Valleygate Dental
SURGERY CENTERS

DELIVERED VIA EMAIL 8/1/2016

August 1, 2016

Valleygate Dental Surgery Centers
2015 Valleygate Drive
Fayetteville, NC 28304

Ms. Lisa Pittman, Project Analyst
Ms. Bernetta Thorne-Williams, 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 Region 4, Health Service Areas I and II; CON Project ID Numbers:

B-011196-16, Surgical Center for Dental Professionals of Asheville
G-011203-16 Valleygate Dental Surgery Center of the Triad

Dear Ms. Pittman and Ms. Thorne-Williams,

On behalf of Valleygate Dental Surgery Center of the Triad, Project ID G-011203-16, thank you for the opportunity to comment on the above referenced applications to develop a Demonstration Dental Ambulatory Surgical Facility in Project Region 4.

CONTEXT

Competing Applications Propose Very Different Service Areas

Two applicants responded to the need identified in the *2016 State Medical Facilities Plan* for one single specialty dental ambulatory surgical facility in Region 4. Because the Plan and statute permit only one award, the decision will have a significant impact on access across this region for years to come. The two applications offer different approaches to quality of dental services, cost of services, need for proposed services, access for underserved populations, and location. The State Health Coordinating Council recommended the Dental Single Specialty Ambulatory Surgical Facility Demonstration in response to petitions from Knowles, Smith, and Associates and Triangle Implant Center that documented the need for accessible operating rooms for surgical patients of dentists and oral surgeons. We believe that the application submitted by Valleygate Dental Surgery Center of the Triad ("Valleygate'), 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 Agency consider not only the standard metrics that have been used in past competitive reviews of operating room applications, but also to other critical factors that affect quality, value and access in this important demonstration project.

In particular, we ask the Agency to pay particular attention to the need for dental and oral surgery services in licensed ambulatory surgical facilities in the diverse geographies in Region 4. Region 4 spans 300+ miles - from Alamance to Cherokee County. For that reason, need in the applicant's proposed service area is a critical factor. The two competing applications propose to serve very different geographies. Valleygate's primary service area counties are Forsyth and Guilford; Surgical Center for Dental Professionals of Asheville (SCDPA) proposes Buncombe, Rutherford, and Haywood as primary counties. As is described in these comments and attachments, Valleygate's proposal to serve the eastern part of Region 4, effectively HSA II, will reach more persons in need. Moreover, pediatric dentists in the Asheville area indicated to Valleygate that access to operating rooms in that area is good. (See letter from Dan Knechtel in Valleygate Exhibit 18).

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's proposal from (SCDPA). SCDPA proposes to credential general dentists for its proposed facility, using its own credentialing system that does not require formal third party training. Valleygate proposes to credential *only* dentists and oral surgeons who demonstrate or possess third party credentials as evidence of training to operate on sedated and anesthetized patients, which Valleygate defines as having a NC sedation permit or having completed a hospital-based postgraduate residency or equivalent training. Many dentists do not pursue formal training in care for sedated or general anesthesia patients.

Furthermore, the proposed patient mix for Valleygate is quite different from the patient mix proposed for SCDPA. Valleygate proposes to care for patients who have more complex dental problems, recognized in one dimension by the difference in anesthesia levels[1]. As indicated in its application, SCDPA proposes to serve the types of patients currently treated efficiently and safely in dental and oral surgery offices. Valleygate proposes to accommodate only cases that truly warrant the services of a licensed surgical facility. Specifically, Valleygate relies on patient selection criteria set by external agencies like Medicaid and Blue Cross.

[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.

Another major difference in the two applications is anesthesia coverage. Although its narrative suggests that its facility will have a licensed physician anesthesiologist providing general anesthesia or sedation coverage for each procedure, the SCDPA application pro formas provide funding for slightly more than one FTE anesthesiologist to cover three rooms running simultaneously. It claims that funds are sufficient to cover an anesthesiologist present for each procedure and all required anesthesia equipment and equipment maintenance. However, data do not support this claim. By contrast, for approximately the same number of cases, Valleygate proposes funding for more than three FTE anesthesia professionals, enough to provide either an anesthesiologist or a Certified Registered Nurse Anesthetist (CRNA) present throughout all operating and procedure room cases. Valleygate capital costs include anesthesia machines for both operating rooms and procedure room. SCDPA does not identify these costs.

Valleygate proposes to serve primarily pediatric patients. SCDPA proposes that two thirds of its patients will be adults. North Carolina statutes make it exceptionally difficult for pediatric dentists to treat patients in hospitals, even though they are trained for hospital practice and the Joint Commission recognizes them as qualified to admit patients to hospitals. Oral surgeons, who serve primarily adults, do not face such a barrier. Moreover, young children are more likely candidates for anesthesia and sedation, because they are less able to tolerate long periods of being still for a complex procedure.

Also of note, SCDP, the parent company of SCDPA, distributed an Offering Memorandum to Investors on March 15, 2016, which outlined its business plan and investing opportunities. The Memorandum confirms many of the differences between Valleygate and SCDP, but also contradicts some of the material in the CON. For reference, Attachment B contains a comparison of key characteristics across each SCDP application and the Offering Memorandum.

SCDPA's Approach to Need Differs Starkly from Valleygate's

The SCDPA application suggests that cases like those currently performed in the oral surgery offices of the Triangle Implant Center ("TIC") should be shifted to a licensed ambulatory surgical facility. SCDPA does not explain why. Today, Triangle Implant Center involves MD anesthesiologists to provide sedation for office procedures. Payers reimburse for this practice under dental fee schedule rules. SCDPA would have these cases occur in a licensed surgical facility increase the fees collected by adding a facility fee. Because dental plans do not typically include facility fees, the dental ambulatory surgical facility would presumably bill under medical plans. The application presents only the owner's statements to support the case that all oral surgery under sedation should be done in a licensed ambulatory surgical facility.

The application also projects that SCDPA will serve pediatric and general dentistry patients in its ambulatory surgical facility, but fails to describe the need of the population to be served for either pediatric or general dentist cases in an ambulatory surgical facility.

In fact, the application states in Section III (p 98) *"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."* On page 24, SCDPA clearly indicates that it will serve pediatric patients. As a result, SCDPA's application is internally contradictory and does not adequately demonstrate the need of the population to be served for its proposed services. See detailed comments on Criterion 3 for SCDPA in Attachment A.

WHY APPROVE VALLEYGATE DENTAL SURGERY CENTER OF THE TRIAD

Competitive Overview

Based on competitive criteria alone, the Valleygate application is better. 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 comparatively superior in each of these four metrics. Moreover, with regard to two other important comparison metrics, Valleygate is also the preferable applicant. Table 1 below includes the two additional metrics:

1. Number of Pediatric Cases: As demonstrated in both the 2015 KSA petition and the Valleygate Region 4 CON application, noted in many of the letters accompanying both, and as echoed by oral surgeons and others who have reviewed these proposals, the needs of pediatric dental surgical patients are the primary driving factor justifying the demonstration projects. Therefore, applications proposing to serve a greater number of pediatric cases are better.
2. Physician/Dentist Ownership: Currently North Carolina law prohibits anyone other than a dentist licensed by the North Carolina Board of Dental Examiners to own a dental practice. Although there is no law restricting ownership of a dental only ambulatory surgical facility to a dentist, Valleygate believes projects that facilities that restrict ownership to dentists will have quality oversight, hence are better.

We believe that Tables 1 and 2 represent 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 provides scores and Table 2 provides the raw data. Both tell a complete story of Valleygate's superiority.

Table 1 - Comparison of Two Application using Suggested Comparison Criteria

Measure	Valleygate Dental Surgery Center of the Triad	Surgical Center for Dental Professionals of Asheville
Medicaid Eligible Children < 9 Receiving Dental Services in Primary Counties of Origin	1	0
Total % Medicare, Medicaid, Charity	1	0
Average Charity Write-Off	1	0
Total Value of Charity	1	0
Average Collections from Charity Patients	1	0
Physician/Dentist Ownership	1	0
Demonstration of Need (b)	1	0
Gross 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
Total	***11***	***0***

Comparison Metric Details

Table 2 shows the stark difference between the proposals. Important explanations or clarifications for the metrics follow the table.

Table 2 - Relative Score on Critical Value Measures

Notes	Measure	Year Two Values (a)	
		Valleygate Triad	SCDPA
a	Primary County Medicaid Eligible Children < 9 Who Received Dental Services in 2015	29,188	11,134
b	Medicare, Medicaid, and Charity as Percent of Total Cases	81.98%	56.20%
c	Average Charity Write-Off as Percent of Charge	96%	60%
d	Total Value of Charity	$168,556	$133,842
e	Average Collections from Charity	$75	$783
f	Physician/Dentist Ownership	100.0%	22.7%
g	Demonstration of Need	See Comments	See Comments
h	Gross Revenue per Case	$1,680	$1,958
i	Total Revenue per Case	$889	$1,309
j	Total Expense per Case	$782	$1,096
k	Number of Pediatric Cases (Under 21)	2,596	880
l	***Total Cases***	***2,771***	***2,710***

Notes:

a. This is the only metric that is not solely from Year Two. Valleygate primary counties, Forsyth and Guilford, represent 53.1 percent of its proposed patient origin (page 117). SCDPA primary counties, Buncombe, Rutherford, Haywood, represent 55.2 percent of SCDPA's proposed patient origin (page 133). These data are for those primary counties and were obtained from the North Carolina Division of Medical Assistance (see raw data in Valleygate application, Exhibit 19).

b. Based on information for payer mix provided in Section VI in each application.

c. Write-off = (Average. Self-Pay Gross Rev (FORM D) – Average. Self-Pay Net Rev (FORM E)) / Average. Self-Pay Gross Rev. (FORM D).

Valleygate Write-off = ($1,701 - $75) / $1,701 = ***96%****.*

SCDPA Write-off = ($1,960 - $784) / $1,960 = ***60%****.*

d. Based on information for charity care provided in Section VI in each application.

e. FORM E, both applications

f. Based on information for ownership provided in Section I of both applications. SCDPA did not specify who will own uncommitted shares of the company dentists or others. Thus, one cannot assume its owners will be dentists or physicians.

g. See comments above regarding need.

h. FORM B, both applications. Total Gross Revenue divided by projected number of cases.

i. SCDPA included some revenue in "Other Revenue" in FORM B/C, including crowns, fixtures, and x-rays. The Agency has historically used the metric, Net Patient Revenue, as a comparative metric. However, in this case, "Other Revenue" in SCDPA's application represents patient revenues, Total Revenue per Procedure would produce a better comparison. Regardless, Valleygate is lower on both metrics.

j. The calculated total Expense per Case for SCDPA is $1,096. However, the amount is understated. SCDPA pro forma expenses are inadequate for its proposed anesthesiologist coverage. The application either drastically understated costs or the applicant did not intend that every case would have MD anesthesiologist coverage, as is suggested in the application. If anesthesiologist coverage were increased to match the amount necessary to provide three operating/procedure rooms in SCDPA with an anesthesiologist, the additional expense could be $755,820 in Year Two, or $279 per procedure ($755,820 / 2,710 procedures = $279 per patient). This would increase the Total Expense per Procedure from $1,096, as presented in the application, to $1,375 ($1,096 + $279 = $1,375). For detailed calculations, see comments on Criterion 5 in Attachment A.

k. Valleygate cases under 21 provided on page 180 of its application. SCDPA projected cases under 21 provided on page 149 of its application.

l. Application Section IV

Non-Conforming SCDPR Application

The application submitted by SCDPA 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 regarding SCDPA and SCDP's other application, many of whom recognize that SCDP's proposals have the potential to substantially, and unnecessarily, increase costs to Medicaid and to the health care delivery system in general.

Regardless of a lower comparative rating than Valleygate, the Agency should deny SCDPA's application. The application should be found non-conforming with Criterion 1, 3, 5, 7, 8, 12, 13c, and 18a. We believe the CON Section should pay particular attention to these review criteria and to SCDPA's pro forma assumptions. For example, its assumption that all dental and oral surgery procedures under sedation would be reimbursed an ambulatory surgical facility "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 demonstration dental-only surgery center certificate of need should not be awarded to the Surgical Center for Dental Professionals of Asheville, 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 the Triad should be approved. Unlike the application filed by Surgical Center for Dental Professionals of Asheville, Valleygate's application:

- Conforms to all the statutory review criteria;
- Proposes to grant privileges only to dentists who have undergone residency or other extensive

training in anesthesia/sedation by a qualified third party;

- Provides sufficient funding for 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 surgical facility;
- Would save patients, payer, and taxpayer dollars by proposing to move surgical procedures from hospitals to a more cost effective ambulatory surgical facility 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; and
- Proposes the most cost effective solution to improving access to operating rooms for dentists, oral surgeons, and their patients

We have included excerpts from the SCDP investor Offering Memorandum, as well as additional letters of support for the Agency's convenience. In addition, we have included a copy of a resolution adopted by Greensboro City Council in support of Valleygate's proposal. 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

ATTACHMENTS

Attachment A

Competitive Review of –
Surgical Center for Dental Professionals of Asheville,
Application for Dental Ambulatory Surgery Center
Project ID# B-011196-16

Competitive Review of – Surgical Center for Dental Professionals of Asheville, Application for Dental Ambulatory Surgery Center Project ID# B-011196-16

OVERVIEW

The Surgical Center for Dental Professionals of Asheville (SCDPA) application to open a dental ambulatory surgery center in Asheville, NC is non-conforming with GS 131E-183(a) CON statutory review criteria: 1, 3, 5, 7, 8, 12, 13c, and 18a. Additionally, the project does not conform with Criterion 1 and 11 of the Dental Single Specialty Ambulatory Surgical Facility Demonstration Project criteria.

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.

SINGLE SPECIALTY DENTAL AMBULATORY SURGERY CENTER DEMONSTRATION PROJECT CRITERIA

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

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 and accompanying narrative in Section I of the application provides percentage ownership for eight doctors, and "Initial Facility Dental Directors." The application does not identify which of the doctors are dentists or oral surgeons, clearly not stating the percentage ownership in the facility by each oral surgeon and dentists. The application indicates some oral surgeons and dentists' ownership interests, but alludes to others. It includes a 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.

SCDPA Does Not Demonstrate That It Will Reasonably Perform 900 Surgical Cases Per Operating Room

Criterion 11 states: *"The proposed facility shall demonstrate that it will perform at least 900 surgical cases per operating room during the third fiscal year of operation. The performance standards in 10A 14C.2103 would not be applicable."*

SCDPA does not demonstrate 900 cases per operating room. The only distinction SCPDA makes between the operating rooms and procedure rooms is to suggest that if special requests for specific rooms are made, those requests are *"likely to be for one of the operating rooms"* (SCDPA App, page 119). Other than a fixed microscope, which will be in one of the *procedure* rooms, the application makes no clinical distinction between the two types of rooms. In fact, the application states on page 199 that most of the procedures in the facility can go in either room type. As a result, SCDPA's assumption that the operating rooms will receive more cases than the procedure rooms is unsupported. It is likely that cases spread evenly among all four rooms. SCDPA proposes 3,012 cases in year three, which is 753 cases per room, and 753 cases per operating room does not meet Demonstration Project Review Criterion 11.

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, SCDPA proposes to provide access to all licensed dentists, regardless of whether they have a completed a hospital-based residency program, have sedation or anesthesia permits from the North Carolina State Board of Dental Examiners, or have other third party training for anesthesia. The SCDPA application states on page 20, *"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."*

Exhibit 29 of the SCDPA application shows that only three dentists, all general dentists, propose to bring cases the facility. Not one of the three general dentists have NC Board of Dental Examiners credentials to provide sedation or anesthesia; and none are 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. SCDP's "solution" revolves around providing MD anesthesiologists for every case, although as will be described, SCDPA does not budget enough anesthesiologists to provide an anesthesiologist in the room during every procedure.

None of these three dentists has completed a post-graduate hospital-based residency program, such as required for oral surgeons and pediatric dentists. All postgraduate programs that teach treatment of patients under general anesthesia also provide supervised experience in the surgery environment, and an extensive knowledge of the multitude of possible medical and physical problems that are associated with sedation dentistry. All of these training programs recognize that administration of general anesthesia is only one issue. The programs also place *significant emphasis* on medical diagnosis and the importance of patient selection when determining if a patient is fit to undergo anesthesia/sedation. Not only are general dentists without sedation permits legally unable to administer sedation or anesthesia themselves, they do not possess the necessary training or experience to know when a patient is clinically fit to be sedated, or anesthetized, even if the sedation is administered by another practitioner. SCDPA does not budget for, design for, or propose that an anesthesiologist will pre-certify all patients of general dentists.

Table 1 - Sedation Permit Status

Name	Permit Status
Myron L. Gottfried	None
Jeffrey A. Loftin	None
Bartel Van Oostendorp	None

Source: NC Dental Board June 2016

SCDPA's proposal appears to create a potentially dangerous clinical situation. The application proposes to recruit dentists who have no previous experience with selecting patients for treatment under general anesthesia or sedation, or experience/training in treating patients under anesthesia, and encouraging them to do so. SCDPA provides no evidence that NC Licensure Section, Joint Commission or AAAHC would certify such an unusual arrangement. Valleygate believes that, at minimum, dentists should hold sedation permits with the NC Board of Dental Examiners or have completed a post-graduate residency program that included operating room training in order to treat patients under general anesthesia. The NC Board of Dental Examiners requires minimum levels of clinical training in order to issue a sedation or anesthesia permit. Further, the Board recognizes that sedation treatment modalities encompass not only operative care but also the pre and post-operative care.

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

1. **Hospital Credentialing Policies.** SCDPA 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. SCDPA suggests hospital bylaws discriminate against general dentists by specifically denying them hospital privileges. This is a misrepresentation of the facts. The application provided no evidence that hospital bylaws discriminate against any particular type of dentist. By-laws often require that any dentist who seeks to perform surgery in hospital operating rooms have 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 that meet typical hospital credentialing standards. For example, Cape Fear Valley Health System requires that dentists meet the 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. Because general anesthesia and surgery are involved, a dental ambulatory surgical facility should meet equivalent standards of safety.

Attachment C contains these two hospital policies.

2. **North Carolina Regulations.** Current North Carolina regulations allow dentists to treat patients under sedation or anesthesia if 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 dentists to treat patients while a CRNA provides sedation, unless the dentist has a license to provide the type of sedation the CRNA is providing. 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 and nitrous oxide…"*

   This suggests the North Carolina Dental Board is very conscious of the need for a well-qualified team for the safe conduct of sedation, and by extrapolation, general anesthesia. This is why sedation and anesthesia experience are major components for pediatric and hospital dentistry residencies.

3. **No Precedent Exists for SCDPA's Proposal.** The SCDPA application proposes the first facility in North Carolina in which permits dentists to perform procedures on patients under general anesthesia without having had formal supervised experience treating such patients. SCDPA proposes a lower standard than its owner members apply in the offices of Triangle Implant Center. Those oral surgeons have the appropriate hospital and operating room based training to perform surgery on anesthetized patients.

   SCDPA's solution for overcoming the possible lack of training in care for 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 [sic], 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, could observe these items via *video, only once,* and meet the requirements for credentialing at SCDPA. 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 D contains excerpts from the Pennsylvania Oral and Maxillofacial Society, and the American Dental Association websites, 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.

4. **Anesthesia Issues with Medicare Conditions of Coverage** It appears that SCDPA will not be operated in a manner that fosters quality and safety. The Medicare Conditions for Coverage, which the ambulatory surgical facility 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 ambulatory surgical facility will have two operating rooms and two procedure rooms, which will be dedicated to providing only dental procedures that require sedation. SCDPA proposes to perform 3,012 procedures in its third year of operation (Application page 142). Assuming a 250-day a year operating schedule, the ambulatory surgical facility will perform 3.0 cases per day in each of its four rooms in the third year (3012 / 250 = 12.0 cases per day / 4 rooms = 3.0 cases per day per room). This volume is certain to result in frequent occasions when three or four cases will occur concurrently. However, SCDP provides only enough expense in its pro formas for a single anesthesiologist. That anesthesiologist would be the only individual administering anesthesia. **(**p22) Such a demand upon the anesthesiologist appears to place patient safety and quality at risk, clearly in opposition to the Medicare billing requirements.

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]

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 seven 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 each of four or more concurrent cases, which is what the SCDP proposes.

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

SCDPA has essentially admitted that the foregoing criticism is valid and correct. SCDP, the parent company of SCDPA, has also filed CON applications for dental single specialty ambulatory surgical facilities in Raleigh and Greenville. Valleygate's competitive comments on those applications included this same criticism, and those applicants and Dr. Reebye did not even attempt to refute the correctness of this criticism in their response to comments or otherwise.

5. **Medical Board Issues.** The application states (page 54) that the manager "will employ" the required pediatrician. The Management Agreement confirms the management company, Papillion Management, will employ the proposed pediatrician. There is no discussion of the pediatrician being in independent contractor. Rather, the application lists the pediatrician as an employee. It is legally impermissible for the corporate non-medical 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.

[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 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.

The SMFP policy GEN-3 (as well as Criterion 18a) promotes implementation of projects that enhance safety and quality. A proposal for a new surgery center model that is less restrictive than the North Carolina Board of Dental Examiners with regard to sedation and that appears to conflict with federal rules governing anesthesia does not "promote safety and quality." As a result, SCDPA does not conform to CON Review Criterion 1. In fact, with its strong focus on general dentistry, it appears SCDPA is attempting to violate the requirements of the North Carolina Board of Dental Examiners and North Carolina corporate law, by engaging in the practice of dentistry through an entity owned by non-dentists. The Board has worked hard to prevent corporate practice of dentistry.

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."

SCDPA proposes and projects to perform three types of services at its facility:

- General Dentistry;
- Pediatric Dentistry; and,
- Oral Surgery.

However, SCDPA's projections and need methodology for each service fails to meet the requirements of Criterion 3.

SCDPA Failed to Demonstrate Any Need for General Dentistry Services at the Facility

SCDPA's application utterly fails to demonstrate a need for *general dentistry* services at the proposed facility. Only three general dentists confirmed they would bring cases to SCDPA, yet SCDPA provided no information describing what kind of cases they would bring. This is important because as a rule, general dentists do not typically require access to a licensed operating room. The application infers that the three dentists who propose to use SCDPA would be completing procedures on sedated or anesthetized patients. Of course, to borrow SCDP's language, *"Dentists in North Carolina can currently obtain oral sedation or anesthesia permits with relative ease"* (Page 76 of SCDPA App). These dentists currently have two options to provide this service, (1) refer patients to a dentist who has a sedation permit or (2) obtain a sedation permit. SCDPA's proposal represents a third option, but makes unsubstantiated claims for the need of this service. By suggesting that sedation dentistry is somehow unsafe on an office setting, SCDPA indicates that the NC Board of Dental Examiners is in error for allowing it to occur. SCDPA provides no hard evidence that general sedation dentistry should <u>never</u> be practiced in an office setting.

In comparison, Valleygate Dental Surgical Center of the Triad will allow general dentists to perform surgical cases as long as they are capable of meeting the credentialing requirements, which will require that every dentist have completed a hospital-based post graduate residency or equivalent training, or hold a sedation or anesthesia permit with the North Carolina State Board of Dental Examiners.

SCDPA's contention that all oral surgery needs an operating room is a flawed assumption. Moreover, the quantitative need methodology in Section III.1.(b) of the SCDPA application does not address general dentistry in any way.

As a result, SCDPA failed to properly demonstrate a need for general dentistry services at the facility.

SCDPA Failed to Demonstrate Any Need for Pediatric Dentistry Services at the Facility

SCDPA provides no supporting evidence that it will have capability to serve pediatric dental surgical cases at the facility. SCDPA projects that, in the third year, the facility will perform 978 cases for patients under age 21. This is 34.5 percent of the facility's projected total cases. Further, SCDPA fails to discuss or provide any information in Section III that specifically and expressly demonstrates any quantified need for pediatric dentistry services in the ambulatory surgical facility it proposes. SCDPA provides no support from any of the local pediatric dentists. In fact, pediatric dentists have told Valleygate there are no access problems in Asheville because hospitals provide adequate access to hospital operating rooms in Asheville. See a letter from Dan Knechtel in Exhibit 18 of the Valleygate application.

The quantitative need methodology in Section III.1.(b) of the SCDPA application does not address pediatric dentistry.

Because the application fails to provide any specific demonstration of need for pediatric dentistry services at the facility, yet proposes to offer pediatric dental procedures, the application is non-conforming with Criterion 3.

Need Methodology is Unreasonable because it is Limited to Oral Surgery

SCDPA bases its need methodology entirely upon oral surgery, but SCDPA proposes to offer pediatric and general dentistry procedures as well. Oral surgery is, by definition, a distinct, separate, subset of dentistry and/or medicine. As described in SCDPA'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 in Section II of the SCDPA application and on Triangle Implant Center's website: http://www.triangleimplantcenter.com. SCDPA 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 ambulatory surgical facility license renewal applications. As illustrated in Table 2, office-based oral surgery cases under sedation form the basis for 70 percent or more of the total need projected by SCDPA.

**Table 2 - 2015 Conservative Estimate of Potential Need:
Office Compared to Licensed Facility in Region 4**

Range	TIC Office-Based	Hospitals and ASF Based	Total	% TIC Office-Based
	a	b	c	d
Low	8,574	3,471	12,045	71.2%
High	16,522	4,237	20,759	79.6%

Notes:

a. SCDPA Application, Page 110

b. SCDPA Application, Page 110

c. SCDPA Application, Page 110

d. a / d

Nowhere in its application does SCDPA quantify the need for general dentistry or pediatric dentistry procedures in operating rooms, despite clearly projecting the performance of such procedures in the facility. Thus, SCDPA's need methodology is unreasonable because it is based entirely on the need for sedation based oral surgery services.

The application further contends (page 98) 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 a proposed ambulatory surgical facility, not for a pediatrician's office. The application provides no explanation of need for the pediatrician. Further, to the extent the proposed ambulatory surgical facility 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, nor does it indicate where in the facility such a person will work.

As a result, the applicant proposes unsupported costs and unjustified procedures and does not conform with Criterion 3.

SCDPA Failed to Show that the Oral Surgeries It Projects Will Be Appropriate for a Surgery Center

On pages 105 and 108 of its application, SCDPA cites the *"total dental and oral surgical cases requiring sedation"* for TIC's Durham, Mebane, and Wilson practices. These totals form the basis for over 71 percent of the need for oral and dental surgery in ambulatory surgical facilities. The underlying assumption in SCDPA's need methodology is that all oral surgery cases under sedation should be completed in an ambulatory surgical facility. 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 the Triad. However, this need is limited to specific subset of procedures.

The truth is that SCDPA's proposed model is much more like a dental office than an ambulatory surgical facility. The following design components of SCDPA are typical of dental offices, not ambulatory surgical facilities:

- SCDPA includes only three recovery rooms in its model to support four case rooms, two operating room and two procedure rooms, for patients under general anesthesia. SCDPA explains this by noting that patients will be recovered inside the operating rooms or procedure rooms (SCDPA App, Page 123).
- Recovery inside the operating rooms reduces efficiency and precludes the presence of family or support persons during recovery. By contrast, if this were a non-sterile dental operatory, family presence would be common.
- SCDPA proposes to support procedures typically performed safely in dental/oral surgery offices under sedation, such as third molar removal and dental implants.

Perhaps the best evidence that oral surgeons do not need an ambulatory surgical facility for all of their sedation procedures is that of the three dentists who have expressed an interest in using SCDPA, not one of them is an oral surgeon. According to the North Carolina Board of Dental Examiners, there are seven oral surgeons located in the Asheville area. Not one provided a letter of support to SCDPA.

Finally, payers recognize that oral surgery belongs in licensed ambulatory surgical facilities only in certain circumstances. Third party payers will only reimburse for specific types of patients and procedures in ambulatory surgical facilities, see payer ambulatory surgical facility Criteria in Attachment G. An otherwise healthy patient undergoing a procedure for wisdom teeth removal or dental implants, a major component of TIC's business, will not qualify for ambulatory surgical facility "facility fee" reimbursement under most of the large payer policies like Blue Cross and Medicaid. Yet, the SCDPA application includes these procedures and proposes reimbursement, page 26.

Clearly, all oral surgery sedation patients do not need licensed operating rooms. Therefore, SCDPA does not adequately demonstrate the need this population has for the services it proposes.

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.

SCDPA Does Not Show Adequate Evidence of Funds Needed for Capital Investment

In Section VIII.3 of its application, SCDPA 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 Asheville 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. There is no evidence of any transaction showing that SCDP, the parent organization of SCDPA, 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, SCDPA states that a letter provided by PNC bank in Exhibit 25 shows 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.

Moreover, SCDPA does not show it has the necessary funds to cover its startup costs. The application states that startup costs will be $140,385, but, the proposed management services contract in Exhibit 2 states that SCDPA will incur a development cost of $18,750 per month, beginning when the Agency awards the CON. Because SCDPA proposes to open one year after CON award, it will incur a total annual cost of $225,000 in these development fees, according to its management contract. It is not possible to determine if the start-up expenses listed in Section IX of the SCDPA application include some of the development fee. The application contains no mention of funding for the development fee portion of capital expense.

SCDP provided additional evidence of the $225,000 development fee associated with SCPDA in an investment Offering Memorandum distributed to dental professionals across North Carolina, in March 2016 (Attachment L). The pro formas for each facility in the Memorandum include the amount of $225,000 as a line item in the "Total Estimated Initial Investment – Per Facility". Moreover, the Memorandum includes $900,000 of working capital per facility, well above the $590,725 working capital presented in the SCDPA application. SCDPA omitted capital expenses from its application that its own statements in other documents confirm it will incur.

As a result, SCDPA does not adequately demonstrate availability of funds for capital needs and did not make reasonable projections. Therefore its application does not conform to Criterion 5.

SCDPA Overstates Revenues

SCDPA's pro formas presented in the application overstate revenues. Some payers will not reimburse SCDPA "facility fees' for many of the cases the application indicates that SCDPA proposes to serve.

For procedures they deem medically necessary for an ambulatory surgical facility, payers, including Medicaid, reimburse ambulatory surgical facilities "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 G 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 they will cover a "facility fee" for procedures completed in ambulatory surgical facilities. In this case, SCDPA, is neither dentist nor physician, and can only bill for the facility fee.

For example, as noted in Attachment G, Blue Cross covers only the following situations in ambulatory surgical facilities 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 old or younger, have severe psychological impairments, classified as ASAIII or above, have significant medical comorbidities, or be otherwise inappropriate or contraindicated for conscious sedation.

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 facility (ASF)."

According to all of these policies, payers will not reimburse ambulatory surgical facilities 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

SCDPA does not discuss payer requirements anywhere in the application; nor does it address why certain dental cases would be appropriate for an ambulatory surgical facility why others would not.

SCDP has suggested that dental insurance will be the primary payer for procedures completed in the ambulatory surgical facility. In comments submitted to the CON Section in a public hearing on June 17th regarding the CON applications for SCDP of Greenville and Valleygate Fayetteville, SCDP suggests, erroneously, that dental insurance will be the primary payer for "facility fees. SCDP fails to recognize that the payers for the "facility fee" portion of its revenues will be medical plans. Dental insurance plans do not currently cover ASF "facility fees." SCDPA assumes that dental insurance plans will, for the first time in North Carolina history, cover a "facility fee" above and beyond a dental professional fee for procedures completed in an ambulatory surgery center. This assumption cannot be taken at face value. It requires supporting documentation. SCDPA provides no supporting documentation from any payer, including Medicaid. SCDPA is, of course, at liberty to charge self-pay patients anything it likes.

The same comments turned in on June 17 state, *"Medicaid, has already indicated its willingness to pay for these cases performed in a licensed setting, as evidenced by the letter of support from Dr. Mark Casey."* The letter from Dr. Casey, also included in Exhibit 30 of the SCDPA application, makes no such claim. Please refer to DMA's actual coverage policy for dental surgery in an ambulatory surgery center in Attachment G. As noted above, NC Medicaid and Health Choice will cover a "facility fee" only for specific types of patients.

Based on discussion provided in SCDP's March 2016 Offering Memorandum, SCDP appears to be aware of the risks of non-payment from third party payers. The memorandum states: *"to a large extent our revenues will be dependent upon the acceptance of surgery center dental surgery procedures as covered benefits under the various programs and our becoming and remaining eligible for reimbursement under these programs. There is no assurance that we will become or remain qualified under these programs or that reimbursement rates under these programs will not be reduced, perhaps significantly. Our failure to become or remain qualified under these third party reimbursement programs or a reduction in reimbursement rates under these programs would have a material adverse effect on us."* SCDP made this statement to help readers identify risks in its proposal. If it had risk-mitigating evidence from payers that it would receive reimbursement for all of its proposed services, SCDP would have provided that information to investors, but it did not.

Moreover, SCDPA assumes third party payers will reimburse for crowns, fixtures, and x-rays. Typically, ambulatory surgical facility fees are bundled to include all services necessary for the surgery, including prep, supplies, surgery, and recovery. There are some exceptions, but CMS ambulatory surgical facility payment rules make clear that x-rays of the jaw, including panoramic x-rays are included in bundled facility fees. CMS ASC payment schedules do not address crowns and fixtures. SCDPA does not provide any documentation that it will receive payment separately for these line item services. Dentists bill separately for these procedures under dental fee schedules, but SCPDA failed to produce documentation from payers showing they will reimburse ambulatory surgical facilities for these services. As a result, bases all of the revenue in the "Other Revenue" line item on SCDPA pro formas on unsupported assumptions, and therefore, SCDPA overstates its revenues by $464,758, $522,843, and $581,007 in its first three years of operation, respectively.

It is clear that SCDPA created its pro forma revenue projections without consideration for whether or not the procedures it projects and the services for which it proposes to bill will actually meet payer criteria. As such, it is impossible to determine whether or not SCDPA revenue projections are accurate. If a significant number of the general dentistry cases involve otherwise healthy adults, then SCDPA would most likely not be able to collect a "facility fee" from third party payers for these cases. In any case, SCDPA has overstated its revenues, significantly.

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

SCDPA Understates Anesthesia Costs

Throughout the application, SCDPA states that it will provide anesthesiologists for all sedation cases under sedation. SCDPA also states in its pro forma assumptions that charges are average bundled fees, which include both facility fees and anesthesia fees. As a result, SCDPA 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 in pro formas assumption 17: *"Professional fees expense includes fees for anesthesiologists and other professional fees, based on the experience of SCDP of Asheville's management company and discussions with anesthesia providers, inflated 2% per year."*

The pro forma assumptions reference information obtained from "anesthesia providers", but does not specify the actual source. To evaluate the reasonableness of SCDPA's anesthesia cost, Valleygate obtained survey information from Medscape.com to form the basis of its anesthesia cost assumptions. This information included an estimate of $413,000 annually for one, self-employed, full-time anesthesiologist[2]. Even ECAA Anesthesia Specialists, SCDPA's chosen anesthesia provider, states on its website: *"The anesthesia care team, just like in all other areas of medicine, consists of a physician and an anesthetist working together. The anesthetist is either a certified registered nurse anesthetist (CRNA) or an Anesthesiologist Assistant (AA). A member of the anesthesia care team, either the anesthesiologist, anesthetist, or both will be with you continuously throughout your procedure.*[3]*"*

Because SCDPA is required to contract with an anesthesiologist, an average contract for a self-employed physician, who must cover her own insurance and benefits expenses, is the appropriate comparison. Moreover, in the planning process for its projects, Valleygate obtained estimates for contract anesthesiologists from the same organization from which SCDPA obtained estimates. The initial estimate was $450,000 per contract anesthesiologist. Thus, Medscape's $413,000 is a conservative, highly defensible estimate for one contract anesthesiologist.

SCDPA proposes two operating rooms and two procedure rooms, each with an anesthesiologist. If SCDPA truly needs all four rooms, then logic holds it would, *at the very least*, run three rooms concurrently each day. Table 3 calculates cost assuming a need for three anesthesiologists every day.

[2] Source: *http://www.medscape.com/features/slideshow/compensation/2016/anesthesiology#page=7 (requires free account)*
[3] Source: http://www.ecaa.com/ourteam-practice.php

Table 3 - Estimated Shortfall in SCDPA Anesthesia Cost

Notes	Metric	FFY2018	FFY2019	FFY2020
a	Anesthesiologist Expense	$498,000	$507,960	$518,119
b	*Growth*		*2.00%*	*2.00%*
c	Cost of One, Contract Full-time Anesthesiologist: Medscape.com	$413,000	$421,260	$429,685
d	Minimum Anesthesiologist FTEs Needed	3.00	3.00	3.00
e	Minimum Anesthesiologist Cost	$1,239,000	$1,263,780	$1,289,055
f	Cost Understatement	$741,000	$755,820	$770,936

Notes:

a. SCDPA Application, FORM B/C

b. Year over year growth of a

c. Medscape.com quote for one full-time, contracted anesthesiologist, grown by percent in b

d. Number of anesthesiologist FTEs required to cover anesthesia/sedation at SCDPA

*e. c*d*

f. e - a

If SCDPA truly needs all four rooms in year three, then it would presumably require more than 3.0 FTE anesthesiologists to cover its six-day schedule 52 weeks a year. Even if it staffed only three FTE anesthesiologists, it would incur a cost exceeding $1.28M annually, a significantly higher cost than projected in SCDPA pro formas.

If SCDPA truly intends to have anesthesiologists cover all procedures, as it says it will, then SCDPA understated its costs by over $740,000, which is more than its projected net income in project years one and two. The all-anesthesiologist model that SCDPA proposes is not financially feasible.

There is clear evidence that SCDP at least considered more realistic anesthesia costs. In the March, 2016 SCDP investor Offering Memorandum, the company put forth a pro forma, which projected operating income for all four SCDP sites. The pro forma shows three income scenarios, “breakeven”, “50% capacity”, and “100% capacity”. It clearly shows that as volume grows, anesthesia professional expenses also grow. At 100% capacity, SCDP projected its facilities would incur $1,350,000 in anesthesia contract fees, a much more reasonable number, well above the amount included in the SCDPA pro formas. Excerpts from the Memorandum are included in Attachment L.

Curiously, in the SCDPA application, SCDP seems to have stuck to its deeply flawed assumptions, despite the opportunity to make corrections. In previous sets of comments filed with the Agency regarding SCDP's Raleigh and Greenville applications, Valleygate made similar observations regarding the obvious lack of anesthesia coverage explaining that SCDP needed at least 3.16 to 3.94 FTE anesthesiologists in Raleigh and needed at least 1.45 to 1.81 FTE anesthesiologist for Greenville and, so, had greatly understated anesthesia costs. See Attachment H for the excerpt of these comments. When faced with [Valleygate's] contentions, SCDP merely affirmed that *more than a single anesthesiologist will be required for each center* and asserted the projected costs were reasonable, despite contradictory projections in its Offering Memorandum. This creates two fatal problems for SCDP.

First, SCDP has never disclosed the number of FTE anesthesiologists it projects to need for each center—contending in both its CONs and written comments, the provision of more than one anesthesiologist. Hence, SCDP has failed to provide sufficient information in its Applications (including the Asheville Application) to show that its projected anesthesia costs are reasonable. Second, in responding to Valleygate's comments, SCDP never refuted Valleygate's contention that 3.16 to 3.94 and 1.45 to 1.81 FTE anesthesiologists needed for its other centers. Hence, SCDP has admitted that Valleygate's projections of the number of minimum FTE anesthesiologist needed for the Raleigh and Greenville centers are correct, which likewise confirms the correctness of Valleygate's projection that the Asheville center will require at least 3.0 FTE anesthesiologists.

Another simple example underscores the problem with SCDP's anesthesia cost projections. In each of the Asheville, Raleigh, and Greenville applications, SCDP states that anesthesia services will be provided only by anesthesiologist physicians, and in each of those applications, SCDP projects that the annual cost for those physician services will be identical after accounting for two percent inflation: $498,000 Year 1; $507,960 Year 2; and $518,119 Year 3 (SCDPA pro forma FORM B/C). However, the total projected cases for the Raleigh center are more than double the projected volume for Asheville and Greenville. It is unreasonable for SCDP to therefore project that the anesthesia cost will be identical in both. Section IV of each application shows that for Raleigh, SCDP projects annual total volume for the first three years of 5,251, 5,908, and 6,564; for Asheville its projects 2,409, 2,710, and 3,012; and for Greenville it projects 2,413, 2,714, and 3,016 cases.

In response to the foregoing direct disclosure of SCDP's flaws, SCDP no doubt will attempt an after-the-fact argument to save itself. No such argument can be credible. It is beyond dispute that the Asheville center, like the Raleigh and Greenville centers, will require more than one anesthesiologist, and SCDP has failed to properly project and document the costs of such anesthesiologists.

SCDP had the opportunity to clarify the number of FTE anesthesiologists it actually proposes to staff in Raleigh or Greenville, but failed to do so. Ultimately, SCDP elected to double down and project exactly the same anesthesia fees in the SCDPA application as other SCDP applications.

The fact is that the SCDPA application, like the other SCDP applications, is woefully short of the necessary resources to provide the anesthesia coverage required by its clinical model. As a result, SCDPA did not provide reasonable financial projections and fails to conform to Criterion 5

SCDPA Understates Management Services Costs

SCDPA proposes to utilize the services of a management company, Papillion Management, LLC to provide management and clinical staffing services. The proposed management agreement in Exhibit 2 of SCDPA's application states Papillion will provide the following services:

- Annual Management Plan;
- Consulting Reports;
- Monthly Executive Summaries;
- Advisory Services;
- Financial Statements;
- Budgets;
- Corporate Compliance;
- Contract Review;
- Financial Consulting; and,
- Quality Assurance and Accreditation.

The application also states that Papillion will employ all staff working in SCDPA. As a result, SCDPA includes the cost of staffing in the management fee expense on its pro formas in FORM B/C. Of note, Exhibit 2, pages 3 and 4, state that the facility Administrator will be responsible for day-to-day operations such as the selection and training of other staff members. The services listed above appear to be the responsibility of Papillion, not the site Administrator. Therefore, Papillion must charge additional fees for the provision of these services. To determine the exact management services fee charged to SCDPA by Papillion, we had to calculate staffing expense using data provided in Section VII of SCDPA's application and subtract that amount from the total management services line item on FORM B/C. The result shows that SCPDA proposes a management services fees of $60,200 in each of its first three years of operation. This equals 1.5 percent of net revenue in the third year of operation (60,200 / $3,943,031. This amount is far too low to provide all of the services listed above, especially for a company that has no other clients, not history of providing such services, and no evidence of other resources. If SCDPA's management services fees were a more typical 4 percent of net revenue, its cost would be $157,721 in the third year. At that amount, we estimate SCDPA understated its costs related to management services (overhead), by $97,521. Table 4 shows the calculations.

Table 4 - Management Services Expense for SCDPA – Each of the First Three Years

Notes	Position	Average Annual Salary	FTEs	Total Salary
a	Facility Administrator	$ 120,000	1	$ 120,000
a	Registered Nurses	$ 55,000	1.5	$ 82,500
a	Physician's Assistant	$ 90,000	0.5	$ 45,000
a	Dental Assistant I	$ 38,000	1.5	$ 57,000
a	Dental Assistant II	$ 52,000	2	$ 104,000
a	Office Administration	$ 48,000	2.5	$ 120,000
a	Pediatrician	$ 150,000	1	$ 150,000
a	Non-health professional and technical personnel	$ 42,000	1.5	$ 63,000
	Total Salaries			$ 741,500
b	Benefits and Taxes Assuming 20%			$ 148,300
	Total Salaries with Benefits and Taxes			$ 889,800
c	Mgmt Fee from FORM B/C			$ 950,000
	Mgmt Fee Less Staffing Costs			$ 60,200

Notes:

a. SCDPA Application, Page 183

b. Benefits and taxes percent not provided in the SCDPA application. 20% is a conservative estimate

c. SCDPA FORM B/C. Note all three years in the pro formas contain the same expense.

SCDPA is far from comparable to Village Family Dental in its current depth of capacity. SCDP states in the aforementioned Offering Memorandum: "*there can be no assurance that Papillion Management, LLC will be able to effectively provide the services contemplated by the Management Services Agreements. If Papillion Management LLC is not able to effectively provide those services, the ADC LLCs [individual facilities] and the Company [SCDP] could be materially adversely affected thereby.* (See Attachment L)"

SCDPA Does Not Provide Reasonable Assumptions Regarding Its Balance Sheet

In its pro forma assumptions for FORM A, SCDPA provides only the following sentence: *"Surgery Center for Dental Professionals of Asheville'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 SCDPA the mix of assets and liabilities it presents in FORM A, it is impossible to determine if these projections are reasonable.

SCDPA Does Not Provide Reasonable Assumptions Regarding Its Capital Expenditure

On page 10 of its application, SCDP states *"The proposed project does not involve the construction of a new facility, but rather a building lease and the upfit of shell space."* Throughout the application, SCDPA repeats its plans to lease space in a building. The primary site on which SCDPA proposes to locate, 170 Sweeten Creek Road in Asheville, contains a 13,025 square foot industrial building currently occupied by a propane retailer called Blossman Gas. Attachment I contains a map of the current site, which SCPDA failed to provide in its application, showing the building. The proposed SCDPA facility is only 9,868 square feet, page 211 of the SCDPA application. It is easy to see that the line drawings provided in SCDPA Exhibit 11 do not match the existing building at 170 Sweeten Creek Road. Of note, both the capital expenditure and the line drawings provided in separate SCDP's applications for surgery centers in Charlotte and Greenville are identical to the information provided in the Asheville application.

SCDPA states on page 48 of its application that a "third party developer" will construct a new building on the eventual site and, presumably, lease it to SCDPA. Attachment J contains a flyer from Lewis Real Estate illustrating that a new building will be built on the 170 Sweeten Creek Road site. However, the flyer clearly indicates that the total available space will be 8,500 square feet and that 1,500 to 3,000 square feet spaces will be available for lease. Therefore, under no scenario can SCDPA lease and up-fit a shell building that is the same size and shape as its proposed floor plans on its primary site. As such, SCDPA provided false information in its CON. It would appear that SCDPA has no intention of developing the building presented in the application at the primary site. Regardless, SCPDA would require a new building on the primary site.

SCDPA also provides alternative sites in Section XI.4 of its application. None of the three alternative sites provided has any existing buildings in the place where SCDPA proposes to put buildings. In order for SCDPA to up-fit an existing building, it would require a shell building. As noted, SCDPA states that a "third party developer" will construct a shell building on behalf of SCDPA. However, no actual developer is named in the application. The application contains no evidence that the unnamed "third party developer" has the ability to finance its part of the project. Although the shell building may not be subject to the CON statute, SCDPA cannot complete its project without the existence of a shell building in the first place. The application completely omits any information confirming the possibility that such a building will ever be constructed on any of its four alternative sites. In the absence of this information, SCDPA would need to fund the development of the building itself. SCDPA provides no evidence of available funds for the shell building. Therefore, the Agency cannot assume that SCDPA's capital projections are accurate for the alternative sites, either.

SCPDPA's assumptions regarding its capital construction projections are not reasonable. SCDPA fails Criterion 5.

SCDP's Assumptions Regarding Anesthesia Equipment are Inconsistent across Its Multiple Dental Surgical Facility Applications

To date, SCDP, the parent company of SCDPA, has filed four certificate of need application for dental ambulatory surgical facilities in 2016. SCDP filed for Raleigh and Greenville in April and for Asheville and Charlotte in June. Each of these applications, despite containing different assumptions regarding the number of procedure rooms and the nature of the anesthesia contracts, contains exactly the same professional fees in the various pro formas. According to the pro formas, the professional fees include the contract cost for the entire anesthesia service. Table 5 summarizes this information.

Table 5 - Comparison of Anesthesia Assumptions across SCDP Applications

Metric	SCDP of Greenville	SCDP of Raleigh	SCDP of Asheville	SCDP of Charlotte
Review Date	**5/1/2016**	**5/1/2016**	**7/1/2016**	**7/1/2016**
Year Three Professional Fees	$518,119	$518,119	$518,119	$518,119
Number of Rooms	4	8	4	4
Annual Anesthesia Cost per Room	$129,530	$64,765	$129,530	$129,530
Proposed Anesthesia Provider	ECAA	Regional Anesthesia (Duke)	ECAA	ECAA
Application States Anesthesia Provider Will Provide Equipment	No	No	Yes	Yes
Pro. Fees Cost Assumption in Pro Forma	*"Professional fees expense includes fees for anesthesiologists and other professional fees, based on the experience of SCDP of Greenville's management company and discussions with Regional Anesthesia, inflated 2% per year."*	*Same as Greenville*	*"Professional fees expense includes fees for anesthesiologists and other professional fees, based on the experience of SCDP of Asheville's management company and discussions with anesthesia providers, inflated 2% per year."*	*Same as Asheville except includes the phrase: "anesthesiologists (including professional services, anesthesia equipment and maintenance)"*
Equip. Maint Assumption Pro Formas	*"Anesthesia equipment will be maintained by the anesthesiologists"*	*Same as Greenville*	*"Anesthesia equipment will <u>be provided</u> and maintained by the anesthesiologists"*	*Same as Asheville*
Year 3 Cases	*3,016*	*6,564*	*3,012*	*3,214*

SCDP changed the Assumption 17 included language in its June applications to show that the anesthesia provider will provide the equipment. This is clearly in response to Valleygate's comments on the April applications that SCDP failed to account for anesthesia equipment costs. Despite statements made in the SCDPA application that ECAA will provide the anesthesia equipment, SCDP budgeted <u>no increase</u> in professional fees over its Greenville application, which also proposes to use ECAA as its anesthesia provider, but does not include anesthesia equipment in Assumption 17.

SCDPA's application's assumptions regarding anesthesia equipment, which is expensive and absolutely essential to providing its service, are not reliable. As a result, SCDPA fails to meet Criterion 5.

SCDPA Is Not Financially Feasible

Considering the revenue overstatements and cost understatements in the application, SCPDA's projected profitability is highly questionable. Table 6 shows a more accurate projection of profitability for SCPDA after adjusting for faulty assumptions.

Table 6 - Adjusted Net Income of SCPDA

Notes	Metric	FY 2018	FY 2019	FY 2020
a	Net Income in Application	$213,915	$ 578,927	$950,276
b	Overstated Revenues	$464,758	$522,843	$581,007
c	Understated Management Fees	$ 97,521	$ 97,521	$97,521
d	Understated Anesthesia Fees	$741,000	$755,820	$770,936
e	Adjusted Net Income	$(1,089,364)	$(797,257)	$(499,188)

Notes:

a. SCDPA FORM B/C

b. Overstated revenue for crowns, fixtures, and x-rays noted above

c. Understated costs for management fees

d. Understated costs for anesthesiologist services noted above

e. a – b – c - d

Criterion 5 Summary

In summary, financial projections for the SCDPA application include:

- Insufficient evidence of available funding for fixed and working capital;
- Overstated revenues;
- Understated cost of anesthesia service;
- Understated cost of management services;
- Lack of assumptions regarding its balance sheet;
- Unreasonable assumptions regarding its fixed capital projections; and,
- Unreliable assumptions regarding the cost of anesthesia equipment.

For these reasons and the fact that SCDPA's model is not financially feasible, 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.

SCDPA Does Not Provide Adequate Evidence That the Site on Which it Proposes to Locate is Available

According to Section XI.2 of its application, SCDPA proposes to lease space in a building located at 170 Sweeten Creek Road. SCDPA shows no evidence, whatsoever, that this property is available to SCDPA. The proposed landlord, Bebe Rose Properties, LLC, as noted in Section I.10 of its application and as provided on the proposed lease agreement (Exhibit 1), does not hold ownership of 170 Sweeten Creek Road. Per the Buncombe County GIS website, Blue Ridge Holdings Partners, LCC is the owner of the site at 170 Sweeten Creek Road[4]. According to its articles of organization, Bebe Rose Properties, LCC was formed on June 3, 2016 with Laura Reebye as the only member (see Attachment K). Nowhere in the application does SCDPA indicate that it has spoken with representatives of Blue Ridge Holdings Partners, LCC. The proposed lease agreement in Exhibit 1 is a proposed lease between SCDPA and Bebe Rose Properties, LLC. As noted, Bebe Rose Properties has no relationship the property at 170 Sweeten Creek Road. The application contains no documentation of a possible site purchase by Bebe Rose Properties, LLC. The application contains no documentation of a possible lease from Blue Ridge Holdings Partners, LLC. Taken at face value, information in Exhibit 1 clearly shows that SCDPA does not have control of its primary Asheville site.

SCDPA clearly recognized its lack of control over the primary site and chose to provide several other "options" for sites in the area. As with 170 Sweeten Creek Road, there is no indication that SCDPA communicated with any of the land owners of the alternative sites and there are no proposed lease agreements with the actual owners of the properties. For all four sites, including the primary site, SCDPA states *"The proposed project will be developed in leased space."* (Pages 203,205,207,209 of the SCDPA App). All three of the alternative sites identified have no building on them today. As such, SCDPA cannot develop anything in *"leased space"* at these properties. The application contains no documentation of discussions with developers who could construct the building, nor information about lease costs.

Moreover, the lack of control over a site is a problem in all but one of SCDP's four dental demonstration project applications. The applications for SCDP of Greenville, SCDP of Charlotte, and SCDP of Asheville contain no evidence that SCDP has even discussed the project with the site owners and no evidence that the site is available for lease. Each one of these applications lists a lessor which bears no relationship with the actual site owners. Table 7 compares the proposed lessor and the owner of the proposed primary site in each of SCDP's application.

[4] Buncombe County GIS website, Retrieved June 22, 2016 : http://gis.buncombecounty.org/buncomap_new/

Table 7 - Comparison of Lessor to Actual Site Owner in All Four SCDP Applications

	SCDP of Greenville	SCDP of Raleigh	SCDP of Asheville	SCDP of Charlotte
Name of lessor in application (Section XI)	PICO Properties, LLC	Solferino North Properties, LLC	Bebe Rose Properties, LLC	Hookie Bones Properties, LLC
Name of actual primary site property owner	Robin E Bowman	Solferino North Properties, LLC	Blue Ridge Holdings Partners, LLC	Hemingway Joan, LLC
Proposed lease includes actual site owner name?	No	Yes	No	No
Application includes letter/confirmation from primary site owner indicating availability?	No	Yes	No	No

Of note, Laura Reebye is the sole member of both Bebe Rose Properties, LLC and Hookie Bones Properties, LLC. Laura Reebye is Uday Reebye's wife and thus a related party to SCDPA and the other SCDP applications. If Bebe Rose Properties or Hookie Bones Properties were to purchase the sites such that each organization could then lease it back to SCDP, as suggested by the lease agreements, this related party would require substantial capital for the purchase. Neither SCDPA nor SCDP of Charlotte provided evidence of funding for such a capital expenditure.

Because SCDPA does not adequately demonstrate the availability of a site necessary to complete the project, its application does not conform to Criterion 7.

SCDPA Fails to Show Sufficient Staffing and Equipment to Manage Anesthesia

Throughout the application, SCDPA describes how all dental surgeries performed in the proposed facility will be conducted by trained dentists and licensed anesthesiologists.

The SCDPA 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 cases. A conservative estimate for a single, contracted anesthesiologist is $413,000. In year one of its pro formas, SCDPA budgets $498,000 for total professional fees, which includes both anesthesiologist fees and "other professional fees"[5]. It is quite obvious this expense is barely enough to cover just over one FTE anesthesiologist.

To further illustrate the fall short in anesthesiologist expense, consider the following logic:

- If SCDPA requires a minimum of three anesthesiologists to cover its four rooms, it must cover all of that service with a maximum of $518,119 in year three.

[5] SCDPA's pro formas combine anesthesiologist expense with "other professional fees." Therefore, the portion of expenses in the Professional Fees line items on FORM B/C which are allocated to the anesthesiologist is less than $498,000.

- $518,119 divided by three equals $179,340 – deflated at 2 percent annually it would be $162,434 in 2015 dollars.
- SCDPA would need to find three anesthesiologists willing to work for $179,340 and pay their own malpractice insurance and benefits.
- For reference, the median salary for a CRNA in Asheville is $153,205 according to salary.com.
- SCDPA provides no evidence that it could find anesthesiologists willing to work for $179,340.
- SCDPA provided no evidence that it could find anesthesiologists willing to work for these unusual rates and provide equipment and maintenance as well.

Moreover, as shown on the equipment list and quote (Exhibit 24) in SCDPA's application, SCDPA does not indicate it will purchase any anesthesia machines, which are required to provide anesthesia. On page 23 of its application, SCDPA states ECAA Anesthesia Specialists will provide equipment and all required maintenance. Because no anesthesia equipment is included in its fixed capital, the cost of providing the equipment must be included in the professional fees expense in its pro formas. Anesthesia machines alone can cost $38,000 each (see Vallygate Triad application Page 193). The budgeted $518,119 annual expense must include salary, benefits, and insurance for three anesthesiologists and the cost of providing equipment and maintenance; $518,119 is not enough to cover these services.

SCDPA therefore does not provide evidence of available manpower or equipment required to provide the proposed services and does not conform to Criterion 7.

8. The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

Page 161 of SCDPA's application identifies David Kornstein as the proposed Medical Director of the facility. Presumably, the Medical Director of the proposed dental ambulatory surgical facility will need to be onsite at least some of the time. Dr. Kornstein practices at Wake Orthodontics and Pediatric Dentistry, which has offices in Raleigh, Smithfield, and Garner. Dr. Kornstein is also listed as the proposed Medical Director for a concurrently filed application for SCDP of Charlotte. According to Google Maps, Asheville is a 3.5-hour drive from Raleigh and at least a one to two-hour drive from Charlotte. It is highly unlikely that Dr. Kornstein could reasonably fulfill his duties as Medical Director in two separate dental surgical facilities that are located hours away and hours apart, and maintain his busy, three-location practice in the Research Triangle. SCDPA provides no explanation for how Dr. Kornstein could reasonably perform Medical Director duties. A Medical Director (or Clinical Director) is a necessity to run a licensed dental ambulatory surgical facility. SCDPA does not demonstrate a viable solution for providing a Medical Director; therefore, its application is non-conforming to Criterion 8.

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.

No Justification for Capital Expense for Procedure Rooms

SCDPA proposes to include two procedure rooms and in the proposed facility. Exhibit 10 in SCDPA's application provides a line drawing of the proposed facility. In Section IV, the application indicates that capacity of the procedure rooms is the same as the operating rooms. The application does not provide the required licensure distinction between the operating rooms and the procedure rooms. It does not provide a separate income statement for the procedure rooms. The application suggests that SCDPA could not estimate the capacity of the procedure rooms, hence treats them as operating rooms. No specific justification for the need of the procedure rooms is provided. Without justification for procedure rooms and without distinction from operating rooms, it is unclear why SCDPA includes them its proposal. Therefore, the capital expense associated with the procedure rooms is unjustified and may unduly increase the cost of providing health services.

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

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

SCDPA Proposes to Limit Access for Low-Income Patients

As demonstrated in SCDPA's, the applicant expects $89,228 of charity care patient net revenue in project Year 2. This is an average projected reimbursement rate of $784 per charity patient. Furthermore, SCDPA projects to receive an average reimbursement of $1,960 for the care of self-pay patients. Average net revenue per patient for each category represent *out-of-pocket* payments.

Table 8 summarizes these SCDPA data.

Table 8 - SCDPA Net Revenue Worksheet, Second Full Fiscal Year

Payment Source	% of Cases	# of Cases	Projected Avg. Reimbursement Rate	Net Revenue	% of Total Net Revenue
Charity Care	4.20%	114	$784	$89,228	3%
Self-Pay	12.40%	336	$1,960	$658,588	22%
Medicaid	52.00%	1,409	$736	$1,037,777	34%
Commercial and other Insurance	31.30%	848	$1,480	$1,255,253	41%
Total	***100%***	***2,707***	***$1,123***	***$3,040,846***	***100%***

Source: SCDPA Application, FORM E

Charity care patients are by definition low-income; the average charity collection implies an access barrier to the lowest of the low income. Many moderate-income "Self-Pay" patients may also find that the $1,960 out-of-pocket prohibitively expensive, when added to the cost of dentist/oral surgeon fees.

SCDPA's assumption that charity patients will pay an average of $784 out-of-pocket, before dentist fees, is unreasonable and unsupported. Its assumption that self-pay patients will pay $1,980 out-of-pocket, before dentist fees, or more than any other payer, is also unsupported. As a result, the application fails to demonstrate that low-income patients will be able to access the facility at the volumes assumed by SCDPA.

By comparison, Valleygate Dental Surgery Center of the Triad projects to collect $75 from charity care patients and $849 from self-pay patients.

Of Note:

- SCDP has suggested in written comments made to the CON section pertaining to its other applications that the nature of dental insurance is the explanation for such high charity and self-pay patient cost.
- SCDPA fails to demonstrate the foundation for its claim that dental insurance plans will cover an additional facility fee for procedures in ambulatory surgery centers, or that patients will have such coverage.

As a result, SCDPA proposes to 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.

SCDPA'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, does not demonstrate a positive impact on quality or safety. The application states numerous times that anesthesiologists will provide sedation and anesthesia staff for 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 18), 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 50), 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 152), the application states that SCDPA 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"*

The proposed expense statement (FORM B/C) appears to provide for slightly more than one FTE anesthesiologist without benefits despite the application's claim to provide anesthesiologists for all procedures in the facility. If the anesthesiologist is to be present throughout the procedure as implied by the application, and as would be required for non-sedation permitted general dentists to perform the procedures, one anesthesiologist can provide sedation or anesthesia for only one patient in one room at time. Therefore, the reviewer must assume that SCDPA will not provide anesthesiologists for all sedation procedures.

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.

None of the three dentists who showed intent to use the facility has a current North Carolina Board of Dental Examiners permits to provide sedation or anesthesia.

Reading the application literally, it says that an untrained person will be delivering anesthesia and monitoring the patient when the one anesthesiologist is not present in the room. This situation does not conform to Dr Reebye's described standards for anesthesia in SCDPA that is presented in Section II and III.

Alternatively, if anesthesiologists will not support all procedures, SCDPA provides no reason for the proposed facility. SCDPA's application confirms this on page 20:

> "*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."*

Notwithstanding the obvious misrepresentations made in the application, there is no feasible way that enough anesthesia coverage exists in SCDPA'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 D 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 formal training to assure quality and safety of care.

The proposal has shortcomings associated with anesthesia coverage and credentialing. SCDPA, as proposed in the application, does not have a positive impact on quality and may have a negative impact on quality. As a result, the applicant does not conform to Criterion 18a.

Attachment B

Comparison of Key Characteristics

Comparison of Key Characteristics Across SCDP Proposals

As demonstrated in its various CON application, the Surgical Center for Dental Professionals of NC, LLC (SCDP) is organized as a parent company to four proposed dental only ambulatory surgical facilities. In addition to the four CON application for each proposed facility, SCDP distributed an Offering Memorandum on March 15, 2016 in hopes of attracting investors to the parent company. The Memorandum outlined the SCDP business plan and investing opportunities. As of the filing date of its Asheville and Charlotte applications on June 15, 2016, SCDP has not demonstrated evidence that it has sold any shares among the 77.35 percent "Class A" shares it intends to sell to private investors. The offering memorandum contains much of the same material used in the application, but also contains statements and data contradictory to the applications. Valleygate provides the following table to demonstrate how each application compares to the others and to the offering memorandum.

Comparison of SCDP CON Applications to SCDP Offering Memorandum

Key Proposal Characteristics	SCDP of Greenville	SCDP of Raleigh	SCDP of Asheville	SCDP of Charlotte	SCDP Offering Memorandum
Includes breakdown of projected cases by dental specialty	No	No	No	No	No
Pro formas allow for two or more anesthesiologists	No	No	No	No	Yes
Demonstrates non-dental ownership	Yes	Yes	Yes	Yes	Yes
Charity care per patient	$784	$784	$784	$784	Not available
Discusses offering of SCDP shares to credentialing committee members at no charge	No	No	No	No	Yes
Discusses offering of SCDP shares to facility medical directors at no charge	Yes	Yes	Yes	Yes	No
Includes "development fees" in project capital expense	No	No	No	No	Yes
Management fees after staffing costs (percent of net income)	$60,200 (1.65%)	$404,742 (5.36%)	$60,200 (1.53%)	$60,200 (1.43%)	Not available
Includes letter/confirmation from site owner showing primary site availability	No	Yes	No	No	No
Listed Medical Director	Uday Reebye	Uday Reebye	David Kornstein	David Kornstein	Not available

Attachment C

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 D

PSOMS and ADA Summaries of Anesthesia Measures

Guidelines for the Use of Sedation and General Anesthesia by Dentists

I. INTRODUCTION

The administration of local anesthesia, sedation and general anesthesia is an integral part of dental practice. The American Dental Association is committed to the safe and effective use of these modalities by appropriately educated and trained dentists. The purpose of these guidelines is to assist dentists in the delivery of safe and effective sedation and anesthesia.

Dentists providing sedation and anesthesia in compliance with their state rules and/or regulations prior to adoption of this document are not subject to *Section III, Educational Requirements*.

II. DEFINITIONS

Methods of Anxiety and Pain Control

analgesia — the diminution or elimination of pain.

conscious sedation[1] **—** a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command and that is produced by a pharmacological or non-pharmacological method or a combination thereof.

In accord with this particular definition, the drugs and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of conscious sedation.

combination inhalation-enteral conscious sedation (combined conscious sedation) — conscious sedation using inhalation and enteral agents.

When the intent is anxiolysis only, and the appropriate dosage of agents is administered, then the definition of enteral and/or combination inhalation-enteral conscious sedation (combined conscious sedation) does not apply.

local anesthesia — the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

Note: Although the use of local anesthetics is the foundation of pain control in dentistry and has a long record of safety, dentists must be aware of the maximum, safe dosage limits for each patient. Large doses of local anesthetics in themselves may result in central nervous system depression, especially in combination with sedative agents.

minimal sedation — a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient's ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.[2]

1 Parenteral conscious sedation may be achieved with the administration of a single agent or by the administration of more than one agent.

2 Portions excerpted from *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*, 2004, of the American Society of Anesthesiologists (ASA). A copy of the full text can be obtained from ASA, 520 N. Northwest Highway, Park Ridge, IL 60068-2573.

Note: In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.

When the intent is minimal sedation for adults, the appropriate initial dosing of a single enteral drug is no more than the maximum recommended dose (MRD) of a drug that can be prescribed for unmonitored home use.

The use of preoperative sedatives for children (aged 12 and under) prior to arrival in the dental office, except in extraordinary situations, must be avoided due to the risk of unobserved respiratory obstruction during transport by untrained individuals.

Children (aged 12 and under) can become moderately sedated despite the intended level of minimal sedation; should this occur, the guidelines for moderate sedation apply.

For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures*.

Nitrous oxide/oxygen may be used in combination with a single enteral drug in minimal sedation.

Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.

The following definitions apply to administration of minimal sedation:

maximum recommended (MRD) — maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.

incremental dosing — administration of multiple doses of a drug until a desired effect is reached, but not to exceed the maximum recommended dose (MRD).

supplemental dosing — during minimal sedation, supplemental dosing is a single additional dose of the initial dose of the initial drug that may be necessary for prolonged procedures. The supplemental dose should not exceed one-half of the initial dose and should not be administered until the dentist has determined the clinical half-life of the initial dosing has passed. The total aggregate dose must not exceed 1.5x the MRD on the day of treatment.

moderate sedation — 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.[3]

Note: In accord with this particular definition, the drugs and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

The following definition applies to the administration of moderate or greater sedation:

titration — administration of incremental doses of a drug until a desired effect is reached. Knowledge of each drug's time of onset, peak response and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation one must know whether the previous dose has taken full effect before administering an additional drug increment.

deep sedation — 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.[3]

general anesthesia — 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 or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.[3]

For all levels of sedation, the practitioner must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

3 Excerpted from *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*, 2004, of the American Society of Anesthesiologists (ASA). A copy of the full text can be obtained from ASA, 520 N. Northwest Highway, Park Ridge, IL 60068-2573.

Routes of Administration

enteral — any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa [i.e., oral, rectal, sublingual].

parenteral — a technique of administration in which the drug bypasses the gastrointestinal (GI) tract [i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), intraosseous (IO)].

transdermal — a technique of administration in which the drug is administered by patch or iontophoresis through skin.

transmucosal — a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.

inhalation — a technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.

Terms

qualified dentist — meets the educational requirements for the appropriate level of sedation in accordance with Section III of these *Guidelines*, or a dentist providing sedation and anesthesia in compliance with their state rules and/or regulations prior to adoption of this document.

must/shall — indicates an imperative need and/or duty; an essential or indispensable item; mandatory.

should — indicates the recommended manner to obtain the standard; highly desirable.

may — indicates freedom or liberty to follow a reasonable alternative.

continual — repeated regularly and frequently in a steady succession.

continuous — prolonged without any interruption at any time.

time-oriented anesthesia record — documentation at appropriate time intervals of drugs, doses and physiologic data obtained during patient monitoring.

immediately available — on site in the facility and available for immediate use.

American Society of Anesthesiologists (ASA) Patient Physical Status Classification[4]

ASA I — A normal healthy patient.

ASA II — A patient with mild systemic disease.

ASA III — A patient with severe systemic disease.

ASA IV — A patient with severe systemic disease that is a constant threat to life.

ASA V — A moribund patient who is not expected to survive without the operation.

4 ASA Physical Status Classification System is reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, IL 60068-2573.

ASA VI — A declared brain-dead patient whose organs are being removed for donor purposes.

E — Emergency operation of any variety (used to modify one of the above classifications, i.e., ASA III-E).

III. EDUCATIONAL REQUIREMENTS

A. Minimal Sedation

1. To administer minimal sedation the dentist must have successfully completed:

   a. Training to the level of competency in minimal sedation consistent with that prescribed in the ADA *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*, or a comprehensive training program in moderate sedation that satisfies the requirements described in the *Moderate Sedation* section of the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced,

   or

   b. An advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage minimal sedation commensurate with these guidelines;

   and

   c. A current certification in Basic Life Support for Healthcare Providers.

2. Administration of minimal sedation 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 Basic Life Support for Healthcare Providers.

B. Moderate Sedation

1. To administer moderate sedation, the dentist must have successfully completed:

   a. A comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the ADA *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced,

   or

   b. An advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines;

   and

   c. 1) A current certification in Basic Life Support for Healthcare Providers and
   2) Either current certification in Advanced Cardiac Life Support (ACLS) or completion of an appropriate dental sedation/anesthesia emergency management course on the same recertification cycle that is required for ACLS.

2. Administration of moderate sedation 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 Basic Life Support for Healthcare Providers.

C. Deep Sedation or General Anesthesia

1. To administer deep sedation or general anesthesia, the dentist must have completed:

   a. 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 *Part IV.C* of these guidelines;

   and

   b. 1) A current certification in Basic Life Support for Healthcare Providers and
   2) 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.

2. 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 Basic Life Support (BLS) Course for the Healthcare Provider.

For all levels of sedation and anesthesia, dentists, who are currently providing sedation and anesthesia in compliance with their state rules and/or regulations prior to adoption of this document, are not subject to these educational requirements. However, all dentists providing sedation and general anesthesia in their offices or the offices of other dentists should comply with the Clinical Guidelines in this document.

IV. CLINICAL GUIDELINES

A. Minimal sedation

1. Patient Evaluation

   Patients considered for minimal sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this may consist of a review of their current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-Operative Preparation

   - The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
   - Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
   - Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.

- A focused physical evaluation must be performed as deemed appropriate.
- Preoperative dietary restrictions must be considered based on the sedative technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.

3. Personnel and Equipment Requirements

Personnel:

- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.

4. Monitoring and Documentation

Monitoring: A dentist, or at the dentist's direction, an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

- **Oxygenation:**
  - Color of mucosa, skin or blood must be evaluated continually.
  - Oxygen saturation by pulse oximetry may be clinically useful and should be considered.
- **Ventilation:**
  - The dentist and/or appropriately trained individual must observe chest excursions continually.
  - The dentist and/or appropriately trained individual must verify respirations continually.
- **Circulation:**
  - Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intraoperatively as necessary (unless the patient is unable to tolerate such monitoring).

Documentation: An appropriate sedative record must be maintained, including the names of all drugs administered, including local anesthetics, dosages, and monitored physiological parameters.

5. Recovery and Discharge

   - Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
   - The qualified dentist or appropriately trained clinical staff must monitor the patient during recovery until the patient is ready for discharge by the dentist.
   - The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory prior to discharge.
   - Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.

6. Emergency Management

   - If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.
   - The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue.

7. Management of Children

   For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures*.

B. Moderate Sedation

1. Patient Evaluation

   Patients considered for moderate sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this should consist of at least a review of their current medical history and medication use. However, patients with significant medical considerations (e.g., ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-operative Preparation

   - The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
   - Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
   - Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.
   - A focused physical evaluation must be performed as deemed appropriate.
   - Preoperative dietary restrictions must be considered based on the sedative technique prescribed.

- Pre-operative verbal or written instructions must be given to the patient, parent, escort, guardian or care giver.

3. Personnel and Equipment Requirements

Personnel:

- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravenous access must be available.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

- **Consciousness:**
  - Level of consciousness (e.g., responsiveness to verbal command) must be continually assessed.
- **Oxygenation:**
  - Color of mucosa, skin or blood must be evaluated continually.
  - Oxygen saturation must be evaluated by pulse oximetry continuously.
- **Ventilation:**
  - The dentist must observe chest excursions continually.
  - The dentist must monitor ventilation. This can be accomplished by auscultation of breath sounds, monitoring end-tidal CO_2 or by verbal communication with the patient.
- **Circulation:**
  - The dentist must continually evaluate blood pressure and heart rate (unless the patient is unable to tolerate and this is noted in the time-oriented anesthesia record).

- Continuous ECG monitoring of patients with significant cardiovascular disease should be considered.

Documentation:

- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics, dosages and monitored physiological parameters. (See *Additional Sources of Information* for sample of a time-oriented anesthetic record).
- Pulse oximetry, heart rate, respiratory rate, blood pressure and level of consciousness must be recorded continually.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- The qualified dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.
- If a pharmacological reversal agent is administered before discharge criteria have been met, the patient must be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.

6. Emergency Management

- If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation and providing the equipment, drugs and protocol for patient rescue.

7. Management of Children

For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures*.

C. Deep Sedation or General Anesthesia

1. Patient Evaluation

Patients considered for deep sedation or general anesthesia must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this must consist of at least a review of their current medical history and medication use and NPO status. However, patients with significant medical

considerations (e.g., ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-operative Preparation

- The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed sedation/anesthesia must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.
- A focused physical evaluation must be performed as deemed appropriate.
- Preoperative dietary restrictions must be considered based on the sedative/anesthetic technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.
- An intravenous line, which is secured throughout the procedure, must be established except as provided in *Part IV. C.6. Pediatric and Special Needs Patients*.

3. Personnel and Equipment Requirements

Personnel: A minimum of three (3) individuals must be present.

- A dentist qualified in accordance with *Part III. C.* of these *Guidelines* to administer the deep sedation or general anesthesia.
- Two additional individuals who have current certification of successfully completing a Basic Life Support (BLS) Course for the Healthcare Provider.
- When the same individual administering the deep sedation or general anesthesia is performing the dental procedure, one of the additional appropriately trained team members must be designated for patient monitoring.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravenous access must be available.
- Equipment and drugs necessary to provide advanced airway management, and advanced cardiac life support must be immediately available.
- If volatile anesthetic agents are utilized, a capnograph must be utilized and an inspired agent analysis monitor should be considered.
- Resuscitation medications and an appropriate defibrillator must be immediately available.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering deep sedation or general anesthesia must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

- **Oxygenation:**
  - Color of mucosa, skin or blood must be continually evaluated.
  - Oxygenation saturation must be evaluated continuously by pulse oximetry.
- **Ventilation:**
  - Intubated patient: end-tidal CO_2 must be continuously monitored and evaluated.
  - Non-intubated patient: Breath sounds via auscultation and/or end-tidal CO_2 must be continually monitored and evaluated.
  - Respiration rate must be continually monitored and evaluated.
- **Circulation:**
  - The dentist must continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.
  - The dentist must continually evaluate blood pressure.
- **Temperature:**
  - A device capable of measuring body temperature must be readily available during the administration of deep sedation or general anesthesia.
  - The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered.

Documentation:

- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics and monitored physiological parameters. (See *Additional Sources of Information* for sample of a time-oriented anesthetic record)
- Pulse oximetry and end-tidal CO_2 measurements (if taken), heart rate, respiratory rate and blood pressure must be recorded continually.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The dentist or clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- The dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.

6. Pediatric Patients and Those with Special Needs

Because many dental patients undergoing deep sedation or general anesthesia are mentally and/or physically challenged, it is not always possible to have a comprehensive physical examination or appropriate laboratory tests prior to administering care. When these situations occur, the dentist responsible for administering the deep sedation or general anesthesia should document the reasons preventing the recommended preoperative management.

In selected circumstances, deep sedation or general anesthesia may be utilized without establishing an indwelling intravenous line. These selected circumstances may include very brief procedures or periods of time, which, for example, may occur in some pediatric patients; or the establishment of intravenous access after deep sedation or general anesthesia has been induced because of poor patient cooperation.

7. Emergency Management

The qualified dentist is responsible for sedative/anesthetic management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of deep sedation or general anesthesia and providing the equipment, drugs and protocols for patient rescue.

V. ADDITIONAL SOURCES OF INFORMATION

American Dental Association. Example of a time oriented anesthesia record at ADA.org.

American Academy of Pediatric Dentistry (AAPD). *Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update*. Developed through a collaborative effort between the American Academy of Pediatrics and the AAPD. Available at www.aapd.org/policies.

~~American Academy of Periodontology (AAP). *Guidelines: In-Office Use of Conscious Sedation in Periodontics.* Available at www.perio.org/resources-products/posppr3-1.html~~. **The AAP rescinded this policy in 2008.**

American Association of Oral and Maxillofacial Surgeons (AAOMS). *Parameters and Pathways: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParPath o1) Anesthesia in Outpatient Facilities*. Contact AAOMS at 847.678.6200 or visit www.aaoms.org/index.php.

American Association of Oral and Maxillofacial Surgeons (AAOMS). *Office Anesthesia Evaluation Manual 7th Edition*. Contact AAOMS at 847.678.6200 or visit www.aaoms.org/index.php.

American Society of Anesthesiologists (ASA). *Practice Guidelines for Preoperative Fasting and the Use of Pharmacological Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures*. Available at https://ecommerce.asahq.org/p-178-practice-guidelines-for-preoperative-fasting.aspx.

American Society of Anesthesiologists (ASA). *Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists*. Available at www.asahq.org/publicationsAndServices/practiceparam.htm#sedation. The ASA has other anesthesia resources that might be of interest to dentists. For more information, go to www.asahq.org/publicationsAndServices/sgstoc.htm.

Commission on Dental Accreditation (CODA). *Accreditation Standards for Predoctoral and Advanced Dental Education Programs*. Available at ADA.org/115.aspx.

National Institute for Occupational Safety and Health (NIOSH). *Controlling Exposures to Nitrous Oxide During Anesthetic Administration* (NIOSH Alert: 1994 Publication No. 94-100). Available at www.cdc.gov/niosh/docs/94-100/.

Dionne, Raymond A.; Yagiela, John A., et al. Balancing efficacy and safety in the use of oral sedation in dental outpatients. *JADA* 2006;137(4):502-13. ADA members can access this article online at jada.ada.org/cgi/content/full/137/4/502.

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

Attachment E

42 CFR 415.110: Medically Directed Anesthesia Services

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 F

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 G

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 <u>detail line 1</u> of the claim.

e. Enter the total operating room time <u>on detail line 1</u> 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 **<u>one electronic claim</u>** 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.

BlueCross BlueShield of North Carolina

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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

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.

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**

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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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****Current Dental Terminology (CDT®) ©2011—2012 American Dental Association, Chicago, IL.**

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Attachment H

Valleygate Comments on SCDP of Raleigh Application, Excerpt

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[2]. 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 are based on 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[3]. 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, SCDPG'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.

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

Utilization forecasts in Section IV are supported by data in Exhibit 29. These include 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 SCDPG 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 running at capacity, all of which are expected to have sedated or anesthetized patients in them.[4]

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.

PAPILLION MANAGEMENT SERVICES, LLC CANNOT LEGALLY EMPLOY PHYSICIANS

The SCDPR application states (page 55) that Papillion Management, LLC[5] "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.

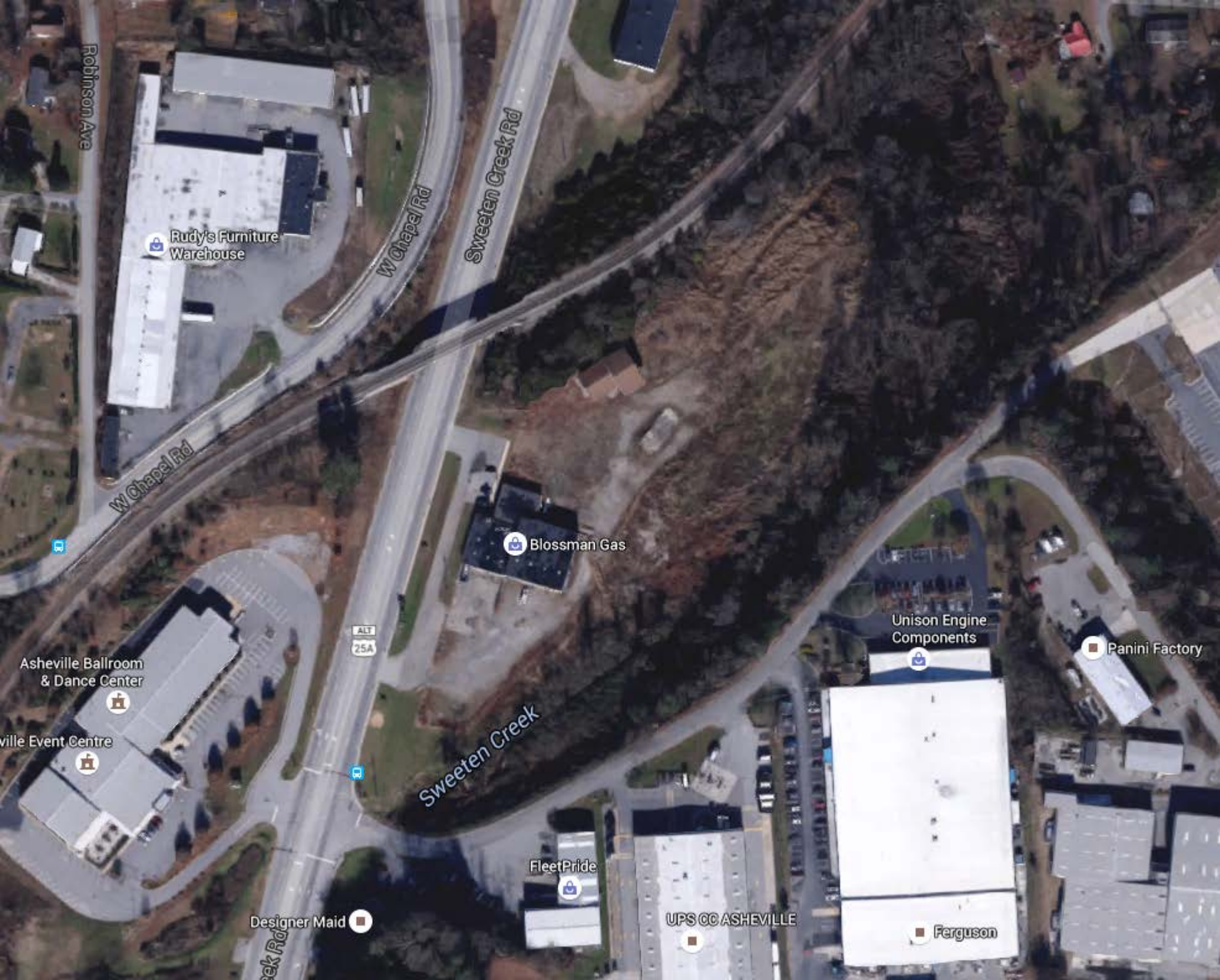
For all of these reasons, the application, it fails to conform to Criterion 7.

[4] 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.

[5] 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.

Attachment I

Current Map of SCDPA Primary Site


Robinson Ave
Rudy's Furniture Warehouse
W Chapel Rd
Sweeten Creek Rd
W Chapel Rd
Blossman Gas
ALT 25A
Asheville Ballroom & Dance Center
ville Event Centre
Sweeten Creek
Unison Engine Components
Panini Factory
FleetPride
Designer Maid
UPS CC ASHEVILLE
Ferguson

Help

Search for Parcel by:

- PINNUM
- Owner (Last Name First Name)
- Address

or

Use the Select Tool to manually select a parcel

PROPCARD:	PROPERTY CARD
Additional GIS Information :	GIS INFO
DEEDBOOK/DEEDPAGE:	5091/1960
PLATBOOK/PLATPAGE:	0140/0194
PINNUM:	965733330600000
OWNER:	BLUE RIDGE HOLDINGS PARTNERS LLC
NMPTYPE:	null
TAXYEAR:	17
CONDOUNIT:	
CONDOBUILDING:	
SUBNAME:	
SUBLOT:	
SUBBLOCK:	
SUBSECT:	
UPDATEDATE:	20160628
HOUSENUMBER:	170
NUMBERSUFFIX:	
DIRECTION:	
STREETNAME:	SWEETEN CREEK
STREETTYPE:	RD
TOWNSHIP:	07
ACREAGE:	10.47000027
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CITY:	CAS
FIREDISTRICT:	
SCHOOLDISTRICT:	
CAREOF:	
ADDRESS:	1091 HENDERSONVILLE RD
CITYNAME:	ASHEVILLE
STATE:	NC
ZIPCODE:	28803
CLASS:	480
TOTALMARKETVALUE:	1295000
APPRAISEDVALUE:	1295000
TAXVALUE:	1295000
LANDUSE:	
NEIGHBORHOODCODE:	SWFA
LANDVALUE:	775300
BUILDINGVALUE:	507900
SALEPRICE:	975000

BUNCOMBE COUNTY
GIS
June 30, 2016

Help

Search for Parcel by:

- PINNUM
- Owner (Last Name First Name)
- Address

or
Use the Select Tool to manually select a parcel

PROPCARD:	PROPERTY CARD
Additional GIS Information :	GIS INFO
DEEDBOOK/DEEDPAGE:	5091/1960
PLATBOOK/PLATPAGE:	0140/0194
PINNUM:	965733330600000
OWNER:	BLUE RIDGE HOLDINGS PARTNERS LLC
NMPTYPE:	null
TAXYEAR:	17
CONDOUNIT:	
CONDOBUILDING:	
SUBNAME:	
SUBLOT:	
SUBBLOCK:	
SUBSECT:	
UPDATEDATE:	20160628
HOUSENUMBER:	170
NUMBERSUFFIX:	
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STREETTYPE:	RD
TOWNSHIP:	07
ACREAGE:	10.47000027
DEEDDATE:	20130416
COUNTY:	BUN
CITY:	CAS
FIREDISTRICT:	
SCHOOLDISTRICT:	
CAREOF:	
ADDRESS:	1091 HENDERSONVILLE RD
CITYNAME:	ASHEVILLE
STATE:	NC
ZIPCODE:	28803
CLASS:	480
TOTALMARKETVALUE:	1295000
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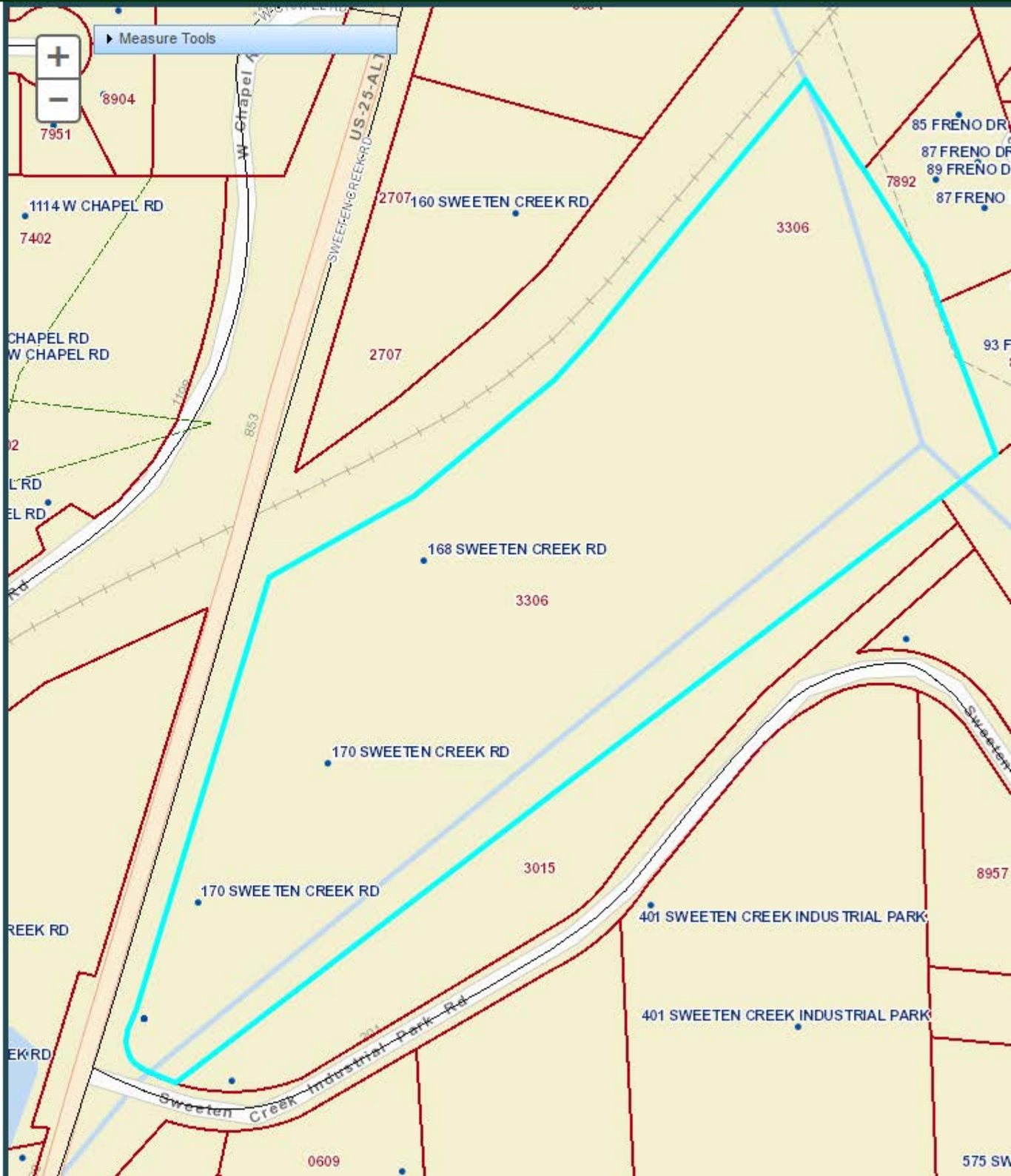
TAXVALUE:	1295000
LANDUSE:	
NEIGHBORHOODCODE:	SWFA
LANDVALUE:	775300

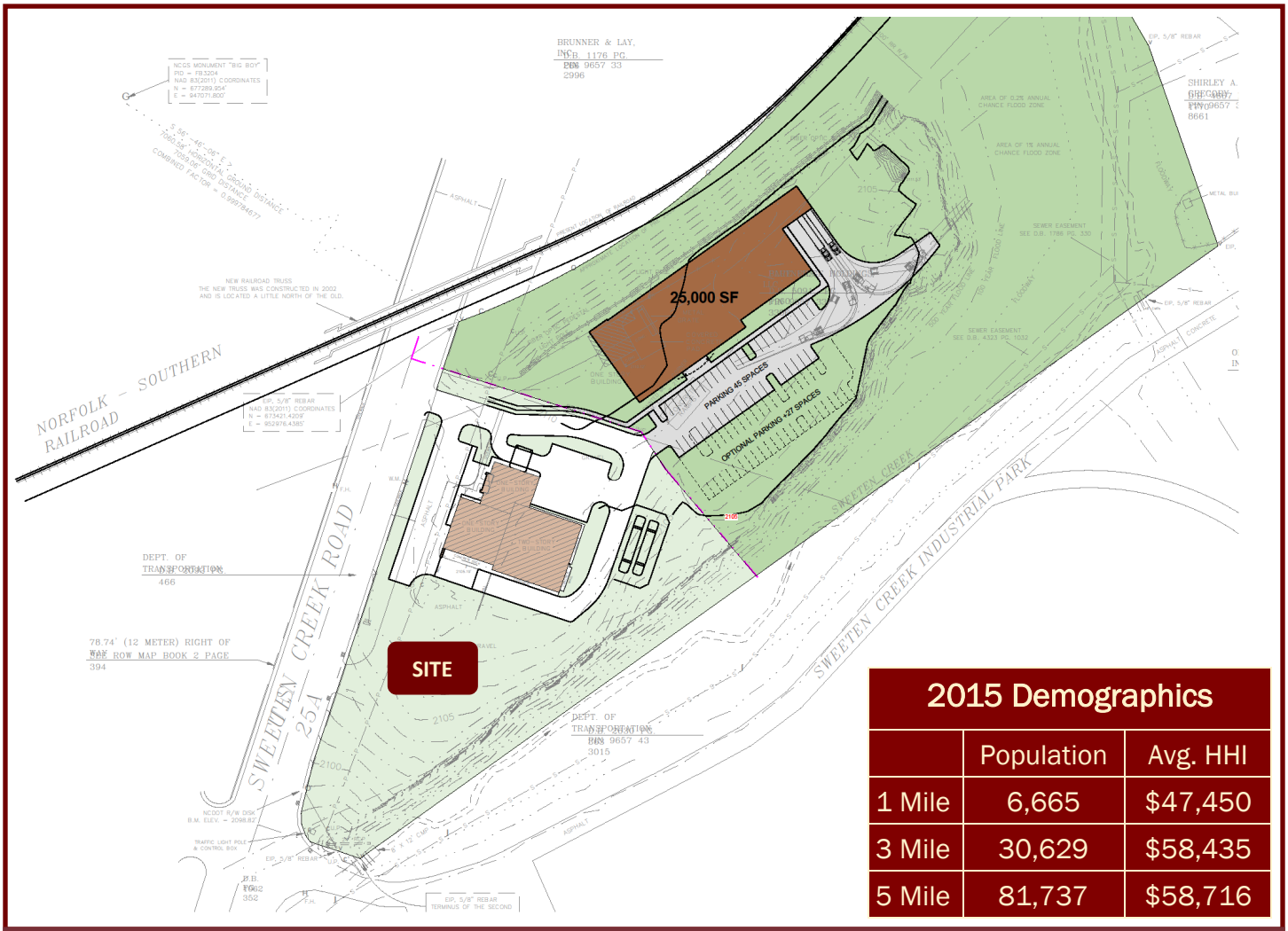


Attachment J

Lewis Real Estate Flyer

LEWIS real estate

SPACE AVAILABLE FOR LEASE



2015 Demographics		
	Population	Avg. HHI
1 Mile	6,665	$47,450
3 Mile	30,629	$58,435
5 Mile	81,737	$58,716

170 Sweeten Creek Road, Asheville, NC 28803

- Proposed 6,500 sf to 8,500 sf building with 1,500 sf—3,000 sf spaces available; including the possibility of a drive-thru
- High visibility/high traffic location near I-40: Exit 51
  - I-40: 108,000 vehicles/day
  - 25A/Sweeten Creek Road: 25,000 vehicles/day
- Location has minimal restaurant competition
- Site is conveniently located near numerous medical, industrial, and educational facilities for regular weekday traffic

170 Sweeten Creek Road, Asheville, NC 28803

Attachment K

Bebe Rose Properties, LLC Articles of Organization

SOSID: 1521892
Date Filed: 6/3/2016 11:25:00 AM
Elaine F. Marshall
North Carolina Secretary of State
C2016 155 00214

ARTICLES OF ORGANIZATION
OF
BEBE ROSE PROPERTIES LLC

Pursuant to §57D-2-20 of the General Statutes of North Carolina, the undersigned does hereby submit these Articles of Organization for the purpose of forming a limited liability company.

1. The name of the limited liability company is: Bebe Rose Properties LLC

2. The name and address of each person executing these articles of organization is as follows:

   Spruillco, LLC
   301 Fayetteville St., Suite 1900
   Raleigh, North Carolina 27601

3. The name of the initial registered agent is: Laura Reebye.

4. The street address and county of the initial registered agent office of the limited liability company is: 746 East Franklin Street, Chapel Hill, North Carolina 27514, Orange County.

5. The mailing address of the initial registered agent office is the same as the street address.

6. The limited liability company has a principal office. The principal office's telephone number is (919) 806-2912 and the street address of the principal office is 746 East Franklin Street, Chapel Hill, North Carolina 27514, Orange County.

7. To the fullest extent permitted by the North Carolina Limited Liability Company Act as it exists or may hereafter be amended, no person who is serving or who has served as a manager of the limited liability company shall have personal liability arising out of an action, whether by or in the right of the limited liability company or any of its members or otherwise, for monetary damages for breach of any duty as a manager. Any repeal or modification of this article shall not adversely affect any right or protection of a manager of the limited liability company existing at the time of such repeal or modification. The provisions of this article shall not be deemed to limit or preclude indemnification of a manager by the limited liability company for any liability that has not been eliminated by the provisions of this article.

8. These articles will be effective upon filing.

This is the 3rd day of June, 2016.

SPRUILLCO, LLC, Organizer

By: _____
David R. Krosner, Vice President

5077665

Attachment L

SCDP Offering Memorandum, Excerpts

SURGICAL CENTER FOR DENTAL PROFESSIONALS OF NC LLC

Offering Memorandum

March 15, 2016

$20,884,500

Surgical Center for Dental Professionals of NC LLC
77,350 Class A Units

AVAILABLE TO ACCREDITED INVESTORS ONLY

THE COMPANY

- Surgical Center for Dental Professionals of NC LLC is a North Carolina limited liability company which was formed to be the sole owner of four North Carolina limited liability companies. Each of these four limited liability companies, which we intend to name Surgical Center for Dental Professionals of Raleigh LLC (which we sometimes refer to as SCDP-R), Surgical Center for Dental Professionals of Charlotte LLC (which we sometimes refer to as SCDP-C), Surgical Center for Dental Professionals of Greenville LLC (which we sometimes refer to as SCDP-G) and Surgical Center for Dental Professionals of Asheville LLC (which we sometimes refer to as SCDP-A) was (or will be) formed to seek a Certificate of Need (or CON) from the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the CON Section) to own and operate a separately licensed dental single specialty ambulatory surgical center in the area of the State of North Carolina designated in its name. If the applicable limited liability company is ultimately awarded its Certificate of Need and the Company raises sufficient funds from this offering and/or secures alternative debt or equity financing, the limited liability company will ultimately upfit, own and operate the applicable dental single specialty ambulatory surgery center, which we refer to herein as an ADC or ambulatory dental surgery center, in its area of the State as more fully described in this offering memorandum.

- In this offering memorandum, except when otherwise indicated or where the context otherwise requires, "we," "us," "Company," "our," and "ours," refer to Surgical Center for Dental Professionals of NC LLC and "ADC LLC" refers to SCDP-R, SCDP-C, SCDP-A and/or SCDP-G.

- At present, Uday N. Reebye, MD, DMD is the Company's sole member and he will remain our sole member until any closing on accepted subscriptions for Class A Units.

- Following the closing of the offering and assuming the Company issues all of the Class B Units it currently anticipates issuing, if the Company sells all of the Class A Units in this offering, the purchasers of the Class A Units will collectively own 77,350 Class A Units representing a 77.350% percentage interest in the Company, Dr. Reebye will own 18,000 Class B Units representing an 18% percentage interest in the Company, and certain other individuals will collectively own 4,650 Class B Units representing a 4.65% percentage interest in the Company.

- Our operating agreement that will be in effect after the initial closing of the offering, or the Company Operating Agreement, will govern our management and the rights and responsibilities of our members, including the rights of members to distributions, voting on certain matters, and transfers of Units. The operating agreements of each of the ADC LLCs, referred to as an ADC Operating Agreement, governs the management and the rights and responsibilities of the Company as the sole member of that ADC LLC.

THE OFFERING

- This offering memorandum relates to the offering by us to accredited investors who meet certain requirements described in this memorandum, of up to 77,350 Class A Units at a purchase price of $270 per Class A Unit for a maximum aggregate offering amount of $20,884,500, subject to our right to increase the maximum aggregate offering amount in the event of an oversubscription.

- A potential investor may not subscribe to purchase less than 100 Class A Units ($27,000) or more than 2,000 Class A Units ($540,000), subject to our right to reduce such minimum subscription amount and/or increase such maximum subscription amount in our discretion.

- All subscriptions are subject to acceptance by the Company in writing. The Company reserves the right to reject any subscription in whole or in part (or to allot to an investor less than the number of Class A Units that such investor desires to purchase) in the Company's sole discretion for any reason.

- This offering will expire on the earlier of subscription of all of the 77,350 Class A Units and December 31, 2016 (unless extended by us), the "Expiration Date." We will close on accepted subscriptions for Class A Units on or before the Expiration Date at a time and place determined by us. We may have multiple closings, with the first closing on accepted subscriptions for Class A Units to occur at a time and place determined by us and subsequent closings on Subscriptions accepted by us thereafter to occur on or before the Expiration Date at such times and places determined by us. If we cancel the offering, all amounts paid in subscription for Class A Units will be returned, without interest.

- We will use the proceeds from the sale of Class A Units by us to pay the expenses of this offering and our start-up expenses, including legal fees and the fees of our CON consultant, which expenses we estimate will be approximately $1 million, and to capitalize each applicable ADC LLC with the equity capital we believe necessary to enable the ADC LLC to pursue CON Section approval for its proposed ambulatory dental surgery center and, if approved, to up-fit, develop and operate that ambulatory dental surgery center. We currently anticipate that the total capital required by each ADC LLC for this purpose will be approximately $4.96 million, including initial cash for working capital purposes of approximately $900,000. We may seek bank or other institutional debt financing for a portion of any needed capital.

- The Operating Agreement will restrict the transfer of Class A Units and, as a result, you may not be able to resell any Class A Units you acquire and you will be required to bear the financial risk of your investment in the Class A Units for an indefinite period of time.

NOTICE TO INVESTORS

- Before subscribing to purchase Class A Units, you should conduct your own examination of us and the Class A Units, including the merits and risks involved. You should not rely on any information, other than as provided in this offering memorandum, or as furnished by us on request. **You should carefully consider the risk factors beginning on page 9 of this offering memorandum before subscribing to purchase Class A Units.**

- We are only offering you Class A Units if you are an "Accredited Investor" as defined in Rule 501(a) of Regulation D adopted under the Securities Act.

- You should request from us at 9650 Strickland Road, Suite 103-177, Raleigh, North Carolina, 27615, any additional information you consider necessary to make an informed investment decision.

	Per Class A Unit	Total
Price to Investors	**$270**	**$20,884,500**

The date of this offering memorandum is March 15, 2016.

for any remaining needed capital or we may elect to pursue less than all four of the proposed ADCs. There can be no assurance that we will be able to obtain any such needed debt or equity financing. If, as a result of us not receiving CON approval for one or more of the proposed ADCs or for any other reason, our Board of Managers determines that a portion of the capital contributions previously made by the holders of the Class A Units (i.e. a portion of the proceeds raised by us in this offering) is no longer needed to further our Company purposes, our Board of Managers will cause the Company to return such unneeded capital to the owners of the Class A Units. Any such unneeded capital which is returned to the owners of the Class A Units will be allocated among such owners in accordance with and in proportion to their respective positive capital account balances at that time.

Risk Factors ..... The risks of investing in the Company and the general, economic, financial and regulatory risks of owning and operating an ambulatory dental surgery center are substantial and such risks could adversely affect us. Many of the factors which may affect us are subject to change or are not within our control. *See "Risk Factors" on page 9.*

Anticipated Ownership ..... Following the closing of the offering, assuming the maximum aggregate offering amount is raised, we will own 100% of each of the ADC LLCs and, assuming we issue all of the Class B Units we currently intend to issue, we will be owned as follows: investors in this offering will own 77,350 Class A Units representing 77.350% of us, Uday N. Reebye, MD, DMD will own 18,000 Class B Units representing 18% of us, J. Shannon Rouse, CPA will own 1,000 Class B Units representing 1% of us and various other individuals who we anticipate will serve on the credentialing board or other committees of or in other capacities for the Company and/or our ADC LLCs will own a total of 3,650 Class B Units representing 3.65% of us.

Immediate Dilution Caused by the Class B Units..... Investors in this offering will purchase Class A Units for $270 per Class A Unit, whereas Dr. Reebye and others will acquire Class B Units for no capital contribution. The Class B Units are intended to be "profits interests" under the Internal Revenue Code and, as such, they will share in only the future profits and appreciation in the value of the Company and would not receive any proceeds if the Company were dissolved immediately after the closing of this offering. The Class A Units and the Class B Units otherwise have identical rights and privileges. Accordingly, the owners of the Class B Units will be entitled to receive their pro rata share of any cash distribution made by the Company (other than dissolution proceeds which would be allocated among the holders of all Units based on their relative positive capital account balances associated with such Units at the time of any such dissolution or a return of unneeded capital to the owners of the Class A Units as specified in more detail herein) even though those owners will have paid nothing for their Class B Units.

Ambulatory Dental Surgery Centers..... The ambulatory dental surgery centers contemplated to be established by each of our ADC LLCs may be established only after the ADC LLC receives a Certificate of Need from the CON Section. As a result, even if our ADC LLCs ultimately receive Certificate of Needs to establish the contemplated ambulatory dental surgery centers, those centers will not be established for some time after the receipt of those CONs during which the facilities are being built and/or up-fitted. Those CONs also will be subject to conditions imposed upon the ADC LLCs regarding the development and operation of the project. In addition, upon commencement of operations at any such dental surgery center, the ADC will

surgery center, which would have a material adverse impact on the potential revenue that could be generated by that ADC and, accordingly, on our ability to meet the financial estimates included herein.

If any of our ADC LLCs receive a CON, that ADC LLC must develop the project and operate the ADC in a manner that is consistent with the representations in the CON application and with the CON issued to the ADC LLC. Specifically, in approving a need for the development of ADCs, the State Medical Facility Plan imposed a number of conditions upon the development and operation of any ADC, including the following:

- The proposed ADC must obtain a license no later than one year from the effective date of the certificate of need.
- At least 3% of the total number of patients served each year by the ADC must be charity care patients and at least 30% of the total number of patients served each year must be Medicaid recipients.
- The proposed facility must be certified by the Centers for Medicare and Medicaid Services (CMS), and must commit to continued compliance with CMS conditions of participation.
- The proposed facility must obtain accreditation no later than one year after licensure by the Accreditation Association for Ambulatory Health Care (AAAHC), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), or The Joint Commission (TJC), and must commit to continued compliance with the standards of the chosen accreditation agency.
- Health care professionals affiliated with the proposed facility, if so permitted by North Carolina law and hospital by-laws, must establish or maintain hospital staff privileges with at least one hospital and must begin or continue meeting Emergency Department coverage responsibilities with at least one hospital.

Failure of the ADC to meet any of these requirements could result in the CON Section's withdrawal of the CON, which would result in the termination of that facility's authority to operate as a licensed ambulatory surgical center and would materially and adversely affect that ADC and its potential future revenue and, hence, our ability to meet the financial estimates included herein.

Our financial estimates are based on assumptions that are subject to significant business, economic and competitive uncertainties.

Attached as Exhibit A are financial estimates that we have prepared reflecting our assumptions regarding the costs for each proposed ADC and the estimated revenues and expenses that may be achieved by each ADC. The estimates were not prepared in accordance with generally accepted accounting principles and do not reflect all items necessary for a fair presentation of the projected financial position and results of operations for the periods presented. By their nature, estimates and projections are based upon assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control. Actual results will undoubtedly vary, likely materially, from those estimated. The estimates are provided solely to describe one possible scenario of many potential scenarios, and prospective investors should not regard the estimates as a representation or guarantee by us, or any other person, that the indicated results will be achieved.

Papillion Management LLC, the entity that will serve as the management company for each of our ADC LLCs, is a newly formed company with no operating history which is owned by Dr. Reebye's wife, Laura Reebye, the office manager for Dr. Reebye's dental practice, Robyn Foushee, and the outside CPA for Dr. Reebye's dental practice and the Company, J. Shannon Rouse. Papillion Management LLC has no experience serving as a professional management company for ambulatory surgery centers and, accordingly, there can be no assurance that it will be able to effectively manage the ADCs.

We intend to cause each of our ADC LLCs to enter into a Management Services Agreement with Papillion Management LLC in substantially the form attached hereto as Exhibit D, pursuant to which such ADC LLC will obtain certain development and management services from Papillion Management LLC. Papillion Management LLC is an entity that is owned 40% by Laura Reebye, Dr. Reebye's wife, 30% by Robyn Foushee, the current office manager for Dr. Reebye's dental practice, Triangle Implant Center, and 30% by J. Shannon Rouse, CPA, one of the partners of Rouse Norton CPA PA, a Raleigh CPA firm which was engaged to assist Dr. Reebye and the Company in the transactions contemplated by this offering memorandum and which is also the CPA firm utilized by Triangle

Implant Center. We believe that these Management Services Agreements will contain terms which are not materially less beneficial to the ADC LLC than that which would be available from unrelated third parties but we have obtained no independent evaluation thereof. It is possible that had the ADC LLC sought to obtain similar development and management services from an unrelated third party, the terms of any such management services agreement may have been more favorable to the ADC LLC than the terms reflected in the proposed Management Services Agreements with Papillion Management LLC. It is also possible that in the future issues between an ADC LLC and Papillion Management LLC could arise under these Management Services Agreements. If any such issues do so arise, they would present an inherent conflict of interest given that each ADC LLC is indirectly owned by our Members, one of which is Dr. Reebye who is also a member of the Company's Board of Managers, and Laura Reebye, J. Shannon Rouse and Robyn Foushee each has a family and/or business relationship with Dr. Reebye or his dental practice. These relationships could cause Dr. Reebye to take positions with respect to any such issues which arise under the proposed Management Services Agreements that are less favorable to the ADC LLC than he would otherwise propose to take if the issues arose under a management services agreement with an unrelated third party. In addition, Papillion Management LLC is a newly formed entity with no material assets and no experience serving as a professional management services company for ambulatory surgery centers. Accordingly, there can be no assurance that Papillion Management LLC will be able to effectively provide the services contemplated by the Management Services Agreements. If Papillion Management LLC is not able to effectively provide those services, the ADC LLCs and the Company could be materially adversely affected thereby.

Even if we receive CON approval to own and operate one or more of the proposed ADCs, the CONs will not be issued until late 2016 or early 2017, at the earliest, and each applicable ADC will not be up-fitted and open for business until approximately one year after its CON is issued. Therefore, even if we receive CON approval to own and operate any one or more of the proposed ADCs, no ADC will be open for business, and the Company will have no revenues, until late 2017, at the earliest.

The CON applications for the proposed ADCs in Raleigh and Greenville, North Carolina are due on April 15, 2016. The CON Section's review of those applications will begin on May 1, 2016, with a decision expected to be issued by late September, 2016. If the applicable ADC LLCs receive such CON approval and no appeal is filed, we expect the CONs for the Raleigh and Greenville ADCs would be issued in late October, 2016. The CON applications for the proposed ADCs in Charlotte and Asheville are due on June 15, 2016. The CON Section's review of those applications will begin on July 1, 2016, with a decision expected to be issued by late November, 2016. If the applicable ADC LLCs receive such CON approval and no appeal is filed, we expect the CONs for the Charlotte and Asheville ADCs would be issued in late December, 2016. After the CONs are issued, the applicable ADC LLC will need to up-fit its facility. As a result, the actual opening for business of any ADC is not expected to occur until approximately one year after the issuance of the CON for that ADC. Appeals of any of the CON Section's decisions could delay the above timetables by a year or more. Accordingly, even if the CONs are approved and the ADCs ultimately become operational, there will be a significant period of time from the date of an investor's purchase of Class A Units until the date any such ADC will have any revenues. Further, we estimate that each ADC will not achieve the 50% capacity level set forth in the attached financial estimates until the end of the ADC's third full-year of operations, and there can be no assurance that level will be achieved within that time frame or ever. Accordingly, there will be a significant period of time from the date of an investor's purchase of Class A Units until the date, if ever, such investor receives any cash distributions from the Company.

The healthcare industry is highly competitive.

The healthcare industry, and the surgical sector in particular, is highly competitive. Many large and well-capitalized companies compete in this sector. Certain of these competitors have, and new competitors may have, greater financial resources than us. Our success will depend upon the effective and efficient operation of the proposed dental surgery centers, which will be affected by competition from health care systems, hospitals, non-dental specific ambulatory surgery centers and dentists and oral surgeons who perform in-office surgical procedures. We will offer services in the same areas as the outpatient surgical departments of various hospitals and other, non-dental specific, ambulatory surgery centers. There can be no assurances that we will be able to successfully compete against these hospitals, non-dental specific ambulatory surgery centers or dental physician practices or other competitors which offer the same or similar services as those contemplated to be offered by our ADCs. *See "Description of Our Business – Competition."*

Our success will depend on relationships with practicing dentists and oral and maxillofacial surgeons who will utilize the proposed dental surgery centers to be owned by our ADC LLCs.

Our success depends on our ability to develop and maintain constructive relationships with dentists and oral and maxillofacial surgeons in the communities that will be served by the proposed dental surgery centers, including those dentists and oral and maxillofacial surgeons who become Members. We may not be successful in identifying and establishing relationships with these dentists and oral and maxillofacial surgeons. Further, dentists and oral and maxillofacial surgeons who become Members or who otherwise indicate an intent to utilize the ADCs owned by our ADC LLCs may fail to maintain successful dental practices or for any number of other reasons they may elect not to use the ADCs. Unless a sufficient number of dentists and oral and maxillofacial surgeons utilize the contemplated dental surgery centers, our potential profitability and ultimately viability will be jeopardized.

Our revenues are dependent upon third-party reimbursement programs.

A significant portion of our patient services revenues are expected to be received through third-party reimbursement programs, including state and federal programs, such as Medicare and particularly Medicaid, and private health insurance programs. Therefore, to a large extent our revenues will be dependent upon the acceptance of surgery center dental surgery procedures as covered benefits under the various programs and our becoming and remaining eligible for reimbursement under these programs. There is no assurance that we will become or remain qualified under these programs or that reimbursement rates under these programs will not be reduced, perhaps significantly. Our failure to become or remain qualified under these third-party reimbursement programs or a reduction in reimbursement rates under these programs would have a material adverse effect on us. *See "Description of Our Business – Payment for Services."*

Any dental surgery center ultimately established by our ADC LLCs will not be certified for Medicare and Medicaid upon commencement of its operations and, consequently, may incur losses until so certified.

Any dental surgery center ultimately established by our ADC LLCs must first be licensed and providing services before it can become certified for Medicare and Medicaid reimbursement. There are no assurances that even then it will become so certified or that, if it becomes certified, it will be reimbursed for the services it provides prior to such certification. Certification is a requirement of any CON issued to the ADC LLCs, and failure to be certified could result in the loss of the CON for an ADC.

Failure by any dental surgery center ultimately established by our ADC LLCs to receive accreditation would materially adversely affect the ADC and its ability to seek reimbursement from private insurers.

Certain private insurers will not reimburse ambulatory surgical centers unless they are accredited by an approved accreditation body. After each ADC is established we intend to pursue such accreditation. The process of accreditation by one such accreditation body, the Accreditation Association for Ambulatory Health Care, or the AAAHC, a national body that accredits ambulatory surgery centers, involves self-assessment by an organization and a survey conducted by the AAAHC. To be eligible for a survey, any dental surgery center established by one of our ADC LLCs must meet several threshold criteria, such as being in compliance with applicable federal, state, and local laws and regulations and having been in operation for a certain number of months, although there is also an early option survey program. Assuming that these criteria are fulfilled, the AAAHC would measure us against a set of national standards, including "core standards" entitled Rights of Patients, Governance, Administration, Quality of Care Provided, Quality Management and Improvement, Clinical Records and Health Information, Infection Prevention and Control and Safety, and Facilities and Environment, and "adjunct standards" where appropriate for an ambulatory surgery center. The term of accreditation depends on an organization's compliance with the applicable standards, with the lengthiest possible term being three (3) years. At the conclusion of the term of accreditation, we must go through another complete survey by the applicable accreditation body.

We may need additional equity or debt to finance our operations.

We have estimated the amount of funds we will need to pursue the CON applications and, if received, to obtain the necessary equipment and up-fit the space to be leased by our ADC LLCs for the establishment of the

EXHIBIT A

FINANCIAL ESTIMATES

(See Attached)

Surgical Center for Dental Professionals of NC LLC

Exhibit B - Preliminary Estimates

Estimated Initial Investment	2 OR/6 Proc
Office Space Upfit (10,500 SF)	$2,855,000
Dental Chairs, Equipment, etc	$695,000
Computer Equipment & Software	$95,000
Cabinetry, Furniture & Furnishings	$190,000
	$3,835,000
Development Fee	$225,000
Working Capital	$900,000
Total Estimated Initial Investment - Per Facility	$4,960,000
Total Estimated Initial Investment - All 4 Facilities	$19,840,000
"Start Up" Expenses - Consultants, Attorneys, CON App, etc	$980,000
Total Estimated Initial Investment - All 4 Facilities	$20,820,000

Estimated Cash Flow Per Facility	Breakeven Annualized	Breakeven Per Day (250)		50% Capacity * Annualized	50% Capacity Per Day (250)		100% Capacity Annualized	100% Capacity Per Day (250)	
Estimated Revenue	$2,400,000	$9,600.00		$8,400,000	$33,600.00		$16,800,000	$67,200.00	
Estimated Expense		$1,200.00	Revenue per Proc		$1,200.00	Revenue per Proc		$1,200.00	Revenue per Proc
Anesthesia - Contract (1,2,3 MD)	$450,000	8.00	Ttl # of Proc per Day	$900,000	28.00	Ttl # of Proc per Day	$1,350,000	56.00	Ttl # of Proc per Day
Supplies (10.0%)	$240,000	1.00	# /8 Rooms	$840,000	3.50	# /8 Rooms	$1,680,000	7.00	# /8 Rooms
Rent Expense	$380,000	0.14	# /7 Hr/8 Rooms	$380,000	0.50	# /7 Hr/8 Rooms	$380,000	1.00	# /7 Hr/8 Rooms
Telephone & Internet	$28,000	2,000.00	Ttl # of Proc per Yr	$28,000	7,000.00	Ttl # of Proc per Yr	$36,000	14,000.00	Ttl # of Proc per Yr
Insurance Expense	$22,000	250.00	Ttl # /8 Rooms	$22,000	875.00	Ttl # /8 Rooms	$36,000	1,750.00	Ttl # /8 Rooms
Advertising & Marketing	$80,000			$80,000			$80,000		
Office Supplies & Expense	$36,000			$48,000			$60,000		
Bank Charges	$10,000			$16,000			$20,000		
Outside Services	$34,000			$52,000			$64,000		
Repairs & Maintenance	$30,000			$48,000			$56,000		
Property Taxes	$32,000			$32,000			$32,000		
Professional Fees	$48,000			$48,000			$60,000		
Other Expenses	$60,000			$210,000			$420,000		
Management Fees (Min $950,000 or 22%)	$950,000			$1,848,000			$3,696,000		
Total Estimated Expenses	$2,400,000			$4,552,000			$7,970,000		
Estimated Net Cash Flow Per Facility	$0			$3,848,000			$8,830,000		

Est 50% of Maximum

Est Maximum 2 Ops & 6 Proc, 7 Hrs, $1200 per Proc = $67,200/Day

Projected Annual Cash Flow Per MI (100,000)	
One Facility	$38.48
Two Facilities	$76.96
Three Facilities	$115.44
Four Facilities	$153.92

Projected Annual Cash Flow Per MI (100,000)	
One Facility	$88.30
Two Facilities	$176.60
Three Facilities	$264.90
Four Facilities	$353.20

* We estimate the 50% capacity level will not be achieved for each facility until after the 3rd full year of operations.

Attachment M

Additional Letters of Support: Dentists

June 2, 2016

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

RE: Letter in support of proposed Valleygate Dental Surgery Center of the Triad

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 the Piedmont Triad area dedicated to the provision of dental procedures for patients requiring anesthesia and sedation.

The dedicated dental ambulatory surgery center in the Triad area will expand access for patients of area dentists to provide dental treatment and oral surgery under general anesthesia. Too often, children in the Piedmont Triad must wait weeks or even 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, especially pediatric dentists, to practice efficiently and maximize their ability to serve dental needs of all age groups.

I am a pediatric dentist practicing in Guilford County.

☑ I /we fully support this proposed center
☑ I fully support the proposed center and expect to perform 3-4 cases there a month, once the facility is operational.
☑ I or my group currently has active staff privileges at HIGH POINT REG. hospital

This is an excellent proposal for a much needed service. I understand the current owners of Knowles, Smith and Associates (KSA), and possibly other dentists will establish the surgery centers. KSA is an organization that has a long-standing reputation for quality dental care and as community partners. I urge the Division of Health Service Regulation to approve their application.

Sincerely,

Signature

(Print name and address)

Name: JOYCE L. WALL

Address: 1005 HUTTON LN, STE. 112, HIGH POINT, NC 27262

Attachment N

Greensboro City Council Resolution

GREENSBORO
CITY COUNCIL
RESOLUTION

RESOLUTION IN SUPPORT OF A CERTIFICATE OF NEED TO BE ISSUED FOR A DENTAL AMBULATORY SURGICAL CENTER IN GREENSBORO

WHEREAS, hospitals and traditional ambulatory surgery centers have either limited or eliminated scheduled operating room blocks for dentists; therefore, Knowles, Smith and Associates, LP (KSA), a multi-specialty dental practice in southeastern North Carolina, is leading an effort to establish alternative dental single specialty ambulatory surgical facilities;

WHEREAS, KSA, a member of the Valleygate Dental Surgery of the Triad, LLC, welcomes all other dentists in the Triad area;

WHEREAS, KSA pediatric dentists pursued the regulatory change to permit the center because they found hospital access increasingly difficult for dentists; and have proposed to open a Greensboro location at 510 Hickory Ridge Road;

WHEREAS, access to these facilities in North Carolina is limited, where a four month wait list is common, and North Carolina Statutes prohibit hospitals from granting admittance privileges to dentists other than oral and maxillofacial surgeons;

WHEREAS, when young children, disabled adults, and others need complex dental procedures, they are faced with significant access restrictions to care that generally require anesthesia in a safe, operating room environment;

WHEREAS, as many as one in four Medicaid children treated by KSA dentists require general anesthesia; and the hospitals in the Triad system support transferring these cases from the hospital to a dental surgery center;

WHEREAS, Valleygate Dental Surgery Center of the Triad will serve dental patients who need sedation in a licensed dental-only ambulatory surgical facility, and pediatric patients will be their primary focus. Certified Registered Nurse Anesthetist's (CRNA's) and Board Certified Anesthesiologists will provide sedation and airway management;

WHEREAS, the facility will be licensed as an ambulatory surgical facility that will seek national accreditation;

WHEREAS, at this time, Valleygate seeks to obtain a Certificate of Need (CON), which is a prerequisite to licensure as a dental ambulatory surgical facility and certification by Medicare and Medicaid;

WHEREAS, as part of the CON application, Valleygate requests support from the City Council of the City of Greensboro.

NOW, THEREFORE, BE IT RESOLVED BY THE CITY COUNCIL OF THE CITY OF GREENSBORO:

That it hereby supports the proposed Greensboro Dental Ambulatory Surgical Center to be located at 510 Hickory Ridge Drive and encourages Division of Health Service Regulation approval of the application for said center.

Adopted this the 19th day of July 2016.