentists and staff to maintain and assure quality and proficiency. The petitioner identified six dedicated dental ASCs currently licensed in the US:

- 1. The dental ambulatory surgery center at the University of New Mexico has two operating rooms associated with a large dental clinic.
- 2. The Center for Pediatric Dentistry, a partnership of the University of Washington & Seattle Children's recently redesigned its Dental Surgical Center with two operating rooms.

⁹ 10A NCAC.13B.1905(a) and 10A NCAC 13B.1902(26)

¹⁰ The JCAHO rule states that the "History & Physical examination must be completed by a physician (as defined in section 1861(r) of the act)". Section 1861(r) of the (U .S. Social Security Act includes Doctor of Dental Surgery and Doctor of Dental Medicine in its definition of a physician.

- Children's Dental Surgery Center in Santa Ana, California, the first pediatric dental surgery center in the nation with Joint Commission accreditation, has one operating room, supports only five pediatric dentists, and serves children between 20 months and 12 years old.¹¹
- 4. PDI Surgery Center, in Windsor, California has been in operation five years. Its two operating rooms serve children from 30 Northern California counties.
- 5. Children's Surgery Center of Lancaster, Pennsylvania. The Lancaster facility has two operating rooms and completed 2,070 cases in 2014, including 5 cases over age 17
- 6. Children's Surgery Center of Malvern, Pennsylvania. The Malvern facility did 2,698 cases that same year, including 532 cases of patients age 18 and over. The Malvern ASC has three operating rooms.

SOUTHEASTERN NORTH CAROLINA ACCESS PROBLEM - EXAMPLE

The petitioner believes the pressing issue is availability of dental operating room time. According to KSAs records, pediatric dentists performed approximately 1,421 pediatric surgeries in 2014, at three hospitals. The waiting time for dental operating room schedule for the petitioner's pediatric dentists is now <u>four</u> months. For children who have dental pain or infection, that is an eternity.

There are not enough facilities available to KSA to meet the surgical needs of their patients. In 2014 KSA pediatric dentists performed surgery at Cape Fear Valley, Southeastern Regional, and Central Carolina. Effective December 31, 2014 Southeastern Regional Medical Center cancelled all dental surgery block time, even at its new ambulatory surgery center. KSA was told not to request credentialing at the ASC.

KSA appreciates efforts by Cape Fear Valley to make block time available However, recent block time overtures have not fit KSA's already overbooked office schedule. KSA sees approximately 17 pediatric patients a day requiring pediatric surgery. <u>Presently, it can get only three on a hospital surgical schedule.</u>

The analysis of block time is in Table 2.

¹¹ <u>http://www.childrensdentalsurgerycenter.com/cds-facilities.htm</u>

Location	Annual Cases 2014	Cases per Block	Blocks Needed per Month	Available Blocks July ¹²	July 2015 Block Deficit	Percent of 2014 cases blocked
Cape Fear at Highsmith Rainey	1,227	3	34	19	15	56%
Southeastern Regional Medical Center	135	3	4	0	4	0%
Central Carolina	59	3	2	2	0	122%
CFVMS -Hoke**	0	3	4	8	-4	200%
Harnett Health	0	3	0	0	0	NA
Total KSA pediatric surgical cases	1,421	15	43	29	14	67%

Table 2. Analysis of KSA Pediatric Operating Room Need,Average Blocks Needed in 2014 and 2015 Available

KSA supplements lack of block by using work-in time from blocks not used by other surgeons. This requires extra scheduling logistics and often results in failure to stay on the operating room schedule on the date patient and dentist show up at the hospital. To do this, KSA books cases three months in advance to try to get the first come first serve time when the block is released. This increases KSA access to operating rooms, but is frequently inconvenient to patients because of the short notice.

Also contributing to inefficiency is the need to coordinate with other providers required to support admission to surgery. Pediatric dentists must arrange for a pediatrician credentialed with the hospital to complete a history and physical. Next, the pediatric dentist must be sponsored by a physician on staff at the hospital in order to admit the patient. Then, the pediatric dentist must arrange for the H&P Update to be completed within 24 hours. Logistically, anesthesiologists are the only ones available to do this if the patient wants to combine this visit with the surgery visit. Medicaid does not pay for this service. Because the Medicaid anesthesia fee is so low, and because KSA has so many patients, the anesthesia group charges KSA for this service to its patients, adding costs to the health care system. At an ASC, the dentist could do the history and physical recertification.

Based on patient need, KSA could significantly increase the number of patients receiving surgery. The practice does 24,750 pediatric patient visits each year. Of those, 17 percent need a follow-up operating room based procedure under general anesthesia. This amounts to 4,208 cases per year. The actual number of surgeries KSA can complete with available block time is only a fraction of 4,208.

Most dental patients are otherwise healthy. Very few have co-morbidities that would prevent medical clearance for treatment in an ambulatory surgery center. At the insistence of Cape Fear Valley anesthesiologists, KSA already sends its complex cases to UNC- Chapel Hill.

Low use of block time in hospitals at the edge of its service area reflects patient problems with transportation more than KSA staff issues. Medicaid pediatric patients make five trips for diagnosis,

¹² July block times available to KSA provided by Virginia Jones, COO

clearance and surgery in hospitals. This is more than some caregivers can handle. A dental ambulatory surgery center could reduce these trips to two.

DMA statistics show that 52 percent of North Carolina Medicaid children receive at least one dental visit. CMS data report that only 24 percent receive treatment. Many participating dentists take only a few Medicaid patients. Hence, opportunities for over use of Medicaid pediatric dental surgery are very limited.

The lack of facilities is creating additional health problems for an at risk population, generally young and low-income patients.

Recruiting pediatric dentists to this rural area is difficult. In a three-year period, the petitioner's practice will hire one of fifteen interviewees. Other practices in the area face similar challenges. In the petitioner's service area (Attachment J), the ratio of dentists to population is well below the state average. Based on the Sheps Center longitudinal dental database, North Carolina had a ratio of 4.546 dentists per 10,000 population in 2013. This ratio is 3.202 in the six county area served by KSA, or 70 percent of the state average. See Table 4, below for details.

Location	July 2013 Estimated Population	Dentist/ 10,000 Pop	Percent of State Average	
North Carolina	986,1952	4.546	100	
Bladen	35,209	1.704	37	
Columbus	57,739	1.559	34	
Cumberland	332,553	4.571	100	
Hoke	50,672	1.381	30	
Robeson	13,010	1.866	41	
Scotland	36,223	2.209	48	
Service Area	646,406	3.202	70	

Table 3. 2013 Supply of Dentists who are Active or Have Unknown Activity Status

Source:

http://www.osbm.state.nc.us/ncosbm/facts_and_figures/socioeconomic_data/population_estima_ tes/demog/countygrowth_cert_2013.html

 $http://www.shepscenter.unc.edu/workforce_product/longitudinal-data-dentist-profile/$

Finally, block time is only part of the problem. None of the local hospitals have operating rooms designed for dental surgery. Tables are flat, working at the patient head involves competing with anesthesia equipment; sterile processing often damages the fine instruments that dentists themselves must supply.

STATEMENT OF ADVERSE EFFECTS ON CONSUMERS, PROVIDERS AND PAYERS IF THE ADJUSTMENT IS NOT MADE

CONSUMERS

Delays associated with hospital OR block scheduling cause pediatric patients to wait four months for dental surgery in the petitioner's service area. If not scheduled promptly, many of these patients will become emergency room patients.

Emergency dental care is expensive and preventable. Untreated early childhood caries result in poor physical development, missed days of school, and poor performance in school. Delayed early childhood dental treatment of dental caries can, at worst, result in a brain abscess or sepsis.¹³ The US Agency for Health Research and Quality reports that dental emergency visits rates are twice as high in rural and non-metropolitan areas as in large metropolitan areas with more than one million residents. The same report found that dental-related ED visit rates were four times higher among patients from the lowest income categories than from the highest income communities.

Untreated children's dental caries:

"Rampant decay can negatively impact a child's overall quality of life, inhibit their cognitive and social development and compromise their growth, function and self-esteem.

Pediatric dental disease is 5 times more common than asthma and 7 times more common than hay fever.

- Left untreated, pediatric dental disease can lead to malnourishment, bacterial infections, required emergency surgery and even death.
- Pain and infection caused by tooth decay can lead to problems in eating, speaking and learning.
- Dental disease has been linked to heart disease, stroke, diabetes, pneumonia, poor pregnancy outcomes and dementia."¹

¹ Facts About Tooth Decay. <u>http://www.ncohf.org/resources/tooth-decay-facts</u> 2012-2015

¹³ Ibid

This report showed 211 ED visits for dental caries per 100,000 population between ages 15 and 19. The payer source for these visits is 30 Medicaid, 40 percent uninsured, and 30 percent private and other.¹⁴ These ED visits do not result in definitive treatment. The patients still require another visit or visits to dentists to treat the problem. These add to the cost of care. This high volume of uninsured and Medicaid dental patients place a large burden on public and private financial resources.

Research also shows that dental care is second only to public speaking on the fear scale. Dental fear translates to care avoidance. Getting young children into a care routine removes that fear factor as they become adults. Long term, this reduces the cost of dental repair.¹⁵

Finally, the extra trips associated with the current system for dental surgery in hospitals result in frustration. Each extra visit equals valuable time away from work and additional travel expense. Caregivers often wear out before they complete the pre-requisites. Cases are often cancelled and forced to be rescheduled on the hospital's OR schedule, exasperating the problem.

The status quo is potentially harmful to consumers, specifically children in low-income families. It has a real economic impact on these families. If patients and caregivers could go to one location, treatments would be easier to coordinate, less expensive, and less time consuming.

PAYERS

Medicaid, private insurance and out-of-pocket expenses pay for dental surgery. Medicare covers beneficiaries only when the dental problem produces a medical emergency. With inadequate access to timely and appropriate intervention, persons for whom preventive care has failed are at risk for use of more expensive interventions. Payers stand to gain healthier, less costly beneficiaries if dental access is improved.

NC Medicaid also stands to gain financially if dental cases move to a more appropriate setting in an ASC. DMA data in Attachment E show that NC Medicaid pays four times as much for an outpatient dental case in a hospital than in an ambulatory surgery center, an average of \$374, compared to \$1,701 per case in 2014.

PROVIDERS

The NC State Board reports 4,856 licensed and active in NC dentists.¹⁶ According to North Carolina Division of Medical Assistance 1,830 dentists, 1,786 in North Carolina will accept NC Medicaid as of February 2015.¹⁷ This implies that as only 37 percent (1,786/4,856) of NC dentists accept Medicaid. This number may be low, based on the possibly of a dentist being active in a research or industry capacity and not in an active clinical practice. Moreover, there are only 176 pediatric dentists, 157 of which accept Medicaid.

¹⁴ H-CUP Statistical Brief #143, Emergency department Visits for Dental Related Conditions, 2009 <u>http://www.hcup-us.ahrq.gov/reports/statbriefs/sb143.pdf</u>

¹⁵ The Pew Center on States, The Cost of Delay State Dental Policies Fail One in Five Children, 2010.

¹⁶ http://www.ncdentalboard.org/publications.htm July 24, 2015

¹⁷ http://www2.ncdhhs.gov/dma/dental/dentalprov.htm

Retaining dentists, especially pediatric dentists willing to serve rural patients, is essential for North Carolina to improve its national dental health status ranking. Most states, including North Carolina have a shortage of dentists. If dentists in North Carolina cannot practice at the top care level of their license, communities outside the state will easily recruit them away. Knowles, Smith & Associates is committed to building a critical mass of highly credentialed and specialized dentists who are willing to tackle the difficult problems associated with care of Medicaid and military beneficiaries. The proposed demonstration project will be attractive to pediatric dentists. It will help KSA and other area practices recruit qualified dentists to serve patients in rural areas of SE North Carolina, especially Medicaid beneficiaries. It may lead pediatric dentists to start new practices in the area. Moreover, it that will assure that providers using the new center will meet the needs describes the SMFP policies by requiring high levels of Medicaid and charity service.

The petitioner accepts the DMA concern that Medicaid access is an issue regardless of age group and is willing to admit patients regardless of age or payment. The petitioner has been particularly plagued by the cumbersome arrangements necessary to provide care for its pediatric patients, but recognizes the state policy issue with regard to all Medicaid patients.

Most importantly, the demonstration project will allow pediatric dentists to provide <u>better</u> care for their patients. Like all providers, pediatric dentists have an obligation and desire to provide the highest quality care.

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

Over the past 15 years, KSA tried and / or considered multiple alternatives to the proposed Demonstration Project.

NON-SMFP ALTERNATIVES

Office sedation with conscious sedation is a solution for some patients, but not an option for all patients. The sedation may be too light, there may be too many required appointments, compromised airways, or long appointments required that are intolerable to young children. Most recent adverse outcomes have occurred under in office conscious sedations. These cases may have avoided those outcomes if general anesthesia had been used. Additionally, in many cases, conscious sedation requires a child to endure multiple procedures, when general anesthesia would require only one.

In 2009, representatives approached the CON Section for an exemption to do surgery in their offices. DHSR staff informed KSA that surgery involving Medicaid payment requires a Certificate of Need for an ambulatory surgery facility. There was then, and is now, no need for operating rooms in the State Medical Facilities Plan. To establish partial relief, representatives met with the Division of Medical Assistance (DMA) to request an additional billing code for the newly required H&P recertification. DMA explained that the Medicaid budget has no room for more codes.

The petitioner met with hospital administration at both Southeastern Regional Medical Center and Cumberland County Health System, and has yet to find a solution that works well within existing constraints. KSA understands the hospitals' own constraints in this low income under-resourced area.

STATUS QUO

Pediatric dentists remain frustrated by their inability to meet the needs of their patients. Maintaining the status quo may cause these providers, the supply of which is already too low in the state, to move elsewhere.

The status quo does not support residents of KSAs service area (Attachment J). At best, patients face delays of four months for service, and, in some cases, receive no service. As population and the need for pediatric dental surgery grow, the status quo will be an even worse alternative. The issue has a reached a critical point. It needs addressing now.

WAIT FOR SMFP TO SHOW NEED

It probably will be a long time before the SMFP shows a need for an additional operating room in Cumberland County. In the 2016 Proposed SMFP Cumberland has a surplus of 2.68 operating rooms. In Robeson County, adjacent to Cumberland, there is a surplus of 4.45 operating rooms. While each of these counties is a separate operating room planning area, their surplus demonstrates that it is unlikely that the SMFP will have a need in the near future. If a need does develop, current rules would result in disapproval of a dental-only surgery center they require multiple specialties.

CHANGE THE SMFP OPERATING ROOM METHODOLOGY

KSA looked long and hard for and additional methodology that would define in the SMFP the number and location of needed dental operating rooms. KSA presented two methodologies to the SHCC in a March 2015 petition. (Attachment B)

The state planning staff recommended that the petition be denied, favoring support for standard OR methodologies, and not "changing policies or methodologies to address issues regarding a single specialty, whether it be a proposed new single-specialty facility or ORs dedicated to a single specialty in an existing facility." The SHCC denied the petition at its meeting on June 3, 2015. The agency recommendation for denial is in Attachment H.

USE OPERATING ROOMS IN OTHER PARTS OF THE SERVICE AREA

KSA pediatric dentists perform some cases at Central Carolina Hospital in Lee County. Central Carolina has capacity and accommodates the cases. However, this scenario is not a sufficient alternative for all KSA patients. Though convenient for patients who live in the Lee County area, Central Carolina is 50 minutes from Fayetteville and 1.5 hours from Lumberton. The block time provides some relief by decreasing waiting times for the surgery schedule, it is inconvenient for many KSA patients and their families, most of whom are low income.

Getting care so far from home increases patient out of pocket costs by adding travel time and expenses.

The petitioner has discussed the feasibility of doing dental cases in the operating rooms at the new First Health Hospital, in Hoke County. While the management of the new facility is willing to work with KSA, and block time became available this spring, this alternative will improve the travel time and accessibility for some pediatric dental cases but will not meet all the need in the service area. Other rural hospitals with underutilized operating room capacity also may be an option, but each will have compromises. Few rural hospitals have the resources to provide dental operatories, dental instrument processing or dental technicians. Lack of appropriate operatories compromises dentist and patient during a long surgery. To compensate for the others, dentists must bring their own instruments and staff. Moreover, KSA dentists face the challenges in regard to finding a "sponsoring" and credentialed physician to complete the history and physical.

CREATE A DEMONSTRATION PROJECT FOR A DEDICATED DENTAL OPERATING ROOM IN CUMBERLAND COUNTY

A demonstration project for dental surgery would provide an opportunity for the state to learn more about dental surgical service, while responding to increasing preference for general anesthesia for pediatric cases. The demonstration would meet the needs of the patients in Cumberland and surrounding counties. These patients, predominately low-income children, would benefit by having their cases performed in a timely manner, in a safe environment with staff and equipment dedicated to dental surgery. The cost to the patient and to payors would be less than in a hospital operating room; and their travel time and costs reduced. A single location for operating room and dental offices would also reduce the numbers of emergency room visits for patients and their families'. Evaluation and presurgery planning could occur at the same visit.

This alternative provides the most desirable alternative for the patient, the family, the provider and for the State, the primary payor for outpatient dental surgery.

EVIDENCE OF NON-DUPLICATION OF SERVICES

The proposed solution is an additional operating room in a dental specific licensed ambulatory surgical facility to serve dental patients, primarily children on NC Medicaid or Health Choice, who live in an area with a demonstrated need. The small scale of the project permits the state to increase capacity for a limited population and to review the progress of this approach. The proposed demonstration will include measuring impact on patients, facility providers and dentists. The hypothesis is that the quality will remain at the same or greater level, thus leaving existing area facility providers unharmed, and professional dental providers will not leave the area.

There is no proposed duplication of service. Currently there are no dedicated dental operating rooms in the proposed service area; and KSA has demonstrated that lack of access limits care. The demonstration project would be open to all providers.

EVIDENCE OF CONSISTENCY WITH NORTH CAROLINA STATE MEDICAL FACILITIES PLAN

OVERVIEW

The proposed demonstration project is consistent with Basic Governing Principles in the 2016 SMFP Basic Governing Principles

1. Safety and Quality

This basic principle notes:

"...the importance of systematic and ongoing improvement

"...priority should be given to safety, followed by clinical outcomes, followed by satisfaction.

"...metrics should be standardized and widely reported and preference should be given to those metrics reported on a national level.

"...the SHCC should regularly review policies and need methodologies and revise them as needed to address any persistent and significant deficiencies in safety and quality in a particular service area."

Assurance of quality oversight is the intent of the licensure and certification components of the policy. Licensure by North Carolina DHSR and Certification by CMS will assure that the dental operating rooms operate by the same standards of quality as other operating rooms in the state. CMS accepts deemed status for operating rooms made available in facilities accredited by the Joint Commission, Accreditation Association for Ambulatory Health Care (AAAHC), or <u>American Association of Accreditation of Ambulatory Surgery Facilities(AAAASF)</u>, and should be accepted for these facilities as well. The petitioner intends to apply for AAAHC accreditation.

North Carolina does not have a dental specific model for this ambulatory surgery facility, but the recently developed clinic and ambulatory surgery center at the University of New Mexico demonstrates that the North Carolina is not the first to address the problem.¹⁸

The proposed demonstration project will require continuous monitoring of utilization and quality measures. This ongoing process help create an environment of continuous quality improvement in the proposed operating rooms. The internationally recognized WHO Surgical Safety Check List will be used as part of this monitoring to assure a safe operating room program.

¹⁸ https://www.healthdesign.org/clinic-design/clinic-examples/university-new-mexico-dental-clinic-and-surgery-center

The American Dental Association (ADA) Dental Quality Alliance is developing measurements, DQA Measure Activities, in several areas of practice. The current focus is on pediatrics. The first measure set is published, and the set "Pediatric Oral Health" is being reviewed. These measures will be used to focus on the interventions used and the outcomes in pediatric dental care. The pediatric measures will focus on:

- Utilization of Services
- Usual Source of Care
- Care Continuity
- Care Coordination
- Evaluation/Treatment Planning
- Prevention
- Treatment
- Clinical Service Quality
- Patient Satisfaction/Experience
- Oral Health Status (disease/function)
- Quality of Life
- Value¹⁹

All KSA providers are licensed by the North Carolina Board of Dental Examiners, and participate in continuous education and Board monitoring. This will be a requirement for any persons requesting surgical privileges in the dental operating rooms. The Board closely monitors the use of sedation / anesthesia by dentists. Anesthesia in the demonstration surgery project will be under the direct supervision of certified anesthesia providers.

2. Access

This basic principle notes:

"The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.

"The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards."

"Comparisons of value and quality are most likely to be valid when services are provided to like populations. Incentives for quality and process improvement, resource maximization, and innovation are most effective when providers deliver services to a similar and representative mixture of patients.

¹⁹ http://www.ada.org/~/media/ADA/Science%20and%20Research/Files/dqa_environmental_scan.ashx

"The needs of rural and small communities that are distant from comprehensive urban medical facilities merit special consideration. In rural and small communities selective competition that disproportionately captures profitable services may threaten the viability of sole providers of comprehensive care and emergency services. For this reason methodologies that balance value, quality, and access in urban and rural areas may differ quantitatively. The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards."

The demonstration project provides for coverage by all payers and care for all age groups. It puts particular emphasis on persons most in need, pediatric dental patients in low-income, non-metropolitan communities. The demonstration does not place additional dental operating rooms in areas where hospitals are willing and able to provide the services.

3. Value

This basic principle notes:

"The SHCC defines health care value as the maximum health care benefit per dollar expended.

"...Cost per unit of service is an appropriate metric...

"...At the same time overutilization of more costly and/or highly specialized low-volume services without evidence-based medical indication may contribute to escalating health costs without commensurate population-based health benefit.

"The SHCC encourages the development of value-driven health care by promoting collaborative efforts to create common resources such as shared health databases, purchasing cooperatives, and shared information management, and by promoting coordinated services that reduce duplicative and conflicting care."

By requiring facilities approved under the proposed change to maintain transfer agreements with at least one hospital, the petition meets this principle. The alternative, not having capacity for pediatric dental surgery, produces multiple unnecessary and costly ED visits that do not treat the problem.

This petition demonstrates the potential Medicaid savings and benefits by offering dental ASC operating room, rather than hospital operating rooms. The ASC Medicaid payment is 22 percent less than the hospital's outpatient payment.

Improved geographic access improves efficiency and decreases overall costs. Patients make fewer visits to the provider and the OR facility, travel less time and delay treatment less often,

Providers and staff decrease their travel time and decrease equipment damage when they do not have to bring their instruments for sterile processing prior to surgery or bring their own technical staff. They should improve utilization, efficiency and outcomes when the work occurs in a dedicated environment.

The petition demonstrates the economic benefit of providing timely treatment of pediatric dental conditions and avoiding emergency department visits as well as long-term health conditions caused by untreated dental disease.

CONCLUSION

Dental surgery is highly specialized. It requires special equipment, including dedicated room design. Medicaid pediatric patients account for a large portion of dental surgery. Delay or deferment of surgery causes patients, families, providers, and the North Carolina Medicaid program to incur significant cost. Few hospitals and ambulatory surgery facilities accommodate pediatric dental cases on a regular basis. North Carolina currently has no model of care facility dedicated to dental ambulatory surgery. However, models are available in other states.

Of the 2.8 million children in the state, over one million are eligible for Medicaid in a given month. There are 157 pediatric dentists, of whom 127 accept Medicaid and 111 are accepting new patients according to DMA. Alone, this is a limiting factor in access to care. Making it easier for dentists to schedule pediatric patients who need general anesthesia should be a priority, especially when the cost to the state can be 22 percent of what the same service would cost in a hospital outpatient operating room.

Encouraging systematic growth of quality pediatric dental care would prevent unnecessary and expensive emergency room visits, support military and low-income families, and help retain and increase the number of highly qualified providers in shortage areas in the state.

A demonstration project that provides an operating room that would provide the essential element for a dedicated, licensed and certified dental ambulatory surgery facility in a geographic area that has significant concentrations of unmet need would provide safe, quality care for patients, affordable options for private and public payors, and increased geographic access for patients, families and providers. A demonstration provides slow, orderly growth of a new model of care, and prevents unnecessary duplication. It also would improve recruitment and retention of dentists in underserved areas, and would bring innovation and value to the state's health care delivery system.

ABOUT THE PETITIONER

Knowles, Smith &Associates, LLP (KSA) is the largest, multi-specialty dental practice in the Fayetteville region. KSA does business under the practice name of Village Family Dental. It has 38 dentists, including: eight pediatric dentists certified by the American Board of Pediatric Dentistry two endodontists, two periodontists, two oral surgeons and four prosthodontists, all Board Certified. Offices are Cumberland County, with additional offices in Robeson, Hoke, and Scotland Counties, each among the poorest and most underserved in the state. Approximately half of its patients come from Cumberland County; the others originate throughout Eastern North Carolina. See Attachment J for a map of KSAs 11 offices.

In 2014, the petitioner completed 1,420 pediatric dental general anesthesia cases in hospitals. KSA dentists are credentialed to practice in five area hospitals.

Two KSA dentists are on faculty at UNC-CH, and ECU Dental schools, respectively. One provider is an MD/Oral Surgeon specializing in facial aesthetics and facial reconstruction. The practice employs six CRNAs, who work in the offices daily to assure safe sedation procedures. Among its dentists, two are IV sedation certified general dentists, and KSA managing partner, Anuj James, DDS, serves on the Board for the American Academy of Group Dental Practices. Faith McGibbon, DDS, a senior partner with KSA and a pediatric dentist, is responsible for the pediatric dental team. Pediatric specialists see 15-20 children daily in each location, approximately *100 children per day*. The majority of these children are in low wealth, minority families and struggle with access to care issues. KSA is one of the few practices in the area that accepts NC Medicaid / HealthChoice, particularly for children under age eight.

KSA's eight pediatric dentists maintain credentials to practice at five hospitals including Cumberland Health System hospitals, Cape Fear Valley Medical Center and Highsmith Rainey Hospital; at Central Carolina Hospital, and at Southeastern Regional Medical Center. Their hospital privileges permit them to do surgical procedures but they must have a sponsor in order to do the hospital inpatient or outpatient admission. The professional practice staff includes 27 licensed Dental Hygienists. The practice collectively serves 30 percent military or retired military and 35 to 40 percent Medicaid beneficiaries.Some individual offices have up to 60 percent Medicaid. Of the pediatric patients, Medicaid covers 90 percent. Overall, 35 to 40 percent of practice patients are covered by Medicaid, About three percent of cases are charity. KSA takes pride in providing the same quality of care for all patients, regardless of their ability to pay or payment method. KSA was founded in 1985 on the principle that every patient is treated the same regardless of socioeconomic class or payer method. In the last thirty years, KSA has focused on prevention and community outreach. Each year, KSA staff visit every primary school in a three county service area and do a presentation about prevention to children pre-kindergarten through fifth grade. Each child receives a dental kit including toothbrush, toothpaste, floss, and a training guide. KSA provides a biweekly cartoon and activity in the Cumberland County schools children's magazine that teaches children how to take care of their teeth. KSA hygienists use the nationally re4cognized CAMBRA (Caries Management by Risk Assessment) assessment program, which gives each patient a risk assessment based on their current status, medical condition, and previous dental history. With the assessment, the patient receives educational material on how to prevent further dental related issues- including brush and floss daily, nutrition, and oral health.

KSA staff also volunteer at the Cumberland County CARE clinic providing free care to uninsured lowincome adults, with America's Dentist Care Foundation Missions of Mercy and with Give Kids a Smile, a national program sponsored by the American Dental Association. Staff also participates in health fairs, festivals, and social events throughout the Fayetteville area, promoting good oral health.

ATTACHMENTS:

Report: <i>The Dental Workforce in North Carolina: Trends, Challenges and Opportunities,</i> UNC Sheps CenterA
Alternate Methodologies for Dental Operating Room NeedB
Letter of Support: North Carolina Dental SocietyC
Dental Reimbursement Rates by CDT CodeD
Data: Medicaid Payments for Dental Surgical Cases, SFY 2014, DMA, Dr. Casey E
G. S. 10A NCAC 13C, Licensing of Ambulatory Surgical Facilities F
2010 State Medical Facilities Plan, Table 6D: Single Specialty Ambulatory Surgery Facility Demonstration ProjectG
Petition to Add New Policy OR-1, Spring 2015 Agency ReportH
Village Family Dental Six-County Service AreaJ
Model to Estimate Ambulatory Dental Surgery Operating use by Pediatric Dental Medicaid Beneficiaries, 2014K

Attachment A

Report: "The Dental Workforce in North Carolina: Trends, Challenges, and Opportunities" UNC Sheps Center

The Dental Workforce in North Carolina: Trends, Challenges and Opportunities

Erin Fraher, PhD MPP

Assistant Professor, Depts. of Family Medicine and Surgery, UNC

With Julie Spero, Katie Gaul and Victoria McGee North Carolina Health Professions Data System

2013 NC Dental Public Health Educational Conference

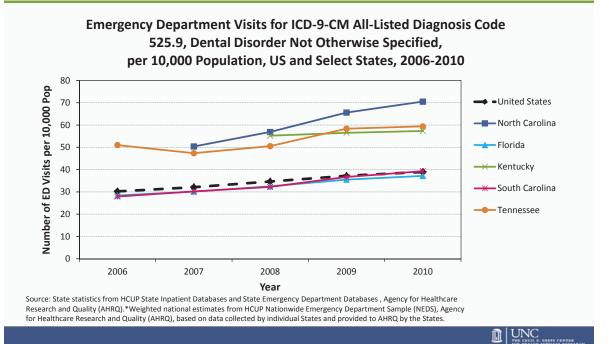
March 5, 2013



Overview of Presentation: The View from 30,000 Feet

- Access to oral health care is multifaceted, more complex than "counting noses"
- But basic data on workforce supply, distribution, demographic and practice characteristics can provide powerful evidence to inform policy
- Projections of future supply allow us to simulate effect of policy, workforce changes and new models of care
- State budget constraints create need to show "bang for buck" for public investments in education
- Rapid pace of health system change provides policy window to improve flexibility in how/where workforce deployed

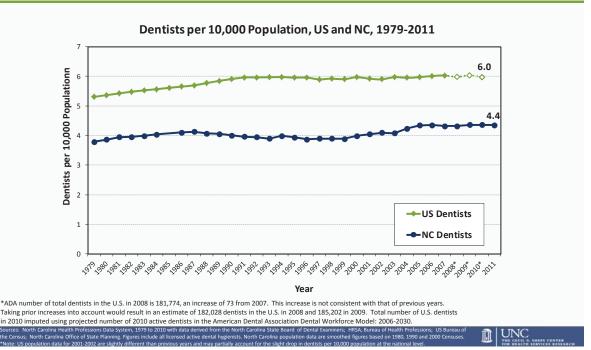
NC has high per capita rate and most rapid increase in ED visits for dental disorders



North Carolina versus the United States: Supply and Distribution



NC has consistently lagged behind US in dentists per capita

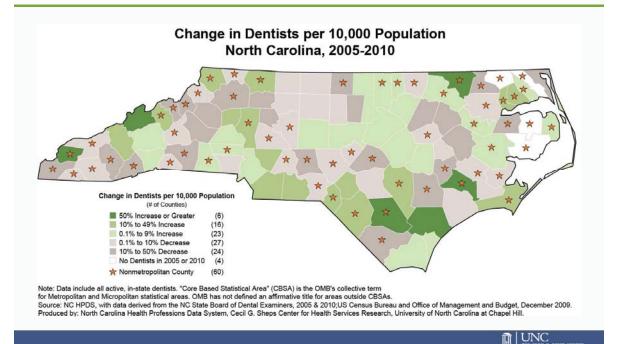


And has lagged behind most states as well...

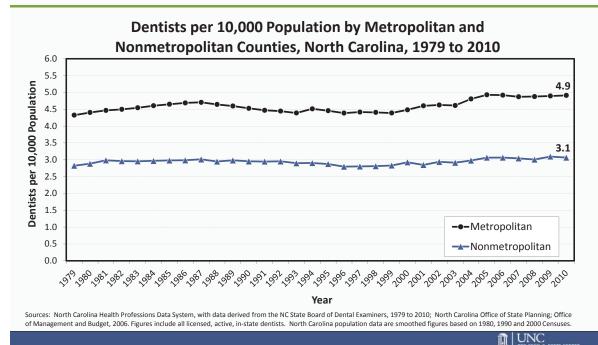
Active Dentists per 10,000 Civilian Population								
	1996		2000		2003		2007	
	Rank	Ratio	Rank	Ratio	Rank	Ratio	Rank	Ratio
United States		6.1		6.1		6.0		6.0
Top Ranked								
Massachusetts	4	8.1	2	8.1	2	8.2	1	8.2
Hawaii	1	8.9	1	8.2	1	8.2	2	8.1
New Jersey	5	8.1	4	7.9	3	7.9	3	8.1
New York	2	8.2	3	8.0	4	7.9	4	7.9
Bottom Ranked								
North Carolina	47	4.4	47	4.2	47	4.4	47	4.5
Alabama	46	4.4	46	4.3	45	4.4	48	4.4
Arkansas	48	4.1	48	4.0	48	4.1	49	4.1
Mississippi	49	4.0	49	3.9	50	4.0	50	4.1

Source: US Department of Health and Human Services. Centers for Disease Control and Prevention, National Center for Health Statistics. (2010). Health, United States, 2010. http://www.cdc.gov/nchs/data/hus/hus10.pdf

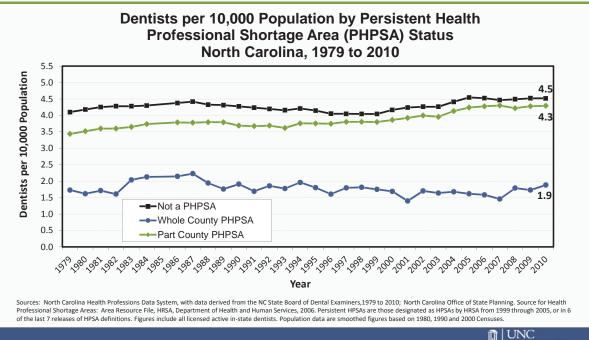
Over half of NC's counties saw a loss or no change in ratio of dentists per capita



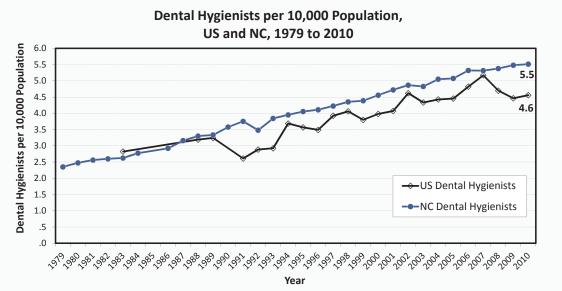
Per capita supply of dentists in nonmetropolitan counties is stagnant...



... And the gap between NC's most underserved and not underserved counties has been slowly widening



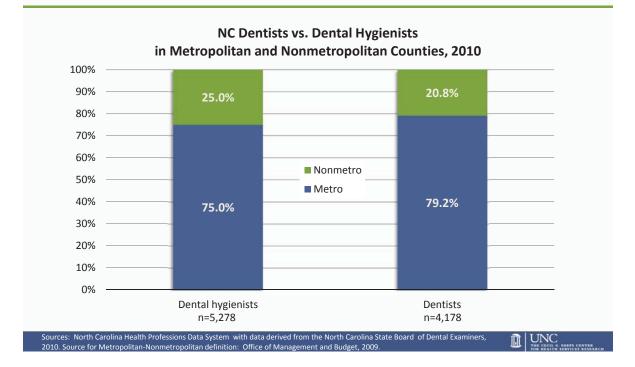
NC has more dental hygienists per capita than the US average



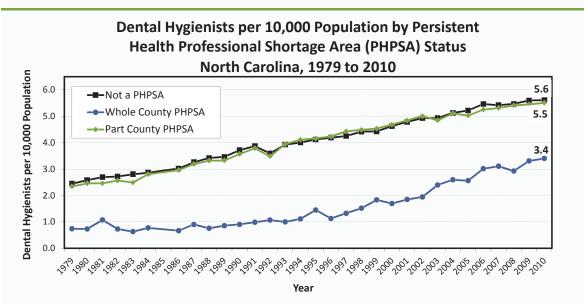
Sources: North Carolina Health Professions Data System, with data derived from the NC State Board of Dental Examiners 1979 to 2010; HRSA, Bureau of Health Professions; US Bureau of the Census; North Carolina Office of State Planning. Figures include all licensed active dental hygienists. North Carolina population data are smoothed figures based on 1980, 1990 and 2000 Censuses.

UNC

Dental hygienists slightly more likely than dentists to practice in nonmetropolitan counties



Unlike dentists, hygienists experienced some growth in supply in NC's most underserved counties



Sources: North Carolina Health Professions Data System, with data derived from the NC State Board of Dental Examiners, 1979 to 2010; North Carolina Office of State Planning. Source for Health Professional Shortage Areas: Area Resource File, HRSA, Department of Health and Human Services, 2006. Persistent HPSAs are those designated as HPSAs by HRSA from 1999 through 2005, or in 6 of the last 7 releases of HPSA definitions. Figures include all licensed active in-state dental hygienists. Population data are smoothed figures based on 1980, 1990 and 2000 Censuses.



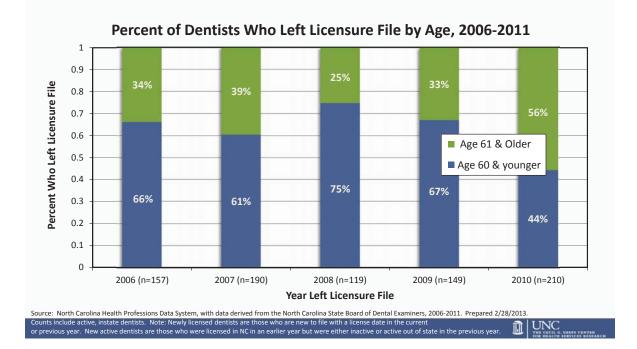
Demographic and Practice Characteristics

Trends look smooth but there is a ~10% churn in workforce every year

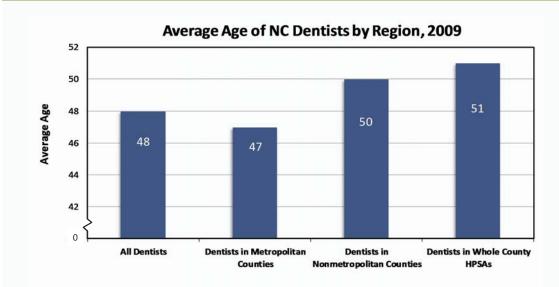
I UNC



Fewer dentists left workforce during recession but older dentists now retiring in greater numbers

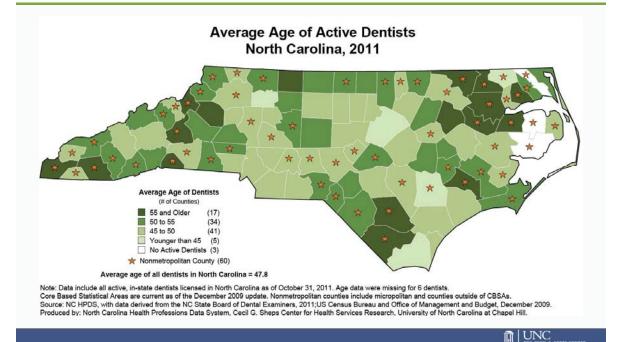


North Carolina's dental workforce is graying

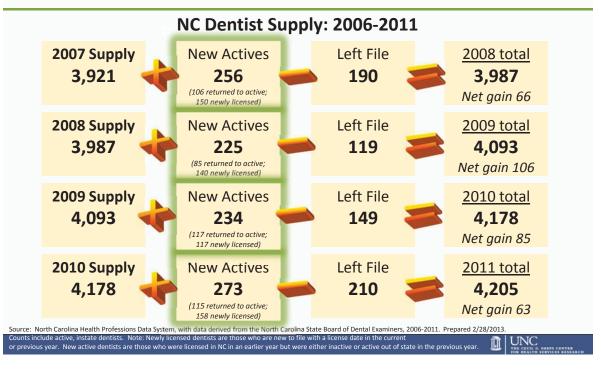


4 counties in NC have dentists whose average age is 60 years or older

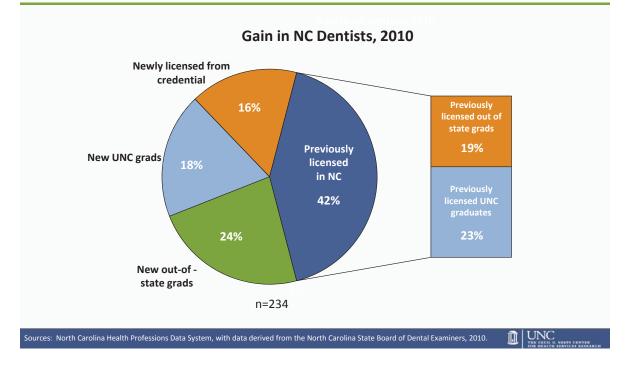
Rural, contiguous counties with older dentists are a concern



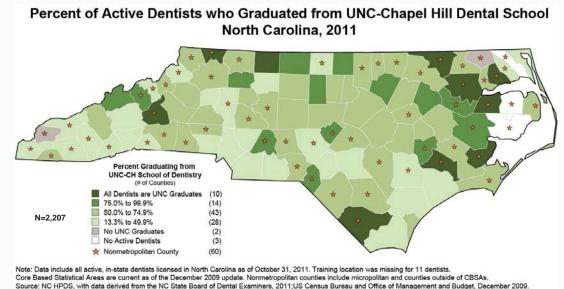
Now let's focus on the new entrants to the dental workforce



Where do our new dentists come from?

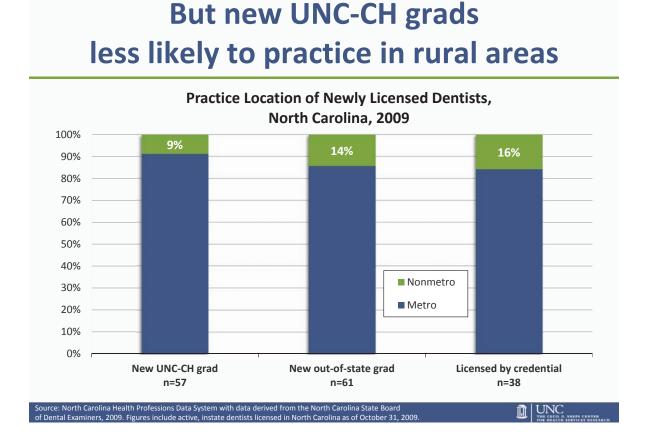


More than half of NC's overall dentist workforce graduated from UNC

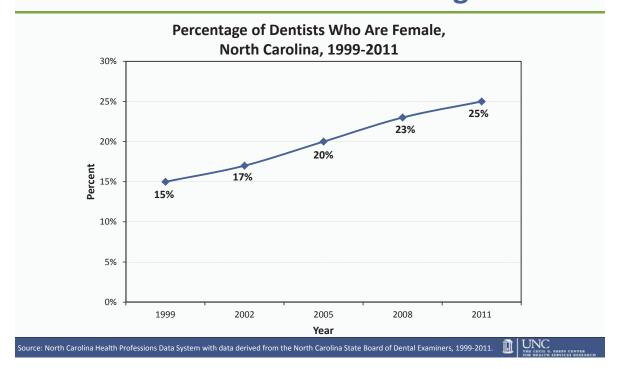


Source: NC HPDS, with data derived from the NC State Board of Dental Examiners, 2011;US Census Bureau and Office of Management and Budget, December 2009. Produced by: North Carolina Health Professions Data System, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill.

UNC



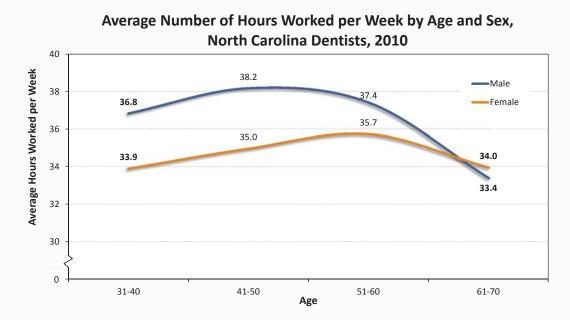
Percent of women in workforce increasing



Male dentists are older than female dentists

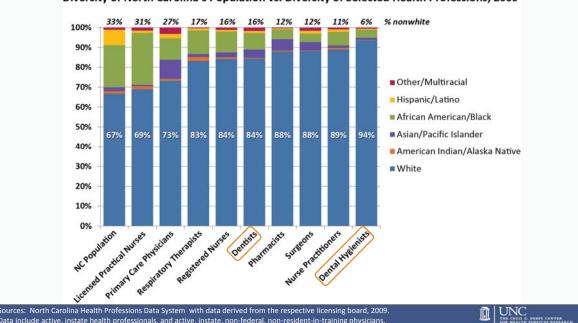
Active NC Dentists by Age and Sex, 2010 females males Age Number of Dentists Sources: North Carolina Health Professions Data System with data derived from the North Carolina State Board ìÌ of Dental Examiners, 2010

Biggest driver of workforce supply is FTE: Male dentists' hours peak in mid-40s, Female dentists peak in mid-50s



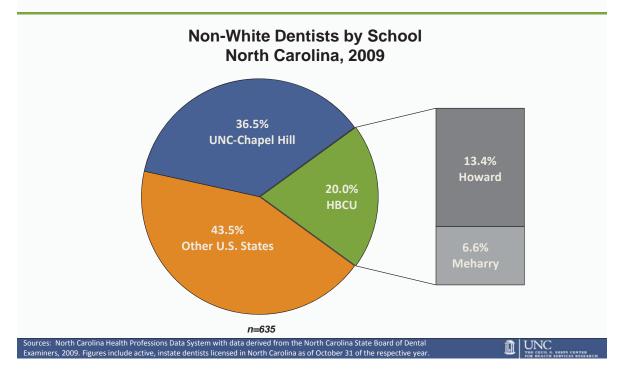
Sources: North Carolina Health Professions Data System with data derived from the North Carolina State Board of Dental Examiners, 2010. Figures include active, instate dentists licensed in North Carolina as of October 31 of the respective year.

Race/Ethnicity of dentist and dental hygienist workforce falls short of matching population diversity



Diversity of North Carolina's Population vs. Diversity of Selected Health Professions, 2009

Most of NC's non-white dentists educated out of state



About three out of four North Carolina dentists are in general practice

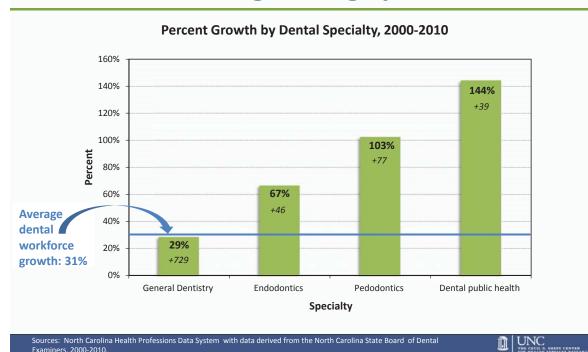
General Practice	78% (3,278)
Orthodontics	6%	(254)
Pediatric Dentistry	4%	(160)
Oral Surgery	4%	(159)
Endodontics	3%	(116)
Periodontics	2%	(106)
Public Health	2%	(70)
Prosthodontics	1%	(52)
Oral/Maxillofacial Radiology	<1%	(8)

UNC

Pediatric and public health dentists are fastest growing specialties

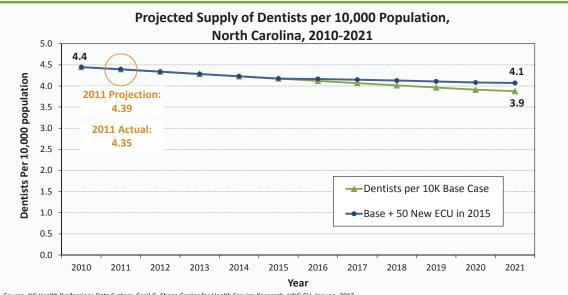
Sources: North Carolina Health Professions Data System with data derived from the North Carolina State Board of Dental Examiners, 2011.

nts include active, instate dentists licensed in North Carolina as of October 31, 2011





What will dentist workforce look like in 20 years?



Source: NC Health Professions Data System, Cecil G. Sheps Center for Health Service Research, UNC-CH, January 2012. Notes: Base case shows scenario with no enrollment increases. Base year for projection (2010) uses data derived from the NC State Board of Dental Examiners and includes all active and instate dentists in that year. 90% retention rate assumed overall. 65% retention rate for UNC-CH based on average of 5 years data from UNC-CH grads. Model accounts for in and out-migration and aging of the workforce. Pooulation estimates and projections are from UINC. accessed April 12. 2011. As of March 12. 2012 neither UNC nor ECU are expanding dental school class size.

Measuring return on investment of public funds spent on education

- Recent policy focus on measuring the "social accountability" of medical education
- Importance of tracking graduates and using data to inform program planning and workforce policy
- What is role of NC's medical schools in improving supply, distribution and diversity of the workforce?
- Since 1993, Sheps Center and AHEC have tracked medical students, now working to extend this work to include medical residents

Medical Student Tracking

- 1993: North Carolina Legislature concerned about primary care shortage
- Required four medical schools to develop programs to increase percentage of primary care graduates
- Set goal for UNC and ECU at 60%
- Set goal for Duke and Wake Forest at 50%
- Required that the Board of Governors track progress and report regularly to General Assembly

NC medical students: Retention of graduates in primary care after five years

School	2005 Graduates	% in Primary Care (Anywhere in US)	% in Primary Care (in NC)
Duke	78	23%	8%
ECU	73	59%	41%
UNC-Chapel Hill	152	38%	21%
Wake Forest	105	37%	17%
Total	408	38%	21%

Retention in North Carolina of Class of 2005 in 2010: Primary Care

NC Medical Students: Retention in Primary Care in NC's Rural Areas

Total Number of 2005 graduates in training of practice as of 2010:

408

Initial residency choice of primary care

261 (64%)

In training/practice in primary care in 2010:

155 (38%)

In primary care in NC in 2010:

the Duke Office of Medical Educat

86 (21%) In PC in rural NC: Class of 2005 (N=422 graduates)

10 (2%)

on, UNC-CH Office of St

Transformed health system will require transformed workforce

Health systems, AHEC, universities, community colleges, regulators, professional bodies need to work together to prepare

- Health professionals already in the workforce to:
 - take on new roles
 - shift to community settings
 - alter the types of services they provide
- New types of health professionals with competencies required in new models of care
- New graduates and existing workers to better function in team-based models of care

Questions?

Erin Fraher and Julie Spero

(919) 966-5012 erin_fraher@unc.edu

Program on Health Workforce Research & Policy http://www.shepscenter.unc.edu/hp http://www.healthworkforce.unc.edu



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Attachment B

Alternate Methodologies for Dental Operating Room Need

ALTERNATE METHODOLOGIES FOR DENTAL OPERATING ROOM NEED

Method 1:

<u>Chapter 6: Operating Rooms</u> should be changed as follows:

• Add a new methodology for pediatric dental ambulatory surgery operating rooms:

In addition to the need identified by the standard methodology, apply the following Methodology for a Pediatric Dental Ambulatory Surgery Facility:

• Step 1. Delineation of Service Area(s)

Define the Pediatric Dental Service Area as the Health Systems Area. This divides the state into six areas of similar population size.

- Step 2. Calculate the number of oral surgery cases in the service area using data in license renewal applications. See Attachment.
- Step 3. Calculate the operating room utilization by Acute Care Service Area (Table 6B, Column H divided by the product of Columns K and S) Step 4. For each HSA in which the number of outpatient oral surgery cases in step 2 exceeds 2000, add one pediatric dental operating room for each 1000 cases, not to exceed two.

HSA	Hospital OP Oral Surgery Cases 2013	Total Outpatient Oral Surgery Cases 2013	Operating Rooms Allocated
1	1,990	2,149	0
П	1,113	1,536	0
III	1,783	1,847	0
IV	2,812	2,840	2
V	3,531	3,633	2
VI	1,858	2,439	2

• Step 5. Allocate the pediatric dental operating rooms from Step 4 to Acute Care Service areas in which the operating occupancy in Step 3 exceeds 90 percent, and the number of Oral Surgery Cases exceeds 900.

Acute Service Area	HSA	Occupancy 2013	Oral Surgery Cases 2013	Operating Rooms Allocated
N/A	IV			0
Cumberland	V	90.8%	1,130	1
New Hanover	V	94.1%	1,698	1
N/A	VI			0

Supporting data are in Attachment A. This methodology appears to work but it suffers from data limitations. It provides for an even allocation of resources, to locations with evidence of high occupancy of operating rooms and a high concentration of oral surgery. However, because the data in licensure reports do not separate pediatric from adult cases, it does not target children with advanced dental disease and an unresolved problem of access to pediatric dental operating room time. Moreover, it allocates pediatric rooms to a county in which the hospital provides no pediatric dental surgery in operating rooms, New Hanover. It also produces a less efficient ambulatory surgery center, with only one operating room.

Method 2:

<u>Chapter 6: Operating Rooms</u> should be changed as follows:

• Add a new methodology for pediatric dental ambulatory surgery operating rooms:

In addition to the need identified by the standard methodology, apply the following Methodology for a Pediatric Dental Ambulatory Surgery Facility:

• Step 1. Delineation of Service Area(s)

Define the Pediatric Dental Service Area as the Health Systems Area. This divides the state into six areas of similar population size.

• Step 2. On a rolling basis, starting in 2016, allocate two pediatric dental operating rooms per year to one Health Systems Agency (HSA), starting with HSA V, unless the surplus of operating rooms in the HSA exceeds 35.

This allocation provides for an even allocation of resources, starting with the area with evidence of the largest need, a high concentration of children with advanced dental disease and an unresolved problem of access to pediatric dental operating room time. It is also the HSA with the lowest surplus of operating rooms according to Table 6B of the 2015 SMFP. (Attachment E)

- Step 3. In subsequent years, allocate pediatric dental operating rooms to other HSAs based on the number of pediatric dentists in the HSA that accept new Medicaid patients, if the number exceeds seven, as reported to the Division of Medical Assistance official website Dental Provider list, unless the surplus of operating rooms in the HSA exceeds 40.¹
- Step 4. If the surplus of operating rooms in any Acute Care Service Area in the HSA identified in Step 3 is ten or greater, allocate the operating rooms to the next HSA in Step 3

Steps 3 and 4 allocate operating rooms based on capacity provide for the need and mitigate duplication in areas with significant surplus operating room capacity.

¹ <u>http://www.ncdhhs.gov/dma/dental/dentalprov.htm</u>

Add to Summary of Operating Room Inventory and Utilization the following paragraph:

'Dental surgery, particularly for pediatric Medicaid patients is problematic for hospitals. The procedures require special accommodations and equipment; new requirements for physicians other than the dental surgeon to revalidate History and Physical information prior to surgery add to costs without offsetting increases in reimbursement. Many hospitals do not offer the service. Yet, cultural dietary patterns, poor understanding of good dental hygiene, an acute shortage of dentists, especially pediatric dentists, and competition for resources contribute to a high incidence of acute dental disease in North Carolina. To make dental surgery more accessible in locations that can concentrate skills and technology, yet remain accessible to the population in need, the State Medical Facilities Plan includes a special allocation of ambulatory surgery dental operating rooms.'

Table 6E Pediatric Dental Operating Room Need Determination

Based on the Pediatric Dental Operating Room Methodology, it is determined that the Pediatric Operating Room Service Area in the table below needs additional operating rooms as specified.

<u>Method 1</u>

Service AreaHSANeeCumberlandV		Need Determination	CON Application* Due Date	CON Beginning Review Date
Cumberland	V	1	TBD	TBD
New Hanover	V	1	TBD	TBD

<u>Method 2</u>

Service Area	HSA Need Determination V 2		CON Application* Due Date	CON Beginning Review Date
V		2	TBD	TBD

To assure access to these rooms by persons with the highest need, applications to provide at least 80 percent of services to pediatric Medicaid beneficiaries should take precedence over others.

Attachment C

Letter of Support: Scott W. Cashion, DDS, MS President, North Carolina Dental Society



ADA

1600 Evans Road, Cary, NC 27513 T 919.677.1396/800.662.8754 F 919.677.1397 ncdental.org

July 27, 2015

Drexdal Pratt, Director NC Department of Health and Human Services Division of Health Service Regulation Certificate of Need Division 2701 Mail Service Center Raleigh, NC 27699-2701

Dear Mr. Pratt,

On behalf of the North Carolina Dental Society, I am writing to express support for a demonstration project of a single specialty dental ambulatory surgical center to serve the needs of children covered by Medicaid who are experiencing significant barriers to dental care.

In North Carolina, there are over one million children under the age of 21 covered by Medicaid. Many of these children have complex dental problems that must be addressed in an operating room setting under general anesthesia. Wait times for pediatric dental surgery cases often approach three to four months especially in areas where operating room access for pediatric dentists is restricted. As a result, children endure unnecessary pain, their conditions worsen, their risk of complications increases, and when the care is finally rendered, it is at greater expense to the Medicaid program.

A dental-only ambulatory surgical center demonstration project will enable access to comprehensive dental care in a timely, safe, efficient fashion for these children. If the pilot is successful, it could be replicated in HSAs around the state, and has the potential to help hundreds of thousands of children in need.

Sincerely,

Scort N. Cashio D.D.S. M.S.

Scott W. Cashion, DDS, MS President North Carolina Dental Society

Attachment D

Dental Reimbursement Rates by CDT Code

NC Medicaid Dental Reimbursement Rates

General Dentist, Oral Surgeon, Pediatric Dentist, Periodontist, & Orthodontist

Effective Date: January 1, 2014

The inclusion of a rate on this table does not guarantee that a service is covered.

Please refer to the Medicaid Billing Guide and the Medicaid and Health Choice Clinical Coverage Policies on the DMA website.

CDT 2014 (including procedure codes, descriptions, and other data) is copyrighted by the American Dental Association. © 2014 American Dental Association. All rights reserved. Applicable FARS/DFARS apply.

CDT 2014 Code	Description	Medicaid Rate
D0120	Periodic oral evaluation	24.51
D0140	Limited oral evaluation - problem focused	34.94
D0145	Oral evaluation for a patient under three years of age and counseling with primary caregiver	34.55
D0150	Comprehensive oral evaluation - new or established patient	42.41
D0160	Detailed and extensive oral evaluation - problem focused, by report	64.89
D0170	Re-evaluation - limited, problem focused (established patient; not post-operative visit)	27.32
D0210	Intraoral - complete series of radiographic image	68.25
D0220	Intraoral - periapical first radiographic image	14.18
D0230	Intraoral - periapical each additional radiographic image	11.44
D0240	Intraoral - occlusal radiographic image	15.19
D0250	Extraoral - first radiographic image	20.46
D0260	Extraoral - each additional radiographic image	16.90
D0270	Bitewing - single radiographicimage	10.79
D0272	Bitewings - two radiographic images	17.59
D0273	Bitewings - three radiographic images	24.02
D0274	Bitewings - four radiographicimages	30.50
D0290	Posterior-anterior or lateral skull and facial bone survey radiographic image	42.70
D0310	Sialography	91.62
D0320	Temporomandibular joint arthrogram, including injection	186.79
D0330	Panoramic radiographic image	56.32
D0340	Cephalometric radiographic image	49.81
D0470	Diagnostic casts	40.66
D0473	Accession of tissue, gross and microscopic examination	46.25
D1110	Prophylaxis - adult	36.21
D1120	Prophylaxis - child	25.87
D1206	Topical application of fluoride varnish	15.25
D1208	Topical application of fluoride	15.25
D1351	Sealant - per tooth	27.17
D1510	Space maintainer - fixed - unilateral	181.53
D1515	Space maintainer - fixed - bilateral	254.14
D2140	Amalgam - one surface, primary or permanent	68.89
D2150	Amalgam - two surfaces, primary or permanent	87.29
D2160	Amalgam - three surfaces, primary or permanent	101.06
D2161	Amalgam - four or more surfaces, primary or permanent	111.25
D2330	Resin-based composite - one surface, anterior	62.64
D2331	Resin-based composite - two surfaces, anterior	77.39
D2332	Resin-based composite - three surfaces, anterior	91.49
D2335	Resin-based composite - four or more surfaces or involving incisal angle (anterior)	115.89
D2390	Resin-based composite crown, anterior	164.74
D2391	Resin-based composite - one surface, posterior	73.72
D2392	Resin-based composite - two surfaces, posterior	97.81
D2393	Resin-based composite - three surfaces, posterior	118.96

D2394	Resin-based composite - four or more surfaces, posterior	144.14
D2930	Prefabricated stainless steel crown - primary tooth	137.15
D2931	Prefabricated stainless steel crown - permanent tooth	147.49
D2932	Prefabricated resin crown	161.15
D2933	Prefabricated stainless steel crown with resin window	179.71
D2934	Prefabricated esthetic coated stainless steel crown - primary tooth	179.71
D2940	Protective restoration	37.80
D2950	Core buildup, including any pins	93.39
D2951	Pin retention - per tooth, in addition to restoration	22.68
D2970	Temporary crown (fractured tooth)	132.82
D3220	Therapeutic pulpotomy (excluding final restoration)	77.09
D3222	Partial pulpotomy for apexogenesis - permanent tooth with incomplete root development	77.09
D3230	Pulpal therapy (resorbable filling) - anterior, primary tooth (excluding final restoration)	136.15
D3240	Pulpal therapy (resorbable filling) - posterior, primary tooth (excluding final restoration)	181.53
D3310	Endodontic therapy, anterior tooth (excluding final restoration)	269.56
D3320	Endodontic therapy, bicuspid tooth (excluding final restoration)	318.58
D3330	Endodontic therapy, molar (excluding final restoration)	389.65
D3351	Apexification/recalcification/pulpal regeneration - initial visit	131.36
D3352	Apexification/recalcification/pulpal regeneration - interim medication replacement	95.57
D3353	Apexification/recalcification - final visit	191.15
D3330	Apicoectomy/periradicular surgery - anterior	247.02
D3410 D4210	Gingivectomy or gingivoplasty - four or more contiguous teeth per quadrant	236.24
D4210	Gingivectomy or gingivoplasty - one to three contiguous teeth per quadrant	87.74
D4211 D4240	Gingival flap procedure, including root planing - four or more contiguous teeth per quadrant	278.39
D4240 D4241	Gingival hap procedure, including root planing - root of more contiguous teeth per quadrant Gingival flap procedure, including root planing - one to three contiguous teeth per quadrant	
	Periodontal scaling and root planing - four or more contiguous teeth per quadrant	235.25
D4341	Periodontal scaling and root planing - not to three teeth per quadrant	95.57
D4342	Full mouth debridement to enable comprehensive evaluation and diagnosis	55.59
D4355	Periodontal maintenance	64.04
D4910	Complete denture - maxillary	47.14
D5110	Complete denture - maximary	555.93
D5120		555.93
D5130	Immediate denture - maxillary	603.07
D5140	Immediate denture - mandibular	603.07
D5211	Maxillary partial denture - resin base	412.27
D5212	Mandibular partial denture - resin base	412.27
D5410	Adjust complete denture - maxillary	30.24
D5411	Adjust complete denture - mandibular	30.24
D5421	Adjust partial denture - maxillary	30.24
D5422	Adjust partial denture - mandibular	30.24
D5510	Repair broken complete denture base	73.33
D5520	Replace missing or broken teeth - complete denture (each tooth)	61.82
D5610	Repair resin denture base	73.33
D5620	Repair cast framework	99.62
D5630	Repair or replace broken clasp	140.68
D5640	Replace broken teeth - per tooth	62.26
D5650	Add tooth to existing partial denture	75.60
D5660	Add clasp to existing partial denture	113.45
D5730	Reline complete maxillary denture (chairside)	128.97
D5731	Reline complete mandibular denture (chairside)	128.97
D5740	Reline maxillary partial denture (chairside)	126.75
D5741	Reline mandibular partial denture (chairside)	126.75
D5750	Reline complete maxillary denture (laboratory)	164.10
D5751	Reline complete mandibular denture (laboratory)	164.10

D5760 D5761	Reline maxillary partial denture (laboratory) Reline mandibular partial denture (laboratory)	160.11 160.11
D6985	Pediatric partial denture, fixed	326.00
D7111	Extraction, coronal remnants - deciduous tooth	49.01
D7140	Extraction, erupted tooth or exposed root	60.40
D7210	Surgical removal of erupted tooth requiring removal of bone and/or sectioning of tooth, and including elevation of mucoperiosteal flap if indicated	103.83
D7210	Removal of impacted tooth - soft tissue	
	Removal of impacted tooth - partially bony	118.12
D7230	Removal of impacted tooth - completely bony	157.79
D7240		183.80
D7241	Removal of impacted tooth - completely bony, with unusual surgical complications	220.56
D7250	Surgical removal of residual tooth roots (cutting procedure)	113.22
D7260	Oroantral fistula closure	362.02
D7270	Tooth reimplantation and/or stabilization of accidentally evulsed or displaced tooth	200.95
D7280	Surgical access of an unerupted tooth	180.86
D7283	Placement of device to facilitate eruption of impacted tooth	203.40
D7285	Biopsy of oral tissue - hard (bone, tooth)	129.86
D7286	Biopsy of oral tissue - soft (all others)	102.84
D7288	Brush biopsy - transepithelial sample collection	102.84
D7310	Alveoloplasty in conjunction with extractions - four or more tooth spaces, per quadrant	97.84
D7311	Alveoloplasty in conjunction with extractions - one to three tooth spaces, per quadrant	91.49
D7320	Alveoloplasty not in conjunction with extractions - four or more tooth spaces, per quadrant	142.76
D7321	Alveoloplasty not in conjunction with extractions - one to three tooth spaces, per quadrant	128.09
D7340	Vestibuloplasty - ridge extension (secondary epithelialization)	497.92
D7350	Vestibuloplasty - ridge extension (including soft tissue grafts)	922.44
D7410	Excision of benign lesion up to 1.25 cm	153.49
D7411	Excision of benign lesion greater than 1.25 cm	201.02
D7412	Excision of benign lesion, complicated	265.06
D7413	Excision of malignant lesion up to 1.25 cm	220.59
D7414	Excision of malignant lesion greater than 1.25 cm	322.88
D7415	Excision of malignant lesion, complicated	386.92
D7440	Excision of malignant tumor - lesion diameter up to 1.25 cm	177.90
D7441	Excision of malignant tumor - lesion diameter greater than 1.25 cm	317.68
D7450	Removal of benign odontogenic cyst or tumor - lesion diameter up to 1.25 cm	169.00
D7451	Removal of benign odontogenic cyst or tumor - lesion diameter greater than 1.25 cm	216.59
D7460	Removal of benign nonodontogenic cyst or tumor - lesion diameter up to 1.25 cm	210.55
D7460	Removal of benign nonodontogenic cyst or tumor - lesion diameter greater than 1.25 cm	336.38
D7461	Destruction of lesion(s) by physical or chemical method, by report	132.98
D7403	Removal of lateral exostosis (maxilla or mandible)	214.53
	Removal of torus palatinus	
D7472	Removal of torus mandibularis	249.06
D7473		247.72
D7485	Surgical reduction of osseous tuberosity	223.26
D7490	Radical resection of mandible with bone graft	2,821.88
D7510	Incision and drainage of abscess - intraoral soft tissue	105.52
D7520	Incision and drainage of abscess - extraoral soft tissue	226.91
D7530	Removal of foreign body from mucosa, skin or subcutaneous alveolar tissue	120.08
D7540	Removal of reaction producing foreign bodies, musculoskeletal system	222.37
D7550	Partial ostectomy/sequestrectomy for removal of non-vital bone	289.54
D7560	Maxillary sinusotomy for removal of tooth fragment or foreign body	363.80
D7610	Maxilla - open reduction (teeth immobilized, if present)	1,456.53
D7620	Maxilla - closed reduction (teeth immobilized, if present)	1,144.32
D7630	Mandible - open reduction (teeth immobilized, if present)	1,435.17
D7640	Mandible - closed reduction (teeth immobilized, if present)	1,127.41

D7650	Malar and/or zygomatic arch - open reduction	1,302.20
D7660	Malar and/or zygomatic arch - closed reduction	1,106.52
D7670	Alveolus - closed reduction, may include stabilization of teeth	452.75
D7680	Facial bones - complicated reduction with fixation and multiple surgical approaches	2,185.90
D7000	Maxilla - open reduction	1,534.36
D7720	Maxilla - closed reduction	1,117.19
D7730	Mandible - open reduction	1,556.59
D7740	Mandible - closed reduction	
D7740	Malar and/or zygomatic arch - open reduction	1,205.24 1,372.47
D7760	Malar and/or zygomatic arch - closed reduction	,
	Alveolus - open reduction stabilization of teeth	1,519.23
D7770 D7780	Facial bones - complicated reduction with fixation and multiple surgical approaches	889.48
	Open reduction of dislocation	2,617.74
D7810	Closed reduction of dislocation	1,420.94
D7820		173.45
D7830	Manipulation under anesthesia	227.71
D7840	Condylectomy	1,838.11
D7850	Surgical discectomy, with/without implant	1,852.79
D7858	Joint reconstruction	1,271.73
D7860	Arthrotomy	566.96
D7865	Arthroplasty	958.14
D7870	Arthrocentesis	117.86
D7872	Arthroscopy - diagnosis, with or without biopsy	440.96
D7873	Arthroscopy - surgical: lavage and lysis of adhesions	524.85
D7910	Suture of recent small wounds up to 5 cm	158.78
D7911	Complicated suture - up to 5 cm	246.69
D7912	Complicated suture - greater than 5 cm	306.17
D7920	Skin graft	812.54
D7940	Osteoplasty - for orthognathic deformities	1,321.86
D7941	Osteotomy - mandibular rami	3,454.87
D7943	Osteotomy - mandibular rami with bone graft; includes obtaining the graft	3,181.87
D7944	Osteotomy - segmented or subapical	2,642.74
D7945	Osteotomy - body of mandible	2,744.68
D7946	LeFort I (maxilla - total)	3,219.12
D7947	LeFort I (maxilla - segmented)	3,253.91
D7948	LeFort II or LeFort III - without bone graft	3,725.91
D7949	LeFort II or LeFort III - with bone graft	4,279.25
D7950	Osseous, osteoperiosteal, or cartilage graft of the mandible or maxilla	913.94
D7955	Repair of maxillofacial soft and hard tissue defect	1,166.56
D7000	Frenulectomy - also known as frenectomy or frenotomy - separate procedure not incidental to another	100.11
D7960	procedure	168.11
D7963	Frenuloplasty	256.02
D7971	Excision of pericoronal gingiva	145.22
D7972	Surgical reduction of fibrous tuberosity	244.60
D7980	Sialolithotomy	289.69
D7981	Excision of salivary gland, by report	511.92
D7982	Sialodochoplasty	554.59
D7983	Closure of salivary fistula	364.69
D7990	Emergency tracheotomy	411.38
D7991	Coronoidectomy	1,307.54
D8080	Comprehensive orthodontic treatment of the adolescent dentition	778.27
D8670	Periodic orthodontic treatment visit (as part of contract)	91.49
D9110	Palliative (emergency) treatment of dental pain - minor procedure	40.47
D9220	Deep sedation/general anesthesia - first 30 minutes	141.65

D9221	Deep sedation/general anesthesia - each additional 15 minutes	60.29			
D9230	D9230 Inhalation of nitrous oxide/anziolysis, analgesia				
D9241	Intravenous conscious sedation/analgesia - first 30 minutes	147.03			
D9242	Intravenous conscious sedation/analgesia - each additional 15 minutes	56.37			
D9410	House/extended care facility call	71.16			
D9420	Hospital or ambulatory surgical center call	112.50			
D9440	Office visit - after regularly scheduled hours	55.59			
D9610	Therapeutic parenteral drug, single administration	33.36			
D9612	Therapeutic parenteral drugs, two or more administrations, different medications	55.14			
D9630	Other drugs and/or medicaments, by report	14.45			

Providers should always bill their usual and customary charges. Please use the monthly NC Medicaid Bulletins for additions, changes, and deletion to this schedule.

Attachment E

Data: Medicaid Payments for Dental Surgical Cases, SFY 2014, DMA, Dr. Casey

Medicaid Payments for Dental Surgical Cases SFY 2014

					FY 2014									
					NCXIX					NCXXI				
					DR3484_Same_MID_Same_DOS_Hosp_Facility_Fees_D_Claims_D942				ees_D_Claims_D9420	DR3484_Same_MID_Same_DOS_Hosp_Facility_Fees_D_Cla				
					Billing Providers	Providers	Patients	Claims	Net Payment	Billing Providers	Providers	Patients	Claims N	et Payment
Claim Type Code	Claim Type	Procedure Code	Place of Service Code Medstat	Place of Service Medstat										
)	DENTAL	D9420	8	Tribal 638 Provider-based Fac						1	1	1	1	\$112.
			11	Office	114	133	711	797	\$38,153.20	19	9 19	21	23	\$1,256.
			12	Patient Home	1	1	1	1	\$0.00					
			21	Inpatient Hospital	6	7	31	31	\$3,551.10	2	2 2	2 2	2	\$231.
			22	Outpatient Hospital	157	208	11,387	12,040	\$1,295,809.43	74	4 93	276	290	\$31,096.
			23	Emergency Room - Hospital	13	13	53	58	\$5,737.64	1	1	2	2	\$225.
			24	Ambulatory Surgical Center	12	16	100	104	\$11,303.94	1	2	2 2	2	\$226.
			31	Skilled Nursing Facility	1	1	2	2	\$0.00					
			99	~Missing/Other	1	1	2	2	\$225.00					
ggregate(Claim Type	e Code Values)				169	218	12,029	13,035	\$1,354,780.31	79	101	293	320	\$33,149.
												12,322		1,387,929.5

DR3484_Same MID Same DOS Subset - D9420_SFY2014 [this is the CDT code we use to identify beneficiaries who have had treatment in the ASC or Hospital Setting]

DR3484_Same MID Same DOS Subset - Anesthesia_SFY2014 [Hospital and ASC anesthesia fees]

					FY 2014											
										NCXXI						
										DR3484_Same_MID_Same_DOS_Hosp_Facility_Fees_D_Claims_D9420						
					Billing Providers	Providers	Patients	Claims	Net Payment	Billing Providers	Providers	Patients	Claims	Net Payment		
Claim Type Code	Claim Type	Procedure Code	Place of Service Code Medstat	Place of Service Medstat												
Р	PROFESSIONAL	00170-00190	1	Pharmacy	1	1	1	1	\$195.84							
			21	Inpatient Hospital	31	56	52	68	\$7,650.24	1	1	1	1	\$217.72		
			22	Outpatient Hospital	98	1,239	9,807	17,198	\$1,890,599.00	57	250	214	368	\$41,039.68		
			24	Ambulatory Surgical Center	13	204	2,380	2,815	\$466,478.90	8	50	76	96	\$16,677.58		
Aggregate(Claim Type Co	Aggregate(Claim Type Code Values)				105	1,390	11,997	20,082	\$2,364,923.98	62	300	289	465	\$57,934.98		

DR3484_Same MID Same DOS Subset - ASC_SFY2014 [ASC facility fees]

					FY 2014									
					NCXIX					NCXXI				
					DR3484_Same_MID_Same_DOS_Hosp_Facility_Fees_D_Claims_D9420				DR3484_Same_MID_Same_DOS_Hosp_Facility_Fees_D_Claims_D9420					
					Billing Providers	Providers	Patients	Claims	Net Payment	Billing Providers	Providers	Patients	Claims	Net Payment
Claim Type Code	Procedure Code	Procedure Modifier Co	Place of Service Code Medstat	Place of Service Medstat										
Р	D0000-D9999	SG	24	Ambulatory Surgical Center	7	15	781	1,264	\$293,184.69	5	10	32	55	\$11,637.34
Aggregate(Claim Type Co	ode Values)				7	15	781	1,264	\$293,184.69	5	10	32	55	\$11,637.34

DR3484_Same MID Same DOS Subset - Hospitals_SFY2014 [Hospital facility fees]

					FY 2014									
					NCXIX		NCXXI DR3484_Same_MID_Same_DOS_Hosp_Facility_Fees_D_Claims_D9420							
					DR3484_Same_N	Fees_D_Claims_D9420								
			Billing Providers	Providers	Patients	Claims	Net Payment Detail Fac	Billing Providers	Providers	Patients	Claims	Net Payment Detail Fac		
Claim Type Code	Claim Type	Diagnosis Code Princi	Place of Service Code Medstat	Place of Service Medstat										
1	INPATIENT	5200-5299	21	Inpatient Hospital	5	5	6	5 10	\$13,549.90					
0	OUTPATIENT	1400-1459	22	Outpatient Hospital	1	1	1	3	\$4,657.42					
		2100	22	Outpatient Hospital	1	1	1	1	\$767.62					
		2104	22	Outpatient Hospital	1	1	2	2 6	\$1,560.69					
		2160	22	Outpatient Hospital	1	1	1	2	\$1,008.40					
		5200-5299	22	Outpatient Hospital	65	65	11,163	8 21,062	\$18,971,529.30	42	42	258	537	\$451,794.94
			99	~Missing/Other	10	10	28	8 29	\$0.00	2	2	2	2	\$0.00
Aggregate(Claim Type	Code Values)				66	66	11,174	21,113	\$18,993,073.33	42	42	258	539	\$451,794.94

					FY 2014											
											NCXXI DR3484_Same_MID_Same_DOS_Hosp_Facility_Fees_D_Claims_D942					
					Billing Providers	Providers	Patients	Claims	Net Payment	Billing Providers	Providers	Patients	Claims	Net Payment		
Claim Type Code	Claim Type	Procedure Code	Place of Service Code Medstat	Place of Service Medstat												
D	DENTAL	D0000-D9999	8	Tribal 638 Provider-based Fac						1	1	1	1	\$935.49		
			11	Office	142	172	1,074	1,545	5 \$811,289.32	24	26	31	44	\$18,740.32		
			12	Patient Home	1	1	1	1	\$0.00							
			21	Inpatient Hospital	7	9	33	37	7 \$50,173.38	2	3	2	3	\$6,999.89		
			22	Outpatient Hospital	167	217	11,487	16,418	3 \$15,881,674.21	75	96	279	397	\$326,708.45		
			23	Emergency Room - Hospital	15	15	56	81	\$62,212.03	1	1	2	2	\$2,543.57		
			24	Ambulatory Surgical Center	14	18	106	118	3 \$119,871.78	1	2	2	2	\$1,862.51		
			31	Skilled Nursing Facility	2	2	3	3	3 \$2,387.60							
			99	~Missing/Other	1	1	2	2	2 \$1,393.06							
Aggregate(Claim Type	Code Values)				189	245	12,040	18,159	\$16,929,001.38	80	103	293	448	\$357,790.23		

DR3484_Same MID Same DOS Subset - Dental_SFY2014 [Dental professional fees includes the D9420 fees in Table 1]

Attachment F

G. S. 10A NCAC 13C, Licensing of Ambulatory Surgical Facilities

SUBCHAPTER 13C – LICENSING OF AMBULATORY SURGICAL FACILITIES

SECTION .0100 – GENERAL

10A NCAC 13C .0101RESERVED FOR FUTURE CODIFICATION10A NCAC 13C .0102RESERVED FOR FUTURE CODIFICATION

10A NCAC 13C .0103 DEFINITIONS

In addition to the terms defined in G.S. 131E-214.13, the following terms shall apply throughout this Subchapter, unless the context clearly requires otherwise:

(1) "Adequate" means, when applied to various areas of services, that the services are satisfactory in meeting a referred to need when measured against professional standards of practice.

(2) "AAAASF" means American Association for Accreditation of Ambulatory Surgery Facilities.

(3) "AAAHC" means Accreditation Association for Ambulatory Health Care.

(4) "Ancillary nursing personnel" means persons employed to assist registered nurses or licensed practical nurses in the care of patients.

(5) "Anesthesiologist" means a physician whose specialized training and experience qualify him or her to administer anesthetic agents and to monitor the patient under the influence of these agents. For the purpose of this Subchapter, the term "anesthesiologist" shall not include podiatrists.

(6) "Anesthetist" means a physician or dentist qualified, as defined in Items (10) and (24) of this Rule, to administer anesthetic agents or a registered nurse qualified, as defined in Items (25) and (27) of this Rule, to administer anesthesia.

(7) "Authority having jurisdiction" means the Division of Health Service Regulation.

(8) "Chief executive officer" or "administrator" means a qualified person appointed by the governing authority to act in its behalf in the overall management of the facility and whose office is located in the facility.

(9) "Current Procedural Terminology (CPT)" means a medical code set developed by the American Medical Association.

(10) "Dentist" means a person who holds a valid license issued by the North Carolina Board of Dental Examiners to practice dentistry.

(11) "Department" means the North Carolina Department of Health and Human Services.

(12) "Director of nursing" means a registered nurse who is responsible to the chief executive officer or administrator and has the authority and direct responsibility for all nursing services and nursing care for the entire facility at all times.

(13) "Financial assistance" means a policy, including charity care, describing how the organization will provide assistance at its facility. Financial assistance includes free or discounted health services provided to persons who meet the organization's criteria for financial assistance and are unable to pay for all or a portion of the services. Financial assistance does not include:

(a) bad debt;

(b) uncollectable charges that the organization recorded as revenue but wrote off due to a patient's failure to pay;

(c) the cost of providing such care to the patients in Sub-Item (13)(b) of this Rule; or

(d) the difference between the cost of care provided under Medicare or other government programs, and the revenue derived therefrom.

(14) "Governing authority" means the individual, agency, group, or corporation appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the ambulatory surgical facility is vested.

(15) "Healthcare Common Procedure Coding System (HCPCS)" means a three tiered medical code set consisting of Level I, II and III services and contains the CPT code set in Level I.

(16) "JCAHO" or "Joint Commission" means Joint Commission on Accreditation of Healthcare Organizations.

(17) "Licensing agency" means the Department of Health and Human Services, Division of Health Service Regulation.

(18) "Licensed practical nurse (L.P.N.)" means any person licensed as such under the provisions of G.S. 90-171.20(8).

(19) "Nursing personnel" means registered nurses, licensed practical nurses, and ancillary nursing personnel.

(20) "Operating room" means a room in which surgical procedures are performed.

(21) "Patient" means a person admitted to and receiving care in a facility.

(22) "Person" means an individual, a trust or estate, a partnership or corporation, including associations, joint stock companies and insurance companies; the State, or a political subdivision or instrumentality of the state.

(23) "Pharmacist" means a person who holds a valid license issued by the North Carolina Board of Pharmacy to practice pharmacy in accordance with G.S. 90-85.3A.

(24) "Physician" means a person who holds a valid license issued by the North Carolina Medical Board to practice medicine. For the purpose of carrying out these Rules, a "physician" may also mean a person holding a valid license issued by the North Carolina Board of Podiatry Examiners to practice podiatry.

(25) "Qualified person," when used in connection with an occupation or position, means a person:

(a) who has demonstrated through experience the ability to perform the required functions; or

(b) who has certification, registration, or other professional recognition.

(26) "Recovery area" means a room used for the post-anesthesia recovery of surgical patients.

(27) "Registered nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice nursing as defined in G.S. 90-171.20(7).

(28) "Surgical suite" means an area that includes one or more operating rooms and one or more recovery rooms.

History Note: Authority G.S. 131E-149; 131E-214.13; S.L. 2013-382, s. 10.1; S.L. 2013-382, s. 13.1; S.L. 2014-100, s. 12G.2;

Eff. October 14, 1978;

Amended Eff. April 1, 2003; November 1, 1989;

Temporary Amendment Eff. December 31, 2014.

SECTION .0200 - LICENSING PROCEDURES

10A NCAC 13C .0201 APPLICATION

(a) A person shall submit an application for a license to establish or maintain an ambulatory surgical facility to the Department in writing on the form provided by the Department. Each application shall contain all necessary and reasonable information that the Department may by rule require, including the following and other pertinent information the Department may deem appropriate to carry out its responsibilities for statistical data collection and long range health planning:

- (1) name of facility,
- (2) address of facility,
- (3) telephone number of facility,
- (4) names of owners,
- (5) names of operator and governing authority,
- (6) name of chief executive officer,
- (7) composition of medical and paramedical staff,
- (8) name of chief of staff,
- (9) director of nursing service,
- (10) number of operating rooms and recovery beds,
- (11) list of surgical procedures to be performed in facility,
- (12) qualification of persons responsible for anesthesia services,
- (13) information regarding use and storage of flammable anesthesia,
- (14) description of laboratory and pathology services,
- (15) name of hospital(s) with which transfer agreement has been made,
- (16) description of arrangements for emergency transportation of patients from the facility,
- (17) description of arrangements for food service, and
- (18) information regarding sanitation inspection and fire inspection.

(b) The person shall make application for a license for a new facility or for the renewal of a license for an existing facility. Applications for licensure for a new facility shall be submitted at least 120 days prior to opening.

(c) Any ambulatory surgical facility desiring licensure which is in operation at the time of promulgation of any applicable rules or regulations shall be given a reasonable time, not to exceed one year from the date of such promulgation, within which to comply with such rules and regulations.

History Note: Authority G.S. 131E-147; 131E-149;

Eff. October 14, 1978;

Amended Eff. November 1, 1989.

10A NCAC 13C .0202 REQUIREMENTS FOR ISSUANCE OF LICENSE

(a) Upon application for a license from a facility never before licensed, a representative of the Department shall make an inspection of that facility. Every building, institution, or establishment for which a license has been issued shall be inspected for compliance with the rules found in this Subchapter. An ambulatory surgery facility shall be deemed to meet licensure requirements if the ambulatory surgery facility is accredited by The Joint Commission (formerly known as "JCAHO"), AAAHC or AAAASF. Accreditation does not exempt a facility from statutory or rule requirements for licensure nor does it prohibit the Department from conducting inspections as provided in this Rule to determine compliance with all requirements.

(b) If the applicant has been issued a Certificate of Need and is found to be in compliance with the Rules found in this Subchapter, then the Department shall issue a license to expire on December 31 of each year.

(c) The Department shall be notified at the time of:

- (1) any change of the owner or operator;
- (2) any change of location;
- (3) any change as to a lease; and

(4) any transfer, assignment, or other disposition or change of ownership or control of 20 percent or more of the capital stock or voting rights thereunder of a corporation that is the operator or owner of an ambulatory surgical facility, or any transfer, assignment, or other disposition of the stock or voting rights thereunder of such corporation that results in the ownership or control of more than 20 percent of the stock or voting rights thereunder of such corporation by any person.

A new application shall be submitted to the Department in the event of such a change or changes.

(d) The Department shall not grant a license until the plans and specifications that are stated in Section .1400 of this Subchapter, covering the construction of new buildings, additions, or material alterations to existing buildings are approved by the Department.

(e) The facility design and construction shall be in accordance with the licensure rules for ambulatory surgical facilities found in this Subchapter, the North Carolina State Building Code, and local municipal codes.

(f) Submission of Plans.

(1) Before construction is begun, schematic plans and specifications and final plans and specifications covering construction of the new buildings, alterations, renovations, or additions to existing buildings shall be submitted to the Division for approval.

(2) The Division shall review the plans and notify the licensee that said buildings, alterations, additions, or changes are approved or disapproved. If plans are disapproved the Division shall give the applicant notice of deficiencies identified by the Division.

(3) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.

(4) Plans shall be submitted in duplicate. The Division shall distribute a copy to the Department of Insurance for review of the North Carolina State Building Code requirements if required by the North Carolina State Building Code which is hereby incorporated by reference, including all subsequent amendments. Copies of the Code may be accessed electronically free of charge at

http://www.ecodes.biz/ecodes_support/Free_Resources/2012NorthCarolina/12NorthCarolina_main. html.

(g) To qualify for licensure or license renewal, each facility shall provide to the Division, with its application, an attestation statement in a form provided by the Division verifying compliance with the requirements defined in Rule .0301(d) of this Subchapter.

History Note: Authority G.S. 131E-91; 131E-147; 131E-149; S.L. 2013-382, s. 13.1;

Eff. October 14, 1978;

Amended Eff. April 1, 2003;

Temporary Amendment Eff. May 1, 2014;

Amended Eff. November 1, 2014.

10A NCAC 13C .0203 SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY

(a) The license may be suspended or revoked at any time for noncompliance with the regulations of the Department.

(b) Suspension or revocation of the license shall be covered by the rules regarding contested cases as found in 10 NCAC 3B .0200.

(c) Notwithstanding Subsection (a) and (b) of this Rule, the Department may summarily suspend the license pursuant to General Statute 150B-3(c).

History Note: Authority G.S. 131E-148; 131E-149; 143B-165; 150B-3(c);

Eff. October 14, 1978;

Amended Eff. November 1, 1989.

10A NCAC 13C .0204 TYPE OF FACILITY DEEMED TO BE LICENSED

An ambulatory surgical facility shall be deemed a suitable facility for the performance of abortions pursuant to G.S. 14-45.1(a).

History Note: Authority G.S. 14-45.1; 131E-147;

Eff. June 30, 1980;

Amended Eff. November 1, 1989.

10A NCAC 13C .0205 ITEMIZED CHARGES

(a) The facility shall either present an itemized list of charges to all discharged patients or include on patients' bills that are not itemized notification of the right to request an itemized bill within three years of receipt of the non-itemized bill or so long as the facility, collections agency, or other assignee asserts the patient has an obligation to pay the bill.

(b) If requested, the facility shall present an itemized list of charges to each patient or his or her representative. This list shall detail in language comprehensible to an ordinary layperson the specific nature of the charges or expenses incurred by the patient.

(c) The listing shall include each specific chargeable item or service in the following service areas:

- (1) Surgery (facility fee);
- (2) Anesthesiology;
- (3) Pharmacy;
- (4) Laboratory;
- (5) Radiology;
- (6) **Prosthetic and Orthopedic appliances; and**
- (7) Other professional services.

(d) The facility shall indicate on the initial or renewal license application that patient bills are itemized, or that each patient or his or her representative is formally advised of the patient's right to request an itemized listing within three years of receipt of a non-itemized bill.

History Note: Authority G.S. 131E-91; 131E-147.1; S.L. 2013-382, s. 13.1;

Eff. December 1, 1991;

Temporary Amendment Eff. May 1, 2014;

Amended Eff. November 1, 2014.

10A NCAC 13C .0206 REPORTING REQUIREMENTS

(a) The Department shall establish the lists of the statewide 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures performed in the ambulatory surgical facility setting to be used for reporting the data required in Paragraphs (c) and (d) of this Rule. The lists shall be based upon data provided by the certified statewide data processor. The Department shall make the lists available on its website.

(b) All information required by this Rule shall be posted on the Department's website at: http://www.ncdhhs.gov/dhsr/ahc and may be accessed at no cost.

(c) In accordance with G.S. 131E-214.13 and quarterly per year, all licensed ambulatory surgical facilities shall report the data required in Paragraph (d) of this Rule related to the statewide 20 most common outpatient imaging procedures and the statewide 20 most common outpatient surgical procedures to the certified statewide data processor in a format provided by the certified statewide processor. This report shall include the related primary CPT and HCPCS codes. The data reported shall be from the quarter ending three months prior to the date of reporting.

(d) The report as described in Paragraph (c) of this Rule shall be specific to each reporting ambulatory surgical facility and shall include:

(1) the average gross charge for each CPT code or procedure if all charges are paid in full without any portion paid by a public or private third party;

(2) the average negotiated settlement on the amount that will be charged for each CPT code or procedure as required for patients defined in Subparagraph (d)(1) of this Rule. The average negotiated settlement shall be calculated using the average amount charged all patients eligible for the facility's financial assistance policy, including self-pay patients;

(3) the amount of Medicaid reimbursement for each CPT code or procedure, including all supplemental payments to and from the ambulatory surgical facility;

(4) the amount of Medicare reimbursement for each CPT code or procedure; and

(5) on behalf of patients who are covered by a Department of Insurance licensed third-party and teachers and State employees, the lowest, average, and highest amount of payments made for each CPT code or procedure by each of the facility's top five largest health insurers.

(A) each ambulatory surgical facility shall determine its five largest health insurers based on the dollar volume of payments received from those insurers;

(B) the lowest amount of payment shall be reported as the lowest payment from each of the five insurers on the CPT code or procedure;

(C) the average amount of payment shall be reported as the arithmetic average of each of the five health insurers payment amounts;

(D) the highest amount of payment shall be reported as the highest payment from each of the five insurers on the CPT code or procedure; and

(E) the identity of the top five largest health insurers shall be redacted prior to submission.

(e) The data reported, as defined in Paragraphs (c) and (d) of this Rule, shall reflect the payments received from patients and health insurers for all closed accounts. For the purpose of this Rule, "closed accounts" are patient accounts with a zero balance at the end of the data reporting period.

(f) A minimum of three data elements shall be required for reporting under Paragraph (c) of this Rule.

(g) The information submitted in the report shall be in compliance with the federal Health Insurance Portability and Accountability Act of 45 CFR Part 164.

(h) The Department shall provide all specific ambulatory surgical facility data reported pursuant to this Rule on its website.

History Note: Authority G.S. 131E-147.1; 131E-214.4; 131E-214.13; S.L. 2013-382, s. 10.1; S.L. 2014-100, s. 12G.2;

Temporary Adoption Eff. December 31, 2014.

SECTION .0300 - GOVERNING AUTHORITY MANAGEMENT

10A NCAC 13C .0301 GOVERNING AUTHORITY

(a) The facility's governing authority shall adopt bylaws or other operating policies and procedures to assure that:

(1) a named individual is identified who is responsible for the overall operation and maintenance of the facility. The governing authority shall have methods in place for the oversight of the individual's performance;

(2) at least annual meetings of the governing authority are conducted if the governing authority consists of two or more individuals. Minutes shall be maintained of such meetings;

(3) a policy and procedure manual is created that is designed to ensure professional and safe care for the patients. The manual shall be reviewed annually and revised when necessary. The manual shall include provisions for administration and use of the facility, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies and services offered; and

(4) annual reviews and evaluations of the facility's policies, management, and operation are conducted.

(b) When services such as dietary, laundry, or therapy services are purchased from others, the governing authority shall be responsible to assure the supplier meets the same local and state standards the facility would have to meet if it were providing those services itself using its own staff.

(c) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.

(d) The governing authority shall establish written policies and procedures to assure billing and collection practices in accordance with G.S. 131E-91. These policies and procedures shall include:

(1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);

(2) how a patient may obtain an estimate of the charges for the statewide 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures based on the primary Current Procedure Code (CPT). The policy shall require that the information be provided to the patient in writing, either electronically or by mail, within three business days;

(3) how a patient or patient's representative may dispute a bill;

(4) issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient has overpaid the amount due to the facility;

(5) providing written notification to the patient or patient's representative, at least 30 days prior to submitting a delinquent bill to a collections agency;

(6) providing the patient or patient's representative with the facility's charity care and financial assistance policies, if the facility is required to file a Schedule H, federal form 990;

(7) the requirement that a collections agency, entity, or other assignee obtain written consent from the facility prior to initiating litigation against the patient or patient's representative;

(8) a policy for handling debts arising from the provision of care by the ambulatory surgical facility involving the doctrine of necessaries, in accordance with G.S. 131E-91(d)(5); and

(9) a policy for handling debts arising from the provision of care by the ambulatory surgical facility to a minor, in accordance with G.S. 131E-91(d)(6).

History Note: Authority G.S. 131E-91; 131E-147.1; 131E-149; 131E-214.13(f); 131E-214.14; S.L. 2013-382, s. 10.1; S.L. 2013-382, s. 13.1;

Eff. October 14, 1978;

Amended Eff. November 1, 1989; November 1, 1985; December 24, 1979;

Temporary Amendment Eff. May 1, 2014;

Amended Eff. November 1, 2014.

10A NCAC 13C .0302 CHIEF EXECUTIVE OFFICER OR ADMINISTRATOR

(a) The governing authority shall appoint a qualified person as chief executive officer of the facility to represent the governing authority and shall define his authority and duties in writing. He shall be responsible for the management of the facility, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these regulations.

(b) The chief executive officer shall designate, in writing, a qualified person to act in his behalf during his absence. In the absence of the chief executive officer, the person on the grounds of the facility who is designated by the chief executive officer to be in charge of the facility shall have reasonable access to all areas in the facility related to patient care and to the operation of the physical plant.

(c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the facility shall notify the Department.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .0303 ADMINISTRATIVE RECORDS

(a) The following essential documents and references shall be on file in the administrative office of the facility:

(1) appropriate documents evidencing control and ownerships, such as deeds, leases, or corporation or partnership papers;

- (2) bylaws of policies and procedures of the governing authority;
- (3) minutes of the governing authority meetings if applicable;
- (4) minutes of the facility's professional and administrative staff meetings;
- (5) a current copy of these regulations;
- (6) reports of inspections, reviews, and corrective actions taken related to licensure; and
- (7) contracts and agreements related to licensure to which the facility is a party.

(b) All operating licenses, permits and certificates shall be appropriately displayed on the licensed premises.

History Note: Authority G.S. 131E-149; Eff. October 14, 1978.

10A NCAC 13C .0304 SURGICAL PROCEDURES PERFORMED

A current listing of all types of surgical procedures offered by the facility shall be available.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .0305 PERSONNEL

(a) Personnel Records

(1) A record of each employee shall be maintained which includes the following:

- (A) employee's identification;
- (B) resume of education and work experience;

(C) verification of valid license (if required), education, training, and prior employment experience; and

(D) verification of references.

(2) Personnel records shall be confidential.

(3) Notwithstanding the requirement found in Subparagraph (a)(2) of this Rule, representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records.

(b) Job Descriptions

(1) Every position shall have a written description which adequately describes the duties of the position.

(2) Each job description shall include position title, authority, specific responsibilities and minimum qualifications. Qualifications shall include education, training, experience, special abilities and license or certification required.

(3) Job descriptions shall be reviewed annually, kept current and given to each employee when assigned to the position and whenever the job description is changed.

(c) Orientation shall be provided to familiarize each new employee with the facility, its policies, and job responsibilities.

(d) All persons having direct responsibility for patient care shall be at least 18 years of age. All other employees working in the facility shall be not less than 16 years of age.

(e) The governing authority shall be responsible for insuring health standards for employees which are consistent with recognized professional practices for the prevention and transmission of communicable diseases.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. November 1, 1989; December 24, 1979.

10A NCAC 13C .0306 QUALITY ASSURANCE

(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the facility. The program shall include the establishment of a committee which shall evaluate:

(1) appropriateness and necessity of surgical procedures performed, and

(2) compliance with facility procedure and policies.

The committee shall determine corrective action if indicated.

(b) The committee shall consist of at least one physician or dentist (who is not an owner), the chief executive officer (or his designee), and other health professionals as indicated. There shall be at least one meeting of the committee quarterly.

(c) The functions of the committee shall include development of policies for selection of patients, review of credentials for staff privileges, peer review, tissue review, establishment of infection control procedures, and approval of additional surgical procedures to be performed in the facility.

(d) Records shall be kept of the activities of the committee. These records shall include as a minimum:

(1) reports made to the governing authority;

(2) minutes of committee meetings including date, time, persons attending, description and results of cases reviewed, and recommendations made by the committee; and

(3) information on any corrective action taken.

(e) Appropriate orientation, training or education programs shall be conducted as necessary to correct deficiencies which are uncovered as a result of the quality assurance program.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .0400 - MEDICAL AND SURGICAL SERVICES

10A NCAC 13C .0401 MEDICAL SERVICES

(a) All patients admitted to the facility shall be under the direct care of a physician or dentist.

(b) The facility shall have available an anesthetist and he or she shall be available to administer regional or general anesthesia.

(c) Any patient undergoing general or regional anesthesia shall, prior to surgery, have a history and physical examination, relative to the intended procedure, performed by a licensed physician or a dentist who has successfully completed a postgraduate program in oral and maxillofacial surgery

accredited by the American Dental Association. Results of the examination and the preoperative diagnosis shall be recorded in the patient's chart prior to surgery.

(d) The attending physician and dentist, prior to surgery, shall obtain written, informed consent of the patient or legal guardian for surgery and shall record this in the patient's medical record.

(e) The facility shall have the capability of obtaining blood and blood products to meet emergency situations.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. November 1, 1985.

10A NCAC 13C .0402 SURGICAL SERVICES

(a) The governing authority shall delineate surgical privileges for each physician and dentist performing surgery in accordance with criteria which it has established provided, however, that no physician or dentist may be given privileges to perform surgical procedures for which he or she does not have privileges to perform at the hospital with which the facility has a transfer agreement as provided in Paragraph (a) in Rule .0403 of this Section.

(b) A roster of medical personnel having surgical and anesthesia privileges at the facility specifying the privileges and limitations of each, shall be readily obtainable by the person in charge of the surgical suite.

(c) The administrator or his designee shall maintain a chronological register of all surgical procedures performed. This shall include type of procedure performed, type of anesthesia used, personnel participating, post operative diagnosis and any unusual or untoward occurrence.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. April 1, 2003.

10A NCAC 13C .0403 EMERGENCY CASES

(a) Each facility shall have a written plan for the transfer of emergency cases to a nearby hospital when hospitalization becomes necessary.

(b) There shall be procedures, personnel and suitable equipment to handle medical emergencies which may arise in connection with services provided by the facility.

(c) There shall be a written agreement between the facility and a nearby hospital to facilitate the transfer of patients who are in need of emergency care. A facility which has documentation of its efforts to establish such a transfer agreement with a hospital which provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .0500 - ANESTHESIA SERVICES

10A NCAC 13C .0501 PROVIDING ANESTHESIA SERVICES

Only a physician, dentist or qualified anesthetist shall administer anesthetic agents (general and regional). Podiatrists shall administer only local anesthesia. The governing authority shall establish written policies and procedures concerning the provision of anesthesia services, including the designation of those persons authorized to administer anesthetics.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .0502 EQUIPMENT

All equipment for the administration of anesthetics shall be readily available, kept clean or sterile, and maintained in good working condition.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .0503 POST ANESTHESIA NOTE

Patient's anesthesiologist or anesthetist shall write a post anesthetic follow-up note prior to the patient's discharge. The note shall include the general condition of the patient and any instructions to the patient pertaining to his care and protection.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .0504 REQUIREMENT OF PERSON TRAINED IN CPR

A person with training and experience in cardio-pulmonary resuscitation shall be on the premises of the facility until all surgical patients are discharged.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .0600 - PATHOLOGY SERVICES

10A NCAC 13C .0601 PROVISION FOR LABORATORY TESTS

(a) Each facility shall have the capability of providing or obtaining laboratory tests required in connection with the surgery to be performed.

(b) The governing authority shall establish written policies requiring examination by a pathologist of all surgical specimens except for those types of specimens which the governing authority has determined do not require examination.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .0602 DISPOSAL OF WASTE

Methods for the disposal of pathological waste, contaminated dressings and other similar material shall meet the approval of governing local and state authorities.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .0700 - RADIOLOGY SERVICES

10A NCAC 13C .0701 PROVISION FOR RADIOLOGY SERVICES

Each facility shall have the capability of providing or obtaining diagnostic radiology services in connection with the surgery to be performed.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .0702 REGULATIONS FOR PERFORMED SERVICES

Radiation protection shall be provided in accordance with the rules and regulations adopted by the Radiation Protection Commission found in 10 NCAC 3G, and the recommendations of the National Council on Radiation Protection and Measurements. Records shall be kept of at least annual checks and calibration of all ionizing radiation therapy equipment used in the facility.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .0800 - PHARMACEUTICAL SERVICES

10A NCAC 13C .0801 DRUG DISPENSING

The governing authority, with the advice of a registered pharmacist, shall assure that there are appropriate methods, procedures and controls for obtaining, dispensing, and administering drugs and biologicals.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .0802 REGULATIONS FOR DISPENSING

When the facility maintains its own pharmaceutical services, it shall comply with applicable regulations adopted by the North Carolina Board of Pharmacy pursuant to General Statute 90-62.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .0900 - NURSING SERVICES

10A NCAC 13C .0901 NURSING ADMINISTRATION

(a) The facility shall have an organized nursing Department under the supervision of a director of nursing who is currently licensed as a registered nurse and who has responsibility and accountability for all nursing services.

(b) The director of nursing shall be responsible and accountable to the chief executive officer for:

(1) provision of nursing services to patients;

(2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. December 24, 1979.

10A NCAC 13C .0902 NURSING PERSONNEL

(a) An adequate number of licensed and ancillary nursing personnel shall be on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the facility and their individual nursing care needs.

(b) At least one registered nurse shall be in the facility during the hours it is in operation. Nursing personnel shall be assigned to duties consistent with their training and experience.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .1000 - MEDICAL RECORDS SERVICES

10A NCAC 13C .1001 MEDICAL RECORD SYSTEM

The facility shall maintain a medical record system designed to provide readily available information on each patient. The medical record system shall be under the supervision of a designated qualified person.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .1002 INDIVIDUAL PATIENT RECORDS

(a) Each patient's medical record shall be maintained in accordance with professional standards and shall include at least the following information:

(1) patient's identification, including name, address, date of birth, next of kin and a patient number;

(2) admitting diagnosis;

(3) preoperative history and physical examination pertaining to the procedure to be performed;

- (4) anesthesia report;
- (5) surgeon's operative report;
- (6) anesthesiologist's or anesthetist's report if applicable;
- (7) pertinent laboratory, pathology and X-ray reports;
- (8) postoperative orders and follow-up care;
- (9) discharge summary, including discharge diagnosis;
- (10) record of informed consent; and
- (11) physician's, dentist's, and nurse's progress notes.

(b) The administrator shall be responsible for safeguarding information on the medical record against loss, tampering, or use by unauthorized persons.

(c) Medical records shall be the property of the facility and shall not be moved from the premises wherein they are filed except by subpoena or court order.

(d) For licensing purposes the length of time that medical records are to be retained is dependent upon the need for their use in continuing patient care and for legal, research, or educational purposes. This length of time shall not be less than 20 years.

(e) Should a facility cease operation, there shall be an arrangement for preservation of records to insure compliance with these regulations. The Department shall be notified, in writing, concerning the arrangements.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .1100 - SURGICAL FACILITIES AND EQUIPMENT

10A NCAC 13C .1101 OPERATING SUITE

(a) Each operating suite shall be adequately equipped for the types of procedures to be performed.

(b) Each recovery area shall be adequately equipped for the proper care of post anesthesia recovery of surgical patients.

(c) The following equipment shall be available in the operating suite and recovery area:

- (1) cardio-pulmonary resuscitation drugs and intubation equipment,
- (2) cardiac monitor,
- (3) resuscitator including oxygen and suction equipment,
- (4) suitable surgical instruments customarily available for the planned surgical procedure,
- (5) defibrillator, and
- (6) tracheostomy set.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .1102 CARE OF OPERATING SUITE

(a) Dry sweeping and dusting shall be prohibited in treatment areas.

(b) Adequate and conveniently located spaces shall be provided for the storage of janitorial supplies and equipment.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .1200 - FUNCTIONAL SAFETY

10A NCAC 13C .1201 GENERAL

(a) The governing authority shall develop written policies and procedures designed to enhance safety within the facility and on its grounds and minimize hazards to patients, staff and visitors.

(b) The policies and procedures shall include establishment of the following:

(1) safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs;

(2) provisions for reporting and the investigation of accidental events regarding patients, visitors and personnel (incidents) and corrective action taken;

(3) provision for dissemination of safety-related information to employees and users of the facility; and

(4) provision for syringe and needle storage, handling and disposal.

(c) Smoking shall be permitted only in designated areas which shall not include patient care and treatment areas.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. December 24, 1979.

10A NCAC 13C .1202 PREVENTIVE MAINTENANCE

A schedule of preventive maintenance shall be developed for all of the medical and surgical equipment in the facility to assure satisfactory operation when needed.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. April 1, 2003.

SECTION .1300 - CONTROL AND SANITATION

10A NCAC 13C .1301 GENERAL

The governing authority shall employ procedures to minimize sources and transmission of infections. Professionally recognized surveillance methods shall be used. The governing authority shall provide space, equipment, and personnel to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. November 1, 1989.

10A NCAC 13C .1302 STERILIZATION PROCEDURES

(a) Policies and procedures shall be established in writing for storage, maintenance and distribution of sterile supplies and equipment.

(b) Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust proof and moisture free units. They shall be properly labeled.

(c) Sterilizing equipment shall be available and of the necessary type and capacity to sterilize instruments and operating room materials, as well as laboratory equipment and supplies. The sterilizing equipment shall have design control and safety features intact. The accuracy of instrumentation and equipment shall be checked quarterly by any professionally recognized method and periodic calibration and preventive maintenance shall be provided as necessary, and a log maintained.

(d) The date of expiration shall be marked on all supplies sterilized in the facility.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. November 1, 1989.

10A NCAC 13C .1303 HOUSEKEEPING

Operating rooms shall be appropriately cleaned in accordance with established written procedures after each operation. Recovery rooms shall be maintained in a clean condition.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .1304 LINEN AND LAUNDRY

(a) An adequate supply of clean linen or disposable materials shall be maintained.

(b) Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately.

(c) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

10A NCAC 13C .1305 SANITATION

(a) All parts of the facility, the premises and equipment shall be kept clean and free of insects, rodents, litter and rubbish.

(b) All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978.

SECTION .1400 - PHYSICAL PLANT CONSTRUCTION

10A NCAC 13C .1401 OPERATING SUITE

The size and design of the suite shall be in accordance with individual programs, but the following basic elements designed to ensure no flow of through traffic must be incorporated in all facilities:

(1) Operating Room(s). The number shall depend on the projected case load and types of procedures to be performed. Rooms used for surgery shall have adequate space to accommodate necessary equipment and personnel.

(2) Service Areas. The following supporting services shall be provided:

(a) scrub-up facilities with foot or knee controls;

(b) personnel locker and dressing areas so located that personnel enter from uncontrolled areas and exit directly into a surgical suite. Locker space shall be provided for each employee; and a toilet, shower, and dressing area shall be provided in each personnel dressing room;

(c) separate rooms for clean and for soiled supplies and equipment;

- (d) anesthesia workroom;
- (e) one clerical-control station; and
- (f) a janitor's closet conveniently located to serve only the licensed facility.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. December 24, 1979.

10A NCAC 13C .1402 RECOVERY AREA

Recovery area with handwashing facilities, secured medication storage space, clerical work space, storage for clerical supplies, linens, and patient care supplies and equipment shall be provided.

History Note: Authority G.S. 131E-149; Eff. October 14, 1978; Amended Eff. December 24, 1979. 10A NCAC 13C .1403 SUPPORTING ELEMENTS

In addition to those areas covered in Rules .1401 and .1402 of this Section, the facility shall provide space for the following:

(1) the receiving and registering of patients in privacy for obtaining confidential information;

(2) waiting space with public toilets, public telephone, drinking fountain, and wheelchair storage;

(3) preoperative preparation and post operative space for both males and females with dressing rooms and toilet facilities; and

(4) secure storage for patients' personal effects.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. April 1, 2003.

10A NCAC 13C .1404 DETAILS AND FINISHES

All details and finishes must meet the following requirements:

(1) Details

(a) The type of construction shall meet the requirement of the current edition of the North Carolina State Building Code for "Business Occupancy-(B)," except that in the construction of new facilities required exit doors to stairs or to the outside shall be no less than 44" wide doors.

(b) Exit corridors, in addition to meeting the appropriate requirements of the North Carolina State Building Code, shall:

(i) be no less than 7'0" clear width between doors from the recovery area or operating rooms and required exit doors; or

(ii) if in a one-story building or on the ground floor of a multi-story building and is less than 7'0" clear width be so arranged as to allow a stretcher to exit from the recovery area or operating room directly into the corridor without turning and move to the required exit without having to make a turn.

(c) Doors between preoperative preparation, operating rooms and recovery areas and recovery rooms and corridors shall be no less than 44" wide. All recovery areas shall have at least one door opening to an exit passage way meeting the requirements of (b)(i) and (b)(ii) of this Rule.

(d) Items such as drinking fountains, telephone booths, vending machines, and portable equipment shall be located so as not to restrict corridor traffic or reduce the corridor width below the required minimum.

(e) No doors shall swing into corridors in a manner that might obstruct traffic flow or reduce the required corridor width except doors to spaces such as small closets which are not subject to occupancy.

(f) Thresholds and expansion joint covers shall be made flush with the floor surface to facilitate use of wheelchairs and carts.

(g) Single use towel dispensers or air driers shall be provided at all handwashing fixtures except scrub sinks.

(h) All other rooms shall have not less than 8'0'' (2.44 m.) high ceilings except that corridors, storage rooms, toilet rooms, and other minor rooms may be not less than 7'-8'' (2.34 m.). Suspended tracks, rails, pipes, etc., located in the path of normal traffic, shall be not less than 7'-6'' (2.28 m.) above the floor.

(2) Finishes

(a) Floors shall be easily cleanable and have wear resistance appropriate for the locations involved. Joints in tile and similar material in such areas shall be resistant to food acids.

(b) Wall bases in operating rooms, soiled workrooms, and other areas subject to frequent wet cleaning shall be integral and covered with the floor, tightly sealed within the wall, and constructed without voids that can harbor vermin.

(c) Walls shall be washable; and, in the immediate area of plumbing fixtures, the finish shall be smooth, moisture resistant, and easily cleaned.

(d) Floor and wall penetrations by pipes, ducts, conduits, etc., shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(e) Ceilings in operating rooms shall be readily washable and without crevices that can retain dirt particles. Finished ceilings may be omitted in mechanical and equipment spaces, shops, general storage areas, and similar spaces except where required for fire rating.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. November 1, 1989; December 24, 1979.

10A NCAC 13C .1405 MECHANICAL REQUIREMENTS

(a) Temperatures and Relative Humidity

(1) The heating and air conditioning systems shall be designed to provide the temperature and humidities shown below:

Area Designation	Temperature	Relative Humidity	
Percent			
Operating	70-75° F* 21-24° C*	50-60	
Recovery	70-75° F* 21-24° C*	30-60	

*Variable Range Required

(2) For all other occupied or use areas, a minimum design temperature of 72° F. (22° C) at winter design conditions shall be provided.

(b) All air-supply and air-exhaust systems for the operating suite and recovery area shall be mechanically operated. All fans serving exhaust systems shall be located at the discharge end of the

system. The ventilation rates shown in this Paragraph shall be minimum acceptable rates and shall not be construed as precluding the use of higher ventilation rates.

(1) Outdoor intakes for operating rooms shall be located not less than 30 feet (9.14 m.) from exhausts from other ventilating systems, combustion equipment and plumbing vents and at least 3 feet 0 inches (.92 m.) above the roof and 6 feet (1.83 m.) above ground level.

(2) The ventilation systems shall be designed and balanced to provide the pressure relationship as shown in this Paragraph.

(3) All air supplied to operating rooms shall be delivered at or near the ceiling of the area served and all exhaust from the area shall be removed near floor level. At least two exhaust outlets shall be used in all operating rooms.

(4) The bottom of any room supply air inlets, recirculation, and exhaust air outlets shall be located not less than 3 inches (7.62 cm.) above the floor.

(5) Corridors shall not be used to supply air to or exhaust air from any room, except that exhaust from corridors may be used to exhaust-ventilate bathrooms, toilet rooms, janitors' closets and electrical or telephone closets opening directly on corridors.

(6) All ventilation or air conditioning systems serving operating rooms shall have a minimum of two filter beds:

(A) Filter bed No. 1 shall be located upstream of the air conditioning equipment and shall have a minimum efficiency of 25 percent. Filter bed No. 2 shall be downstream of the supply fan and of recirculating spray water and water reservoir-type humidifiers. Filter bed No. 2 shall have a minimum efficiency of 90 percent.

(B) All filter efficiencies shall be certified by an independent testing agency and shall be based on the atmospheric dust spot efficiency determination in accordance with ASHRAE Standard 52-68; except that the exhausts from all laboratory hoods in which infectious or radioactive materials are processed shall be equipped with filters having a 99 percent efficiency based on the DOP (dioctyophthalate) test method and there shall be equipment and procedure for the safe removal of contaminated filters.

(C) Filter frames shall provide an airtight fit with the enclosing ductwork. All joints between filter segments and the enclosing ductwork shall be gasketed or sealed to provide a positive seal against air leakage. Each filter bed serving sensitive areas or central air systems shall have a manometer installed across each filter bed.

(D) Ventilation systems serving recovery rooms shall not be tied in with soiled holding or work rooms, janitors' closets, or waiting rooms if the air is to be recirculated in any manner except through approved filters.

(7) Air handling duct systems shall not have duct linings.

(8) The following general air pressure relationships and ventilation shall apply:

Minimum

Pressure	Total Air	All Ai	r			
Relationship	Changes per	Exhaust	ted	Recircu	lated	
Area	to Adj	jacent	Hour S	upplied	Directly to	Within

Designation Units	Areas	to Room	Outdoors	Room
Operating Room with	Р	25	Optional	Only
approved				
filters.				
Recovery Room Sub-	E	6	Optional	See
paragraph				
(b)(6)(D)				
of this				
Rule.				
Soiled Workroom				
or				
Soiled Holding	Ν	10	Yes	lo
Clean Workroom				
or				
Clean Holding Optional	Р	4	Optional	
Examination Room Optional	+/-	6	Optional	
Treatment Room Optional	+/-	6	Optional	
Medication room Optional	Р	4	Optional	
X-Ray (Diagnostic				
And Treatment) Optional	+/-	6	Optional	
Laboratory (general) Optional	Ν	6	Optional	

P = Positive	
required	

N = Negative E = Equal +/- = continuous Directional control not

equir

(9) Operating rooms or procedure rooms which are used with either life sustaining electrical equipment or identified as a critical care location shall comply with the requirements for ventilation in NFPA 99, Chapter 5, Environmental Systems.

(10) Prior to occupancy of the facility, the facility shall obtain documentation verifying that all mechanical systems have been tested, balanced, and operated to demonstrate that the installation and performance of these systems conform to the approved design. Test results shall be maintained in the facility maintenance files.

(11) Upon completion of equipment installation, the facility shall acquire and maintain a complete set of manufacturers' operating, maintenance, and preventive maintenance instructions, parts lists, and procurement information including equipment numbers and descriptions.

(12) Operating staff shall be provided with instructions for properly operating systems and equipment.

(c) Medical gases: The performance, maintenance, installation, and testing of medical gas systems shall comply with the requirements of National Fire Protection Association Standard 99. When any piping or supply of medical gases is installed, altered, or augmented, the altered zone shall be tested and certified as required by National Fire Protection Association Standard 99. Testing shall be conducted by the facility and at least one other independent testing organization to ensure that the system is safe for patient use.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. April 1, 2003; December 24, 1979.

10A NCAC 13C .1406 PLUMBING AND OTHER PIPING SYSTEMS

(a) All building plumbing systems shall be installed in accordance with the requirements of the North Carolina State Building Code, Volume II.

(b) Plumbing Fixtures

(1) The material used for plumbing fixtures shall be of non-absorptive acid-resistant material.

(2) Lavatories and sinks required shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches (12.7 cm.) above the rim of the fixture. All fixtures used by medical and nursing staff shall be trimmed with valves which can be operated without the use of hands. Where blade handles are used for this purpose, they shall not exceed four and one-half inches (11.43 cm.) in length, except that handles on scrub sinks and clinical sinks shall be not less than six inches (15.24 cm.) long.

(3) Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

(c) Water Supply Systems

(1) Systems shall be designed to supply water to the fixtures and equipment at a sufficient pressure to operate all fixtures and equipment during maximum demand periods.

(2) Each water service main, branch main, riser and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture.

(3) Backflow preventers shall be installed on hose bibbs and on all fixtures to which hoses or tubing can be attached.

(4) Hot water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. Hot water at the handwashing and bathing facilities shall not exceed 116° F (46.6°C).

(d) Drainage Systems

(1) Drain lines from sinks in which acid wastes may be poured shall be fabricated from an acid-resistant material.

(2) Piping systems shall be designed to avoid, insofar as is possible, installations in the ceiling directly over operating rooms.

(3) Floor drains shall not be installed in operating rooms.

(4) Building sewers shall discharge into a community sewerage system. Where such a system is not available, a facility providing sewage treatment which conforms to applicable local and state regulations is required.

(e) Non-flammable medical gas system installations shall be in accordance with the requirements of NFPA Standard 99 and NFPA 50. Clinical vacuum (suction) system installations shall be in accordance with the requirements of NFPA Standard 99. The minimum number of outlets is shown below.

Minimum Medical Gas Station Outlets and Vacuum Station Inlets

Location Oxygen Vacuum Medical Air Operating Room 2/room 3/room 1/room Recovery Room 1/bed 3/bed

1/bed

(f) Service outlets for built-in housekeeping vacuum systems, if used, shall not be located within operating rooms.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978; Amended Eff. April 1, 2003.

10A NCAC 13C .1407 ELECTRICAL REQUIREMENTS

(a) General

(1) All material including equipment, conductors, controls and signaling devices shall be installed to provide a complete electrical system with the necessary characteristics and capacity to supply the electrical facilities shown in the specifications or indicated on the plans. All materials shall be listed as complying with applicable standards of Underwriters' Laboratories, Inc., or other similarly established standards, where such standards have been established.

(2) All material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of North Carolina State Building Code, Volume VII IV, Electrical. A written record of performance tests on electrical systems and equipment shall show compliance with applicable codes and standards.

(3) Lighting and appliance panelboards shall be located on the same floor as the circuits they serve.

(b) Lighting

(1) All spaces occupied by people and equipment shall have electric lighting.

(2) Operating rooms shall have general lighting for the room in addition to local lighting provided by special lighting units at the surgical and obstetrical tables. Each fixed special lighting unit at the tables, except for portable units, shall be connected to an independent circuit.

(c) Power

(1) If non-flammable anesthetics are to be used, the facility shall meet the requirements of NFPA 99, Health Care Facilities Code.

(2) Procedures that create a direct electrical pathway to the heart or create conditions meeting the definition of a wet location shall be provided with an isolated power system (IPS) in the patient care area.

(3) Procedures that require electrically powered devices that because of patient safety cannot tolerate an outage due to equipment faults shall be provided with an isolated power system (IPS) in the patient care area.

(4) Procedures that can be safely carried out with conventional grounded power systems shall be provided with ground fault circuit interrupters on each circuit installed in the operating or procedure room serving the patient care area.

(5) Critical care areas require a Type 1 essential electrical system.

(6) Procedures requiring the use of electrical life support equipment require a Type 1 essential electrical system.

(7) All facilities shall have as a minimum a Type 3 essential electrical system.

(8) All devices, switches, receptacles connected to the essential electrical system shall be distinctively identified so that personnel can easily select which device is expected to operate during failure of normal source of power.

(9) Fuel for the essential electrical system generator shall be stored on site in sufficient quantity to provide for not less than 24 hours of operation.

(d) Receptacles

(1) Each operating or procedure room shall have at least eight 120 volt duplex receptacles.

(2) In locations where mobile X-ray is used, an additional receptacle, distinctively marked for X-ray use, shall be provided.

(3) Fixed and mobile X-ray equipment installations shall conform to Article 660 of the North Carolina State Building Code, Electrical.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;

Amended Eff. April 1, 2003.

10A NCAC 13C .1408 GENERAL

The design, construction, maintenance and operation of a facility shall be in accordance with those codes and standards listed in Rule .1409, LIST OF REFERENCED CODES AND STANDARDS, and codes, ordinances, and regulations enforced by city, county, or other state jurisdictions with the following requirements:

(1) The facility shall notify the Division when all construction or renovation has been completed, inspected and approved by the architect and engineer having responsibility, and the facility is ready for a final inspection. Prior to using the completed project, the facility shall receive from the Division, written approval for use.

(2) In the absence of any requirements by other authorities having jurisdiction, the facility shall develop a master fire and disaster plan with input from the local fire department and local emergency management agency to fit the needs of the facility. The plan shall require:

(A) Training of facility employees in the fire plan implementation, in the use of fire-fighting equipment, and in evacuation of patients and staff from areas in danger during an emergency condition;

(B) Conducting of quarterly fire drills on each shift;

(C) A written record of each drill shall be on file at the facility for at least three years;

(D) The testing and evaluation of the emergency electrical system(s) once each year by simulating a utility power outage by opening of the main facility electrical breaker(s). Documentation of the testing and results shall be completed at the time of the test and retained by the facility for three years; and

(E) Disaster planning to fit the specific needs of the facility's geographic location and disaster history, with at least one documented disaster drill conducted each year;

(3) The facility structure, component parts, and building systems shall be kept in good repair and maintained with consideration for the safety and comfort of patients, staff and visitors; and

(4) There shall be a definite assignment of maintenance functions to qualified personnel under supervision.

History Note: Authority G.S. 131E-149;

Eff. April 1, 2003.

10A NCAC 13C .1409 LIST OF REFERENCED CODES AND STANDARDS

The following codes and standards are adopted by reference including subsequent amendments. Copies of these publications can be obtained from the various organizations at the addresses listed:

(1) The North Carolina State Building Code, current edition, all volumes. Copies of this code may be purchased from the N.C. Department of Insurance Engineering Division located at 410 North Boylan Avenue, Raleigh, NC 27603 at a cost of four hundred eight dollars (\$408.00).

(2) The National Fire Protection Association codes and standards listed below, current editions. Copies of these codes and standards may be obtained from the National Fire Protection Association, 1 Batterymarch Park, PO Box 9101, Quincy, MA 02269-9101 at the cost shown for each code or standard listed.

(a)	10	Portable Fire Extinguishers	\$29.75
(b)	13	Installation of Sprinkler Systems	\$42.75
(c)	20	Installation of Centrifugal Fire Pumps	\$29.75
(d)	22	Water Tanks for Private Fire Protection	\$29.75
(e)	25	Water-Based Fire Protection Systems	\$32.75
(f)	30	Flammable and Combustible Liquids Code	\$32.25
(g)	31	Installation of Oil-Burning Equipment	\$29.75
(h)	37	Stationary Combustion Engines and Gas Turbines	\$26.75
(i)	50	Bulk Oxygen Systems at Consumer Sites	\$22.25
(j)	53	Fire Hazards in Oxygen-Enriched Atmospheres	\$29.75
(k)	54	National Fuel Gas Code	\$35.25
(1)	55	Compressed and Liquefied Gases in Portable Cylinders	\$22.25
(m) \$35.25	58	Storage and Handling of Liquefied Petroleum Gases	
(n)	59A	Liquefied Natural Gas (LNG)	\$26.75
(0)	72	National Fire Alarm Code	\$42.75
(p)	80	Fire Doors and Windows	\$29.75
(q)	82	Incinerators, Waste and Linen Handling Systems and Equipment	\$22.25
(r)	90A	Installation of Air Conditioning and Ventilating Systems	\$26.75
(s)	90B	Installation of Warm Air Heating and Air Conditioning Systems	\$22.25
(t)	92A	Smoke-Control Systems	\$26.75
(u)	92B	Smoke Management Systems in Malls, Atria, Large Areas	\$26.75
(v)	99	Health Care Facilities	\$42.75

(w)	101	Safety to Life from Fire in Buildings and Structures	\$53.50
(x)	101A	Alternative Approaches to Life Safety	\$35.25
(y)	105	Smoke-Control Door Assemblies	\$22.25
(z)	110	Emergency and Standby Power Systems	\$26.75
(aa)	221	Fire Walls and Fire Barrier Walls	\$22.25
(bb) \$26.75	241	Construction, Alteration, and Demolition Operations	
(cc)	780	Lightning Protection Code	\$29.75
(dd)	801	Facilities Handling Radioactive Materials	\$26.75

(3) American Society of Heating, Refrigerating & Air Conditioning Engineers, (ASHRAE) HVAC APPLICATIONS, current edition. Copies of this document may be obtained from the American Society of Heating, Refrigerating & Air Conditioning Engineers at United Engineer Center, 345 East 47th Street, New York, NY 10017 at a cost of one hundred forty-four dollars (\$144.00).

History Note: Authority G.S. 131E-149;

Eff. April 1, 2003.

10A NCAC 13C .1410 APPLICATION OF PHYSICAL PLANT REQUIREMENTS

The physical plant requirements for each facility shall be applied as follows:

(1) All newly licensed facilities shall comply with the requirements of Section .1400;

(2) Existing licensed facilities shall meet licensure and code requirements in effect at the time of construction, alteration, or modification;

(3) New additions, alterations, modifications, and repairs of existing licensed facilities shall meet the technical requirements of Section .1400, however, where strict conformance with current requirements would be impractical, the authority having jurisdiction shall approve alternative measures where the facility can demonstrate to the Division's satisfaction that the alternative measures do not reduce the safety or operating effectiveness of the facility;

(4) Rules contained in Section .1400 are minimum requirements and not intended to prohibit buildings, systems or operational conditions that exceed minimum requirements;

(5) Equivalency: Alternate methods, procedures, design criteria, and functional variations from the physical plant requirements, because of extraordinary circumstances, new programs, or unusual conditions, shall be approved by the authority having jurisdiction when the facility can effectively demonstrate to the Division's satisfaction, that the intent of the physical plant requirements are met and that the variation does not reduce the safety or operational effectiveness of the facility; and

(6) Where rules, codes, or standards have any conflict, the most stringent requirement shall apply.

History Note: Authority G.S. 131E-149;

Eff. April 1, 2003.

10A NCAC 13C .1411 ACCESS AND SAFETY

Projects involving replacement of, alterations of, and additions to existing licensed facilities shall be planned and phased so that construction will minimize disruptions of facility operations. Facility access, exit ways, safety provisions, and building and life safety systems shall be maintained so that the health and safety of the occupants will not be jeopardized during construction. Additional safety and operating measures shall be planned, documented, and executed to compensate for hazards related to construction or renovation activities to maintain an equivalent degree of health, safety, and operational effectiveness to that required by rules, standards, and codes for a facility not under construction or renovation.

History Note:Authority G.S. 131E-149;Eff. April 1, 2003.

Attachment G

2010 State Medical Facilities Plan Table 6D: Single Specialty Ambulatory Surgery Facility Demonstration Project

Table 6D: Single Specialty Ambulatory Surgery FacilityDemonstration Project

CRITERIA	CRITERIA BASIC PRINCIPLE AND RATIONALE
 Establish a special need determination for three new separately licensed single specialty ambulatory surgical facilities with two operating rooms each, such that there is a need identified for one new ambulatory surgical facility in each of the three following service areas: Mecklenburg, Cabarrus, Union counties (Charlotte Area) Guilford, Forsyth counties (Triad) Wake, Durham, Orange counties (Triangle) 	Value At least one county in each of the groups of counties has a current population greater than or equal to 200,000 and more than 50 total ambulatory/shared operating rooms and at least 1 separately licensed Ambulatory Surgery Center. Locating facilities in high population areas with a large number of operating rooms and existing ambulatory surgery providers prevents the facilities from harming hospitals in rural areas, which need revenue from surgical services to offset losses from other necessary services such as emergency department services.
In choosing among competing demonstration project facilities, priority will be given to facilities that are owned wholly or in part by physicians.	Value Giving priority to demonstration project facilities owned wholly or in part by physicians is an innovative idea with the potential to improve safety, quality, access and value. Implementing this innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation's impact.
Each demonstration project facility shall provide care to the indigent population, as described below: The percentage of the facility's total collected revenue that is attributed to self-pay and Medicaid revenue shall be at least seven percent, which shall be calculated as follows: The Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid cases divided by the total collected revenues for all surgical cases performed in the facility.	Access Requiring service to indigent patients promotes equitable access to the services provided by the demonstration project facilities.
 Following are examples of the calculation of self pay and Medicaid revenue: If Medicare allows \$300 for a surgical procedure and a self-pay patient pays the facility \$0, then \$300 is considered self-pay revenue. If Medicare allows \$300 for a surgical procedure and a self-pay patient pays the facility \$50, then \$250 is considered self-pay revenue. 	

CRITERIA	CRITERIA BASIC PRINCIPLE AND RATIONALE
If Medicare allows \$300 for a surgical procedure and Medicaid pays the facility \$225, then \$75 is considered Medicaid revenue.	
Demonstration project facilities shall report utilization and payment data to the statewide data processor as required by G.S. 131E-214.2.	
The Agency will monitor compliance with indigent care requirements by analyzing payment data submitted by the facilities.	
Demonstration project facilities shall complete a "Surgical Safety Checklist (adapted for use in the US)" before each surgery is performed. Note: "Surgical Safety Checklist is based on the WHO Surgical Safety Checklist developed by: World Health Organization"	Safety and Quality Implementing a system for measuring and reporting quality promotes identification and correction of quality of care issues and overall improvement in the quality of care provided.
Each demonstration project facility shall develop a system to measure and report patient outcomes to the Agency for the purpose of monitoring the quality of care provided in the facility. If patient outcome measures are available for a facility's particular surgical specialty, the facility shall identify those measures and may use them for reporting patient outcomes. If patient outcome measures are not available, the facility shall develop its own patient outcome measures that will be reported to the Agency. Demonstration project facilities shall submit annual reports to the Agency regarding the results of patient outcome measures. Examples of patient outcome measures include: wound infection rate, post-operative infections, post- procedure complications, readmission, and medication errors.	
Demonstration project facilities are encouraged to develop systems that will enhance communication and ease data collection, for example, electronic medical records that support interoperability with other providers.	Safety and Quality, Access, Value Electronic medical records improve the collection of quality and access to care data and collecting data is the first step in monitoring and improving quality of care and access. Interoperability facilitates communication among providers, enhancing care coordination.
Demonstration project facilities are encouraged to provide open access to physicians.	Access Services will be accessible to a greater number of surgical patients if the facility has an open access policy for physicians.

CRITERIA	CRITERIA BASIC PRINCIPLE AND		
CRITERIA	RATIONALE		
	RAIIONALE		
Physicians affiliated with the demonstration project facilities are required to establish or maintain hospital staff privileges with at least one hospital and to begin or continue meeting Emergency Department coverage responsibilities with at least one hospital, with the following caveat: This requirement has to be available to the physicians and not denied based upon charges that physicians are engaging in competitive behavior by providing services at a facility that is perceived to be in competition with the hospital if it so happens that the CON is issued to an organization other than the hospital.	Safety and Quality Encouraging physicians to establish or maintain hospital staff privileges and to begin or continue meeting Emergency Department coverage responsibilities helps prevent a decrease in the quality of the overall healthcare system resulting from lack of resources.		
Additionally, physicians affiliated with the demonstration project facilities are required to provide annually to the Agency data related to meeting their hospital staff privilege and Emergency Department coverage responsibilities. Specific data to be reported, such as number of nights on call, will be determined by the Agency. Facilities shall obtain a license no later than two years from the date of issuance of the certificate of need, unless this requirement is changed in a subsequent State Medical Facilities Plan.	Access and Value Timely project completion increases access to services and enhances project value.		
The Single Specialty Ambulatory Surgery Work Group values the collective wisdom of the North Carolina Hospital Association and the North Carolina Medical Society and requests that the two organizations work together to assist the demonstration project facilities in developing quality measures and increasing access to the underserved.	Safety and Quality, Access and Value Collaboration between the North Carolina Hospital Association and the North Carolina Medical Society in an effort to develop quality measures and increase access to the underserved promotes all three Basic Principles.		
 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 at the end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility thereafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress toward meeting the demonstration project criteria. 	Safety and Quality, Access, Value Timely monitoring enables the Agency to determine if facilities are meeting criteria and to take corrective action if facilities fail to meet criteria. This ensures that all three Basic Principles are met by the demonstration project facilities.		

CRITERIA	CRITERIA BASIC PRINCIPLE AND
	RATIONALE
The Agency will evaluate each facility after each facility	
has been in operation for five years. If the Agency	
determines that the facilities are meeting or exceeding all	
criteria, the work group encourages the State Health	
Coordinating Council to consider allowing expansion of	
single specialty ambulatory surgical facilities beyond the	
original three demonstration sites. The Agency may	
require corrective action if the Agency determines that a	
facility is not meeting or is not making good progress	
toward meeting the demonstration project criteria.	
If the Agency determines that a facility is not in	
compliance with any one of the demonstration project	
criteria, the Department, in accordance with G.S. 131E-	
190, "may bring an action in Wake County Superior Court	
or the superior court of any county in which the certificate	
of need is to be utilized for injunctive relief, temporary or	
permanent, requiring the recipient, or its successor, to	
materially comply with the representations in its	
application. The Department may also bring an action in	
Wake County Superior Court or the superior court of any	
county in which the certificate of need is to be utilized to	
enforce the provisions of this subsection and G.S.	
131E-181(b) and the rules adopted in accordance with this	
subsection and G.S. 131E-181(b)."	

Attachment H

Petition to Add New Policy OR-1, Spring 2015 Agency Report

Acute Care Services Committee Agency Report Petition to Add New Policy OR-1 to the Proposed 2016 State Medical Facilities Plan

Petitioner:

Knowles, Smith & Associates, LLP 2015 Valleygate Drive Fayetteville, NC 28304

Contact: Virginia Jones Chief Operating Officer

Request:

The petitioner requests the creation of Policy OR-1 to establish certain conditions that would exempt operating rooms (ORs) in licensed and CMS-certified ambulatory surgical facilities dedicated to pediatric dental surgery from the standard OR methodology in Chapter 6 of the State Medical Facilities Plan (SMFP). The petitioners provide information to support the claim that pediatric dental patients have special problems of access to surgical services, which warrants the creation of a policy to address this specialty. Further, the petition sets out conditions that facilities would be required to meet should the exemption be granted.

Background Information:

North Carolina General Statute § 131E-146 defines ambulatory surgical facilities as follows:

(1) "Ambulatory surgical facility" means a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. An ambulatory surgical facility may only admit patients for a period of less than 24 hours and must provide at least one designated operating room..., have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part 4...."

The methodology in the SMFP establishes the conditions under which need for ORs is determined. The "SHCC assigns the highest priority to a need methodology that favors providers delivering services to a patient population representative of all payer types in need of those services in the service area" (p. 2, 2015 SMFP).

The OR methodology determines need based on how the projected population growth in a service area is estimated to affect the need for additional ORs. Need is projected for a period four years after the year for which data are collected. The methodology distinguishes between inpatient and ambulatory procedures, but does not distinguish among surgical specialties. It also does not distinguish among inpatient ORs, shared ORs, hospital-based ambulatory surgical facilities, and free-standing ambulatory surgical facilities when projecting OR need. The 2015 SMFP shows a statewide surplus of 262 ORs.

Chapter 2 of the State Medical Facilities Plan (SMFP) describes the purpose and process for submitting petitions to amend the SMFP during its development. Early in the planning year petitions related to basic SMFP policies and methodologies that have a statewide impact may be submitted. The SMFP defines changes with the potential for a statewide impact as "the addition, deletion, and revision of policies or projection methodologies" (p.7, 2015 SMFP). If approved, the policy proposed in this petition would be applicable statewide.

Analysis/Implications:

The petitioner describes medical, regulatory, financial, and geographical challenges to serving children with significant dental health needs, especially those children whose dental care is covered by Medicaid.

A medical challenge lies in the average 2.5 hour duration of pediatric dental surgery, as cited by the petitioner. A recent study (cited in the petition) of pediatric dental surgeries performed in a large metropolitan children's hospital reported an average of 110 minutes, excluding room turnover time.¹ The standard average case time used in the SMFP methodology is 1.5 hours for ambulatory cases and 3 hours for inpatient cases. In 2012-2013, NC License Renewal Applications showed that oral surgery accounted for 0.4% of inpatient surgical cases, 2.3% of ambulatory cases in hospitals, and 0.8% of cases in ambulatory surgical facilities. Overall, oral surgery accounted for 2.0% of all ambulatory surgery cases, nor does it contain a breakdown of payer type.

A regulatory challenge noted by the petitioner is that North Carolina hospital licensure rules do not allow dentists to admit surgical patients directly (10A NCAC 13B.1905(a), 10A NCAC 13B.1902(26)). On the other hand, ambulatory surgery centers do allow dentists to admit patients independently. Both types of facilities require recertification by a physician of the patient's history and physical examination within 24 hours before admission. North Carolina law does not define dentists as physicians.² This challenge lies outside the purview of the SHCC.

¹ Forsyth, Anna R., Seminario, Ana Lucia; Scott, Joanna; Berg, Joel; Ivanova, Iskra; Lee, Helen. (2012). General Anesthesia Time for Pediatric Dental Cases. *Pediatric Dentistry*. 23(5), 129-135.

² NC General Statutes § 90-9.1. Oral surgeons, however, are defined as physicians under NC law.

The petition points out that medical and regulatory challenges can translate into financial barriers, especially for patients covered by Medicaid. Medicaid reimburses anesthesia costs for procedures done in ORs only, so dentists may be unlikely to perform operative procedures in the office setting, even if the facility has the proper equipment and staff. Given the long average duration of pediatric dentistry surgical cases, Medicaid reimbursement rates reportedly are not attractive, which may serve to limit block time for pediatric dental surgery in settings outside of the dental practice.

In 2011, the SHCC formed a Pediatric OR workgroup, charged to investigate and develop recommendations about whether the standard operating room methodology should include a determination of need for dedicated pediatric ORs. This workgroup focused on hospital-based ORs. Recognizing the differences between the needs and characteristics of pediatric and adult surgery patients, the workgroup recommended to the Acute Care Services (ACS) Committee that pediatric cases be weighted heavier than adult cases in determining OR need. The ACS Committee, however, determined that a change to the policy was not warranted and did not forward the workgroup's recommending that hospitals with high volumes of pediatric OR cases should consider submitting adjusted need determination petitions to address needs for pediatric ORs. The motion included a request that such petitions address issues related to pediatric surgical case types and times (in comparison to average adult case times) and appropriate age groupings. Regardless, hospitals are free to designate existing ORs for pediatric surgery.

Policies in the SMFP, by definition, have statewide impact. The Agency acknowledges the general shortage of dentists in North Carolina, the importance of comprehensive pediatric dental care, and the substantial challenges to providing such care to children in families of low income. The petition and supporting documents focus almost exclusively on characteristics of and problems reportedly encountered in Health Service Area (HSA) V, however. What is not clear from this petition and comments received is whether limited access to ORs for pediatric dental surgery is a statewide phenomenon. The SHCC "encourages the development of value-driven health care by promoting collaborative efforts … and promoting coordinated services that reduce duplicative and conflicting care" (pp. 3-4, 2015 SMFP). While cooperative efforts may have experienced challenges in HSAV, the petition does not provide data that describes the situation statewide.

Agency Recommendation:

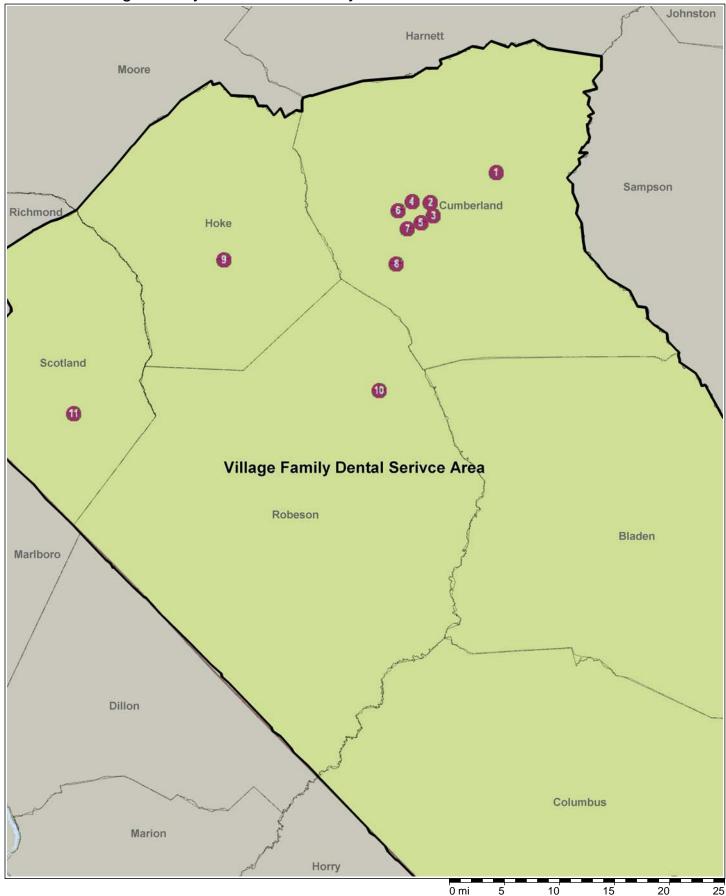
The SHCC historically has not favored creating or changing policies or methodologies to address issues regarding a single specialty, whether it be a proposed new single-specialty facility or ORs dedicated to a single specialty in an existing facility.

Given available information submitted by the March 20, 2015 deadline date for comments on petitions, and in consideration of factors discussed above, the agency recommends denial of this petition. The Agency supports the standard methodology for OR need determinations. While the SMFP shows that the state has a sufficient number of ORs to serve pediatric dental patients, the Agency recognizes that accessing surgical services can present challenges for some types of patients, specialties, and providers. Additional analysis and discussion would be necessary to examine whether these challenges exist statewide. The ACS Committee may choose to recommend a stakeholder group or other mechanism to explore options and alternatives to address this request.

Attachment J

Village Family Dental Six-County Service Area

Village Family Dental Six-County Service Area and Office Locations



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Attachment K

Model to Estimate Ambulatory Dental Surgery Operating use by Pediatric Dental Medicaid Beneficiaries, 2014

Model to Estimate Ambulatory Dental Surgery Operating Room use by Pediatric Dental Medicaid Beneficiaries 2014

	а	b	С	d	е	f	g	h	i	j	k
HSA		Medicaid Children in Largest County		Percent Medicaid Childred Screened	Percent Screened Need of Dental Surgery	Percent in Need Treated Per Year	Annual Dental Surgery Cases	Hours Per Case	Operating Room Hours Per Year	Hours Per Room Per Year	Number of OR's needed for Ped Medicaid
I	155,287	24,198	Buncombe	50%	17%	15%	1,980	2.5	4,950	1,872	3
11	188,957	56,849	Guilford	50%	17%	15%	2,409	2.5	6,023	1,872	3
III	217,875	107,602	Mecklenburg	50%	17%	15%	2,778	2.5	6,945	1,872	4
IV	172,993	70,217	Wake	50%	17%	15%	2,206	2.5	5,514	1,872	3
V	170,849	36,925	Cumberland	50%	17%	15%	2,178	2.5	5,446	1,872	3
VI	161,887	18,106	Pitt	50%	17%	15%	2,064	2.5	5,160	1,872	3
Total	1,067,846	313,897		50%	17%	15%	13,615	2.5	34,038	1,872	18

Notes:

July 2014 county enrollees in: AFDC under 21, Other Child, Infants and Children, MCHIP, and one half of those in categories CHIP and CHIP Extended Coverage per DMA report, summed by Health Service Area

b Same as (a) , for largest county in the HSA

c Largest county determined by largest number of Medicaid Children

d Assumption based on recent North Carolina experience

e Assumption based on Knowles, Smith and Associates experience

f Estimate - for modelling purpose

g d*e*f

h Maximum time per pediatric case in American Academy of Pediatric Dentistry Guidelines, 2009-10, confirmed by KSA experience

i g*h

j SMFP Operating Room Methodology standard hours per operating room per year. Step 3 f.

k i/j