Valleygate Dental
SURGERY CENTERS

DELIVERED VIA EMAIL 5/27/2016

May 31, 2016

Valleygate Dental Surgery Centers
2015 Valleygate Drive
Fayetteville, NC 28304

Ms. Martha Frisone, Assistant Chief
Mr. Michael McKillip, Project Analyst
Healthcare Planning and Certificate of Need
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Comments on Competing Application for a Certificate of Need for a Demonstration Dental Ambulatory Surgical Facility in Wake County, Health Service Area IV; CON Project ID Number:

J-011170-16, Surgical Center for Dental Professionals of Raleigh
J-011175-16 Valleygate Dental Surgery Center of Raleigh

Dear Mr. McKillip and Ms. Frisone:

On behalf of Valleygate Dental Surgery Center of Raleigh, LLC, Project ID J-011175-16, thank you for the opportunity to comment on the above referenced applications for the development of a dental ambulatory surgical facility in the Dental Demonstration Project Region 1.

CONTEXT

Two applications were submitted for the need identified in the *2016 State Medical Facilities Plan* for one single specialty dental surgery facility in Region 1. Because the Plan and statute permit only one award, the decision will have a significant influence on access across this region. Impact on quality of dental services, cost of services, need for proposed services, accessibility to underserved populations, and location are critical selection elements. The Dental Single Specialty Ambulatory Surgical Facility Demonstration Project in the Plan was created in response to petitions from Knowles, Smith, and Associates and Triangle Implant Center that documented the need for accessible operating rooms for dentists and oral surgeons. We believe that the application submitted by Valleygate Dental Surgery Center of Raleigh, more closely matches the spirit and intent of the demonstration project. Moreover, the application submitted by Valleygate is the only application that meets CON review criteria as an approvable application.

We appreciate the complexity of reviewing competitive applications, and the careful thought it requires on the part of Agency staff. We request that the CON Section give careful consideration to not only the standard competitive criteria that have been used in past competitive reviews of operating room applications, but also to other critical factors that we believe affect quality, value and access in this important project.

Critical Differences between Surgical Center for Dental Professionals and Valleygate Dental Surgery Center Proposals

To properly compare the two applications, it is important to understand the fundamental differences that separate Valleygate Dental Surgical Center of Raleigh's (Valleygate) proposal from the Surgical Center for Dental Professional or Raleigh's (SCDPR). SCDPR proposes to credential dentists interested in performing surgical cases in its proposed facility based on its own credentialing system, regardless of their formal training. Valleygate is proposing to credential *only* dentists who possess the required training to operate on sedated and anesthetized patients, which Valleygate defines as having a NC sedation permit or having completed a postgraduate residency.

Furthermore, the proposed patient mix for Valleygate is quite different from the patient mix proposed for SCDPR. Valleygate is proposing to care for patients with more complex needs, as defined by the difference in anesthesia levels[1]. As indicated in its application, SCDPR proposes to serve patients who are currently treated efficiently and safely in dental and oral surgery offices. Valleygate proposes to treat only cases that truly warrant the services of a surgical center. To make the distinction, Valleygate relies on criteria set by external agencies like Medicaid and Blue Cross.

Another noteworthy difference between the two proposed facilities is size of each facility relative to the number of operating and procedure rooms. SCDPR is proposing to build a 10,542 square foot facility that will house two operating rooms and six procedure rooms. Valleygate is proposing to build a 11,688 square foot facility which will house two operating rooms and one procedure room. Valleygate is proposing to build a facility that is 1,146 square feet larger with same number of operating rooms and five fewer procedure rooms. Valleygate's planning efforts and consultation with accreditation and certification experts revealed this extra space as necessary for support services, such as patient recovery. Recovering patients in the sterile core limits contact with important patient family support.

Another major difference is in anesthesia coverage. Though the narrative suggests the facility will have general anesthesia or sedation coverage for each procedure, the SCDPR application provides funding for just one FTE anesthesiologist and no anesthesia equipment. Valleygate proposes funding for more than three FTE anesthesia professionals, sufficient to provide either an anesthesiologist or a Certified Registered Nurse Anesthetist present for all operating and procedure room cases. Valleygate capital costs include anesthesia machines for both operating rooms and procedure room.

[1] SCDP proposes to restrict patients to American Society of Anesthesia (ASA) level I and II; Valleygate will accommodate ASA Levels, I, II, III and, in rare cases, ASA IV. The higher level is more complex.

WHY APPROVE VALLEYGATE DENTAL SURGERY CENTER OF RALEIGH, LLC

Competitive Overview

Based on competitive criteria alone, the application from Valleygate is easily preferable to SCDPR. Historically, the Agency has compared competitive operating rooms on five issues:

- Geographic Accessibility
- Access to Underserved Groups
- Demonstration of Need
- Revenues
- Operating Expenses

The application from Valleygate is preferable in each of these metrics. Moreover, in other comparison metrics, which are important to this review, Valleygate is also preferable. Table 1 below includes the three additional metrics:

1. Number of Pediatric Cases: As demonstrated in both the 2015 KSA petition and the Valleygate CON application, and noted in many of the letters in both application, the needs of pediatric dental surgical patients were a major factor in the Agency's recognition of need for the demonstration projects. . Therefore, applications proposing to serve a greater number of pediatric cases served should be preferable.
2. Management Fee as a Percent of Total Net Revenue: The proposed management services companies for both applicants share ownership with the proposed dental surgery centers. Each applicant includes a management fee, which is represented as a percent of total net revenue. Regardless of ownership, lower management fees increase the value of the proposed project by reducing its operating expenses. Thus, lower management fee percentages are preferred.
3. Percent Military/Tricare: Applicants that provide access to a diverse group of patients should be seen as preferable. In addition to Medicare, Charity, Medicaid, and commercial payers, military and military families represent an important group in Eastern North Carolina. North Carolina has more than 114,000 active duty military, one of the largest concentrations in the country.[2] It has 775,000 veterans and 20,000 Reservists. The North Carolina National Guard's Joint Force Headquarters is located in Raleigh.[3] All of the state's military bases are in the eastern part of the state. As such, applicants who project a greater percentage of military patients are comparatively better.

[2] Governing the States and Localities, Military Active-Duty Personnel, Civilians by state, data for August 30, 2013, provided by Defense Manpower Data Center, accessed on line May 2016. http://www.governing.com/gov-data/military-civilian-active-duty-employee-workforce-numbers-by-state.html

[3] The Economic Impact of the Military in North Carolina, North Carolina Department of Commerce, 2015 https://www.nccommerce.com/Portals/47/Publications/Industry%20Reports/2015-Economic-Impact-of-the-Military-on-North-Carolina.pdf

We believe that the following summary presents a strong and reasonable comparison of the two applications with regard to value elements. It the gives the applicant with the preferable metric a score of "1," and gives the other a zero, unless the scores are identical, then both score a "1."

Table 1 - Comparison of Two Application using Suggested Comparison Criteria

Measure	Valleygate Dental Surgery Center of Raleigh	Surgical Center for Dental Professionals of Raleigh
Geographic Accessibility	1	0
Total % Medicare, Medicaid, Charity	1	0
Demonstration of Need	1	0
Gross Revenue per Case	1	0
Net Patient Revenue per Case	1	0
Total Revenue per Case	1	0
Total Expense per Case	1	0
Number of Pediatric Cases (Under 21)	1	0
% Mgmt Fee of Total Rev. (less Staffing)	1	0
Percent Military/Tricare	1	0
Total	***10***	***0***

Comparison Metric Details

Table 2 below shows the actual results for each metric. Important explanations or clarifications for some of the metrics follow the table.

Table 2 - Relative Score on Critical Value Measures

Notes	Measure	Valleygate Dental Surgery Center of Raleigh	Surgical Center for Dental Professionals of Raleigh
a.	Geographic Accessibility	See comments	See comments
	Medicare, Medicaid, Charity Percent of Gross	92.70%	71%
b.	Demonstration of Need	Yes	No
	Gross Revenue per Case Year 03	$1,297	$1,960
	Net Patient Revenue per Case Year 03	$537	$981
c.	Total Revenue per Case Year 03	$710	$1,150
d.	Total Expense per Case Year 03	$684	$836
	Number of Pediatric Cases (Under 21) Year 03	2,845	2,696
e.	Mgmt Fee as Percent of Total Rev. (less Staffing)	4%	7%
f	Percent Military	1.1%	0%

Notes:

a. As described in Section III.2 of Valleygate's application, Valleygate's proposed site in Garner is closest to the population in need of its proposed service, particularly Medicaid beneficiaries under age nine. Southeast Raleigh has a much greater concentration and number of Medicaid beneficiaries than central and northern Raleigh/Wake County. SCDPR's location across Glenwood Avenue (Route 70) from Crabtree Valley Mall in Raleigh is much less accessible to the population in greatest need. Both locations are equally accessible to surrounding counties via main thoroughfares, such as I-440, I-40, and US-70. Therefore, its preferable location within Wake County makes Valleygate's location the preferable alternative for CON review purposes.

b. The SCDPR application suggests that all oral surgery that is done under sedation is appropriate to be completed in an ambulatory surgical center (ASC). Yet the application presents only the owner's statements to support the case that all oral surgery under sedation should be done in an ASC. It also projects to serve pediatric and general dentistry patients in its ASC without describing the need of the population to be served for the service. In fact, the application states in Section III (p 96) *"Pediatric patients as a whole, particularly those treated by pediatric dentists, do not necessarily represent an underserved group with regard to access to operating rooms."*

Yet the application clearly proposes to serve pediatric patients. As a result, SCDPR's application does not adequately demonstrate the need of the population to be served for its proposed services. See detailed comments on Criterion 3 for SCDPR in Attachment A.

We are aware that granting of privileges may not be an issue (hospitals and ASC are not necessarily denying privileges to pediatric dentists) but pediatric dentists are having a great deal of difficulty obtaining block time in operating rooms and managing the logistics of H&P's in hospitals. This is the obstacle to patient care delivery.

c. Both Valleygate and SCDPR included some revenue in "Other Revenue". Valleygate includes Anesthesia revenue in Other Revenue. SCDPR includes crowns, fixtures, and x-rays in its pro formas. The Agency has historically used the metric, Net Patient Revenue as a comparative metric. However, in this case, because of the unique role of "Other Revenue" in these applications, Total Revenue per Procedure would produce a better comparison. Regardless, Valleygate is lower on both metrics.

d. The calculated total Expense per Case for SCDPR is $634. However the amount is understated. SCDPR pro forma expenses are inadequate for its proposed anesthesiologist coverage. The application either drastically understated costs or the applicant did not intend the statement that every case would have anesthesiologist coverage. If anesthesiologist coverage were increased to match the amount necessary to cover every procedure in SCDPR with an Anesthesiologist, the additional expense could be $1.328,715 in Year Three, or $202 per procedure ($1,328,715 / 6,564 procedures = $202 pp). This would increase the Total Expense per Procedure from $634, as presented in the application, to $836 ($634 + $202 = $836). For detailed calculations, see comments on Criterion 5 in Attachment A.

e. Per SCDPR's pro forma assumptions, management fees charged by Papillion Mgmt. will be the greater of $950,000 or 22 percent of net revenue. SCDPR's pro formas also state that staffing is included in management fees. As a result, we used the staffing data provided in Table VII.2 and Exhibit 2 Exhibit C of the SCDPR application to calculate SCDPR staffing costs and deducted them from the total management expenses to make the fees comparable.

f. TriCare benefits apply to military, dependents and retirees. Valleygate is proposing to serve these patients, while SCDPG is not proposing to serve any Tricare or military members. Unfortunately many of the children of active military also fall into the low income group.

Non-Conforming SCDPR Application

The application submitted by SCDPR presents a service that does not stand up to numerous CON review criteria. In many cases, it contains misleading information. We encourage the CON Section to consider, not only these comments, but also letters submitted and statements made by members of the public, many of whom recognize that SCDP of Raleigh's proposal has the potential to substantially, and unnecessarily, increase costs.

In addition to a lower comparative rating lower rating than Valleygate, SCDPR's application should be denied. The application should be found non-conforming with Criterion 1, 3, 5, 7, 12, 13c, and 18a. We believe the CON Section should pay particular attention to these review criteria and to SCDPR's pro forma assumptions. For example, its assumption that all dental and oral procedures under sedation would be reimbursed an ASC "facility fee" when the overwhelming majority of those procedures are presently completed safely in dental offices should warrant particular scrutiny.

Detailed discussions in the Attachment A to this letter elaborate reasons why the dental surgery center certificate of need should not be awarded to the Surgical Center for Dental Professionals of Raleigh, LLC.

CONCLUSION

Based on all the facts presented in both applications, as well as other facts discussed in these comments and attachments, it is clear that the application filed by Valleygate Dental Surgery Centers of Raleigh, LLC should be approved. Unlike the application filed by Surgical Center for Dental Professionals of Raleigh, Valleygate's application:

- Conforms to all the statutory review criteria;
- Proposes to grant privileges to dentists who have undergone residency or other extensive training;
- Proposes delivery and maintenance of sedation and anesthesia by qualified professionals including supervised CRNAs;
- Provides reasonable assumptions regarding payer reimbursement;
- Demonstrates adequate capital and financial viability;
- Proposes to serve only those patients who need procedures in a licensed ambulatory surgery facility;
- Saves patients, payer, and taxpayer dollars by proposing to move surgical procedures from hospitals to a more cost effective ASC setting and by adding preventive care training aimed at reducing the incidence of severe dental caries in children;
- Proposes to provide more services to Medicaid beneficiaries;
- Demonstrates a commitment to quality and patient safety;
- Proposes the most cost effective solution to improving access to operating rooms for dentists, oral surgeons, and their patients; and
- Demonstrates willingness to serve military beneficiaries.

We have included additional letters of support in Attachments G and H of this document for the Agency's convenience. Thank you for your time and consideration. Please do not hesitate to call me if you have any questions.

Sincerely,

Virginia Jones

Virginia Jones
Chief Operating Officer
Knowles, Smith, and Associates, LLP
910-485-7070 ext. 2612

Attachment(s)

ATTACHMENTS

Attachment A

Competitive Review of –
Surgical Center for Dental Professionals of Raleigh,
Application for Dental Ambulatory Surgery Center
Project ID# J-011170-16

Competitive Review of – Surgical Center for Dental Professionals of Raleigh, Application for Dental Ambulatory Surgery Center Project ID# J-011170-16

OVERVIEW

The Surgical Center for Dental Professionals of Raleigh (SCDPR) application to open a dental ambulatory surgery center in Raleigh, NC is non-conforming with CON statutory review criteria: 1, 3, 5, 7, 12, 13c, and 18a. Additionally, the project does not comply with Criterion 1 of the Dental Single Specialty Ambulatory Surgical Facility Demonstration Project criteria as required by the *2016 State Medical Facilities Plan.*

SINGLE SPECIALTY DENTAL AMBULATORY SURGERY CENTER DEMONSTRATION PROJECT CRITERIA

SCDPR Does Not Contain a Description of Ownership Interest in the Facility by Each Oral Surgeon or Dentist

Chapter 6 of the *2016 State Medical Facilities Plan (SMFP)* established the Dental Single Specialty Ambulatory Surgical Facility Demonstration Project and states that each applicant shall demonstrate that the proposal meets certain criteria in its certificate of need application.

Criterion 1 states: *"The application shall contain a description of the percentage ownership interest in the facility by each oral surgeon and dentist."*

Exhibit 4 provides percentage ownership for eight doctors, and "Initial Facility Dental Directors." It does not identify which of the doctors are dentists or oral surgeons. This clearly does not state the percentage ownership in the facility by each oral surgeon and dentists. While some oral surgeons and dentists' ownership interests are described, others cannot be discerned. It includes another category of "Dental Prof, Anest, Other Clinical & Non Clinical Investors" who own 77.35 percent of the LLC. It is not possible to determine *each oral surgeon and dentist in this group.*

The applicant does not meet Demonstration Project Criterion 1.

CON REVIEW CRITERIA

1. **The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, ambulatory surgery operating rooms, or home health offices that may be approved.**

THE PROPOSAL DOES NOT MEET SMFP POLICY GEN-3

Policy GEN-3 of the *2016 SMFP* states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended."*

In its proposal, SCDPR proposes to provide access to all licensed dentists, regardless of whether they have a completed a hospital-based residency program or hold sedation or anesthesia permits from the North Carolina State Board of Dental Examiners. The SCDPR application states on page 22: "The proposed project will overcome these barriers by allowing all licensed dental professionals, regardless of specialty, access to operating rooms within a licensed, regulated ambulatory surgery center in which to perform dental procedures and surgeries requiring sedation or anesthesia with anesthesia services provided by licensed anesthesiologists."

Of the 69 dentists who showed intent to use the facility, 36 are not currently licensed to provide sedation or anesthesia and are not Pediatric Dentists or Oral Surgeons. These dentists, by NC Regulation, 21 NCAC 16Q .0201(a), are not permitted to provide anesthesia or sedation without an anesthesiologist or a dentist who is certified to provide the type of sedation/anesthesia being present. Attachment I contains the list of dentists and the sedation permit status according to the NC Dental Board as of April, 2016.

Moreover, these 36 dentists have not completed a post-graduate surgical residency program, such as those required by Oral Surgeons and Pediatric Dentists. In all postgraduate programs that teach treatment of patients under general anesthesia, training includes experience of the surgery environment, and an extensive knowledge of the multitude of possible medical and physical problems that are associated with the use of this modality. In addition, all of these training programs recognize not only the process of general anesthesia, but the programs also place significant emphasis on medical diagnosis and the importance of patient selection when determining if a patient is fit to undergo such a procedure.

SCDPR's proposal creates an environment with the potential for a dangerous clinical situation. The application proposes to recruit dentists who have no previous experience in selecting patients for treatment under general anesthesia or sedation, or experience/training in treating patients under anesthesia and encourages them to do so. Valleygate believes that, at minimum, patients treated under sedation or dentists who hold sedation permits with the NC Board of Dental Examiners, or have completed a post-graduate residency program that included operating room training should treat general anesthesia. The NC Board of Dental Examiners requires minimum levels of clinical training in order to hold a sedation or anesthesia permit. Further, the Board recognizes that these treatment modalities encompass not only the operative care but also the pre and post-operative care these patients require.

Aside from the obvious training difference, additional evidence that dentists without proper training should not treat sedated or anesthetized patients is as follows:

1. **Hospital Credentialing Policies.** SCDPR states several times throughout its application that hospital bylaws prevent general dentists and other dentists who are not oral surgeons or pediatric dentists from obtaining privileges at hospitals. SCDPR suggests hospital bylaws discriminate against general dentists by specifically denying them hospital privileges. It presents no evidence to support these statements. Hospital bylaws do not typically discriminate against any particular type of dentist. Most require that any dentist who seeks to perform surgery in hospital operating rooms have the required postgraduate training. Oral Surgeons and Pediatric Dentists, by definition, have the required training. Some General Dentists may also have been through postgraduate residency programs and meet the typical hospital credentialing standards. For example, Cape Fear Valley Health System requires that dentists meet the following criterion: *"Successful completion of an approved one-year general practice residency (general dentists) or specialty training program (specialists)."*

   Central Carolina Hospital's requires the following minimum training:

   "Applicants must have completed a hospital based residency in general dentistry, a pediatric dental residency training program, or have equivalent experience as a dentist member of a hospital medical staff. Central Carolina Hospital may grant privileges to general practice dentists for routine dental treatments or for performing surgical or emergency procedures when applicants can demonstrate appropriate training and experience." By providing these training requirements, hospitals ensure that providers allowed to do surgery in their operating rooms have the required training. A dental ASC should be no different.

   Attachment D contains these two hospital policies.

2. **North Carolina Regulations.** North Carolina regulations do not prohibit dentists from treating patients under sedation or anesthesia provided a qualified professional is also present to administer the sedation/anesthesia and manage the patient's sedation during the procedure. However, North Carolina regulations do not allow even dentists to treat patients while a CRNA provides sedation unless the dentist has a license to provide the type of sedation being provided by the CRNA. 21 NCAC 16Q .0301 states:

> *"For a dentist to employ a certified registered nurse anesthetist to administer moderate conscious sedation, moderate conscious sedation limited to oral routes and nitrous oxide or moderate pediatric conscious sedation, the dentist must demonstrate through the permitting process that he or she is capable of performing all duties and procedures to be delegated to the CRNA. The dentist must not delegate said CRNA to perform procedures outside of the scope of the technique and purpose of moderate conscious sedation, moderate pediatric conscious sedation or moderate conscious sedation limited to oral routes and nitrous oxide as defined in Rule .0101 of this Subchapter."*

This suggests the State Board is very conscious of the need for a well-qualified team in the safe conduct of sedation (and by extrapolation) general anesthesia. This is why sedation and anesthesia is a major component in pediatric and hospital dentistry residencies.

3. **No Precedent Exists for SCDPR's Proposal.** If the SCDPR proposal is approved and implemented as proposed in the application, it will become the first facility in North Carolina in which dentists or other dental subspecialists who have no experience treating patients under general anesthesia will be allowed to do so. This is a lower standard than is applied in the offices of Triangle Implant Center. Those Oral Surgeons have the proper hospital and operating room based training to perform surgery on anesthetized patients. According to the SCDPR application on page 78, TIC does not allow general dentists into its own practices to perform procedures. The application states other dentists seeking to perform procedures at TIC "cannot be accommodated". The SCDPR proposal does not have the same clinical rigor.

   SCDPR's solution for overcoming the possible lack of training on anesthetized patients is to provide a minimal amount of training as part of the provider orientation process. Exhibit 18 of the application contains the proposed credentialing policy. The orientation course includes three items:

   1. An "Introduction to Facility Video"
   2. A requirement to "Observe Dental Professional in Operating Room with a live Patient via Video or at pre-scheduled appointment times"
   3. A requirement to "Complete 15-20 minute Check List that every Dental Professional must pass to see first patient."

Under #2, the policy states that the prospective surgery center provider will observe "Proper ways to operate around intubated anesthetized patient," "Importance of maintain intubation, iv and monitoring equipment Placement," "Sealing of the oropharynx with a throat pack and removal of throat pack," "Proper draping and securing of the head for protection," "Taking x-rays with patient in supine position," and "Focus on efficiency to minimize sedation time." Apparently, prospective dentists who have no prior experience in operating rooms or with anesthetized patients will be able to observe these items via *video, only once,* and meet the requirements for credentialing at SCDPR. The applicant suggests that a video is an adequate replacement for months, or even years of clinical training with anesthetized patients, as is current practice in pediatric dentistry/oral surgery residency programs.

Attachment J contains excerpts from the Pennsylvania Oral and Maxillofacial Society, and the American Dental Association, both of which emphasize the importance of extensive training on the part of the dentist who cares for patients under general anesthesia. This applies regardless of whether an anesthesia professional is also present.

Moreover, generally speaking, general dentists throughout the State of North Carolina annually treat hundreds of thousands of cases safely in offices.

4. **Anesthesia Issues with Medicare Conditions of Coverage** It appears that SCDPR will not be operated in a manner that fosters quality and safety. The Medicare conditions for coverage (which the ASC is required to meet) require that surgical procedures "be performed in a safe manner." 42 C.F.R. § 416.42(a). SCDP's plans for anesthesia services do not appear to meet this requirement.

   The ASC will have two operating rooms and six procedure rooms, which will be dedicated to providing only dental procedures that require sedation. Assuming a 52-week operations schedule, SCDPR projects that in the third year, the ASC will perform 3.8 cases per day in each of the two operating rooms and 2.9 cases per day in each of the six procedure rooms. (Application page 135) This volume is certain to frequently result in four to five concurrent cases being performed. However, the applicant proposes to have only a single anesthesiologist at the ASC and to have that anesthesiologists be the only individual administering anesthesia. (p22) Such a demand upon the anesthesiologist appears to place patient safety and quality at risk, as the Medicare billing requirements show.

   Medicare permits an anesthesiologist to provide "medically directed" anesthesiology for a maximum of four concurrent cases. 42 CFR § 415.110; CMS Internet-Only Manual 100-04 (Medicare Claims Processing Manual), Chapter 12, Section 50 (the "Manual"). In "medically directed" cases, the anesthesiologist personally performs seven elements of the anesthesia service (the "7 Elements") and medically directs qualified individuals who perform the remainder of the services.[1]

[1] The 7 Elements that the anesthesiologist must perform are: (i) perform the pre-anesthesia examination and evaluation; (ii) prescribe the anesthesia plan; (iii) personally participate in the most demanding aspects of the anesthesia plan procedures; (iv) ensure that all plan procedures that he/she does not perform are performed by a qualified individual; (v) monitor the

Critically important, Medicare states that an anesthesiologist may medically direct "*no more than four anesthesia services concurrently.*" 42 C.F.R. 415.110. In this regard, the Manual states that an anesthesiologist who is concurrently directing the administration of anesthesia in four cases *cannot ordinarily be involved in furnishing additional services to other patients.*

If Medicare will not permit an anesthesiologist to "medically direct" more than four concurrent cases—which means the anesthesiologist is personally performing the 7 Elements and directing qualified personnel who perform the rest of the anesthesia service for the four concurrent cases—then it necessarily follows that is not safe or consistent with high quality for an anesthesiologist to personally perform the entirety of the anesthesia services for four or more concurrent cases, which is what the SCDP proposes.

These rules are included in Attachments E and F of these comments.

5. **Medical Board Issues.** The application states (page 55) that the manager "will employ" the required pediatrician. The Management Agreement confirms this. Section 4(c)(ii) and Exhibit C. It is legally impermissible the manager to employ the pediatrician in North Carolina—such would violate the requirements of the North Carolina Medical Board. See additional discussion in Criterion 7.

The SMFP policy GEN-3 (as well as Criterion 18a) seeks to prevent projects from being implemented that have the potential to create quality or safety risks. A proposal for a surgery center model never seen before which allows dentists the opportunity to perform in an environment in which they are not trained to perform surgery comes with risk. A project with safety risks clearly does not "promote safety." As a result, SCDPR does not conform to CON Review Criterion 1.

course of anesthesia administration at frequent intervals; (vi) remain physically present and available for immediate diagnosis and treatment of emergencies; and (vii) provide indicated post-anesthesia care.

3. The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

INTRODUCTION

Criterion 3 requires that the application (i) identify the population to be served by the project and (ii) demonstrate the need this population has for the proposed services. As a result, Section III.1.(a) of the application form requires that the applicant "describe the need for each of the services proposed to be provided

SCDPR proposes and projects to perform three types of services at its facility: (A) general dentistry, (B) pediatric dentistry, and (C) oral surgery. However, SCDPR's projections and need methodology for each service fails to meet the requirements of Criterion 3.

SCDPR FAILED TO DEMONSTRATE ANY NEED FOR GENERAL DENTISTRY SERVICES AT THE FACILITY

SCDPR's application utterly fails to demonstrate a need for *general dentistry* services at the proposed facility. In fact, an overwhelming flaw in the application is SCDPR's projection that at least 31 percent of all cases will be performed by *general dentists.* This is serious flaw because—in contrast to oral surgeons and pediatric dentists—*general dentists,* as a rule, do not typically require access to surgery centers or operating rooms for their practices, as is confirmed by KSA's thirty-year experience of operating a large multi-specialty (which currently has approximately [40] dentists). Moreover, SCDPR failed to properly demonstrate need for general dentistry services at the facility.

SCDPR's utilization projections are based entirely on cases to be performed by (i) 45 general dentists, (ii) 18 pediatric dentists, five dental subspecialists (Orthodontists, Prosthodontists, and Endodontists), and one Oral Surgeon. (Exhibit 29) Consistent with this large number of *general dentists*, the application contains numerous references providing general dentistry services at the facility. Moreover, SCDPR's own data in Exhibit 29 shows that **31 to 40 percent** of all cases at the facility will be performed by general dentists—not oral surgeons or pediatric dentists—as the chart below demonstrates.

Table 1 - Percent Procedures Projected by SCDPR by Dental Specialty

Notes	Category	Low	High
a	Monthly Subtotal General Dentists	174	219
b	Monthly Subtotal Pediatric Dentists	135	149
c	Monthly Subtotal Oral Surgery	1.0	2.0
d	Monthly Subtotal Other Dental Specialists	37	40
e	Monthly Subtotal from Piedmont Health (Type Unknown)	200	200
f	Monthly Total	547	610
g	Percent General Dentistry	31.81%	40.04%
h	Percent Pediatric Dentistry	24.68%	27.24%
i	Percent Oral Surgery	0.18%	0.37%
j	Percent Other Dental Specialists	6.76%	7.31%
k	Percent Piedmont	36.56%	36.56%

Notes: *a - e: Totals from SCDPR Application, Exhibit 29*
f: a + b + c+ d + e
g: a / f
h: b / f
i: c / f
j: d / f
k: e / f

Despite contending that at least 31 percent of all procedures will be performed by *general dentists*, SCDPR fails to discuss or provide information in Section III demonstrating need for general dentistry services to be performed in an ambulatory surgical facility. This is not surprising at all because , as a rule, there is limited need for general dentistry services to be performed in a facility, as KSA's thirty-year experience confirms. Moreover, as discussed under Criterion 5, SCDPR fails to demonstrate that these "general dentistry" services would be reimbursed by third-party payers in the context of a surgical facility. Given the magnitude of the number of general dentistry cases that SCDPR projects and the fundamental flaw upon which those projections are based, it is clear that the application fails to conform with Criterion 3, and as a result, the application necessarily fails to conform with numerous of the other review Criteria, including without limitation Criterion 5.

SCDPR FAILED TO DEMONSTRATE ANY NEED FOR PEDIATRIC DENTISTRY SERVICES AT THE FACILITY

SCDPR's utilization projections are based upon having 18 pediatric dentists. Based on upon SCDPR's data in Exhibit 29, pediatric dentists will perform at least 31percent of the facility's cases. Section II.1 of the application (Page 24) clearly notes that pediatric dentistry is a component of SCDPR. Further, SCDPR fails to discuss or provide any information in Section III that specifically and expressly demonstrates any quantified need for pediatric dentistry services to be performed in an ambulatory surgical facility. Because the application

completely fails to provide any specific demonstration of need for pediatric dentistry services at the facility, the application is non-conforming with Criterion 3

THE NEED METHODOLOGY IS UNREASONABLE BECAUSE IT IS LIMITED TO ORAL SURGERY

SCDPR's need methodology is based entirely upon oral surgery. Oral surgery is, by definition, a distinct subset of dentistry and/or medicine. As described in SCDPR's application, oral surgeons perform procedures such as wisdom teeth removal, dental implants, and orthognathic surgery. These procedures and other oral surgery procedures are described in detail on Triangle Implant Center's website: http://www.triangleimplantcenter.com . SCDPR bases the need methodology presented in Section III.1.b on two sets of data, (1) data for oral surgery cases provided under sedation at Triangle Implant Center's (TIC) offices in Wilson, Durham, and Mebane and (2) oral surgery data reported on hospital and ASC license renewal applications. As illustrated in the table below, oral surgery cases under sedation specifically from TIC form the basis for two-thirds of the total need projected by SCDPR.

Table 2 - 2015 Conservative Estimate of Potential Need: Office and Licensed Facility Combined

	TIC Based Estimates	Hospitals and ASC Based Estimates	Total	% TIC Based (Calculated)
Notes	a	b	c	d
Low	5,373	2,338	7,711	69.7%
High	10,452	2,713	13,165	79.4%

Notes: *a-c: SCDPR Application, Page 108*
d: a / d

Nowhere in its application does SCDPR quantify the need for general dentistry and pediatric dentistry procedures in operating rooms, despite clearly projecting the performance of such procedures in the facility. Moreover, an argument that general dentists will treat pediatric cases would only support the need if those persons had training in care of anesthetized patients. The application provides no such information. Thus, SCDPR's need methodology is unreasonable because it is based entirely on the need for oral surgery services and hence fails to include a need methodology demonstrating need for general dentistry services and pediatric dentistry services at the facility.

The application further contends (page 96) that "relevant" need for pediatric patients is the need for access to a pediatrician. This "need" is not relevant to the application because the application is for an ASC, not for a pediatrician office. Further, to the extent the ASC will have a pediatrician on-site, the pediatrician will provide only the limited services of an H&P for dental surgery, and will not meet any general need for pediatric care for children. The application makes no attempt to quantify the need for a full time pediatrician.

Also in Exhibit 29, data for Piedmont Health utilization are based on letters of support from four Piedmont Health offices (pages 561-564). Careful review of these letters shows that no dentists from Piedmont Health propose to bring patients to the proposed center. The CEO of

Piedmont Health, who is not a dentist, signed the letters. The form letters state " I propose to perform 50 procedures per month ..." Clearly, this is not possible and the letters are invalid.

As a result, the applicant does not conform with Criterion 3.

SCDPR FAILED TO SHOW THAT THE ORAL SURGERIES IT PROJECTS WILL BE APPROPRIATE FOR A SURGERY CENTER

As noted above, SCDPR's need methodology in Section III.1.b of its application is based entirely upon "use rates" for oral surgery at (i) Triangle Implant Center, an oral surgery practice and (ii) hospitals and ASCs—with 70% to 80% of the cases based on Triangle Implant Center's use rates. However, the application fails to demonstrate that all of these Triangle cases would be appropriate for an ambulatory surgical facility, and as a result, the projections are unreasonable.

Supporting the fact that SCDPR plan to serve patients otherwise suited for a dental office is the facility design itself. SCDPR only includes two recovery rooms in its model, despite having eight rooms (two operating room and six procedure rooms) which can have patients under general anesthesia at any given time. SCDPR explains this by noting that patients will be recovered inside the operating rooms or procedure rooms. Page 117 of SCDPR's application states, "*However, based on the dental cases proposed for the proposed facility, and the experience of Triangle Implant Center, SCDP of Raleigh expects that most of the prep and recovery will be done in the operating room or procedure room.*" SCDPR's plans also include a lab and a CERAC machine with which to make crowns. These items are typically found in dental offices and are not necessary for a surgery center. SCDPR's model is much more like a dental office than an ASC.

Perhaps the best evidence that most patients treated by oral surgeons do not need an ASC to perform all of their procedures is that of the 69 non-TIC dentists / oral surgeons who have expressed an interest in using SCDPR, only one is an Oral Surgeon; that person proposed to bring one or two cases per month to the facility. According to the North Carolina Board, of Dental Examiners, there are 48 oral surgeons located in Wake, Durham, Orange, Chatham, and Johnston counties, all counties within a reasonable distance of the proposed SCDPR location. The only oral surgeons committed to using SCDPR are Huyen-Chau Dunn and surgeons on the Triangle Implant Center staff.

Pennsylvania Oral and Maxillofacial Society website provides clear distinctions about appropriate locations for oral surgery. [2] The section on Anesthesia , which is included in Attachment J to these comments, describes a very narrow group of oral surgery patients as appropriate for care in a surgery center or hospital.

Valleygate agrees that some oral surgery cases can and should be completed in licensed operating room environment. In fact, Valleygate proposes to serve oral surgery cases in Valleygate Dental Surgery Center of Raleigh. However, this need is limited. According to SCDPR's need methodology, all office based oral surgery cases under sedation should be done in a licensed ASC and should be reimbursed an additional "facility fee," which would not otherwise be charged if the procedure were done in an office setting.

[2] http://www.psomsweb.org/anesthesia.aspx

Finally, some third party payers will only reimburse for specific types of patients in ASCs (see Payer ASC Criteria in Attachment C). An otherwise healthy patient undergoing a procedure for wisdom teeth removal or dental implant, a major component of TIC's business, will not qualify for ASC "facility fee" reimbursement under some payer policies. Yet, the SCDPR application includes these procedures (page 25). Clearly, payers recognize that oral surgery belongs in licensed ASCs only in certain circumstances.

Oral surgery patients represent a large portion of proposed patients at SCDPR. SCDPR's need methodology presumes that all in-office oral surgery sedation patients need licensed operating rooms. Clearly, *all* oral surgery sedation patients do not need licensed operating rooms. Therefore, SCDPR does not adequately demonstrate the need this population has for the services it proposes.

The application is confusing in another respect. Among the procedures listed as candidates for the ASC are Reconstructive Surgery and TMJ surgery. These long and complex cases require specialized equipment and are done primarily in hospitals.

Lacking a demonstration of need of the population to be served for the services proposed, the application does not conform to Criterion 3.

5. Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs, as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

SCDPR DOES NOT SHOW ADEQUATE EVIDENCE OF FUNDS NEEDED FOR CAPITAL INVESTMENT

In Section VIII.3 of its application, SCDPR states:

> *"SCDP of NC expects to fund the proposed project with cash reserves acquired through the sale of ownership shares as described above.*

However, as not all of these transactions have taken place as of the date of submission of this CON application, for the purpose of documenting the availability of funds for the proposed project, SCDP of Raleigh has provided a letter from PNC Bank indicating its willingness to finance the entirety of the project with a loan (Exhibit 25)."

As the applicant notes many times, only 22.65 percent of SCDP's capital requirements have been committed. Exhibit 4 shows which individuals have "proposed membership interests". Of the 22.65 percent, two percent is called "initial facility dental directors," which suggests that this portion is allotted to a yet-to-be named individual or individuals. The only named dental director on page 179 is Uday Reebye, MD, DMD. Therefore, only 20.65 percent of the total capital need has been "proposed" to be provided by named individuals. There is no evidence of any transaction showing that SCDP, the parent organization of SCDPR, has actually received any capital investment. There are no letters from the individuals with "proposed membership interests" in Exhibit 4 committing to providing capital. There are no letters from CPAs showing availability of reserves from any of the proposed owners, including Uday Reebye.

Thus if the applicant truly intends to use cash reserves to fund the project, there is no evidence that any cash reserves exist.

In response to this, SCDPR states that a letter provided by PNC bank (Exhibit 25) show evidence of available funding. Exhibit 25 contains a letter and preliminary term sheet from PNC Bank which together "merely constitute a statement of suggested terms for the Credit Facility [for $5M] and....do not constitute a binding commitment to offer to lend with respect to these transactions [emphasis added]."

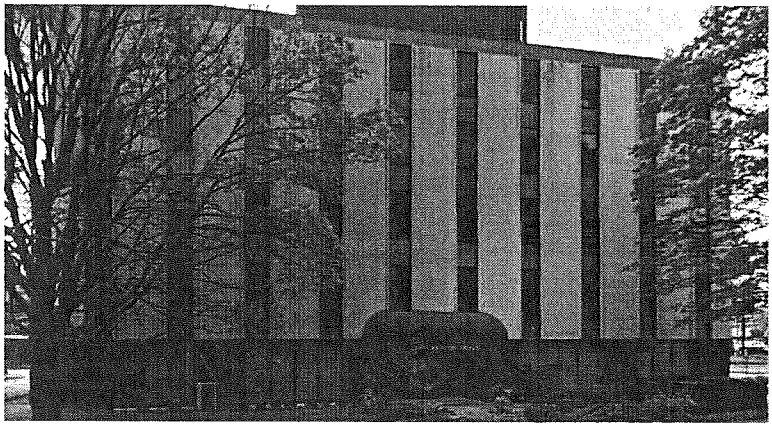
The letter goes on state: "PNC hereby consents to your providing a copy of this letter and Preliminary Term Sheet to DHHS in connection with your CON application for the Project, provided that DHHS may not rely on this letter or the Preliminary Term Sheet for any purpose other than as evidence that we have provided this proposal to the Company for preliminary discussion purposes." By including this language, PNC eliminates the letter as a possible tool for determining financial viability.

As a result, SCDPR does not show adequately demonstrate the availability of funds for capital and operating needs and therefore its application does not conform with Criterion 5.

SCDPR PROPOSES TO LEASE SPACE IN A BUILDING WHICH THE LANDOWNER PROVIDES NO GUARANTEE OF AVAILABLE CAPITAL TO RENOVATE AND PROVIDES NO HISTORY OF CLINICAL SERVICE CONSTRUCTION

SCDPR proposes to lease space from a building currently owned by Solferino North Properties, LLC. The application provides only a site plan; it has no other description of the "existing" building in which SCDPR proposes to locate. 2209 Century Drive is currently a five story, unoccupied building located across Glenwood Avenue from Crabtree Valley Mall. The photo below, taken in April 2015, was obtained from Google Maps. The building appears exactly the same today.

Figure 1 - 2209 Century Drive, April 2015



Source: Google Maps

Line drawings in Exhibit 10 of SCDPR's application show only three stories. It does not mention demolition, which would be required to convert a five-story building to a three-story building. Drawings for the three floors in Exhibit 10 show that this means of construction requires an extra investment in life safety fire protection of vertical circulation. The plans do not show the extra investment needed to separate the whole envelope of the surgery center from the other non-clinical space in the facility to meet North Carolina Licensure and CMS Conditions of Participation. Because more than four patients at a given time would be unable to get out on their own in case of fire, this entire envelope must meet higher construction standards. According to information provided to Valleygate members in a meeting with NC Construction Section, other clinical life safety standards will apply to the whole building, for the fire alarm system must be identical throughout the building.

Floor plans show that much of the space on the first and third floors is not part of the proposed ASC, including the main lobby and entrance of the building, to which all patients of SCDPR would presumably need access in order to reach the elevators to the second floor. The application does not mention how the building will be viable if the owner fails to develop other parts of the building. Plans for sustaining the cost of the full building renovation is not included in the application. In fact, plans for rest of the building are not addressed in the application.

The sole member of Solferino North Properties, LLC is Laura Reebye (see Attachment B). Therefore, in order to support the proposed project, Solferino North Properties, LLC, or its sole member, Laura Reebye, would need to have access to the capital necessary to complete the renovations.

The application does not even address Solferino North's access to capital let alone provide documentation from a bank or CPA providing evidence of existing or promised capital.

Moreover, the application does not provide any evidence that Solferino North Properties, LLC, or its sole member Laura Reebye, has any experience in developing and constructing dental office buildings or ambulatory surgery centers.

Because SCDPR does not adequately demonstrate the availability of funds for capital necessary to complete the project, its application does not conform to Criterion 5.

SCDPR OVERSTATES REVENUES

SCDPR's pro formas presented in the application overstate revenues. Some payers will not reimburse SCDPR "facility fees' for many of the cases the application indicates that SCDPR proposes to serve. The SCDPR application assumes that third parties or individuals will provide reimbursement for all proposed cases. It also assumes that in Year Three, more than 1,800 people classified as Self-Pay or Charity Care cases will pay, out-of-pocket, between $784 and $1,960 per case (see discussion under Criterion 13a).

For procedures deemed medically necessary for an ASC, payers, including Medicaid, reimburse ASCs "facility fees" in addition to reimbursement paid to the performing physician/dentist and anesthesiologist/CRNA. All payers have policies for which types of procedures qualify as medically necessary and therefore qualify for a "facility fee" payment under a medical plan. Attachment C contains three such policies, one from NC Medicaid, one from Blue Cross Blue Shield of North Carolina, and one from Cigna. All of them provide specific limitations to the kinds of dental and oral surgery procedures for which it will cover a "facility fee" for procedures completed in ASCs.

For example, Blue Cross covers only the following situations in ASCs when dental care or oral surgery is concerned:

- Complex oral surgical procedures for which a high probability of complications due to the nature of the surgery; or
- Concomitant systemic disease for which the patient is under current medical management and which increases the probability of complications; or
- When anesthesia is required for the safe and effective administration of dental procedures for young children (below the age of nine years old), persons with serious mental or physical conditions or persons with significant behavioral problems.

Cigna requires that patients be seven years or younger, have severe psychological impairments, is classified as ASAIII or above, has significant medical comorbidities, or when conscious sedation is otherwise inappropriate or contraindicated.

North Carolina Medicaid's Policy (which includes Health Choice) states, "...if a Medicaid or NCHC beneficiary is physically unmanageable, medically compromised, or severely developmentally delayed and will not cooperate for treatment in the dental office, treatment may be completed in an ambulatory surgical center (ASC)."

According to all of these policies, payers will not reimburse ASCs facility fees for the following procedures:

- Wisdom teeth removal for otherwise healthy adults
- Dental implants for otherwise healthy adults
- Bone grafting on otherwise healthy adults
- General dentistry procedures on otherwise healthy adults

The table with projected monthly volumes at the beginning of SCDPR's Exhibit 29 forms the basis of its utilization. This is evidenced by the fact that the "low" total monthly volume in Exhibit 29 is 547. Annualized, 547 cases equal 6,564, the exact number SCDPR projects for its third year of operations. Of the 6,564 cases, SCDPR expects general dentists to perform 2,088, dental subspecialists to do 444 cases and pediatric dentists to do 1,620 cases.

Other than the pediatric dentists, whose cases can be likely be justified for an ASC under payer rules, the majority of cases SCDPR projects do not appear to meet payer criteria for ambulatory surgery centers. SCDPR does not discuss payer requirements anywhere in the application; nor does it address why certain dental cases would be appropriate for an ASC why others would not. SCDPR also apparently assumes that all oral surgery cases belong in ASC, despite evidence to the contrary (see discussion under Criterion 3 above).

In Section III (Page 115), SCDPR states that all cases currently performed at Triangle Implant Wilson will be candidates for the proposed ambulatory surgery center:

> *"Triangle Implant Center has provided a [sic] letters of support for SCDP of Raleigh documenting that it has historically performed 1,735 and 1,343 cases respectively, at its Durham and Mebane offices, all of which would be appropriate to be performed at SCDP of Raleigh."*

It is clear that SCDPR created its procedure projections and its pro forma revenue projections without consideration for whether or not the procedures it projects actually meet payer criteria.

It is impossible to determine whether or not its revenue projections are accurate. If a significant number of the general dentistry cases are for otherwise healthy adults, then SCDPR would not be paid a "facility fee" for these cases.

As a result, SCDPR does not adequately demonstrate its financial projections are reasonable and does not conform to Criterion 5.

SCDPR UNDERSTATES COSTS

Throughout the application, SCDPR states that it will provide anesthesiologists for all cases under sedation. SCDPR maintains that anesthesiologists provide the highest quality of care, even going so far as to state that it will not include the use of CRNAs, an option proven to be an efficient way to cover anesthesia. Page 23 of the application states:

"SCDP of Raleigh intends to utilize only licensed anesthesiologists in the ASC rather than certified registered nurse anesthetists [CRNAs], again in order to ensure the highest level of quality, safety, and patient-centric care possible."

This is in conflict with the many landmark studies that confirm that CRNAs achieve the same level of safety and quality as their physician counterparts[3]. In fact, researchers consistently find anesthesia care is equally safe whether provided by a CRNA working alone, an anesthesiologist working alone or a CRNA working with an anesthesiologist. There are few facilities providing anesthesia for medical/surgical cases that do not rely on CRNA's for the delivery of high quality patient care

SCDPR also states in its pro forma assumptions that charges are average bundled fees, which include both facility fees and anesthesia fees. As a result, SCDPR must account for the cost of the anesthesiologists in the application. FORM B provides a line item for professional fees, for which the application notes: "Professional fees expense includes fees for anesthesiologists and other professional fees, based on the experience of SCDP of Raleigh's management company and discussions with Regional Anesthesia, inflated 2% per year."

The pro forma assumptions reference information obtained from Regional Anesthesia. Valleygate also obtained information from Regional Anesthesia to form the basis of its anesthesia cost assumptions. This information included an estimate of $450,000 annually for full-time coverage of one anesthesiologist[4]. The estimate provided to Valleygate is likely to be very similar to that provided to SCDPR. Valleygate is confident the anesthesia contract estimate provided to them is reasonable. For comparison, Medscape.com, a reliable source for average provider salaries, states the average annual anesthesia contract to be approximately $420,000 in 2015[3].

Even if SCDPR Anesthesiologists maximize efficiency by floating among rooms and being willing to work less than a full FTE, SCDPR's cost presented in its pro formas on FORM B/C are significantly understated. The following table recalculates cost to a more reasonable amount. These calculations include very conservative assumptions, such as average procedure lengths of one hour and that anesthesiologists will not work a full FTE.

[3] CRNA's, The Future of Anesthesia Care Today, American Association of Nurse Anesthetists, 2016 http://www.future-of-anesthesia-care-today.com/research.php

[4] Of note, Valleygate also included the cost of CRNAs because a single anesthesiologist cannot cover all cases in the facility.

[3] Source: *http://www.medscape.com/features/slideshow/compensation/2015/anesthesiology#page=5*

Table 3 – Estimated SCDPR Anesthesia Cost Understatement

Notes	Metric	FFY 2018	FFY 2019	FFY 2020
a	Professional Fees in Expense in SCDPR's pro formas (which include Anesthesiologist)	$ 498,000	$507,960	$518,119
b	*Growth*		*2.00%*	*2.00%*
c	Cost of One, Full-Time Anesthesiologist: KSA Proposal	$ 450,000	$459,000	$468,180
d	Projected Procedures	5,251	5,908	6,564
e	Hours per Procedure	1.0	1.0	1.0
f	Total Anesthesia Hours Needed	5,251	5,908	6,564
g	Percent Anesthesia Charting/ Admin time	20%	20%	20%
h	Minimum Anesthesiologist Hours Needed	6,564	7,385	8,205
i	Minimum Anesthesiologist FTEs Needed	3.16	3.55	3.94
j	Minimum Anesthesiologist Cost	$1,420,042	$1,629,671	$1,846,834
k	**Cost Understatement**	**$922,042**	**$1,121,711**	**$1,328,715**

Notes: a: SCDPR Application, FORM B/C
b: Year over year growth in a
c: Valleygate Dental Surgery Centers of Fayetteville CON Application, Pro forma assumptions, grown by percent in b
d: SCDPR Application, FORM D
e: Conservative assumption of one hour per procedure (data not available in SCDPR application), Valleygate assumes longer case lengths
*f: d * e*
g: Conservative assumption
h: f / (1 –g)
i: h / 2080
*j: i *c*
k: j - a

As noted, this is a conservative approach. If SCDPR truly needs all eight procedure rooms running all the time, then it would presumably require more than 3.94 FTEs anesthesiologists. Even if it staffed only 6 FTEs anesthesiologists, they would cost over $2.8M annually, substantially more than SCDPR projected in its pro formas.

If SCDPR truly intends to utilize anesthesiologists to cover all procedures, as it says it will, then SCDPR understated its costs by over $1M. As a result, SCDPR did not provide reasonable financial projections and fails to conform to Criterion 5.

SCDPR Overstates Utilization

The application references Exhibit 29 as support for u forecasts in Section IV. Exhibit 29 shows 200 procedures a month from Piedmont Health. As noted in the discussion of Criterion 3, supporting data on pages 561-564 are not valid. The person who signed the letter is neither a dentist nor an oral surgeon and could not perform procedures in the proposed center.

Without these 2,400 annual procedures, the proforma income statement will show losses and the application will not demonstrate immediate and long term viability of the proposal.

SCDPR Does Not Provide Reasonable Assumptions Regarding Its Balance Sheet

In its pro forma assumptions for FORM A, SCDPR provides only the following sentence: *"Surgery Center for Dental Professionals of Raleigh's projected balance sheet is based on forecasted financial performance through the third project year."*

This single sentence does not serve as adequate evidence that the applicant's pro forma assumptions are reasonable. Without additional information explaining why SCDPR the mix of assets and liabilities it presents in FORM A, it is impossible to determine if these projections are reasonable.

Summary

Financial projections for the SCDPR application involve:

- Overstated Collected Revenue for the forecast procedures
- Understated cost of anesthesia service
- Overstated utilization representing approximately one-third of Year 03 cases
- Inadequate information to document availability of fixed and working capital.

For these reasons, the application is non-conforming to Criterion 5.

7. **The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.**

SCDPR FAILS TO SHOW SUFFICIENT STAFFING AND EQUIPMENT TO MANAGE ANESTHESIA

Throughout the application, SCDPR describes how all dental surgeries performed in the proposed facility will be conducted by trained dentists and licensed anesthesiologists. In Section II.1, the applicant states,, "*The driving force behind the proposed project is Dr. Uday Reebye's vision to create access for dental professionals to state-of-the-art, patient-centric facilities in which they can perform dental procedures and surgeries on their patients requiring sedation in the safest possible setting with sedation or anesthesia services provided by licensed anesthesiologist.*"

The SCDPR application indicates that an anesthesiologist will staff all procedures. As described above under Criterion 5, the application does not provide documentation to account for enough anesthesiologist expense to provide coverage for all of the proposed procedures.

Confirming the anesthesiologist deficit, SCDP of Greenville's application (J-011171-16) contains the exact same Anesthesia expense as the SCDPR application. Clearly, the applicant included only a single Anesthesiologist in its pro forma assumptions. A single anesthesiologist cannot cover eight rooms simultaneously. Yet the application indicates that all operating and procedure rooms will be in use and all will involve treatment for sedated or anesthetized patients.[5]

Moreover, as shown on the equipment list and quote (Exhibit 24) in SCDPR's application, SCDPR does not indicate they will purchase any anesthesia machines, which are required to provide anesthesia. No mention of an anesthesia machine equipment purchase is made in SCDPR's application and no expense is accounted for in the financial information provided with the application.

Given the lack of anesthesia coverage and necessary equipment to anesthetize a patient, the applicant does not provide evidence of available manpower or equipment required to provide the proposed services and SCDPR does not conform to Criterion 7.

As demonstrated above, if SCDPR were to provide enough anesthesiologist coverage and necessary equipment, it would drastically increase both its operating costs and its proposed capital costs.

[5] Letters provided by Triangle Implant oral surgeons, including Dr. Reebye, state: "Triangle Implant Center does not anticipate that there will be capacity to shift cases to Surgical Center for Dental Professionals of Raleigh given the support of local dentist (Exhibit 29)." This suggests that the eight proposed rooms in the facility will be running at capacity, otherwise, TIC oral would presumably shift their cases into SCDPR.

PAPILLION MANAGEMENT SERVICES, LLC CANNOT LEGALLY EMPLOY PHYSICIANS

The SCDPR application states (page 55) that Papillion Management, LLC[6] "will employ" a "required" pediatrician. The Management Agreement (Exhibit 2) confirms this. It is legally impermissible for Papillion Management Services, LLC, a Limited Liability Corporation, to employ a pediatrician in North Carolina. Only professional corporations, PLLCs (N. C. Gen. Stat. § 55B-1 to 15), Hospitals (33 N.C. Att'y Gen. Rep. 43 (1955)), and HMOs (N. C. Gen. Stat. § 58-67-35(a)(3); 58-67-170(c)) are permitted to employ physicians under NC law.

Under these assumptions, the applicant cannot legally provide the necessary resources for the services it proposes to provide.

For all of these reasons, the application, it fails to conform to Criterion 7.

12. **Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.**

SCDPR PROVIDES NO JUSTIFICATION FOR CAPITAL EXPENSE FOR PROCEDURE ROOMS

SCDPR proposes to include six procedure rooms as part of the proposed facility. Exhibit 10 in SCDPR's application provides a line drawing of the proposed facility, which consists of two operating rooms and six procedure rooms. The application does not provide sufficient explanation to show why these procedure rooms are needed. It does not provide the required licensure distinction between the operating rooms and the procedure rooms. It does not provide separate income statement in its pro formas for the procedure rooms. The need for the procedure rooms was not adequately justified and therefore the capital expense associated with the procedure rooms was not adequately justified.

The absence of information about the viability of the facility in which SCDPR proposes to locate raises questions about the impact of the impact of means of construction on the costs to provide the service. The design requires substantial fire protection costs to place the facility on the third floor of a commercial office building. See additional discussion in Criterion 5.

As a result, the applicant should be found non-conforming to Criterion 12.

[6] The SCDPR application refers to the management company as Papillion Management, LLC. However, according to the NC Secretary of State, Papillion Management, LLC does not exist. However, Papillion Management Services, LLC exists and the registered agent for this company is Laura Reebye. We assume Papillion Management Services, LLC is the correct entity to reference.

13. The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

SCDPR IS PROPOSING TO LIMIT ACCESS FOR LOW-INCOME PATIENTS

The pro forma provided with SCDPR's CON application, forecasts $1,224,696 of charity care net revenue in project Year 2. This is an average projected reimbursement rate of $784 per patient. Furthermore, SCDPR projects to receive an average reimbursement of $1,960 for the care of self-pay patients, totaling to $604,629 of net revenue. Because these patients, by definition, are uninsured, the $784 and $1,960 average net revenue per patient for each category represent *out-of-pocket* payments.

The $784 average collections from charity patients and the $1,960 average collections from self-pay patients does not include the fees associated with the services rendered by the dentist, which can be substantial. The table below summarizes these data.

Table 4 - SCDPR Net Revenue Worksheet, Second Full Fiscal Year

	% of Cases	# of Cases	Projected Avg. Reimb. Rate	Net Revenue	% of Total Net Revenue
Charity Care	23.80%	1,562	$784	$1,224,696	19%
Self-Pay	4.70%	309	$1,960	$604,629	9%
Medicaid	47.10%	3,092	$736	$2,276,779	35%
Commercial and other Insurance	24.40%	1,602	$1,480	$2,370,151	37%
Total	**100%**	**6,564**	**$9,87**	**$6,476,255**	**100%**

Source: SCDPR Application, FORM B/C

As illustrated by the table, above, SCDPR expects 19 percent of net revenue to come out of the pockets of patients classified at Charity patients.

Charity care patients are by definition low-income; however, many "Self-Pay" patients will likely find that the $1,960 out-of-pocket cost is also prohibitively expensive. SCDPR's "Sliding Fee Discount Program" classifies those with household incomes of at or under 200 percent of the federal poverty level as Charity. For a family of four, 200 percent of the FPL is $48,600. This means that SCDPR will ask that a family of four with a household income of $50,000 will require $1,960 out-of-pocket for a dental procedure in SCDPR. This will be a substantial burden for some families. When they discover that the same service is available in offices and does not include a facility fee, the patients are likely to look elsewhere, for cost reasons. The medical literature is replete with studies showing that patients shop medical costs.

SCDPR's assumption that charity patients will pay an average of $784 out-of-pocket, before dentist fees, is unsupported. Its assumption that self-pay patients will pay $1,980 out-of-pocket, before dentist fees, is also unreasonable. Low-income individuals, and for that matter many other individuals, will not be able to afford these services at these prices. As a result, the application fails to demonstrate that low-income patients will be able to access the facility as assumed by SCDPR.

As a result, SCDPR is limiting access to medically underserved, specifically low-income, patients and therefore does not conform to Criterion 13c.

18. a. The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.

SCDPR'S PROPOSAL DOES NOT INCLUDE ANESTHESIOLOGIST COVERAGE FOR ALL PROCEDURES, DESPITE ITS OWN STATEMENTS THAT ALL PROCEDURES WILL BE COVERED BY AN ANESTHESIOLOGIST

The program proposed in this application, though proposing noble intent, does not demonstrate a positive impact on quality or safety. The application states numerous times that anesthesiologists will provide sedation and anesthesia staff the facility. The application states repeatedly that providing anesthesiologists to manage sedation and anesthesia for dental and oral surgery procedures increases the quality and safety of the service. For example:

- In Section II.1 (Page 19), the application states: "*The driving force behind the proposed project is Dr. Uday Reebye's vision to create access for dental professionals to state-of-the-art, patient-centric facilities in which they can perform dental procedures and surgeries on their patients requiring sedation in the safest possible setting with sedation or anesthesia services provided by licensed anesthesiologists.*"
- In response to demonstration project criterion #3 (page 51), the application states: "*As previously discussed, the guiding vision behind the proposed project is to provide access to operating rooms and anesthesia services provided by board certified anesthesiologists for any credentialed dental professional who has patients requiring dental procedures under sedation or anesthesia. Only procedures requiring sedation or anesthesia will be provided at the proposed facility.*"

In Section IV (Page 140), the application states that SCDPR will be "the first dental-only ambulatory surgical facility to be developed in the state, particularly one that proposes the scope and quality of services included in this project, such as the use of anesthesiologists for sedation"

Despite SCDPR's claim to provide anesthesiologists for sedation and anesthesia, which apparently was central to the motivation to create the surgery center in the first place, its proposal provides for no more than 1.11 FTEs of anesthesiologist, not even enough to cover one room for six days a week. (See row d in table below.) SCDPR proposes to operate Monday through Saturday. SCDPR proposes to have two operating rooms and six procedure rooms. It proposes to have 6,564 procedures, all under sedation, completed in these eight rooms. One anesthesiologist can only provide sedation or anesthesia for one patient in one room at time. Therefore, the reviewer must assume that SCDPR will not provide anesthesiologists for all sedation procedures. This conflicts other statements in the application that anesthesiologists will staff all sedation procedures.

Estimated Number of Anesthesiologists at SCDPR

Notes	Metric	FFY2018	FFY2019	FFY2020
a	SCDP Anesthesiologist Expense	$498,000	$ 507,960	$ 518,119
b	*Growth*		*2.00%*	*2.00%*
c	Cost of One, Full-Time Anesthesiologist: KSA Proposal From Regional Anesthesia	$450,000	$459,000	$468,180
d	Estimated Number of Anesthesiologists at SCDP	1.11	1.11	1.11

Notes: *a: SCDPR Application, FORM B/C*
b: Year over year growth in a
c: Valleygate Dental Surgery Centers of Fayetteville CON Application, Pro forma assumptions, grown by percent in b
d: a / c

Perhaps most importantly, the shortage of anesthesiologists will lead to situations that could jeopardize quality and patient safety. It is unlawful for a dentist without a sedation permit to treat a patient under sedation without an anesthesiologist or other professional licensed to provide anesthesia present.

Data on the website for the North Carolina Board of Dental Examiners, of the 69 dentists who showed intent to use the facility, 36 are not currently not permitted to provide sedation or anesthesia and are not pediatric dentist or oral surgeons. Together, these dentists, all general dentists, pledged 1,608 of the total 6,564 projected procedures in FY 2020 (25percent). These dentists, by NC regulation are not permitted to provide anesthesia or sedation without an anesthesiologist present.

SCDPR's application confirms this on page 21: "They (dentists) can complete requisite training and obtain oral sedation or anesthesia permits through approval by the North Carolina State Board of Dental Examiners and provide sedation or anesthesia themselves in their office without the supervision of a licensed anesthesiologist, or they can partner with licensed anesthesiologists for the provision of sedation or anesthesia services in their offices."

Therefore, 25 percent of the projected procedures at SCDPR require another practitioner licensed to provide sedation present for those procedures, yet only one Anesthesiologist will be present in the building at any given time. The facility proposes to run eight rooms, all with exclusively sedated patients.

Notwithstanding the obvious misrepresentations made in the application, there is no feasible way that enough anesthesia coverage exists in SCDPR's proposal to lawfully sedate and anesthetize the patients it proposes to serve.

With regard to impact on quality, the application suggests that presence of an anesthesiologist can compensate for a dentist's lack of formal training in anesthesia. As discussed in Criterion 1, caring for a patient who is under general anesthesia requires team participation and understanding of airway maintenance on the part of both anesthesiologist and dentist or surgeon, Attachment J also describes the external peer review required to license an oral surgeon in Pennsylvania to perform general anesthesia. This indicates that other states besides North Carolina take very seriously the importance of training to assure quality and safety of care.

With the problems associated with anesthesia coverage and credentialing, SCDPR, as proposed in the application, does not have a positive impact on quality. In fact, it may have a negative impact on quality. As a result, the applicant does not conform to Criterion 18a.

Attachment B

Solferino North Properties, LLC Annual Report

CA201602601397

SOSID: 1391029
Date Filed: 3/16/2016 11:59:00 PM
Elaine F. Marshall
North Carolina Secretary of State
CA2016 026 01397
CA201602601397

LIMITED LIABILITY COMPANY ANNUAL REPO

NAME OF LIMITED LIABILITY COMPANY: Solferino North Properties LLC

SECRETARY OF STATE ID NUMBER: 1391029 STATE OF FORMATION: NC

REPORT FOR THE YEAR: 2016

Filing Office Use Only

☒ Changes

SECTION A: REGISTERED AGENT'S INFORMATION

1. NAME OF REGISTERED AGENT: Laura Reebye

2. SIGNATURE OF THE NEW REGISTERED AGENT:

SIGNATURE CONSTITUTES CONSENT TO THE APPOINTMENT

3. REGISTERED OFFICE STREET ADDRESS & COUNTY

746 East Franklin Street
Chapel Hill, NC 27514 Orange

4. REGISTERED OFFICE MAILING ADDRESS

746 East Franklin Street
Chapel Hill, NC 27514 Orange

SECTION B: PRINCIPAL OFFICE INFORMATION

1. DESCRIPTION OF NATURE OF BUSINESS: Rental Real Estate

2. PRINCIPAL OFFICE PHONE NUMBER: 919-806-2912

3. PRINCIPAL OFFICE EMAIL: lreebye@gmail.com

4. PRINCIPAL OFFICE STREET ADDRESS & COUNTY

746 E. Franklin Street
Chapel Hill, NC 27514 Orange

5. PRINCIPAL OFFICE MAILING ADDRESS

746 E. Franklin Street
Chapel Hill, NC 27514

SECTION C: COMPANY OFFICIALS (Enter additional Company Officials in Section E.)

NAME:	NAME:	NAME:
Laura Reebye		
TITLE: Member/Manager	TITLE:	TITLE:
ADDRESS: 746 E. Franklin Street	ADDRESS:	ADDRESS:
Chapel Hill, NC 27514		

SECTION D: CERTIFICATION OF ANNUAL REPORT. Section D must be completed in its entirety by a person/business entity.

SIGNATURE — DATE: 1.20.16

Form must be signed by a Company Official listed under Section C of this form.

Laura Reebye
Print or Type Name of Company Official

Manager/Member
Print or Type The Title of the Company Official

SUBMIT THIS ANNUAL REPORT WITH THE REQUIRED FILING FEE OF $200
MAIL TO: Secretary of State, Corporations Division, Post Office Box 29525, Raleigh, NC 27626-0525

Attachment C

Selected Ambulatory Surgery Center Coverage Policies

Table of Contents

1.0 Description of the Procedure, Product, or Service

Dental services are defined as diagnostic, preventive, or corrective procedures provided by or under the supervision of a dentist. This includes services to treat disease, maintain oral health, and treat injuries or impairments that may affect a beneficiary's oral or general health. Such services shall maintain a high standard of quality and shall be within the reasonable limits of services customarily available and provided to most persons in the community with the limitations hereinafter specified. **Only the procedure codes listed in this policy are covered under the North Carolina Medicaid and Health Choice Dental Programs.**

The Division of Medical Assistance (DMA) has adopted procedure codes and descriptions as defined in the most recent edition of *Current Dental Terminology* (CDT 2015).

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid and NCHC policies)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise)*; or
   2. the NC Health Choice *(NCHC is NC Health Choice program, unless context clearly indicates otherwise)* Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term "Specific" found throughout this policy only applies to this policy)

a. <u>Medicaid</u>
None Apply.

b. <u>NCHC</u>
None Apply.

A.19 Billing for Dental Treatment in an Ambulatory Surgical Center

If a Medicaid or NCHC beneficiary is physically unmanageable, medically compromised, or severely developmentally delayed and will not cooperate for treatment in the dental office, treatment may be completed in an ambulatory surgical center (ASC). Dental providers enter "24" under place of treatment in field 38 on the 2006 ADA claim form. Services that normally require prior approval are handled in the usual manner.

A.20 Billing for Anesthesia Services in an Ambulatory Surgical Center

Anesthesiologists and certified registered nurse anesthetists (CRNAs) bill for anesthesia services rendered in ambulatory surgical centers using a CMS-1500 claim form. Claims are paid based on total anesthesia time. Anesthesia time begins when the anesthesiology provider prepares the beneficiary for induction of anesthesia and ends when the beneficiary can be placed under postoperative supervision and the anesthesiology provider is no longer in personal attendance.

Providers must complete the CMS-1500 claim form as follows:

a. Enter a dental ICD-10-CM diagnosis codes in block 21.
b. Enter place of service code "24" for the ambulatory surgical center in block 24B.
c. Enter CPT anesthesia code "00170" *(anesthesia for intraoral procedures, including biopsy; not otherwise specified)* in block 24D.
d. Enter one of the following modifiers in block 24D:

   QX—Services performed by CRNA with medical direction by a physician

   QZ—Services performed by CRNA without medical direction by a physician

   QY—Medical direction of one CRNA by an anesthesiologist

   QK—Medical direction of 2, 3, or 4 concurrent anesthesia procedures involving qualified individuals

   AA—Anesthesia services performed personally by anesthesiologist

   QS—Monitored anesthesia care service (must be billed along with one of the modifiers listed above)
e. Enter total anesthesia time in minutes in block 24G on the claim form.

A.21 Billing for Facility Charges by an Ambulatory Surgical Center

The Ambulatory Surgical Center (ASC) must submit claims for dental facility use with an **electronic claim** in NCTracks. Paper claims are no longer accepted. These claims are priced based on total time for the case using one of the following groups:

ASC Group	Total Time	Reimbursement
1	Up to 30 minutes	$307.50
2	31–60 minutes	$411.85
3	61–90 minutes	$470.95
4	Over 90 minutes	$581.76

Providers must complete the claim as instructed below:

a. Enter the place of service code as "24" for the Ambulatory Surgical Center.

b. Enter the dental procedure codes (*Code on Dental Procedures and Nomenclature* CDT-2015) for the services provided by the dentist.

   Note: All dental codes begin with the "D" prefix. Only the dental procedure codes (CDT-2015) listed in the Clinical Coverage Policy 4A Dental Services **Subsection 5.3, Limitations or Requirements** are valid for billing in ASC cases.

c. Enter modifier SG for each procedure code.

d. Enter all charges on detail line 1 of the claim.

e. Enter the total operating room time on detail line 1 of the claim (1 unit = 1 minute).

f. For all remaining detail lines, enter the number of times (units) each dental procedure was provided with zero charges.

g. Submit all dental procedure codes on **one electronic claim** for the surgery date.

A.22 Billing for Services Covered by Medicare and Medicaid

Federal law mandates that Medicaid be the payer of last resort when beneficiaries are covered by both Medicare and Medicaid. According to the *Medicare Benefit Policy Manual* published by CMS, Medicare ***does not cover*** "services in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting the teeth.... 'Structures directly supporting the teeth' means periodontium, which includes the gingivae, dentogingival junction, periodontal membrane, cementum of the teeth, and alveolar process."

Medicare Part B ***does*** cover certain oral surgical services performed by dentists or oral surgeons as long as they are not provided primarily for the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth. Examples of Medicare-covered services include extractions in preparation for radiation therapy, reduction of jaw fractures, and removal of tumors of the jaw.

Services that are ***not covered*** by Medicare but ***are covered*** by Medicaid shall be filed directly with Medicaid on the 2006 ADA claim form. Services ***covered*** by Medicare and performed either in the emergency room or in the office must first be filed with the Medicare Part B carrier using the CMS-1500 claim form.

Note: For dually eligible Medicare and Medicaid beneficiaries, dental services covered by Medicare ***do not*** require Medicaid prior approval.

The dental services listed below must be filed first with the beneficiary's Medicare Part B carrier on a CMS-1500 claim form. Typically, it is necessary to file such Medicare claims using *Current Procedural Terminology* (CPT) codes, published by the American Medical Association; therefore, convert the CDT codes shown here to CPT codes.

D7285	D7465	D7740	D7872	D7948
D7286	D7490	D7750	D7873	D7949
D7288	D7540	D7760	D7910	D7950
D7410	D7610	D7780	D7911	D7955
D7411	D7620	D7810	D7912	D7980
D7412	D7630	D7820	D7920	D7981
D7413	D7640	D7830	D7940	D7982
D7414	D7650	D7840	D7941	D7983
D7415	D7660	D7850	D7943	D7990
D7440	D7680	D7858	D7944	D7991
D7441	D7710	D7860	D7945	
D7460	D7720	D7865	D7946	
D7461	D7730	D7870	D7947	

Professional claims filed to Medicare as the primary payer should be crossed over automatically to Medicaid. In order for the crossover claim to process, the NPI on the Medicare claim must be on file for a North Carolina Medicaid Provider Number (MPN). It is the provider's responsibility to check the Medicaid Remittance and Status Report to verify that the claim was crossed over from Medicare.

Claims that do not crossover and have been paid by Medicare can be filed as an 837 professional transaction by completing the Coordination of Benefits (COB) loop. Refer to the implementation guide at http://wpc-edi.com and the NC Medicaid HIPAA Companion Guide on DMA's website at http://www.ncdhhs.gov/dma/hipaa/compguides.htm for instructions on completing the 837 professional transaction.

Claims that do not cross over, have been paid by Medicare, and are included on the electronic submission exceptions list at http://www.ncdhhs.gov/dma/provider/ECSExceptions.htm can be filed on a CMS-1500 claim form. The paper claim form must be submitted with the Medicare voucher attached. If claims do not cross over, have been paid by Medicare, and are not included on the electronic submission exceptions list, the claims must be submitted electronically.

When the procedure(s) is denied by Medicare, the provider shall submit the comparable 2015 CDT code(s) directly to Medicaid on a paper 2006 ADA claim form with the Medicare voucher and Medicaid Resolution Inquiry form attached. This will allow the claim to process appropriately according to DMA policy.

Corporate Medical Policy

Dental Criteria for use of Hospital Inpatient or Outpatient Facility Services or Ambulatory Surgery Center Facility Services

File Name:	dental_inpatient_and_outpatient_services
Origination:	5/1987
Last CAP Review:	10/2015
Next CAP Review:	10/2016
Last Review:	10/2015

Description of Procedure or Service

Dental treatment and/or oral surgery can usually be provided in an office setting. However, hospital inpatient, hospital outpatient or ambulatory surgery facilities may be indicated in some situations. When it is medically necessary that the services be provided in a setting other than an office, the facilities may be hospital based or free-standing.

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Hospital Inpatient or Outpatient Facility Services or Ambulatory Surgery Center Facility services used to provide dental services when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

Note: **This policy addresses the Hospital Inpatient or Outpatient Facility services and Ambulatory Surgery Center Facility services, not the provision of dental care or oral surgery. Professional dental services are covered only to the extent that the member has dental benefits.**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

See Dental Treatment Covered Under Your Medical Benefit.

When Use of Hospital Inpatient or Outpatient Facility Services or Ambulatory Surgery Center Facility Services for Dental is covered

1) **The use of an Ambulatory Surgery Center or Hospital Outpatient facility services may be medically necessary when providing dental care or oral surgery in the following situations:**
    a) Complex oral surgical procedures with a high probability of complications due to the nature of the surgery;

    b) Concomitant systemic disease for which the patient is under current medical management and which increases the probability of complications; or

c) When anesthesia is required for the safe and effective administration of dental procedures for young children (below the age of 9 years), persons with serious mental or physical conditions or persons with significant behavioral problems.

2) **The use of Hospital Inpatient facility services may be medically necessary when providing dental care or oral surgery in the following situations:**

a) Complex oral surgical procedures with a greater than average incidence of life threatening complications, such as excessive bleeding or airway obstruction;

b) Concomitant, non-dental systemic conditions for which the patient is under current medical management and which currently are not in optimal control and, therefore, may increase the risk of serious complications.

c) Postoperative complications following outpatient dental/oral surgery.

d) When anesthesia is required for the safe and effective administration of dental procedures for young children (below the age of 9 years), persons with serious mental or physical conditions or persons with significant behavioral problems.

When Use of Hospital Inpatient or Outpatient Facility Services or Ambulatory Surgery Center Facility Services for Dental is not covered

In the absence of the medical criteria shown above.

For the dentist's or patient's convenience.

Policy Guidelines

Claims should be reviewed for documentation of medical necessity.

Prior review and certification are required for inpatient admission for dental/oral surgery.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *There is no specific code for these services.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual

Medical Policy Advisory Group Review - 3/99

Dental Criteria for use of Hospital Inpatient or Outpatient Facility Services or Ambulatory Surgery Center Facility Services

General Assembly of North Carolina, House Bill 1119, General Statues '58-3-122.

MEDLINE and MD Consult literature search from 1995 to present.

Specialty Matched Consultant Advisory Panel - 5/2001

Specialty Matched Consultant Advisory Panel - 5/2003

Specialty Matched Consultant Advisory Panel - 5/2005

Specialty Matched Consultant Advisory Panel - 5/2007

Specialty Matched Consultant Advisory Panel- 11/2009

Senior Medical Director Review- 8/2010

Specialty Matched Consultant Advisory Panel- 10/2011

Specialty Matched Consultant Advisory Panel- 9/2012

Specialty Matched Consultant Advisory Panel- 10/2013

Specialty Matched Consultant Advisory Panel- 10/2014

Medical Director Review- 10/2014

Specialty Matched Consultant Advisory Panel 10/2015

Medical Director Review 10/2015

Policy Implementation/Update Information

99/99	Revised: Coding revisions – ImplementInfo
5/87	Original Policy
1/97	Reaffirmed
3/99	Reviewed by MPAG. Reaffirmed
9/99	Reformatted, Medical Term Definitions added, Combined Inpatient and Outpatient Policies
10/00	System coding changes.
2/01	Reaffirm. No change in criteria.
5/01	Specialty Matched Consultant Advisory Panel review (5/2001). No change to policy. Coding format change.
5/02	Policy clarified to indicate that the services addressed are the inpatient, outpatient, or ambulatory services, not the dental care or oral surgery services.
6/03	Specialty Matched Consultant Advisory Panel review (5/30/2003). No changes to criteria. Revised Benefits Application section. Typos corrected.
3/04	Billing/Coding section updated for consistency.
5/05	Specialty Matched Consultant Advisory Panel review. No changes to criteria.

Dental Criteria for use of Hospital Inpatient or Outpatient Facility Services or Ambulatory Surgery Center Facility Services

8/28/06 Medical Policy changed to Evidence Based Guideline. (pmo)

10/2/06 Evidence Based Guideline changed to Medical Policy. (pmo)

6/18/07 Under "When Covered" section 1.c. and 2.d. changed "and" to "or persons with significant behavioral problems." Reference source added. (pmo)

9/28/10: Under "When Covered" section 1.c. and 2.d. changed from 9 years and under to below the age of 9 years. Under Policy Guidelines added "Prior review and certification are required for inpatient admission for dental/oral surgery." Under Policy Guidelines, changed statement "Claims should be reviewed by individual consideration for documentation of medical necessity to "Claims should be reviewed for documentation of medical necessity." Specialty Matched Consultant Advisory Panel review 1/2010. Reviewed by Senior Medical Director. (lpr)

11/8/11 Specialty Matched Consultant Advisory Panel review 10/26/2011. No changes to policy statement. (lpr)

10/30/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. No changes to policy statement. (lpr)

11/12/13 Specialty Matched Consultant Advisory Panel review 10/21/2013. No changes to policy statement. (lpr)

11/11/14 Specialty Matched Consultant Advisory Panel review 10/2014. Medical Director Review 10/2014. No changes to policy statement. (td)

12/30/15 Specialty Matched Consultant Advisory Panel review 10/29/2015. Medical Director Review 10/2015. (td)

Cigna Medical Coverage Policy

Subject Anesthesia and Facility Services for Dental Treatment

Effective Date 8/15/2015
Next Review Date 8/15/2016
Coverage Policy Number 0415

Table of Contents

Hyperlink to Related Coverage Policies

Orthognathic Surgery

INSTRUCTIONS FOR USE

*The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2015 Cigna*

Coverage Policy

Facility and/or monitored anesthesia care (MAC)/general anesthesia services provided in conjunction with dental treatment may be impacted by benefit plan language and governed by state mandates. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

Cigna covers MAC/general anesthesia and associated facility charges in conjunction with dental surgery or procedures performed by a dentist, oral surgeon or oral maxillofacial surgeon normally excluded under the medical plan as medically necessary when there is an appropriately trained and licensed professional to both administer and monitor MAC/general anesthesia in EITHER of the following locations:

- a properly-equipped and staffed office
- a hospital or outpatient surgery center

for ANY of the following:

- individual age seven years or younger
- individual who is severely psychologically impaired or developmentally disabled
- individual with American Society of Anesthesiologists (ASA) Physical Status Classification * of P3 or greater
- individual who has one or more significant medical comorbidities which:
  - preclude the use of either local anesthesia or conscious sedation OR

- for which careful monitoring is required during and immediately following the planned procedure

- individuals in whom conscious sedation would be inadequate or contraindicated for any of the following procedures:

  - removal of two or more impacted third molars
  - removal or surgical exposure of one impacted maxillary canine
  - surgical removal of two or more teeth involving more than one quadrant
  - routine removal of six or more teeth
  - full arch alveoplasty
  - periodontal flap surgery involving more than one quadrant
  - radical excision of tooth-related lesion greater than 1.25 cm or ½ inch
  - tooth-related radical resection or ostectomy with or without grafting
  - placement or removal of two or more dental implants
  - tooth transplantation or removal from maxillary sinus
  - extraction with bulbous root and/or unusual difficulty or complications noted
  - removal of exostosis involving two areas
  - removal of torus mandibularis involving two areas

Cigna does not cover anesthesia and/or associated facility charges for dental and oral surgery services which are of a cosmetic nature.

*See page four in the General Background for definitions of American Society of Anesthesiologists (ASA) Physical Status Classification

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General Background

Deep sedation, or general anesthesia services, may be required to receive comprehensive dental care for some patients who have special challenges related to their age, behavior, developmental disabilities, medical status, intellectual limitations, or special needs. Oral conditions, such as caries and periodontal diseases, if left untreated, can result in loss of function, infection, and pain (American Academy of Pediatric Dentistry [AAPD], 2005).

Sedation and anesthesia procedures performed on dental patients in nontraditional settings have increased over the past several years. These services could be provided in an office, outpatient facility, or hospital. This care should be provided by qualified and appropriately trained individuals and in facilities accredited in accordance with state regulations and professional society guidelines (AAPD, 2012b; American Society of Anesthesiologists [ASA], 2014b; ASA, 2013; American Dental Association [ADA], 2012a; Nick, et al., 2003).

A carefully obtained and reviewed preoperative medical history, physical examination, and laboratory tests (as necessary), designed to identify high-risk patients with potential medical contraindications to office-based anesthesia, is recommended to prevent anesthetic emergencies by applying strict inclusion criteria (AAPD, 2006; Perrott, et al., 2003; D'eramo, et al., 2003; Iverson, 2002; Hoefflin, et al., 2001). Office-based facilities must ensure timely access to the healthcare system for complications that may occur during, or days after, the surgery (AAPD, 2012b; ASA, 2014b; Fleisher, et al., 2004).

It is recommended that facilities that administer general anesthesia be equipped with anesthesia emergency drugs, appropriate resuscitation equipment, and properly trained staff to quickly and skillfully respond to anesthetic medical emergencies (Doyle and Colletti, 2006; ASA, 2013). Outpatient surgery studies have generally reported a low incidence of surgery-related morbidity with proper patient selection. However, studies of adverse events following outpatient surgery suffer from limitations associated with selection bias, incomplete reporting and limited follow-up. For example, a recent study from Florida, one of few states that requires the central reporting of adverse events, observed a 10-fold increase of adverse events with surgeries performed in doctors' offices when compared to ambulatory surgical centers (Vila, et al., 2004). Factors known to be associated with adverse events include patient age (with high risk among the very young and very old), the

length of the procedure, health status, the type of procedure, provider qualifications and facility accreditation (Fleisher, et al., 2004).

Literature Review

Perrott et al. (2003) conducted a prospective cohort study to provide an overview of current anesthetic practices of oral and maxillofacial surgeons in the office-based ambulatory setting. The patients received local anesthesia, conscious sedation, or deep sedation/general anesthesia. The predictor variables were categorized as demographic, anesthetic technique, staffing, adverse events, and patient-oriented outcomes. The sample comprised 34,191 patients, 71.9% of whom received deep sedation/general anesthesia. A total of 14,912 patient satisfaction forms were completed by patients who had deep sedation/general anesthesia. The overall complication rate was 1.3 per 100 cases, and the complications were minor and self-limiting. The lowest complication rate (0.4%) was associated with the use of local anesthesia, and the highest complication rate was with deep sedation/general anesthesia (1.5%). The conscious sedation complication rate was (0.9%) ($p<0.001$). Two patients who both received deep sedation/general anesthesia experienced complications requiring hospitalization. The patients receiving deep sedation/general anesthesia were overwhelmingly satisfied, with 95.8% reporting extreme or moderate satisfaction.

Coté et al. (2000) developed a database consisting of descriptions of adverse sedation events in pediatric patients, derived from the Food and Drug Administration's adverse drug event reporting system, from the U.S. Pharmacopeia, and from a survey of pediatric specialists. A total of 95 cases were reviewed for factors that may have contributed to adverse sedation events, ranging from death to no harm. Thirty-two of the 95 cases involved sedation/anesthesia for dental procedures, most in a nonhospital-based venue. Twenty-nine cases resulted in death or permanent neurological injury. Three cases resulted in prolonged hospitalization without injury or no harm. The authors stated this may be a result of the fact that general dentists have little pediatric training, particularly in drugs used for sedation/analgesia. The training and skills of the dental specialists was not clear from the case reports. Inadequate resuscitation was often associated with a nonhospital-based setting. In all venues, inadequate and inconsistent physiologic monitoring contributed to poor outcomes. Other issues included: inadequate presedation medical evaluation, lack of an independent observer, medication errors, and inadequate recovery procedures. The authors recommended that uniform, specialty-independent guidelines for monitoring children during and after sedation are needed. Appropriate equipment and medications for resuscitation should be immediately available, regardless of where the child is sedated. Also, all healthcare providers who sedate children should have advanced airway assessment and management training with resuscitation skills to safely rescue patients if an adverse sedation event occurs.

Professional Organizations/Societies

American Society of Anesthesiologists (ASA): The ASA definition of levels of sedation/analgesia (ASA, 2014):

- Minimal sedation (i.e., anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.
- Moderate sedation/analgesia (i.e., conscious sedation) is a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- Deep sedation/analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation, drug-induced depression, or neuromuscular function. Cardiovascular function may be impaired.

*Note: Reflex withdrawal from a painful stimulus is not considered a purposeful response.

The ASA states that Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

The ASA has developed a Physical Status Classification System. The ASA states that there is no additional information to further define these categories (ASA, 2014d):

- ASA 1: normally healthy patient
- ASA II: patient with mild systemic disease
- ASA III: patient with severe systemic disease
- ASA IV: patient with severe systemic disease that is a constant threat to life
- ASA V: moribund patient who is not expected to survive without an operation
- ASA VI: A declared brain-dead patient whose organs are being removed for donor purposes

The ASA position on monitored anesthesia care states that, "Monitored anesthesia care is a specific anesthesia service for a diagnostic or therapeutic procedure. Indications for monitored anesthesia care include the nature of the procedure, the patient's clinical condition and/or the potential need to convert to a general or regional anesthetic. Monitored anesthesia care includes all aspects of anesthesia care – a preprocedure visit, intraprocedure care and postprocedure anesthesia management. During monitored anesthesia care, the anesthesiologist provides or medically directs a number of specific services, including but not limited to:

- diagnosis and treatment of clinical problems that occur during the procedure
- support of vital functions
- administration of sedatives, analgesics, hypnotics, anesthetic agents or other medications as necessary for patient safety
- psychological support and physical comfort
- provision of other medical services as needed to complete the procedure safely

Monitored anesthesia care may include varying levels of sedation, analgesia and anxiolysis as necessary. The provider of monitored anesthesia care must be prepared and qualified to convert to general anesthesia when necessary. If the patient loses consciousness and the ability to respond purposefully, the anesthesia care is a general anesthetic, irrespective of whether airway instrumentation is required" (ASA 2013c).

The ASA statement on distinguishing monitored anesthesia care (MAC) from moderate sedation/analgesia (conscious sedation) states that, "This physician service can be distinguished from Moderate Sedation in several ways. An essential component of MAC is the anesthesia assessment and management of a patient's actual or anticipated physiological derangements or medical problems that may occur during a diagnostic or therapeutic procedure. While Monitored Anesthesia Care may include the administration of sedatives and/or analgesics often used for Moderate Sedation, the provider of MAC must be prepared and qualified to convert to general anesthesia when necessary. Additionally, a provider's ability to intervene to rescue a patient's airway from any sedation-induced compromise is a prerequisite to the qualifications to provide Monitored Anesthesia Care. By contrast, Moderate Sedation is not expected to induce depths of sedation that would impair the patient's own ability to maintain the integrity of his or her airway. These components of Monitored Anesthesia Care are unique aspects of an anesthesia service that are not part of Moderate Sedation (ASA, 2013b).

The ASA guidelines for office-based anesthesia state that, compared with licensed ambulatory surgical facilities and acute-care hospitals, offices currently have little or no regulation, oversight, or control by federal, state, or local laws. Therefore, ASA members must investigate areas taken for granted in the hospital or ambulatory surgical facility, such as governance, organization, construction and equipment; and policies and procedures including: fire, safety, drugs, emergencies, staffing, training, and unanticipated patient transfers (ASA, 2014).

The ASA statement on qualifications of anesthesia providers in the office-based setting recommends that where anesthesiologist participation is not practicable, nonphysician anesthesia providers must, at a minimum, be supervised by the operating practitioner or other licensed physician. The supervising operating practitioner, or other licensed physician, should be specifically trained in sedation, anesthesia, and rescue techniques appropriate to the type of sedation or anesthesia being provided, and to the office-based surgery being

performed. The ASA recommends that these guidelines be read in conjunction with the ASA's guidelines for office-based anesthesia (ASA, 2014c).

The 2002 ASA evidence-based practice guideline for sedation and analgesia by non-anesthesiologists applies to procedures performed in a variety of settings (e.g., hospitals, freestanding clinics, dentist, and other offices) (Gross, et al., 2002). The guidelines allow clinicians to provide patients the benefits of sedation/analgesia while minimizing the associated risks. Numerous recommendations are included in the guideline. The following is a subset of the recommendations:

- A designated individual other than the practitioner performing the procedure should be present to monitor the patient throughout the procedures performed with sedation/analgesia. During deep sedation, this individual should have no other responsibilities.
- Whenever possible, appropriate medical specialists should be consulted prior to administration of sedation to patients with significant underlying conditions.

There have been no updates to the guideline since 2002.

American Academy of Pediatric Dentistry (AAPD): In 2006, the AAPD and the American Academy of Pediatric (AAP) published an updated guideline for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. This updated statement unifies the guidelines for sedation used by medical and dental practitioners, adds clarification regarding monitoring modalities, provides new information from the medical and dental literature, and suggests methods for further improvement in safety and outcomes. With this guideline, the Joint Commission on Accreditation of Healthcare Organizations, the ASA, the AAP, and the AAPD will use similar language to define sedation categories and the expected physiologic responses. The AAPD and AAP recommend the following:

- Candidates for minimal, moderate, or deep sedation are patients who are in ASA Classes I and II. Children in ASA Classes III and IV, children with special needs, and those with anatomic airway abnormalities or extreme tonsillar hypertrophy present issues that require additional and individual consideration, particularly for moderate and deep sedation. Practitioners are encouraged to consult with appropriate subspecialists and/or an anesthesiologist for patients at increased risk of experiencing adverse sedation events because of their underlying medical/surgical conditions.

- The pediatric patient should be accompanied to and from the treatment facility by a responsible person (e.g., parent or legal guardian). It is recommended that two or more adults accompany children who are in car safety seats if transportation to and from a treatment facility is provided by one of the adults.

- The practitioner who uses sedation must have immediate available facilities, personnel, and equipment to manage emergency and rescue situations. The most common serious complications of sedation involve compromise of the airway or depressed respirations resulting in airway obstruction, hypoventilation, hypoxemia, and apnea. Hypotension and cardiopulmonary arrest may occur, usually from inadequate recognition and treatment of respiratory compromise. Rare complications may include seizures and allergic reactions.

- A protocol for access to back-up emergency services shall be identified, with an outline of the procedures necessary for immediate use. For nonhospital facilities, a protocol for ready access to ambulance service and immediate activation of the emergency medical system for life-threatening complications must be developed and maintained. The availability of emergency medical services does not replace the practitioner's responsibility to provide initial rescue in managing life-threatening complications.

- An emergency cart or kit must be immediately accessible and contain equipment to provide the necessary age- and size-appropriate drugs and equipment to resuscitate a nonbreathing and unconscious child. The contents of the kit must allow for the provision of continuous life support while the patient is being transported to a medical facility or to another area within a medical facility. All equipment and drugs must be checked and maintained on a scheduled basis. Monitoring devices must have a safety and function check on a regular basis as required by local or state regulation.

- The time and condition of the child at discharge from the treatment area or facility should be documented; this should include documentation that the child's level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge as recognized by the following criteria:

    - cardiovascular function and airway patency are satisfactory and stable
    - patient is easily arousable, and protective reflexes are intact
    - patient can talk (if age-appropriate)
    - patient can sit up unaided (if age-appropriate)
    - for a very young or handicapped child incapable of the usually expected responses, the presedation level of responsiveness or a level as close as possible to the normal level for that child should be achieved
    - state of hydration is adequate

There have been no updates to the guideline since 2006.

The AAPD policy statement on the use of deep sedation and general anesthesia in the pediatric dental office states that "The AAPD endorses the in-office use of deep sedation or general anesthesia on select pediatric dental patients administered in an appropriately-equipped and staffed facility as outlined in the Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (AAPD, 2012b).

The AAPD guideline on the use of anesthesia care personnel in the administration of in-office deep sedation/general anesthesia to the pediatric patient is to be used to assist the dental provider who elects to use an anesthesia care provider for the administration of deep sedation/general anesthesia for pediatric dental patients in a dental office or other facility outside of an accredited hospital or surgicenter. The guideline addresses personnel, facilities, documentation, and risk management and quality mechanisms required to provide responsible and optimal care to the pediatric dental patient. The guideline states that office-based deep sedation/general anesthesia techniques require at least three individuals and all personnel should be trained in emergency procedures (AAPD, 2012c).

The AAPD clinical guideline on management of dental patients with special healthcare needs addresses behavior guidance recommending that, "Because of dental anxiety or a lack of understanding of dental care, children with disabilities may exhibit resistant behaviors. These behaviors can interfere with the safe delivery of dental treatment. With the parent/caregiver's assistance, most patients with physical and mental disabilities can be managed in the dental office. Protective stabilization can be helpful in patients for whom traditional behavior guidance techniques are not adequate. When protective stabilization is not feasible or effective, sedation or general anesthesia is the behavioral guidance armamentarium of choice. When in-office sedation/general anesthesia is not feasible or effective, an out-patient surgical care facility might be necessary" (AAPD, 2012a).

American Dental Association (ADA): The 2012 ADA guideline for the use of sedation and general anesthesia by dentists recommends that to administer deep sedation or general anesthesia, the dentist must have completed:

- an advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with the deep sedation or general anesthesia clinical guidelines in this ADA guideline
- a current certification in Basic Life Support for Healthcare Providers and either current certification in Advanced Cardiac Life Support (ACLS) or completion of an appropriate dental sedation/anesthesia emergency management course on the same re-certification cycle that is required for ACLS

The guideline states that administration of deep sedation or general anesthesia by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in BLS Course for the Healthcare Provider.

The ADA guideline recommends that patients must be evaluated prior to the start of any sedative/anesthetic procedure. Healthy or stable patients (i.e., ASA I or II) may require only a review of their medical history, including medication use. Patients who are medically unstable, or who have a significant health disability (i.e., ASA III or IV), may require consultation with their primary physician, or consulting medical specialist. The guidelines state that a minimum of three individuals must be present: a qualified dentist to administer and monitor the deep sedation/general anesthesia; two individuals who are competent in basic life support, or its equivalent; another individual trained in patient monitoring, if the same individual administering deep sedation/general anesthesia is performing the dental procedure. The guidelines recommend that suitable equipment must be on the premises to provide advanced airway maintenance and advanced life support along with in-line oxygen analyzers for intubated patients. Further recommendations address strict monitoring, documentation, recovery, and discharge criteria (ADA, 2012a).

American Association of Oral and Maxillofacial Surgeons (AAOMS): In the 2012 AAOMS Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery section on Patient Assessment the authors state, "In all cases of ASA class II or greater patients, consideration should be given to consultation with a physician for medical clarification of the patient's physiologic condition clearance to assist the OMS in determining the appropriateness for outpatient OMS procedures that may include sedation or general anesthesia". The authors state that, "The practitioner's selection of a particular technique for controlling pain and anxiety during a specific procedure has to be individually determined for each patient, considering the risks and benefits for each case". The section addressing Anesthesia in Outpatient Facilities discusses three subpopulations of individuals (i.e., children, pregnant women and individuals with obesity) who are at higher risk of anesthesia complications due to anatomical and physiological variations. Additionally, numerous health conditions are identified that may be impacted by anesthesia. The authors identify specific factors affecting risk for deep sedation/general anesthesia including:

- loss of the ability to respond purposefully to physical stimulation or verbal command and/or loss of protective
- cardiopulmonary reflexes and the ability to maintain an airway independently
- factors compromising airway patency
- factors compromising cardiovascular function
- noncompliance with or conditions affecting NPO requirements
- psychological aversion to intravenous or intramuscular injections and/or anesthetic mask
- presence of intraoral abscess or cellulitis
- presence of facial anomalies and anatomical variations that might prevent or impede adequate airway management
- presence of a recent or active upper respiratory infection
- regulatory and/or third-party decisions concerning access to care, indicated therapy, drugs, devices, and/or materials
- special needs patients

Use Outside of the US
No relevant information.

Summary
Dental treatment with monitored anesthesia care (MAC) or general anesthesia allows dentists and specialists to improve treatment conditions and provide higher quality of care to many patients with medical and physical disabilities and other special needs. Professional societies have published guidelines that address the use of, and requirements to administer, deep sedation or general anesthesia to the dental patient. The guidelines address personnel, facilities, documentation, and quality mechanisms required to provide responsible and optimal care to patients.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

The scope of this policy is limited to medical plan coverage of the facility and/or monitored anesthesia care (MAC)/general anesthesia services provided in conjunction with dental treatment, and not the dental or oral surgery services. The professional dental procedure codes listed are for reference only and do not imply coverage of dental procedures.

Covered when medically necessary when used to report facility charges for dental procedures performed outpatient:

CPT®* Codes	Description
01999	Unlisted anesthesia procedure(s)
41899	Unlisted procedure, dentoalveolar structures

CDT®** Codes	Description
D7140	Extraction, erupted tooth or exposed root (elevation and/or forceps removal)
D7230	Surgical extraction of partially bony impacted tooth
D7240	Surgical extraction of completely bony impacted tooth
D7241	Surgical extraction of completely bony impacted tooth, with unusual surgical complications
D7250	Surgical removal of residual tooth roots (cutting procedure)
D7272	Tooth transplantation (includes transplantation from one site to another and splinting and/or stabilization)
D7310	Alveoplasty in conjunction with extractions – four or more teeth or tooth spaces per quadrant
D7321	Alveoplasty not in conjunction with extractions – one to three teeth or tooth spaces, per quadrant.
D7471	Removal of lateral exostosis (maxilla or mandible)
D7473	Removal of torus mandibularis
D9220	Deep sedation/general anesthesia, first 30 minutes
D9221	Deep sedation/general anesthesia; each additional 15 minutes

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Attachment D

Sample Policy: Hospital Credentialing

CAPE FEAR VALLEY HEALTH SYSTEM
(Cape Fear Valley Medical Center/Highsmith Rainey Specialty Hospital/Hoke Healthcare)
DELINEATION OF PRIVILEGES – **Dentistry**

APPLICANT: _____ **DATE:** _____

PLEASE INDICATE FACILITY(ies) WHERE PRIVILEGES ARE BEING REQUESTED:
___ **CFVMC** ___ **HRSH** ___ **Hoke Healthcare**

LIFE THREATENING EMERGENCY: At the time of a clinical emergency, a member of the medical staff who holds clinical privileges may render whatever care he/she believes to be indicated.

EDUCATION/TRAINING/EXPERIENCE

To be eligible to request privileges in Dentistry all applicants must meet the following minimal guidelines:

EDUCATION:	**DDS/DMD**
TRAINING:	**Successful completion of an approved one-year general practice residency (general dentists) or specialty training program (specialists).**
EXPERIENCE:	**The applicant must demonstrate that he or she has provided full-time dental services for at least 12 of the past 18 months. Recent residency training satisfies this request.**

Documentation of Experience should be attached to this Request for Privileges.

SPECIAL REQUIREMENT:

A dentist will be required to admit in conjunction with a physician member of the medical staff. The physician member of the medical staff assumes responsibility for the overall aspects of the patient's care throughout the hospital stay, including performing and recording the medical history and physical examination and recording a medical discharge summary. Patients admitted to the hospital for dental care must be given the same appraisal as patients admitted for other services. The physician supervision continues until the discharge of the patient.

A physician member of the medical staff is responsible for the care of any medical problem that may be present or that may arise during the hospitalization of dental patients. The dentist is responsible for dental care of the patient, including the dental history and physical examination and all appropriate elements of the patient's record.

CORE PRIVILEGES

Core privileges in dentistry include the ability to admit, consult, work up, and provide diagnostic, preventive and therapeutic oral health care to patients of all ages to correct or treat various routine conditions of the oral cavity. Core privileges include minimal sedation (anxiolysis). These core privileges do not include the following special requests.

SPECIAL REQUESTS

Applicants who are qualified for "core privileges" in Dentistry may request privileges to perform the following provided the applicant is qualified based on the credentialling guidelines noted for each procedure.

___ Extractions Below the Gumline
CREDENTIALLING GUIDELINES: Documentation of training and satisfactory performance of the procedure during the previous 12 month period.

___ Preparation of Existing Jaw Bone for Oral Prosthesis
CREDENTIALLING GUIDELINES: Documentation of training and documentation of satisfactory performance of the procedure during the previous 12 month period.

___ Moderate Sedation/Analgesia (conscious sedation)
CREDENTIALLING GUIDELINES: Applicant must have completed residency within the previous two-year period and document training during residency OR must provide documentation of appropriate post-residency CME training within the previous two years (on-site program is available). (NOTE: At the time of reappointment individuals wishing to continue privileges in moderate sedation/analgesia will be required to document completion of relevant CME during the reappointment period).

APPLICANT: _____

SUBSPECIALTY REQUESTS

Applicants who are qualified for core privileges in dentistry and who have satisfactorily completed a formal dental subspecialty training program and can document full-time practice in the subspecialty area for at least 12 months out the previous 18 months are eligible to request subspecialty dental privileges concurrent with their training and practice experience. Indicate below subspecialty dental privileges requested:

___ Endodontics

___ Orthodontics

___ Pedodontics

___ Periodontics

___ Prosthodontics

I request core privileges in the practice of Dentistry. If appropriate, I have indicated special procedures or subspecialty area(s) for which I am requesting privileges and have attached documentation of compliance with the credentialling guidelines as outlined.

_____ _____

Signature Date

****

Approved 7/7/97; Revised 5/99; 7/03; January 2015

Attachment E

CMS Claims Manual for Anesthesiology Services Ambulatory Surgery, Excerpt

Payment is not generally allowed for an assistant surgeon when payment for either two surgeons (modifier "-62") or team surgeons (modifier "-66") is appropriate. If A/B MACs (B) receive a bill for an assistant surgeon following payment for co-surgeons or team surgeons, they pay for the assistant only if a review of the claim verifies medical necessity.

50 - Payment for Anesthesiology Services

(Rev. 1859; Issued: 11-20-09; Effective Date: For services furnished on or after 01-01-10; Implementation Date: 01-04-10)

A. General Payment Rule

The fee schedule amount for physician anesthesia services furnished on or after January 1, 1992 is, with the exceptions noted, based on allowable base and time units multiplied by an anesthesia conversion factor specific to that locality. The base unit for each anesthesia procedure is communicated to the A/B MACs (B) by means of the HCPCS file released annually. The public can access the base units on the CMS homepage through the anesthesiologist's center. The way in which time units are calculated is described in §50.G. CMS releases the conversion factor annually.

B. Payment at Personally Performed Rate

The A/B MAC (B) must determine the fee schedule payment, recognizing the base unit for the anesthesia code and one time unit per 15 minutes of anesthesia time if:

- The physician personally performed the entire anesthesia service alone;
- The physician is involved with one anesthesia case with a resident, the physician is a teaching physician as defined in §100, and the service is furnished on or after January 1, 1996;
- The physician is involved in the training of physician residents in a single anesthesia case, two concurrent anesthesia cases involving residents or a single anesthesia case involving a resident that is concurrent to another case paid under the medical direction rules. The physician meets the teaching physician criteria in §100.1.4 and the service is furnished on or after January 1, 2010;
- The physician is continuously involved in a single case involving a student nurse anesthetist;
- The physician is continuously involved in one anesthesia case involving a CRNA (or AA) and the service was furnished prior to January 1, 1998. If the physician is involved with a single case with a CRNA (or AA) and the service was furnished on or after January 1, 1998, A/B MACs (B) may pay the physician service and the CRNA (or AA) service in accordance with the medical direction payment policy; or

- The physician and the CRNA (or AA) are involved in one anesthesia case and the services of each are found to be medically necessary. Documentation must be submitted by both the CRNA and the physician to support payment of the full fee for each of the two providers. The physician reports the "AA" modifier and the CRNA reports the "QZ" modifier for a nonmedically directed case.

C. Payment at the Medically Directed Rate

The A/B MAC (B) determines payment for the physician's medical direction service furnished on or after January 1, 1998, on the basis of 50 percent of the allowance for the service performed by the physician alone. Medical direction occurs if the physician medically directs qualified individuals in two, three, or four concurrent cases and the physician performs the following activities.

- Performs a pre-anesthetic examination and evaluation;
- Prescribes the anesthesia plan;
- Personally participates in the most demanding procedures in the anesthesia plan, including induction and emergence;
- Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified anesthetist;
- Monitors the course of anesthesia administration at frequent intervals;
- Remains physically present and available for immediate diagnosis and treatment of emergencies; and
- Provides indicated-post-anesthesia care.

Prior to January 1, 1999, the physician was required to participate in the most demanding procedures of the anesthesia plan, including induction and emergence.

For medical direction services furnished on or after January 1, 1999, the physician must participate only in the most demanding procedures of the anesthesia plan, including, if applicable, induction and emergence. Also for medical direction services furnished on or after January 1, 1999, the physician must document in the medical record that he or she performed the pre-anesthetic examination and evaluation. Physicians must also document that they provided indicated post-anesthesia care, were present during some portion of the anesthesia monitoring, and were present during the most demanding procedures, including induction and emergence, where indicated.

For services furnished on or after January 1, 1994, the physician can medically direct two, three, or four concurrent procedures involving qualified individuals, all of whom could be CRNAs, AAs, interns, residents or combinations of these individuals. The

medical direction rules apply to cases involving student nurse anesthetists if the physician directs two concurrent cases, each of which involves a student nurse anesthetist, or the physician directs one case involving a student nurse anesthetist and another involving a CRNA, AA, intern or resident.

For services furnished on or after January 1, 2010, the medical direction rules do not apply to a single resident case that is concurrent to another anesthesia case paid under the medical direction rules or to two concurrent anesthesia cases involving residents.

If anesthesiologists are in a group practice, one physician member may provide the pre-anesthesia examination and evaluation while another fulfills the other criteria. Similarly, one physician member of the group may provide post-anesthesia care while another member of the group furnishes the other component parts of the anesthesia service. However, the medical record must indicate that the services were furnished by physicians and identify the physicians who furnished them.

A physician who is concurrently directing the administration of anesthesia to not more than four surgical patients cannot ordinarily be involved in furnishing additional services to other patients. However, addressing an emergency of short duration in the immediate area, administering an epidural or caudal anesthetic to ease labor pain, or periodic, rather than continuous, monitoring of an obstetrical patient does not substantially diminish the scope of control exercised by the physician in directing the administration of anesthesia to surgical patients. It does not constitute a separate service for the purpose of determining whether the medical direction criteria are met. Further, while directing concurrent anesthesia procedures, a physician may receive patients entering the operating suite for the next surgery, check or discharge patients in the recovery room, or handle scheduling matters without affecting fee schedule payment.

However, if the physician leaves the immediate area of the operating suite for other than short durations or devotes extensive time to an emergency case or is otherwise not available to respond to the immediate needs of the surgical patients, the physician's services to the surgical patients are supervisory in nature. A/B MACs (B) may not make payment under the fee schedule.

See §50.J for a definition of concurrent anesthesia procedures.

D. Payment at Medically Supervised Rate

The A/B MAC (B) may allow only three base units per procedure when the anesthesiologist is involved in furnishing more than four procedures concurrently or is performing other services while directing the concurrent procedures. An additional time unit may be recognized if the physician can document he or she was present at induction.

E. Billing and Payment for Multiple Anesthesia Procedures

Physicians bill for the anesthesia services associated with multiple bilateral surgeries by reporting the anesthesia procedure with the highest base unit value with the multiple procedure modifier "-51." They report the total time for all procedures in the line item with the highest base unit value.

If the same anesthesia CPT code applies to two or more of the surgical procedures, billers enter the anesthesia code with the "-51" modifier and the number of surgeries to which the modified CPT code applies.
Payment can be made under the fee schedule for anesthesia services associated with multiple surgical procedures or multiple bilateral procedures. Payment is determined based on the base unit of the anesthesia procedure with the highest base unit value and time units based on the actual anesthesia time of the multiple procedures. See §§40.6-40.7 for a definition and appropriate billing and claims processing instructions for multiple and bilateral surgeries.

F. Payment for Medical and Surgical Services Furnished in Addition to Anesthesia Procedure

Payment may be made under the fee schedule for specific medical and surgical services furnished by the anesthesiologist as long as these services are reasonable and medically necessary or provided that other rebundling provisions (see §30 and Chapter 23) do not preclude separate payment. These services may be furnished in conjunction with the anesthesia procedure to the patient or may be furnished as single services, e.g., during the day of or the day before the anesthesia service. These services include the insertion of a Swan Ganz catheter, the insertion of central venous pressure lines, emergency intubation, and critical care visits.

G. Anesthesia Time and Calculation of Anesthesia Time Units

Anesthesia time is defined as the period during which an anesthesia practitioner is present with the patient. It starts when the anesthesia practitioner begins to prepare the patient for anesthesia services in the operating room or an equivalent area and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the patient, that is, when the patient may be placed safely under postoperative care. Anesthesia time is a continuous time period from the start of anesthesia to the end of an anesthesia service. In counting anesthesia time for services furnished on or after January 1, 2000, the anesthesia practitioner can add blocks of time around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption.

Actual anesthesia time in minutes is reported on the claim. For anesthesia services furnished on or after January 1, 1994, the A/B MAC computes time units by dividing reported anesthesia time by 15 minutes. Round the time unit to one decimal place. The A/B MAC does not recognize time units for CPT codes 01995 or 01996.

For purposes of this section, anesthesia practitioner means a physician who performs the anesthesia service alone, a CRNA who is not medically directed, or a CRNA or AA, who is medically directed. The physician who medically directs the CRNA or AA would ordinarily report the same time as the CRNA or AA reports for the CRNA service.

H. Base Unit Reduction for Concurrent Medically Directed Procedures

If the physician medically directs concurrent medically directed procedures prior to January 1, 1994, reduce the number of base units for each concurrent procedure as follows.

- For two concurrent procedures, the base unit on each procedure is reduced 10 percent.
- For three concurrent procedures, the base unit on each procedure is reduced 25 percent.
- For four concurrent procedures, the base on each concurrent procedure is reduced 40 percent.
- If the physician medically directs concurrent procedures prior to January 1, 1994, and any of the concurrent procedures are cataract or iridectomy anesthesia, reduce the base units for each cataract or iridectomy procedure by 10 percent.

I. Monitored Anesthesia Care

The A/B MAC (B) pays for reasonable and medically necessary monitored anesthesia care services on the same basis as other anesthesia services. Anesthesiologists use modifier QS to report monitored anesthesia care cases. Monitored anesthesia care involves the intra-operative monitoring by a physician or qualified individual under the medical direction of a physician or of the patient's vital physiological signs in anticipation of the need for administration of general anesthesia or of the development of adverse physiological patient reaction to the surgical procedure. It also includes the performance of a pre-anesthetic examination and evaluation, prescription of the anesthesia care required, administration of any necessary oral or parenteral medications (e.g., atropine, demerol, valium) and provision of indicated postoperative anesthesia care.

Payment is made under the fee schedule using the payment rules in subsection B if the physician personally performs the monitored anesthesia care case or under the rules in subsection C if the physician medically directs four or fewer concurrent cases and monitored anesthesia care represents one or more of these concurrent cases.

J. Definition of Concurrent Medically Directed Anesthesia Procedures

Concurrency is defined with regard to the maximum number of procedures that the physician is medically directing within the context of a single procedure and whether

these other procedures overlap each other. Concurrency is not dependent on each of the cases involving a Medicare patient. For example, if an anesthesiologist directs three concurrent procedures, two of which involve non-Medicare patients and the remaining a Medicare patient, this represents three concurrent cases. The following example illustrates this concept and guides physicians in determining how many procedures they are directing.

EXAMPLE

Procedures A through E are medically directed procedures involving CRNAs and furnished between January 1, 1992 and December 31, 1997 (1998 concurrent instructions can be found in subsection C.) The starting and ending times for each procedure represent the periods during which anesthesia time is counted. Assume that none of the procedures were cataract or iridectomy anesthesia.

Procedure A begins at 8:00 a.m. and lasts until 8:20 a.m.
Procedure B begins at 8:10 a.m. and lasts until 8:45 a.m.
Procedure C begins at 8:30 a.m. and lasts until 9:15 a.m.
Procedure D begins at 9:00 a.m. and lasts until 12:00 noon.
Procedure E begins at 9:10 a.m. and lasts until 9:55 a.m.

Procedure	Number of Concurrent Medically Directed Procedures	Base Unit Reduction Percentage
A	2	10%
B	2	10%
C	3	25%
D	3	25%
E	3	25%

From 8:00 a.m. to 8:20 a.m., the length of procedure A, the anesthesiologist medically directed two concurrent procedures, A and B.

From 8:10 a.m. to 8:45 a.m., the length of procedure B, the anesthesiologist medically directed two concurrent procedures. From 8:10 to 8:20 a.m., the anesthesiologist medically directed procedures A and B. From 8:20 to 8:30 a.m., the anesthesiologist medically directed only procedure B. From 8:30 to 8:45 a.m., the anesthesiologist medically directed procedures B and C. Thus, during procedure B, the anesthesiologist medically directed, at most, two concurrent procedures.

From 8:30 a.m. to 9:15 a.m., the length of procedure C, the anesthesiologist medically directed three concurrent procedures. From 8:30 to 8:45 a.m., the anesthesiologist medically directed procedures B and C. From 8:45 to 9:00 a.m., the anesthesiologist medically directed procedure C. From 9:00 to 9:10 a.m., the anesthesiologist medically directed procedures C and D. From 9:10 to 9:15 a.m., the anesthesiologist medically directed procedures C, D and E. Thus, during procedure C, the anesthesiologist medically directed, at most, three concurrent procedures.

The same analysis shows that during procedure D or E, the anesthesiologist medically directed, at most, three concurrent procedures.

K. Anesthesia Claims Modifiers

Physicians report the appropriate anesthesia modifier to denote whether the service was personally performed, medically directed, or medically supervised.

Specific anesthesia modifiers include:

AA - Anesthesia Services performed personally by the anesthesiologist;

AD - Medical Supervision by a physician; more than 4 concurrent anesthesia procedures;

G8 - Monitored anesthesia care (MAC) for deep complex complicated, or markedly invasive surgical procedures;

G9 - Monitored anesthesia care for patient who has a history of severe cardio-pulmonary condition;

QK - Medical direction of two, three or four concurrent anesthesia procedures involving qualified individuals;

QS - Monitored anesthesia care service;

QX - CRNA service; with medical direction by a physician;

QY - Medical direction of one certified registered nurse anesthetist by an anesthesiologist;

QZ - CRNA service: without medical direction by a physician; and

GC - these services have been performed by a resident under the direction of a teaching physician.

The GC modifier is reported by the teaching physician to indicate he/she rendered the service in compliance with the teaching physician requirements in §100.1.2. One of the payment modifiers must be used in conjunction with the GC modifier.

The QS modifier is for informational purposes. Providers must report actual anesthesia time on the claim.

The A/B MAC (B) must determine payment for anesthesia in accordance with these instructions. They must be able to determine the uniform base unit that is assigned to the anesthesia code and apply the appropriate reduction where the anesthesia procedure is medically directed. They must also be able to determine the number of anesthesia time units from actual anesthesia time reported on the claim. The A/B MAC (B) must multiply allowable units by the anesthesia-specific conversion factor used to determine fee schedule payment for the payment area.

L. Anesthesia and Medical/Surgical Service Provided by the Same Physician

Anesthesia services range in complexity. The continuum of anesthesia services, from least intense to most intense in complexity is as follows: local or topical anesthesia, moderate (conscious) sedation, regional anesthesia and general anesthesia. Prior to 2006, Medicare did not recognize separate payment if the same physician provided the medical or surgical procedure and the anesthesia needed for the procedure.

Moderate sedation is a drug induced depression of consciousness during which the patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Moderate sedation does not include minimal sedation, deep sedation or monitored anesthesia care. In 2006, the CPT added new codes 99143 to 99150 for moderate or conscious sedation. The moderate (conscious) sedation codes are A/B MAC (B) priced under the Medicare physician fee schedule.

The CPT codes 99143 to 99145 describe moderate sedation provided by the same physician performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status. The physician can bill the conscious sedation codes 99143 to 99145 as long as the procedure with it is billed is not listed in Appendix G of CPT. CPT codes 99148 to 99150 describe moderate sedation provided by a physician other than the health care professional performing the diagnostic or therapeutic service that the sedation supports.

The CPT includes Appendix G, Summary of CPT Codes That Include Moderate (Conscious) Sedation. This appendix lists those procedures for which moderate (conscious) sedation is an inherent part of the procedure itself. CPT coding guidelines instruct practices not to report CPT codes 99143 to 99145 in conjunction with codes listed in Appendix G. The National Correct Coding Initiative has established edits that bundle CPT codes 99143 and 99144 into the procedures listed in Appendix G.

In the unusual event when a second physician other than the health care professional performing the diagnostic or therapeutic services provides moderate sedation in the facility setting for the procedures listed in Appendix G, the second physician can bill 99148 to 99150. The term, facility, includes those places of service listed in Chapter 23 Addendum -- field 29. However, when these services are performed by the second physician in the nonfacility setting, CPT codes 99148 to 99150 are not to be reported.

If the anesthesiologist or CRNA provides anesthesia for diagnostic or therapeutic nerve blocks or injections and a different provider performs the block or injection, then the anesthesiologist or CRNA may report the anesthesia service using CPT code 01991. The service must meet the criteria for monitored anesthesia care. If the anesthesiologist or CRNA provides both the anesthesia service and the block or injection, then the anesthesiologist or CRNA may report the anesthesia service using the conscious sedation code and the injection or block. However, the anesthesia service must meet the requirements for conscious sedation and if a lower level complexity anesthesia service is provided, then the conscious sedation code should not be reported.

If the physician performing the medical or surgical procedure also provides a level of anesthesia lower in intensity than moderate or conscious sedation, such as a local or topical anesthesia, then the conscious sedation code should not be reported and no payment should be allowed by the A/B MAC (B). There is no CPT code for the performance of local anesthesia and as payment for this service is considered in the payment for the underlying medical or surgical service.

60 - Payment for Pathology Services

(Rev. 2714, Issued: 05-24-13, Effective: 07-01-12 Implementation: 06-25, 13)

A. Payment for Professional Component (PC) Services

Payment may be made under the physician fee schedule for the professional component of physician laboratory or physician pathology services furnished to hospital inpatients or outpatients by hospital physicians or by independent laboratories, if they qualify as the re-assignee for the physician service.

B. Payment for Technical Component (TC) Services

1. General Rule

Payment is not made under the physician fee schedule for TC services furnished in institutional settings where the TC service is bundled into the facility payment, e.g., hospital inpatient and outpatient settings. Payment is made under the physician fee schedule for TC services furnished in institutional settings where the TC service is not bundled into the facility payment, e.g., an ambulatory surgery center (ASC). Payment may be made under the physician fee schedule for the TC of physician pathology services furnished by an independent laboratory, or a hospital if it is acting

Attachment F

42CFR 415.110 Medically Directed Anesthesia Servcies

42 CFR 415.110

§ 415.110 Conditions for payment: Medically directed anesthesia services.

(a) General payment rule. Medicare pays for the physician's medical direction of anesthesia services for one service or two through four concurrent anesthesia services furnished after December 31, 1998, only if each of the services meets the condition in § 415.102(a) and the following additional conditions:

(1) For each patient, the physician --

(i) Performs a pre-anesthetic examination and evaluation;

(ii) Prescribes the anesthesia plan;

(iii) Personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;

(iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in operating instructions;

(v) Monitors the course of anesthesia administration at frequent intervals;

(vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and

(vii) Provides indicated post-anesthesia care.

(2) The physician directs no more than four anesthesia services concurrently and does not perform any other services while he or she is directing the single or concurrent services so that one or more of the conditions in paragraph (a)(1) of this section are not violated.

(3) If the physician personally performs the anesthesia service, the payment rules in § 414.46(c) of this chapter apply (Physician personally performs the anesthesia procedure).

(b) Medical documentation. The physician alone inclusively documents in the patient's medical record that the conditions set forth in paragraph (a)(1) of this section have been satisfied, specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable.

Attachment G

Additional Letters of Support: Patients

May 9, 2016

Ms. Martha Frisone, Assistant Chief
Certificate of Need Section
Division of Health Services Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699

Re: Community support letter for Valleygate Dental Surgical Center's Certificate of Need applications to develop dental specialty surgical centers in Cumberland and Wake Counties

Dear Ms. Frisone:

My name is Giovanna Arroyo I have lived in Johnston County for 5 years. I am writing this letter to express support for Valleygate's Certificate of Need applications to establish licensed dental surgical centers in Cumberland County and Wake Counties.

Village Family Dental, a Valleygate affiliate, helped to build the dental care workforce in underserved communities in Eastern North Carolina, and has advocated for regulatory and other changes that help retain dentists, particularly pediatric dentists in our communities. My family is pleased with the care and their approach to helping families to understand how to maintain their teeth so they last the rest of their lives.

As you are probably aware, having dental surgery is stressful, particularly for children. It is also cumbersome to arrange in North Carolina. What Valleygate is proposing in its Certificate of Need application will be far more comfortable than a hospital, and will reduce the long delays.

☐ Eastern and Central North Carolina will be better off if Valleygate is awarded a Certificate of Need to establish a dental ambulatory surgical facility in Fayetteville.

☑ Fayetteville and Garner are both good locations for this service.

Additional Comments:

_____

_____

I sincerely urge the state of North Carolina to examine the strong merits of Vallegate's proposal, and grant its approval as quickly as possible.

Sincerely,

Giovanna Arroyo

Signature

Giovanna Arroyo

Print Name

Address 505 Lake View Dr Clayton NC

5 24, 2016

Ms. Martha Frisone, Assistant Chief
Certificate of Need Section
Division of Health Services Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699

Re: Community support letter for Valleygate Dental Surgical Center's Certificate of Need applications to develop dental specialty surgical centers in Cumberland and Wake Counties

Dear Ms. Frisone:

My name is Jessica Thompson. I have lived in Harnett County for 31 years. I am writing this letter to express support for Valleygate's Certificate of Need applications to establish licensed dental surgical centers in Cumberland County and Wake Counties.

Village Family Dental, a Valleygate affiliate, helped to build the dental care workforce in underserved communities in Eastern North Carolina, and has advocated for regulatory and other changes that help retain dentists, particularly pediatric dentists in our communities. My family is pleased with the care and their approach to helping families to understand how to maintain their teeth so they last the rest of their lives.

As you are probably aware, having dental surgery is stressful, particularly for children. It is also cumbersome to arrange in North Carolina. What Valleygate is proposing in its Certificate of Need application will be far more comfortable than a hospital, and will reduce the long delays.

☑ Eastern and Central North Carolina will be better off if Valleygate is awarded a Certificate of Need to establish a dental ambulatory surgical facility in Fayetteville.

☐ Fayetteville and Garner are both good locations for this service.

Additional Comments:

I sincerely urge the state of North Carolina to examine the strong merits of Vallegate's proposal, and grant its approval as quickly as possible.

Sincerely,

Jessica Thompson
Signature

Jessica Thompson
Print Name

Address 1758 Lane Rd Dunn NC 28334

05 24, 2016

Ms. Martha Frisone, Assistant Chief
Certificate of Need Section
Division of Health Services Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699

Re: Community support letter for Valleygate Dental Surgical Center's Certificate of Need applications to develop dental specialty surgical centers in Cumberland and Wake Counties

Dear Ms. Frisone:

My name is Gloria Quick. I have lived in Harnett County for 12 years. I am writing this letter to express support for Valleygate's Certificate of Need applications to establish licensed dental surgical centers in Cumberland County and Wake Counties.

Village Family Dental, a Valleygate affiliate, helped to build the dental care workforce in underserved communities in Eastern North Carolina, and has advocated for regulatory and other changes that help retain dentists, particularly pediatric dentists in our communities. My family is pleased with the care and their approach to helping families to understand how to maintain their teeth so they last the rest of their lives.

As you are probably aware, having dental surgery is stressful, particularly for children. It is also cumbersome to arrange in North Carolina. What Valleygate is proposing in its Certificate of Need application will be far more comfortable than a hospital, and will reduce the long delays.

☑ Eastern and Central North Carolina will be better off if Valleygate is awarded a Certificate of Need to establish a dental ambulatory surgical facility in Fayetteville.

☑ Fayetteville and Garner are both good locations for this service.

Additional Comments:

I sincerely urge the state of North Carolina to examine the strong merits of Vallegate's proposal, and grant its approval as quickly as possible.

Sincerely,

Gloria Quick
Signature

Gloria Quick
Print Name

Address 400 Forever lane
Coats, Nc, 27521

Attachment H

Additional Letters of Support: Community and Dentists

North Carolina Department of Health and Human Services
Division of Medical Assistance

Pat McCrory
Governor

Richard O. Brajer
Secretary

Dave Richard
Deputy Secretary for Medical Assistance

May 11, 2016

Ms. Martha Frisone, Assistant Chief
Healthcare Planning and Certificate of Need Section
North Carolina Division of Facilities Services
809 Ruggles Drive
Raleigh, NC 27603

Re: Valleygate Dental Surgery Centers, 2016 CON Applications for Demonstration Dental Ambulatory Surgical Centers

Dear Ms. Frisone:

As Dental Officer for the North Carolina Division of Medical Assistance (DMA), I would like to express my support for the Certificate of Need (CON) demonstration project applications for freestanding dental specific ambulatory surgical centers (ASC) in the Garner, Fayetteville, Charlotte and Triad regions.

I am familiar with the leadership team of the applicants, Valleygate Dental Surgical Centers. They are active participants in the NC Medicaid and Health Choice dental programs, and long term advocates for DMA's beneficiaries. The dental professionals at Knowles, Smith & Associates, LLP are enrolled Medicaid providers in good standing and have provided quality dental care, including surgical and pediatric care, to disadvantaged Medicaid/CHIP beneficiaries for decades. My past interaction with the leadership team at Valleygate gives me confidence that they will follow through on their commitment to improving the health status of underserved patients throughout North Carolina in this CON demonstration initiative.

Valleygate representatives met with the DMA leadership team to discuss development of four freestanding dental-only surgical centers. I am aware that their proposed centers will be designed around the needs of pediatric and special needs adults, who face barriers to accessing timely dental care in this state. DMA strongly supports development of these facilities. Our agency believes that the initiative should help us achieve cost predictability and stabilization in the Medicaid budget, as well as improve access for our beneficiaries.

Valleygate' s dedication to high quality care is exemplified by their plans to adhere to state and federal regulations governing ambulatory surgery centers, their commitment to adhere to NC Board of Dental Examiners' requirements, and their plans to meet third-party accreditation rules. DMA believes that this project will promote cost effective approaches, expand access to health care services for the medically

underserved, and encourage quality health care services and increase availability of certified ambulatory surgical facilities equipped to render deep sedation/anesthesia services for dental surgical care.
I wish to convey my enthusiastic support and that of my DMA colleagues for this project. I believe that the Valleygate Dental Surgical Center applications merit careful consideration. Their leadership has worked with the Division on problems of access in underserved areas and has consistently delivered quality in all of its endeavors.

Please contact me should you have any questions or concerns regarding this letter of support.

Sincerely,

Mark W. Casey DDS, MPH

Mark W, Casey, DDS. MPH
DMA Dental Officer

PROVIDER SUPPORT

May 16, 2016

Ms. Virginia Jones
Chief Operating Officer
Knowles, Smith and Associates
2015 Valleygate Drive
Fayetteville, NC 28304

RE: Letter in support of proposed dental ambulatory surgery center operated by Knowles, Smith and Associates in Wake County

Dear Ms. Jones,

I am writing this letter to express support for the certificate of need application to develop a freestanding ambulatory surgery center in Wake County dedicated to the provision of dental procedures for patients requiring sedation.

The dedicated dental ambulatory surgery center in Garner will expand access for patients of area dentists and oral surgeons by offering dental surgery, under either conscious sedation or general anesthesia, in a safe outpatient setting. Too often, children in the region must wait months for available operating room slots at existing hospitals or surgery centers. The proposed dental ASC will significantly reduce these delays. It will be good for the community and will have a huge impact on the health and well-being of residents of the region, particularly children. Moreover, it will allow area dentists to practice efficiently and maximize their ability to serve dental needs of all age groups.

I am an Endodontist, practicing in Cumberland County.

(•) I fully support the proposed center and I will refer patients to the dentists who use the facility, approximately 15 per month

☐ I fully support the proposed center and am interested in becoming an investor/ owner

☐ I fully support the proposed center and expect to perform _____ cases there a month, once the facility is operational.

- ☐ I or my group currently has active staff privileges at_____ hospital
- ☐ If so permitted by NC law and hospital by-laws, I commit to pursuing hospital staff privileges and assisting with ED dental coverage with at least one hospital in the area.

Insert personal comments as needed about need/current barriers, service to low-income populations, and benefits of the ASC.

This is an excellent proposal for a much needed service. Knowles, Smith and Associates has a long-standing reputation for quality dental care and as a community partner. I urge the Division of Health Service Regulation to approve their application.

Sincerely,

Signature Hal I. Coe, Jr.

(Print name and address)
Name: Dr. Hal I. Coe, Jr. Address: 1312 Avon Street : Fayetteville, NC 28304

NCCHCA
Serving Community & Migrant Health Centers

North Carolina Community Health Center Association

4917 Waters Edge Drive, Suite 165, Raleigh, NC 27606-2459 (919) 469-5701 Fax: (919) 469-1263 www.ncchca.org

May 5, 2016

Ms. Martha Frisone, Assistant Chief
Health Planning and Certificate of Need Section
North Carolina Division of Facilities Services
701 Barbour Dr.
Raleigh, NC 27603

Re: Valleygate Dental Surgical Centers
CON Application for the Dental Surgery Demonstration Ambulatory Surgical Center
May 1, 2016 and July 1, 2016 Review Periods

Dear Ms. Frisone:

The North Carolina Community Health Center Association (NCCHCA) would like to express its support for the CON Application submitted by Valleygate Dental Surgical Centers (hereafter Valleygate) for freestanding dental only ambulatory surgical centers in the Raleigh, Fayetteville, Charlotte and Triad regions of the State. NCCHCA serves as the collective voice for North Carolina's 39 Federally Qualified Health Centers (FQHCs) and Look-alikes (LAs). FQHCs provide a patient-governed, patient-centered health care home that integrates high quality medical, dental, behavioral health, pharmacy, and enabling services without regard to a person's ability to pay. Federally Qualified Health Centers (aka Community Health Centers) are geographically dispersed across 74 counties and operate nearly 200 clinical sites. In 2014, North Carolina's FQHCs served nearly 457,000 patients. Nearly 50% of these patients are uninsured for medical and dental care. Our dentists routinely experience difficulty referring patients in need of dental procedures which require sedation or general anesthesia.

Representatives of Valleygate met with NCCHCA to discuss the development of a freestanding dental only surgical centers across the State to improve access to dental surgical care for residents of North Carolina, including the needs of the Medicaid and uninsured population with whom we work. We strongly support the development of these facilities.

Valleygate's commitment to high quality care is exemplified by credentialing dentists using the centers and providing Board Certified Anesthesiologists and Certified Registered Nurse Anesthetists in the operatory during procedures. Their model promotes cost-effectiveness and expands access to the medically underserved. They have committed to ensuring that patients without medical and dental homes are referred into Community Health Centers for on-going care.

Please convey my enthusiastic support for the Valleygate proposal to the Certificate of Need Section at the North Carolina Division of Health Services Regulation.

Sincerely,

E. Benjamin Money
CEO and President
North Carolina Community Health Center Association

East Carolina University
Tomorrow starts here.

School of Dental Medicine
Ledyard E. Ross Hall
1851 MacGregor Downs Road
Mail Stop 701
East Carolina University
Greenville, NC 27834-4354

252-737-7000 office
252-737-7049 fax
www.ecu.edu/dental

May 25, 2016

Ms. Martha Frisone, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Dear Ms. Frisone:

On behalf of East Carolina University (ECU) School of Dental Medicine, I am offering strong support for the Division of Health Services Regulation to develop four dental-only ambulatory surgical centers in North Carolina. I understand that one will be located in Eastern North Carolina. The ECU School of Dental Medicine has Community Service Learning Centers in Robeson and Harnett Counties as part of our mission to provide care in rural and underserved areas of North Carolina. A dental-only surgical center could have tremendous value to the area's vulnerable populations, as well as to the School's mission. We are particularly concerned about vulnerable populations, like children and adults who have developmental disabilities, many of whom require extensive restorative and/or oral surgery procedures. Similarly, adults and children with anxiety or behavioral issues who require moderate or deep sedation as part of their overall dental treatment would also benefit from such a center.

From a dental education standpoint, I appreciate how a local ambulatory surgical center could provide both pre-doctoral students and Advanced Education in General Dentistry Residents with rich community-based clinical learning experiences. The centers present an opportunity for them to work with properly credentialed faculty in providing care to unique at-risk patients under moderate sedation and general anesthesia. We feel with such experience, they will be more likely to pursue sedation credentialing after graduation and/or treat vulnerable and complex patients under sedation when they are in practice. The ECU School of Dental Medicine plans to start enrollment for our Advanced Specialty Education Program in Pediatric Dentistry in late summer 2016. As our programs grow, it will be important to have locations around the state where graduates can practice.

Representatives of Valleygate and other centers have described to us their plans to compete for the privilege of starting ambulatory surgical centers. The ECU School of Dental Medicine would like to work with any approved centers to provide educational experiences for our residents and students, as well as care for our patients.

In summary, we believe there is a significant and growing need for the demonstration centers and are very supportive of your office issuing a Certificate of Need.

Sincerely,

D. Gregory Chadwick, DDS, MS
Dean

Attachment I

List of SCDPR Referring Dentists and Sedation Permit Status

List of SCDP of Raleigh Users with Projected Volumes, Sedation Permit Status and Dental Board Specialty Type

Name	County	Specialty (from Exhibit 29)	Specialty (from Dental Board)	Monthly		Annual		Sedation Permit (Y/N)
				Low	High	Low	High	
Allen Acton	Wake	General	General Practice	0	5	0	60	N
Tarun Agarwal	Wake	General	General Practice	5	5	60	60	Y
Tanya E. Ashe	Durham	General	General Practice	2	2	24	24	N
Jennifer Bell	Wake	General	General Practice	4	4	48	48	N
Debora Bolton	Durham	General	General Practice	2	2	24	24	N
Richard Brooks	Wake	Pediatric	Pediatric Dentistry	3	3	36	36	N
Brian Cahill	Durham	General	General Practice	3	5	36	60	N
Chad Edward Ceremuga	Wake	General	General Practice	2	2	24	24	Y
Ritu Chandak	Wake	Pediatric	Pediatric Dentistry	3	3	36	36	Y
Josiah Chen	Wake	General	General Practice	1	1	12	12	Y
Robin Reese Croswell	Wake	Pediatric	Pediatric Dentistry	8	10	96	120	N
William Joshua Daily	Wake	General	General Practice	4	4	48	48	N
Christi Davis	Wake	Pediatric	Pediatric Dentistry	20	20	240	240	N
Olen Ben Davis	Wake	Pediatric	Pediatric Dentistry	8	8	96	96	N
William Alex Drake	Granville	General	General Practice	2	3	24	36	Y
Daniel Wayne Driskill	Wake	General	General Practice	4	12	48	144	N
Huyen-Chau Dunn	Wake	Oral Surgeon	Oral Surgery	1	2	12	24	Y
Sammuel R. Emrich	Wake	General	General Practice	4	5	48	60	N
Kenneth E. Evins	Granville	General	General Practice	6	6	72	72	N
Angelina Carol Franklin	Wake	General	General Practice	1	1	12	12	N
Rawley Fuller	Alamance	General	General Practice	2	4	24	48	N
Manisha N. Ghodke	Wake	General	General Practice	0	3	0	36	N
Kara Henderson	Warren	General	General Practice	5	10	60	120	N
Travis Hicks	Wake	Pediatric	Pediatric Dentistry	6	10	72	120	N
Robert Hollowell	Wake	Pediatric	Pediatric Dentistry	5	5	60	60	Y
Anthony Horalek	Wake	Endodontist	Endodontics	4	4	48	48	Y
Burton Horwitz	Johnston	Pediatric	Pediatric Dentistry	6	10	72	120	N
Andrek Jeffery Ingersoll	Wake	General	General Practice	10	10	120	120	Y
Laree Johnson	Wake	Pediatric	Pediatric Dentistry	15	15	180	180	Y
Martha Ann Keels	Durham	Pediatric	Pediatric Dentistry	6	6	72	72	Y
Brandon Dale Kofford	Wake	General	Prosthodontics	1	1	12	12	N

David Kornstein	Wake	Pediatric	Pediatric Dentistry	15	15	180	180	Y
Jin Yi Kwon	Orange	General	General Practice	4	4	48	48	N
Christine D. Laster	Wake	General	General Practice	1	1	12	12	N
Laszlo Ledenyi	Johnston	Pediatric	Pediatric Dentistry	6	6	72	72	N
Folden Lee	Johnston	General	General Practice	5	5	60	60	N
Angel Lopez	Durham	Oral Surgeon	General Practice	8	8	96	96	Y
Siti Aisha Lowrey	Wake	General	General Practice	1	2	12	24	N
Matthew McNutt	Wake	Orthodontist	Orthodontics	4	6	48	72	N
Ralph Mensah	Alamance	General	General Practice	5	5	60	60	N
Robert Moran. Jr.	Wake	Pediatric	Pediatric Dentistry	6	10	72	120	N
Larry J. Moray	Wake	Orthodontist	Orthodontics	25	25	300	300	N
Clark Morris	Wake	Pediatric	General Practice	15	15	180	180	Y
Paresh Naran	Wake	General	General Practice	1	2	12	24	Y
Derrick Cortney Nelson	Caswell	General	General Practice	4	4	48	48	N
David Douglas Olson	Wake	Pediatric	Pediatric Dentistry	5	5	60	60	Y
Shelley Barker Olson	Granville	General	General Practice	1	1	12	12	N
Amit Patel	Wake	General	General Practice	5	5	60	60	N
Christopher Matthew Pennisi	Wake	General	General Practice	1	1	12	12	N
Allen S Porter	Wake	Pediatric	Pediatric Dentistry	5	5	60	60	N
Stephen Pretzer	Wake	Pediatric	Pediatric Dentistry	6	6	72	72	N
Kamran Qureshy	Wake	General	General Practice	5	5	60	60	Y
Michael Riccobene	Wake	General	General Practice	10	20	120	240	Y
Theresa Robinson	Orange	General	General Practice	10	12	120	144	Y
David Slawinsky	Wake	Pediatric	Pediatric Dentistry	10	10	120	120	Y
Jacob Smith	Wake	General	General Practice	2	2	24	24	Y
Thomas Steet	Wake	General	General Practice	5	5	60	60	N
Barton D. Swarr	Wake	Pediatric	Pediatric Dentistry	2	2	24	24	N
Rebecca S. Tate	Durham	General	General Practice	1	4	12	48	N
DeWayne Taylor	Wake	General	General Practice	2	2	24	24	N
Eric James Wagoner	Halifax	General	General Practice	4	4	48	48	N
Mark Wainwright	Wake	General	General Practice	2	2	24	24	Y
Zhengyan Wang	Durham	Pediatric	General Practice	1	2	12	24	N
Tracy Waters	Durham	General	General Practice	8	8	96	96	N
Anita Jones Wells	Wake	General	General Practice	2	2	24	24	N

Brigette Wesley	Durham	General	General Practice	10	10	120	120	N
Michael Craig Williams	Wake	General	General Practice	1	1	12	12	N
Robert Wright	Orange	Prosthodontics	Prosthodontics	3	4	36	48	N
Mark A. Zubick	Moore	General	General Practice	3	3	36	36	N
Carrboro Community Health Center	Orange	??	??	50	50	600	600	??
Moncure Community Health Center	Chatham	??	??	50	50	600	600	??
Prospect Hill Community Health Center	Caswell	??	??	50	50	600	600	??
Siler City Community Health	Chatham	??	??	50	50	600	600	??
Total: Dentists w/ Sedation Permits or Pediatric Dentists				**137**	**152**	**1,644**	**1,824**	**36**
Total: Dentists w/o Sedation Permits				**210**	**258**	**2,520**	**3,096**	**33**
Grand Total				**547**	**610**	**6,564**	**7,320**	**69**

Source: SCDP of Raleigh Exhibit 29; License Data Obtained from the NC Dental Board

Attachment J

POMS Summary of Anesthesia Measures

Anesthesia

Several methods of anesthesia are available. The method of anesthesia that is chosen for or by a patient depends upon the nature of the surgical procedure and the patient's level of apprehension. The following table illustrates the choices of anesthesia, a description of the anesthetic technique, and the usual indications for that technique.

Method of Anesthesia	Description of Technique	Usual Indications
Local Anesthetic	The patient remains totally conscious throughout the procedure. A local anesthetic (e.g. lidocaine) is administered in the area where the surgery is to be performed. Local anesthetic is used in conjunction with the other methods of anesthesia in all oral surgery procedures.	Simple oral surgery procedures such as minor soft tissue procedures and basic tooth extractions. Patients may elect to have wisdom teeth removed with local anesthetic.
Nitrous Oxide Sedation with Local Anesthetic	A mixture of nitrous oxide (laughing gas) and oxygen is administered through a nasal breathing apparatus. The patient remains conscious in a relaxed condition. Nitrous oxide has a sedative and analgesic (pain-controlling) effect.	Simple oral surgery procedures to more involved procedures such as removal of wisdom teeth and placement of dental implants.
Office Based Intravenous Anesthesia with Local Anesthetic*	Medications are administered through an intravenous line (I.V.). The patient falls asleep and is completely unaware of the procedure being performed. Medications most commonly used are Fentanyl (opiate), Versed (benzodiazepine), Ketamine, and Diprivan. Supplemental oxygen is delivered through a nasal breathing apparatus and the patient's vital signs are closely monitored.	Intravenous anesthesia includes I.V. sedation and general anesthesia for all types of oral surgery. A patient may choose intravenous anesthesia for simple procedures depending on their level of anxiety. Most people having their wisdom teeth removed or having a dental implant placed will choose intravenous anesthesia. General anesthesia and/or I.V. sedation may be necessary if local anesthesia fails to anesthetize the surgical site which often occurs in the presence of infection.
Hospital or Surgery Center Based General Anesthesia	A patient is admitted to a hospital or surgery center where anesthesia is administered by an anesthesiologist.	Indicated for patients undergoing extensive procedures such as face and jaw reconstruction and TMJ surgery. Also indicated for patients with medical conditions such as heart disease or lung disease who require general anesthesia.

*To administer general anesthesia in the office, an oral surgeon must have completed at least three months of hospital based anesthesia training. Qualified applicants will then undergo an in office evaluation by a state dental board appointed examiner. The examiner observes an actual surgical procedure during which general anesthesia is administered to the patient. The examiner also inspects all monitoring devices and emergency equipment and tests the doctor and the surgical staff on anesthesia related emergencies. If the examiner reports successful completion of the evaluation process, the state dental board will issue the doctor a license to perform general anesthesia. The license is renewable every two years if the doctor maintains the required

amount of continuing education units related to anesthesia.

Again, when it comes to anesthesia, our first priority is the patient's comfort and safety. If you have any concerns regarding the type of anesthesia that will be administered during your oral surgery procedure, please do not hesitate to discuss your concerns with your doctor at the time of your consultation.

Intravenous Sedation ("Twilight Sedation")

Oral and Maxillofacial Surgery offices offer their patients the option of Intravenous Sedation or Dental Intravenous Anesthesia or to some it is referred to as "Twilight Sedation" for their dental treatment. Intravenous Sedation or "twilight sleep" helps you to be comfortable and calm when undergoing dental procedures. Your treatment can be completed under intravenous sedation. Intravenous sedation or "IV sedation" (twilight sedation) is designed to better enable you to undergo your dental procedures while you are very relaxed; it will enable you to tolerate as well as not remember those procedures that may be very uncomfortable for you. IV sedation will essentially help alleviate the anxiety associated with your treatment. You may not always be asleep but you will be comfortable, calm and relaxed, drifting in and out of sleep – a "twilight sleep".

If you choose the option of intravenous sedation your IV sedation/anesthesia is administered and monitored by your Oral Surgeon therefore eliminating the costly expense of having your treatment carried out in an operating room or same day surgical facility.

How is the IV Sedation Administered?

A thin needle will be introduced into a vein in your arm or hand. The needle will be attached to an intravenous tube through which medication will be given to help you relax and feel comfortable. At times a patient's vein may not be maintainable, in these situations the medications will be administered and the needle retrieved - both scenarios will achieve the same desired level of conscious sedation. Once again some patients may be asleep while others will slip in and out of sleep. Some patients with medical conditions and/or on specific drug regimens may only be lightly sedated and may not sleep at all.

The goal of IV sedation is to use as little medication as possible to get the treatment completed. It is very safe, much safer than oral sedation. With IV sedation a constant "drip" is maintained via the intravenous tube. At any time an antidote can be administered to reverse the effects of the medications if necessary. Along with IV sedation there are also other different "levels" of sedation available to you in our office. There is nitrous oxide analgesia.

Sedation Dentistry for the Elderly

As we age, our oral health becomes more important than ever. Periodontal disease can lead to bone and tooth loss, which affects nearly every part of our daily lives. To lead full and active lives, we need our teeth and gums. They allow us enjoy food, support speech and good conversation, and facilitate digestion. Your Oral Surgeon is dedicated to treating elderly patients with care and commitment to comfort and health.

Elderly patients as a group tend to avoid dental visits for a variety of reasons, including: more pressing medical concerns, anxiety about treatment, the hardship of transportation, or fixed incomes. Once their oral health has reached an unmanageable point, fear and embarrassment further keep these patients away from the dentist.

For elderly patients embarrassed or fearful of their current oral state, sedation dentistry provides the opportunity for your Oral Surgeon to treat these conditions while the patient remains relaxed and unaware until "awaking" to an improved oral state!

Sedation Dentistry for the Disabled

It may be especially difficult for people with disabilities to obtain access to proper dental care. They must find a dentist who is skilled and compassionate, and who can provide services for which some dentists may not be qualified. Your Oral Surgeon provides the expertise, state-of-the-art-equipment, and dedication to assisting special-needs patients necessary to ensuring great oral care for our patients.

Disabled patients may face added challenges in maintaining their oral health. Their disability may make it difficult to brush or floss regularly; they may also suffer a severe gag reflux, or dry mouth as a result of medication. Your Oral Surgeon meets these challenges with sedation dentistry for the disabled. He/she is skilled in anesthesia for special-needs patients, and can ease the fear associated with out-of-control oral hygiene with one visit.

Sedation Dentistry for the Fearful

Dental phobia is a real, often overwhelming reality for thousands of people. Negative previous dental

experiences, fear of needles or drills, and severe gag refluxes are just some of the reasons people feel extreme anxiety when thinking about visiting the dentist.

If you suffer from dental phobia- fear no more! Your Oral Surgeon is committed to understanding the very real nature of your fears. Not only will our staff treat you with delicacy and care, but IV sedation will allow you to experience dentistry in a whole new way. While engaging in a pleasant sleeplike experience, your Oral Surgeon will be hard at work making sure you "wake up" with the results you desire.

Nitrous Oxide (Laughing Gas)

Nitrous Oxide is a sweet smelling, non irritating, colorless gas which you can breathe. Nitrous Oxide has been the primary means of sedation in dentistry for many years. Nitrous oxide is safe; the patient receives 50-70% oxygen with no less than 30% nitrous oxide. Patients are able to breathe on their own and remain in control of all bodily functions. The patient may experience mild amnesia and may fall asleep not remembering all of what happened during their appointment.

There are many advantages to using Nitrous Oxide

- The depth of sedation can be altered at any time to increase or decrease sedation.
- There is no after effect such as a "hangover".
- Inhalation sedation is safe with no side effects on your heart and lungs, etc.
- Inhalation sedation is very effective in minimizing gagging.
- It works rapidly as it reaches the brain within 20 seconds. In as few as 2-3 minutes its relaxation and pain killing properties develop.

Reasons to not use Nitrous Oxide

Though there are no major contraindications to using nitrous oxide, you may not want to use it if you have emphysema, exotic chest problems, M.S., a cold or other difficulties with breathing. You may want to ask your dentist for a "5 minute trial" to see how you feel with this type of sedation method before proceeding.

Cancel