Comments in Opposition to
Project ID # F-11195-16
Surgical Center for Dental Professionals of Charlotte, LLC

Comments Submitted by Carolinas Center for Ambulatory Surgery, LLC

Pursuant to North Carolina Gen. Stat. § 131E-185, Carolinas Center for Ambulatory Surgery, LLC ("CCAD") submits these comments in opposition to the application filed by Surgical Center for Dental Professionals of Charlotte, LLC ("SCDP" or "the applicant") to develop an ambulatory surgery center ("ASC") with two licensed operating rooms and two procedure rooms in Charlotte, in response to the need determination in the *2016 SMFP* for a dental single specialty ambulatory surgical facility demonstration project in Region 2: HSA III. As discussed below, the applicant's project is non-conforming with several applicable CON criteria. A comparative analysis also shows that the CCAD project is the superior alternative to the applicant's project.

On page 16 of its application, the applicant states:

> *"It should be noted that the demonstration project parameters as described in the special need determination are based on the model proposed by Triangle Implant Center. . . . in particular, the SHCC rejected the proposal to limit the scope of the demonstration project to pediatric dentistry only, choosing instead a more broad commitment to meeting the needs of the underserved, including the Medicaid and uninsured population, as advocated by Dr. Reebye in his petition."*

The applicant seems to suggest that its proposal should be granted favorable treatment because its petition was the so-called "model" for the demonstration project. This is incorrect. Just as it is irrelevant which applicant generates a need that appears in the SMFP, it is also irrelevant which petition served as the "model" for a demonstration project, as there is no review criteria or special rule that relates to this. Both applicants must be treated the same with respect to the review criteria and applicable rules. Both applicants must prove the need for their proposals; as stated below, SCDP has failed to do so.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

(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, operating rooms, or home health offices that may be approved.

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."*

The applicant proposes to provide access to all licensed dentists, regardless of whether they have a completed a hospital-based residency program or hold sedation or anesthesia permits from the North Carolina State Board of Dental Examiners. On page 20 of the application, the applicant states,

> *"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 application shows that five general practitioner dentists propose to bring cases the ASC. Four of these five dentists [Drs. Cline, Edwards, Oblinger, and Woodman] who committed to performing surgical cases at SCDP do not have North Carolina State Board of Dental Examiners ("North Carolina Dental Board") permits to provide sedation or anesthesia. These dentists, by North Carolina 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.

Oral Surgeons and Pediatric Dentists complete a post-graduate hospital-based residency program, providing them with the necessary experience to treat sedated patients. In all postgraduate programs that teach treatment of patients under general anesthesia, training includes experience in the surgical environment, and extensive training in the multitude of possible medical and physical problems that are associated with the use of this modality. In addition, all of these training programs recognize not only the process of general anesthesia, but the programs also place *significant emphasis* on medical diagnosis and the importance of patient selection when determining if a patient is fit to undergo such a procedure. Not only are these general practitioner dentists legally unable to provide sedation or anesthesia themselves but they do not possess the necessary knowledge, obtained through a post-graduate hospital-based residency program, to know when a patient is clinically fit to be sedated, or anesthetized in the first place, even if the sedation is performed by another practitioner.

The applicant appears to create an environment with potential for dangerous clinical situations. The application proposes to recruit dentists who have no previous experience in selecting patients for treatment under general anesthesia or sedation, or experience/training in treating patients under anesthesia, and encourages these dentists to treat sedated or anesthetized patients. CCAD believes that, at minimum, dentists should hold sedation permits with the North Carolina Dental Board or have completed a post-graduate residency program that included operating room training in order to treat patients under general anesthesia. The North Carolina Dental Board requires minimum levels of clinical training in order to hold a sedation or anesthesia permit. Further, the North Carolina Dental Board recognizes that these treatment modalities encompass not only the operative care but also the pre- and post-operative care these patients require.

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

1. **Hospital Credentialing Policies.** The applicant states several times throughout its application that hospital bylaws prevent general practitioner dentists and other dentists

who are not oral surgeons or pediatric dentists from obtaining privileges at hospitals. The applicant suggests hospital bylaws discriminate against general practitioner 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. Bylaws often require that any dentist who seeks to perform surgery in hospital operating rooms have the required postgraduate training. Oral Surgeons and Pediatric Dentists, by definition, have the required training. Some general practitioner dentists may also have been through postgraduate residency programs that meet the typical hospital credentialing standards.

For example, Cape Fear Valley Health System requires that dentists meet the following criterion:

> *"Successful completion of an approved one-year general practice residency (general dentists) or specialty training program (specialists)."*

Central Carolina Hospital's requires the following minimum training:

> *"Applicants must have completed a hospital based residency in general dentistry, a pediatric dental residency training program, or have equivalent experience as a dentist member of a hospital medical staff. Central Carolina Hospital may grant privileges to general practice dentists for routine dental treatments or for performing surgical or emergency procedures when applicants can demonstrate appropriate training and experience."*

By providing these training requirements, hospitals ensure that providers allowed to do surgery in their operating rooms have the required training. In this respect, because general anesthesia and surgery are involved, a dental ASC should be no different. Please refer to Attachment A.

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

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

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

3. **No Precedent Exists for SCDP of Charlotte's Project.** If the applicant's project is approved and implemented as proposed in the application, it will become the first ASC in North Carolina in which dentists or other dental subspecialists without formal supervised experience treating patients under general anesthesia will be allowed to do so. This is a lower standard than is even applied in the applicant's owner's dental practice of Triangle Implant Center. Those oral surgeons have the appropriate hospital and operating room based training to perform surgery on anesthetized patients. According to the application on page 77, Triangle Implant Center does not allow general practitioner dentists into its own

practices to perform procedures under general anesthesia or sedation. The application states that other dentists seeking to perform any procedures at Triangle Implant Center "cannot currently be accommodated". SCDP of Charlotte's project does not have the same clinical rigor.

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

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

Under #2, the policy states that the prospective surgery center provider will observe "Proper ways to operate around intubated anesthetized patient," "Importance of maintain intubation, IV and monitoring equipment placement," "Sealing of the oropharynx with a throat pack and removal of throat pack," "Proper draping and securing of the head for protection," "Taking x-rays with patient in supine position," and "Focus on efficiency to minimize sedation time." Apparently, prospective dentists who have no prior experience in operating rooms or with anesthetized patients will be able to <u>observe these items via video, only once, and meet the requirements for credentialing at the ASC</u>. 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.

Please see Attachment B for excerpts from the Pennsylvania Oral and Maxillofacial Society, and the American Dental Association, both of which emphasize the importance of

extensive training on the part of the dentist who cares for patients under general anesthesia. This applies regardless of whether an anesthesia professional is also present.

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

   The ASC will have two operating rooms and two procedure rooms, which will be dedicated to providing only dental procedures that require sedation. The applicant proposes to perform 3,214 procedures in its third year of operation (Application page 138). Assuming a 250 day a year operations schedule, the ASC will perform 3.0 cases per day in each of its four rooms in the third year [3,214 / 4 = 804 cases per room / 250 days = 3.2 cases per room per day]. This case volume is certain to frequently result in three or four concurrent cases being performed. However, the applicant only provides enough expense in its pro forma financial statements for a single anesthesiologist and therefore expects to have that anesthesiologist be the only individual administering anesthesia. Such a demand upon the anesthesiologist appears to place patient safety and quality at risk, as the Medicare billing requirements show.

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

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

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

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

Please refer to Attachment C.

5. **Medical Board Issues.** On page 54 of the application, the applicant states that the manager "will employ" the required pediatrician. The Development and Management Agreement confirms the management company, Papillion Management, will employ the proposed pediatrician. Thus, Papillion Management will be engaged in the practice of medicine. It is legally impermissible for the manager to employ the pediatrician in North Carolina—such would violate the requirements of the North Carolina Medical Board. According to the Official Position Statement, Papillion Management is potentially subject to injunctive relief.

   Please refer to Attachment D.

SMFP Policy GEN-3, as well as Criterion (18a), promotes implementation of projects which enhance safety and quality. A project for a new ASC model that is less restrictive than the North Carolina Dental Board requirements with regard to sedation and that appears to conflict with federal rules governing anesthesia and the North Carolina Medical Board's Official Position Statement does not "promote safety and quality."

The North Carolina Medical Board states:

> *"It is the position of the Board that, except as discussed below, businesses practicing medicine in North Carolina must be owned in their entirety by persons holding active North Carolina licenses. The owners of a business engaged in the practice of medicine must be licensees of this Board or one of the combinations permitted in N.C. Gen. Stat. § 55B-14."*

As shown on page 13 of the application, none of the individuals associated with Papillion Management is a licensee of the North Carolina Medical Board. Additionally, none of the combinations in N.C. Gen. Stat. § 55B-14 applies.

Therefore, the applicant is non-conforming with Criterion (1).

(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.

The applicant fails to adequately identify the population to be served by the proposed project or the need that this population has for the services proposed. The applicant's entire Need and projected Utilization is based on an unreasonable methodology and assumptions. The following discussion highlights the problems with the methodology that results in unreasonable volume projections.

Need Methodology

On page 108 of the application, the applicant states:

> *"SCDP of Charlotte believes that the assumptions and methodologies presented in the application represent the most reasonable and well-supported rationale for projecting utilization, patient origin, payor mix, patient age (over/under 21) and financial results based on the data available."*

The applicant also notes on page 107 of the application that it has very little in the way of local relationships and had to rely on the experience of dental professionals "in other areas of the state."

As a Triangle-based provider with no Charlotte-based partner to assist it with projecting utilization, patient origin, payor mix, patient age (over/under 21), or financial results, the applicant only offers "data available" from other areas of the State and expects the Agency to believe the "data available" is the most reasonable and well-supported rationale. It should also be noted that on page 108 of the application the applicant is relying on two other CON applications, SCDP of Greenville, LLC (Project ID # Q-11171-16) and SCDP of Raleigh, LLC (Project ID # J-11170-16), which are currently under review and have not been approved as of this time. These submitted CON applications are not an authoritative data "source" and do not provide a statistically reliable method for determining utilization of a Charlotte-based facility. The following discussion

demonstrates that the applicant's data are useless in projecting utilization, patient origin, payor mix, patient age (over/under 21) and financial results.

Beginning on page 101, the applicant appeals to the Agency to believe that its unrelated assumptions from different areas of the State far from Charlotte are "the minimum estimate" of need. The applicant's assumptions are unreasonable and show that the applicant does not know what the need is.

The applicant offers three scenarios in establishing a dental and oral surgical cases requiring sedation use rate per 1,000 population to apply to the 8-county Region 2, HSA III with a population of 2.1 million by using only 2,000 Triangle Implant Center ("TIC") patients in three non-Charlotte locations; Durham, Alamance and Wilson. On page 101 of the application, the applicant acknowledges that TIC is not an ASC. The applicant does not attempt to quantify the number of cases performed at the TIC facilities that could have been appropriately performed in an ASC; rather, the applicant simply *assumes* that all of these cases could have been appropriately performed in an ASC. It is unreasonable to assume that all oral surgery cases currently being sedated in an unlicensed oral surgery office will automatically meet criteria that best serves the patient to be moved to an ASC. Only a small number of those patient cases should qualify to be moved. Thus, the applicant's "use rates," as shown on the following table, are unsupported and unreasonable:

County	Total TIC Cases	Under 21	21 +
Durham Cases	808	89	719
Durham Population	297,807	83,060	214,747
Durham Use Rate	**2.71**	1.07	3.35
Alamance Cases	833	151	682
Alamance Population	157,624	43,259	114,365
Alamance Use Rate	**5.28**	3.48	5.97
Wilson Cases	378	110	268
Wilson Population	81,677	22,128	59,549
Wilson Use Rate	**4.63**	4.99	4.50

To this point, the applicant has calculated the use rate per 1,000 population for Durham County, Alamance County, and Wilson County based on 808 cases, 833 cases, and 378 cases, respectively. Because of the lack of data, the applicant refers to these use rates as "conservative." In addition to its erroneous assumption that all of these cases could have been appropriately performed in an ASC, the applicant does not attempt to explain why these counties and their use rates are similar to Region 2 for the purpose of applying the use rate to a population of 2.1 million. In fact, the applicant does not explain why it does not use the use rate per 1,000 population generated by the total number of cases performed at each of the three TIC offices for the multicounty markets that they serve, rather than just applying a one-county use rate from the county where the TIC office is located.

Then the applicant applies the "conservative" use rate to the 8-county, Region 2 service area to project 2015 and 2020 "conservative" "potential" cases:

	Total	**Under 21**	**21 +**
2015 Region 2 Population	2,111,157	589,604	1,521,553
Durham Use Rate "Cases"	**5,726**	632	5,094
Alamance Use Rate "Cases"	**11,131**	2,054	9,077
Wilson Use Rate "Cases"	9,782	2,940	6,841

	Total	**Under 21**	**21 +**
2020 Region 2 Population	2,287,109	609,487	1,677,622
Durham Use Rate "Cases"	**6,270**	653	5,617
Alamance Use Rate "Cases"	**12,131**	2,123	10,008
Wilson Use Rate "Cases"	10,583	3,039	7,543

The results indicate "conservative" "potential" cases between 6,270 cases and 12,131 cases in 2020. Again, the applicant does not attempt to explain why these counties and their use rates are similar to Region 2 for the purpose of applying the use rate to a population of 2.1 million.

Next, on page 105, the applicant differentiates between dental and oral surgical cases requiring sedation performed in a dental office from those performed in either a hospital or ASC by calculating an additional

use rate per 1,000 population for dental and oral surgical cases requiring sedation performed in a hospital or ASC:

	North Carolina	Region 2
OP Oral Surgery Cases	13,612	2,203
2014 Population	9,953,687	2,078,052
Use Rate per 1,000	1.37	1.06
	2015	**2020**
Region 2 Population	2,111,157	2,287,109
North Carolina Use Rate	2,887	3,128
Region 2 Use Rate	2,238	2,425

The applicant combines the two calculations to project "conservative" "potential" oral surgery cases requiring sedation in Region 2 and then applies a utilization of 900 cases per operating room to establish an operating room need in Region 2 as shown in the following table:

	TIC Case Estimate	Hospital and ASC Estimates	Total Estimates	Operating Rooms Needed
2015 Low Estimate	5,726	2,238	7,965	9
2015 High Estimate	11,131	2,887	14,018	16
2020 Low Estimate	6,270	2,425	2,695	10
2020 High Estimate	12,131	3,128	15,259	17

On page 106 of the application, the applicant incorrectly assumes that all dental and oral surgical cases requiring sedation should be only be performed in an operating room. It has been an established "standard of care" that most dental and oral surgical cases requiring sedation can safely be performed in an office-based setting.

There are many surgical and procedure cases that require more than minimal sedation including endoscopies, colonoscopies, liposuction, nasal reconstruction, breast augmentation, and some obstetric and gynecological cases that are safely performed in office-based settings that are NOT included in the

methodology to determine the number of operating rooms needed in an area or for a population. As such, the methodology that the applicant offers is unreasonable because the applicant assumes that all sedation-related cases are appropriate for the demonstration project's ASC-setting. This is unreasonable because most dental and oral surgical cases requiring sedation can safely be performed in an office-based setting, closer to the patient's home, not requiring a patient from Statesville in Iredell County to travel to Charlotte in Mecklenburg County for dental and oral surgical cases requiring sedation.

General Dentistry Need

The applicant utterly fails to demonstrate a need for *general dentistry* services at the ASC. Five general practitioner dentists confirmed they would bring cases to the ASC, yet the applicant never provided information as to what kind of cases they would bring. Additionally, general practitioner dentists do not typically require access to an operating room. Only one of the five identified general practitioner dentists [Dr. Cox] holds a North Carolina sedation permit. For the other four, they would presumably be completing procedures on sedated or anesthetized patients despite the fact that this is not a standard part of their own private practice. It would be an entirely new clinical experience for them. Of course, to borrow SCDP's language on page 76 of the application:

> *"Dentists in North Carolina can currently obtain oral sedation or anesthesia permits with relative ease"*.[2]

These general practitioner 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. The applicant's ASC represents a third option, but makes unsubstantiated claims for the need of this service. By suggesting that sedation dentistry is somehow unsafe in an office setting, the applicant suggests that the North Carolina Dental Board is in error for allowing it to occur. The applicant provides no evidence that general sedation dentistry should never be practiced in an office setting.

In comparison, CCAD will allow general practitioner dentists to perform surgical cases as long as they are capable of meeting the credentialing requirements, which include that every dentist either have completed

[2] The applicant also states on page 76 of the application that such permits will be more difficult to obtain in the future. Even if this statement is correct, the applicant provides no evidence showing that the fur general practitioner dentists are willing to obtain anesthesia/sedation permits.

a hospital-based post graduate residency or hold a sedation or anesthesia permit with the North Carolina Dental Board.

While flawed in its assumption that all oral surgery needs an operating room, the applicant's quantitative need methodology in Section III.1.(b) does not address general dentistry in any way. As a result, the applicant fails to properly demonstrate a need for general dentistry services at the ASC.

Pediatric Dentistry Need

The applicant provides no supporting evidence it has the capability of serving pediatric dental surgical cases at the ASC. The applicant projects that, in the third year, the facility will perform 1,110 cases for patients under 21 or 34.5 percent of the ASC's projected total cases. Further, the applicant fails to discuss or provide any information in Section III that specifically and expressly demonstrates any quantified need for pediatric dentistry services to be performed in an ambulatory surgical facility. The applicant provides limited support from local pediatric dentists (only one [Dr. Webb] is listed as potentially bringing cases)[3], making it difficult to serve these cases, especially for those children under age nine, for which pediatric dentists often specialize.

As with general dentistry, the applicant's quantitative need methodology in Section III.1.(b) does not address pediatric dentistry in any way. As a result, the applicant fails to properly demonstrate a need for pediatric dentistry services at the ASC.

Utilization

The applicant begins its utilization projections by acknowledging two major weaknesses in its proposal: (1) it lacks reliable data; and (2) it does not have strong relationships in the location where it plans to develop the facility.

On pages 107 and 108 of the application, the applicant states that "data, especially publicly-available data were scarce." To compensate, the applicant states that it relied on "an incredible and expansive group of dental professionals that provided data based on their experience *in other areas of the state.*" (emphasis added). The applicant then says it consulted an "extensive list of experts" which includes accountants,

[3] Dr. Webb does not have an anesthesia or sedation permit.

hospital executives, architects, developers, healthcare planners and healthcare attorneys." The applicant does not identify these experts or explain how their expertise contributed to the need methodology in the application. Regardless, accountants, hospital executives, architects, developers, healthcare planners and healthcare attorneys will not be performing cases in the ASC and they will not be referring patients to the ASC.

On page 108 of the application, the applicant states:

> *"Triangle Implant Center does not have an existing office in Region 2. Thus, SCDP of Charlotte does not have the same degree of local data and relationships with the community to rely on in projecting its experience. Given these factors, SCDP of Charlotte has provided its most reasonable and supported estimates for its project using the best data available to it."*

Based on this statement, the applicant wants the Agency to accept without question its unrelated data used to project its utilization because the applicant claims that was the best it had available. The Agency is not bound to accept unrelated data. The applicant's reliance on unrelated data and its candid admission that it lacks local data and local relationships stands in contrast to CCAD's proposal, in which utilization is founded on the local experience of Carolinas Center for Oral and Facial Surgery, the experience of many other local pediatric dentists, and DMA data.

On pages 108 and 109 of the application, the applicant begins its utilization methodology by calculating its "implied market share"[4] for Demonstration Project Region 1 and Region 3, because it has previously submitted applications for these two regions. This is entirely unreasonable. Whatever "implied market share" the applicant believes it may have in Regions 1 and 3 has no bearing on what its experience may be in Region 2. Moreover, neither the SCDP Region 1 or Region 2 applications has been approved at this point so they are not precedent. The following table shows the "implied market shares" for Regions 1 and 3 based on lower estimated market need and higher estimated market need:

[4] The term "implied market share" appears to be a term the applicant coined; no definition is provided.

	Lower Estimated Market Need	**Higher Estimated Market Need**
Region 1 Implied Market Share	78.0%	45.8%
Region 3 Implied Market Share	25.0%	14.0%
Ratio	3.13	3.26

On pages 110 and 111 of the application, the applicant tries to explain the difference in "implied market shares" by showing the differences between Region 1 and Region 3. The differences identified by the applicant include the number of HSAs, the number of counties, number of urban centers, and the number of rural counties that border urban centers. Regardless of this explanation, the fact is the applicant provides no real bases for its market share in either Raleigh or in Greenville. The applicant believes that it has a higher "implied market share" in Region 1 because it has fewer counties, is physically smaller, and has a more closely aligned population centered on several proximate urban centers. The reasons presented for a higher "implied market share" are the exact reasons why the applicant's market share should be smaller, not 3.1 times larger. In a more concentrated service area, there will be more providers and more competition because there is a larger population centered on urban settings that are closely adjacent to each other. The applicant's logic is flawed.

On page 112 of the application, the applicant asserts:

> *[that it] "would be reasonable to assume that it will have an implied market share that is similar to SCDP of Raleigh based on the similarities of geography and location."*

There are at least two problems with this statement. First, the Agency has not determined whether the methodology and assumptions used in the SCDP of Raleigh application are reasonable. One pending application is not "precedent" for another pending application. It is one thing to make assumptions in the SCDP of Raleigh application about the utilization of the Raleigh facility, but it is something else to take those yet-to-be-approved assumptions about a facility that does not exist (SCDP of Raleigh) and then apply them to another non-existent facility in a different part of the state. The applicant is merely layering assumptions on top of assumptions. Second, the applicant states several times in the application that it does not have the same strong relationships in the Charlotte area that it claims to have in Raleigh. The lack of local relationships casts serious doubt on the applicant's projections. Even the applicant recognizes this on page 113 of the application, as it discounts its Raleigh/Greenville "ratio" but then inexplicably proceeds

to assume that its "implied market share" will be 1.5 times that of SCDP of Greenville. Greenville is another area of North Carolina where the applicant does not have strong professional relationships. Aside from the aforementioned problem of layering assumptions on top of assumptions, the applicant does not provide a statistical basis for its determination that its "implied market share" in Charlotte would be 1.5 times higher than its "implied market share" in Greenville. The applicant merely notes that 1.5 is roughly half of the Raleigh/Greenville "ratio" and supposedly factors in geographic differences between Greenville and Charlotte. There is no basis for making any assumptions about the applicant's "implied market share" in Charlotte based on its "implied market share" in Greenville --- let alone an assumption that the "implied market share" in Charlotte would let alone be 1.5 times higher its "implied market share" in Greenville. Picking a number that is roughly half of some other number is not evidence of reasonableness or reliability. The best that can be said of the Charlotte/Greenville hypothetical that the applicant poses is that they are both cities where the applicant does not have strong professional relationships.

The applicant then assumes, without adequate explanation, that SCDP of Charlotte shares similarities to SCDP of Raleigh, but will have an "implied market share" of 1.5 times that of SCDP of Greenville. Even if the "implied market share" method was credible, which it is not, the applicant assumes data contained in pending applications is somehow "precedent" for SCDP of Charlotte. Pending applications, despite their own flaws, are not adequate source material. For SCDP of Charlotte, the applicant has essentially made up a market share assumption by using the following formula, which is not stated in the application:

> [SCDP of Raleigh "Implied Market Share" Ratio – Market Differences = Assumed Ratio]
> Thus,
> [3.13 – existing relationships in Region 2 are more similar to SCDP of Greenville = 1.5]

How the applicant valued the existing relationships in Region 2 as being more similar to SCDP of Greenville to be equal to 1.63 is unknown.

Next, on page 114, the applicant applies the previously calculated Assumed Ratio to the SCDP of Greenville "Implied Market Share" of Region 3 to generate the SCDP of Charlotte "Implied Market Share" of Region 2. In essence, the applicant has multiplied a ratio that it fails to explain how it was calculated to an "implied market share" for a 44-county region in eastern North Carolina to project its "implied market share"

for the 8-county Region 2 and then uses those implied market shares" to project "potential" Year 3 cases, as shown in the following table:

	Lower Estimated Market Need	Higher Estimated Market Need
SCDP of Greenville Implied Market Share of Region 3	25.0%	14.0%
Assumed Ratio	1.5	1.5
SCDP of Charlotte Implied Market Share of Region 2	**37.4%**	**21.1%**
Region 2 Market Need	8,695	15,259
SCDP of Charlotte Year 3 Volume	**3,255**	**3,214**

The applicant believes that its projected case volume of 3,214 cases is supported by the support letters included in Exhibit 29. The applicant includes the list of dental professional who sent letters of support to the applicant including Dr. Gregory Tull, an oral surgeon at the Carolinas Center for Oral and Facial Surgery. Dr. Tull is an oral surgeon who is a part of the application submitted by CCAD. Dr. Tull will be sending a letter to the Agency during the Public Comment Period withdrawing his referrals to SCDP of Charlotte. Dr. Tull sent the letter to the applicant in error due to multiple emails being sent by several members of each application. As a result, the applicant will have 120 fewer referrals annually and cannot use the high estimate of 10 cases per month to apply to referral sources.

Please refer to Attachment E.

Even using Dr. Tull's projected volumes, the applicant fails to support the fanciful volume projection of 3,214 cases. First, on page 114 of the application, the applicant identified the range of cases to be performed at the ASC by eight dental professionals; the range being 13 to 45 cases per month or 156 to 540 cases per year. It is highly unlikely that each dental professional will attain the high end of the estimates. Second, the applicant applies the range of cases to be performed (1 to 10 per month) to the remaining seventeen dental professional who only stated that they would refer patients to the ASC. This sounds simple enough, but a review of the support letters shows that Drs. Allen, Anonuevo, and Summerville did not identify that they would refer to the ASC, only that they would consider being investors in the application. Please see the doctors' letters on pages 527, 528, and 541 of the application. Further, according to the North Carolina Dental Board website (Please see Attachment F), Dr. William S. Kirk, Jr.

practices in Goldsboro, Wayne County, North Carolina. It is most unlikely that a dentist located more than 3 hours and 200 miles away from the proposed facility will be in a position to refer any patients to a Charlotte-based facility. Thus, the table on page 115 of the application is not accurate.

On page 115, the applicant asks the Agency to engage in the following speculation:

> *"[i]f each of those 17 dental professionals refers a similar number of patients as those who provided specific volumes, between one and 10 patients per month, this group would constitute another 204 to 2,040 patients annually."*

There are two problems with this. First, as noted above, there are not 17 dental professionals who said they would refer; Drs. Allen, Anonuevo, and Summerville only stated that they would consider being investors in SCDP. Dr. Kirk practices on the other side of the State so he is not likely to refer any patients to SCDP of Charlotte. Thus, a more accurate number of referring dental professionals is 13, not 17. Second, nothing in the letters in Exhibit 29 suggests that the dental professionals would refer any particular number of patients per month. It is entirely unreasonable to speculate that the 13 dental professionals who said they would refer will refer between 1 and 10 patients per month.

But even accepting the applicant's speculation, and using the correct number of dental professionals (13) who indicated that they would refer to the ASC and the range of cases to be performed (1 to 10 per month) would result in 156 (13 x 12) to 1,560 (13 x 120) cases. Again, it is not likely that each dental professional will attain the high end of the estimates. Further, only one out of the eight dental professionals who said they would perform cases in the facility, Dr. Tull, a CCAD-related oral surgeon, indicated that he would perform, on the high end, 10 cases per month, so instead of using a range of volumes a better method would be to use an average of cases per month, which results in 1.1 cases to 3.75 cases per month. Using the correct number of dental professionals who indicated that they would refer to the ASC and the average cases per month to be performed (1.1 to 3.75 per month) would result in 185 (14 x 13.2) to 630 (14 x 45) cases. Based on the actual dental professionals identified in the application and a reasonable average of cases per month, the applicant has failed to demonstrate that it has local support to validate a volume of 3,214 cases.

The applicant continues the utilization methodology on page 116 by assuming:

> *"...most of its projected cases would be appropriate to be performed in either the two operating rooms or in the two proposed procedure rooms. Patients will be priority scheduled in the operating rooms based on the request of the user."*

Based on this statement, the applicant sees no difference between the operating rooms and the procedure rooms. The applicant believes that any of its projected dental cases that require sedation can be performed in a non-licensed procedure room, which is where they are currently being performed at the convenience of the patients. The applicant believes it is reasonable to estimate that each operating room will provide 1,000 cases annually, leaving the procedure rooms with 607 cases annually, for a total of 3,214 cases in Year 3. However, this distribution of cases is not reasonable and will most likely not be how the ASC operates. Since the applicant believes that the procedure rooms are no different from the operating rooms, it is more likely that the four rooms will be scheduled in a manner that equalizes the annual volumes or 803 [3,214 / 4] cases per operating and procedure room annually, which does not meet the 900 cases per operating room performance standard.

The applicant spends six pages (pages 139-145) discussing Region 2's age mix and payor mix by age mix. However, where it previously believed that Region 1 was more similar to Region 2, now it believes that Region 3 is more similar to Region 2. The applicant provides no valid reasons to base the age mix or payor mix by age mix in the 8-county Region 2 by slightly adjusting the age mix and payor mix by age mix in the 44-county Region 3. As discussed above, it is unreasonable to base payor mix on assumptions contained in a pending application.

Patient Origin

In response to Section III.6, the applicant states on pages 129-130 of the application:

> *"SCDP of Charlotte projected its patient origin based on support from its dental professionals in counties in the region, population data, the proposed location of the facility, and the experience of its dental professional supporters and investors in other areas of the state. Given these factors, SCDP of Charlotte assumes that 65 percent of its patients*

> *would originate from Mecklenburg County, the county in which the proposed facility will be located."*

The applicant does not explain how any of these factors, especially the "dental and professional supporters and investors in other areas of the state," lead to 65.0 percent of patients originating from Mecklenburg County. Only five of the dental professionals who stated they would actually perform cases in the facility are based in Mecklenburg County. Only 13 dental professionals who said they would refer cases are located in Mecklenburg County, and it is unknown how many cases these professionals actually would refer to SCDP. Even the data the applicant provides in Section III does not support the assumption that 65.0 percent of patients would originate from Mecklenburg County. As discussed beginning on page 101, the TIC office in Durham performed 1,735 total dental and oral surgical cases requiring sedation, of which 808 originated from Durham County where the TIC office is located; this results in a patient origin of 46.6 percent. The TIC office in Wilson performed 1,077 total dental and oral surgical cases requiring sedation, of which 378 originated from Wilson County where the TIC office is located; this results in a patient origin of 35.1 percent.

Stricter General Anesthesia and Sedation Regulations

In response to Section III.1(a), on page 76 of the application the applicant states:

> *"The proposed rule changes, included in Exhibit 5, will make oral sedation or anesthesia permits more difficult to obtain."*

However, the rules included in Exhibit 5 show no changes to the requirements for receiving oral sedation or anesthesia permits and are current as of changes made on September 1, 2007[5].

The applicant's entire need methodology and utilization methodology are based on unreasonable assumptions and unrelated data. Therefore, the applicant is non-conforming with Criterion (3).

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[5] One of the rules included in Exhibit 5 of the application, 21 NCAC 16Q.0403 was effective on February 1, 2009.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

On pages 130 through 134 of the application, the applicant describes the alternatives to the proposal it considered, which were limited to the Status Quo, Develop Project in a Different Area, Develop a Pediatric-Only ASC, and Develop Project as Proposed. Additionally, the SCDP of Charlotte application make clear that many of the cases which will supposedly "be performed" at SCDP of Charlotte are currently the same types of cases which are completed currently, without issue, in oral surgery offices like the Triangle Implant Center for lower charges. As such, the applicant fails to prove that the status quo is not a better option for the applicant. In addition, since the application is non-conforming with Criteria (1), (3), (5), (6), (7), (12), and (18a), it should also be found non-conforming with Criterion (4).

(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.

As discussed in Criterion (3), the applicant fails to demonstrate that its projected operating room volumes are reasonable, credible, or supported. Thus, the application must also be found non-conforming with Criterion (5) because the project will not be financially feasible. As discussed below, there are other problems with the application under Criterion (5).

Working Capital Funding

In response to Section IX.1(a), the applicant states that its estimated start-up expenses will total $142,242. The applicant fails to identify how the estimated start-up expenses were calculated in either Section IX or the pro forma financial statements, so the Agency cannot determine what constitutes the start-up expenses or the expenses incurred prior to operation.

The Development and Management Services Agreement, included in Exhibit 2, includes a development fee of $18,750 per month to begin on the CON Award date and end when the ASC becomes operational. The Proposed Development Schedule in Section IX shows a 12-month development period; as such, the applicant will incur $225,000 in development fees prior to operation. Clearly, the applicant has not included this development fee in its estimated start-up expenses and has thus erred in determining its Total Working Capital Required.

Professional Fees

Throughout the application, the applicant states that it will provide anesthesiology coverage for all cases under sedation. The applicant also states in its pro forma financial statement assumptions that charges are average bundled fees, which include both facility fees and anesthesia fees. As a result, the applicant must account for the cost of all of the required 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 (including professional services, anesthesia equipment, and maintenance) and other professional fees, based on the experience of SCDP of Charlotte's management company and discussions with anesthesia providers, inflated 2% per year."*

The pro forma financial statement assumptions reference information obtained from "anesthesia providers", but does not specify the actual source. To evaluate the reasonableness of the applicant's anesthesia cost, CCAD 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[6].

It should be noted that in the CCAD application, CCAD also includes the cost of CRNAs because a single anesthesiologist cannot cover all cases in the facility. CRNA models are used nationwide and have been proven to be effective. Even ECAA Anesthesia Specialists, the applicant'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.*[7]"

The applicant claims to be running two operating rooms and two procedure rooms, each with an anesthesiologist. If the applicant truly needs all four rooms, then logic holds it would, *at the very least*, run three rooms concurrently each day. The following table calculates cost assuming that three anesthesiologists are required every day to provide the anesthesiology coverage for all cases under sedation.

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

Table 1 – Estimated SCDPC Anesthesia Cost Understatement

Notes	Metric	FFY2018	FFY2019	FFY2020
a	Anesthesiologist Expense	$498,000	$507,960	$518,119
b	Growth		2.0%	2.0%
c	Cost of One, Contract Full-time Anesthesiologist: Medscape.com	$413,000	$421,260	$429,685
d	Minimum Anesthesiologist FTEs Needed	3.0	3.0	3.0
e	Minimum Anesthesiologist Cost	$1,239,000	$1,263,780	$1,289,055
f	Cost Understatement (3.0 FTEs vs. 1.0 FTE)	$741,000	$755,820	$770,936
g	Net Income	$414,439	$805,202	$1,200,271
h	**Adjusted Net Income**	**$(326,561)**	**$49,382**	**$429,335**

Notes: a: SCDPC 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 SCDPC
e: c * d
f: e - a
g: SCDPC Form B/C
h: f - g

If the applicant truly needs all four rooms running all the time, then it would presumably require more than 3.0 FTE anesthesiologists. Even if the ASC staffed only 3.0 FTE anesthesiologists, then it would incur a cost exceeding $1.28 million annually, a significantly higher Professional Fee cost than projected in pro forma financial statements.

If the applicant truly intends to utilize anesthesiologists to cover all procedures, as it says it will, then the applicant understated its costs by over $740,000 in Year 1, which makes the facility unprofitable in Year 1. The all-anesthesiologist model the applicant proposes is not financially feasible.

Patient Revenues

The applicant's pro forma financial statements overstate patient revenues. Some payers will not reimburse "facility fees" for many of the cases the applicant indicates that the ASC will serve.

For procedures deemed medically necessary for an ASC, payers, including Medicaid, reimburse ASC "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" reimbursement under a medical plan.

Medically Necessary policies provide specific limitations to the kinds of dental and oral surgery procedures for which a payer will cover a "facility fee" for procedures completed in ASCs. The following discussion summarizes the Medically Necessary policies from Blue Cross Blue Shield of North Carolina, Cigna, and North Carolina Medicaid.

Blue Cross Blue Shield of North Carolina covers only the following situations in ASCs when dental care or oral surgery is concerned:

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

Cigna requires the following to be medically necessary;

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

North Carolina Medicaid's Policy (which includes Health Choice) states, "...if a Medicaid or North Carolina HC beneficiary is

- physically unmanageable,
- medically compromised, or
- severely developmentally delayed and
- will not cooperate for treatment in the dental office,

- treatment may be completed in an ambulatory surgical center (ASC)."

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

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

Please refer to Attachment G for copies of the identified medically necessary policies.

The applicant does not discuss payer requirements anywhere in the application; nor does it address why certain dental cases would be appropriate for an ASC and why others would not. It is clear that the applicant created its procedure projections and its pro forma financial statement revenue projections without consideration for whether or not the procedures it projects actually meet payer criteria.

It is impossible to determine whether or not the applicant's revenue projections are accurate. If a significant number of the general dentistry cases are for otherwise healthy adults, then the applicant will most likely not be able to collect a "facility fee" from payers for these cases. In any case, the applicant has overstated its revenues.

Based on the applicant's pro forma financial statements, the applicant has not provided accurate working capital costs, operating costs, and patient revenue. Therefore, the application should be found non-conforming with Criterion (5).

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, the applicant did not adequately demonstrate that its proposal will not result in unnecessary duplication of existing or approved health service capabilities or facilities. In fact, the applicant presents a service that would duplicate oral surgery and dental procedures in a different setting at higher cost. Therefore, the application should be found non-conforming with Criterion (6).

(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.

On page 54 of the CON application, the applicant states:

> *"As previously stated, SCDP of Charlotte, LLC will not directly employ any staff for the proposed facility. Papillion Management, LLC will employ the required RN, DA I, DA II, Pediatrician, Physician Assistant, Administration, and non-health professional FTEs and will provide the staff to the ASC through its management agreement with SCPD of Charlotte, LLC."*

The applicant identifies the staff that Papillion Management will provide to the ASC in two responses, in the response to Section VII.2 and in the Development and Management Services Agreement included in Exhibit 2. However, the proposed staffing is inconsistent. The following table identifies the proposed staffing in the two locations:

Position	Salary	Section VII FTEs	Total Salaries	Exhibit 2 FTEs	Total Salaries
Facility Administrator	$120,000	1.0	$120,000	1.0	$120,000
Registered Nurses	$55,000	1.5	$82,500	1.0	$55,000
Physician's Assistants	**$90,000**	**0.5**	**$45,000**	**1.0**	**$90,000**
Dental Assistant I	$38,000	1.5	$57,000	1.5	$57,000
Dental Assistant II	$52,000	2.0	$104,000	2.0	$104,000
Office Administration	$48,000	2.5	$120,000	2.5	$120,000
Pediatrician	$150,000	1.0	$150,000	1.0	$150,000
Non-health professional and technical personnel	$42,000	1.5	$63,000	1.5	$63,000
Total Salaries		**11.5**	**$741,500**	**11.5**	**$759,000**
Benefits and Taxes at 20%			$148,300		$151,800
Total Salaries and Benefits and Taxes			**$889,800**		**$910,800**
Management Agreement Fee			$950,000		$950,000
Remaining Management Agreement Fee For other Management Services			**$60,200**		**$39,200**

While the total FTEs (11.5) is the same in Section VII and Exhibit 2, the applicant does not explain why the number of FTEs for certain positions (i.e., registered nurses and physician's assistants) differs. Thus, the Agency must ask which number is accurate. The Agency cannot be asked to guess what the applicant intends. In addition, neither the application nor the Development and Management Services Agreement identifies the Benefits and Taxes percentage to determine the reasonableness of the Management Services fee. Assuming the same Benefits and Taxes percentage as proposed by CCAD (20.0%); Papillion Management will spend $910,800 on salaries, benefits, and taxes in Year 1, leaving only $39,200 to accomplish an extensive list of other management services:

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

It is unreasonable to assume that the remaining management services can be accomplished for $39,200; thus, it is impossible to assume that the $930,000 management fee in Years 1-3 is reasonable.[8]

In response to Section VII.9(a), the applicant identifies the ASC's Medical Director as David Kornstein, DDS. The Medical Director for the ASC located in Charlotte, Mecklenburg County will be located in Raleigh, Wake County, over 164 miles away. The applicant does not explain how it will be reasonable for Dr. Kornstein to fulfill his medical director responsibilities at such a great distance. See the discussion under Criterion (8) for further information. By contrast, medical directorship for the CCAD proposal will be

[8] And if the Section VII numbers of FTEs are correct, that would leave $60,200 for the remaining management services, which is also too small to cover the range of services proposed.

provided by a Charlotte-based oral surgeon, Dr. Dale Misiek of CCOFS. Please see page 169 of the CCAD application.

In Section IV of the application, the applicant projects 2,571 cases, 2,893 cases, and 3,214 cases in Years 1-3, respectively; however, in response to Section VII.8(a) the applicant states:

> *"Please see Exhibit 29 for letters of support from providers who intend to utilize the proposed facility."*

A review of Exhibit 29 shows eight dental professionals indicating that they would perform cases at the ASC. Minus Dr. Tull, who has withdrawn his support for the SDCP project, equals seven dental professionals indicating that they would perform up to 420 total dental cases at the ASC. The applicant has not shown that it has the dental professional manpower to perform 2,571 cases in Year 1.

Anesthesiology Coverage

The ASC will have two operating rooms and two procedure rooms, which will be dedicated to providing only dental procedures that require sedation. The applicant proposes to perform 3,214 procedures in its third year of operation (Application page 138). Assuming a 250 day a year operations schedule, the ASC will perform 3.0 cases per day in each of its four rooms in the third year [3,214 / 4 = 804 cases per room / 250 days = 3.2 cases per room per day]. This case volume is certain to frequently result in three or four concurrent cases being performed. However, the applicant only provides enough expense in its pro forma financial statements for a single anesthesiologist and therefore expects to have that anesthesiologist be the only individual administering anesthesia. Such a demand upon the anesthesiologist appears to place patient safety and quality at risk,

Employment of Pediatrician

As earlier discussed under Criterion (1), Papillion Management <u>cannot</u> employ a pediatrician. In a footnote on page 179 of the application, SCDP acknowledges this problem but says it is an issue for the agencies to determine, and that in any event, SCDP has budgeted sufficient funds for the hiring of the pediatrician. This answer is insufficient. The North Carolina Medical Board's position on this subject is clear and not open to debate. Additionally, the Official Position Statement makes it clear that employment versus

independent contractor status is <u>not</u> determinative. Thus, it is not possible for SCDP to offer all of the staff its application claims is essential to the project.

Please see Attachment D.

Based on the fact that the applicant cannot show its management company can provide all of the identified management services and does not provide an adequate number of dental professional manpower to perform all of the projected dental cases in Year 1 or provide complete anesthesiology coverage, the application should be found non-conforming with 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 and ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated within the existing health care system.

The applicant admits on page 108 of the application that Triangle Implant Center does not have an office in Region 2 and that SCDP does not have the same degree of local data and relationships with the community as it claims to have elsewhere. The lack of local relationships is a serious flaw in the application; it is those local relationships that will drive the ASC's utilization. The number of cases that local dental professionals actually believe they will perform in the facility fall woefully short of the utilization projections contained in the application, and show that the project is not going to be coordinated within the existing health care system, i.e., the local community.

As noted earlier, in Exhibit 11 of the application, the applicant's proposed Medical Director, Dr. Kornstein, practices dentistry in Raleigh. The proposed ASC will be in Charlotte. The application contains no information about Dr. Kornstein's willingness to travel to Charlotte (approximately 2.5 to 3 hours each way from Raleigh) to perform his duties as Medical Director. While the Medical Director is not required to be on site a particular amount of time, regular on site presence would be expected, especially when the ASC is getting started and seeking to be accredited by The Joint Commission and AAAHC. See application, page 52. In addition to its Raleigh location, Dr. Kornstein's practice, Wake Orthodontics and Pediatric Dentistry, maintains a pediatric dentistry office in Garner. See http://www.wakeorthopedo.com/garner-office/. Dr. Kornstein is also listed as the Medical Director of SCDP of North Carolina's proposed facility in Asheville (Project I.D. No. B-11196-16). The application does not explain how it will be possible for Dr. Kornstein to fulfill his Medical Directorship responsibilities in two geographically-dispersed locations that are far from where Dr. Kornstein practices. It is unreasonable and unrealistic to suggest that a dentist practicing full-time in Raleigh and Garner is going to be spending the time in Charlotte (in addition to Asheville) necessary to carry out the duties of Medical Director.

The support for the project contained in Exhibit 29 is divided into three categories: 1) those who say they would perform cases at the facility and provide an estimate; 2) those who claim they would refer cases;

and 3) "support from other regions." The first category of letters is the most important. Using the high estimate of cases and deducting Dr. Tull's estimate because he no longer supports the project, there are only 35 cases per month, for a total of 420 cases per year as shown on page 517 of the application. Only five of the providers who stated they would actually use the ASC are in Mecklenburg County, and combined, these five providers (using the high end of the estimate) would perform 300 cases annually. See Exhibit 29. This cannot be reconciled with the applicant's extremely high utilization estimates or its projection that 65.0 percent of its patients will originate from Mecklenburg County. As noted earlier, it is also unlikely that each of these providers would reach the high end of the estimate.

As to those providers who indicate that they would refer to the ASC, a total of fourteen such letters are included in the application. There is no way to know the number of patients these physicians claim they would refer. Further, one of the so-called referring dental professionals, Dr. William S. Kirk, Jr., is based in Goldsboro, in Wayne County. It is highly unlikely that Dr. Kirk is going to be referring patients to SCDP of Charlotte.

Please see Attachment F.

The last category of letters (support from other regions) is not helpful to the applicant's cause. A dental professional from "another region" is not going to use a Charlotte-based ASC or send patients to a Charlotte-based ASC. For example, on page 559 of the application, Dr. Kornstein, the Medical Director, signed such a letter. Dr. Kornstein, who is based in Raleigh, is not going to be performing cases in Charlotte, and he is not going to be referring cases to Charlotte. In fact, these letters of support from "other regions" are intended for use in both of the CON applications that the applicant submitted on June 15th; SCDP of Charlotte and SCDP of Asheville, LLC. So these letters are just generic expressions of support that provide no evidence concerning how the project will be coordinated within the "existing health care system," i.e., the local community.

In the 2011 Wake County Operating Room CON Review (Please see Attachment H), the Agency discounted the support provided by the Medical Director of the proposed Novant Health facility in Holly Springs because the Medical Director was based in Winston-Salem, not the local community of Holly Springs or Wake County.

The applicant has failed to adequately demonstrate that its proposal will be coordinated with the existing health care system, and accordingly, its application should be disapproved under 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.

North Carolina Gen. Stat. § 131E-181(a) states, "A certificate of need shall be valid only for the defined scope, physical location, and person named in the application." The Agency assumes that if the CON application is approved that the Certificate of Need will only be valid only for the physical location of the proposed primary site identified in Section XI.2.(c). As shown by the questions in Section XI, the applicant has to provide information showing the primary and any alternative sites are available to the applicant. The Agency cannot determine if an applicant's construction costs are reasonable when it does not know if the site on which the applicant proposes to develop its project is even available. The lack of information included in the CON application related to the proposed primary site and either of the alternative sites shows that the applicant's project is non-conforming with Criterion (12).

The following discussion illustrates that the applicant cannot show that it has a site available to develop its proposed ASC:

In Section I.10(b), the application identifies that the building will be leased from Hookie Bones Properties, LLC and directs the Agency to Exhibit 1 for a copy of the proposed lease agreement. Exhibit 1 includes a blank lease agreement. The blank lease agreement does not include the following information:

- Rentable square footage
- Location
- Rent

Although sample blank lease agreements have been included in CON applications in the past, this blank lease agreement is especially troubling because as of the CON application submission, Hookie Bones Properties, LLC does not have control of any of the three proposed sites either through acquisition, lease, or other arrangement.

Specifically;

Hookie Bones Properties, LLC

- Hookie Bones Properties, LLC was just incorporated on June 3, 2016. It is unreasonable for the Agency to assume that at the time the CON application was submittal that Hookie Bones Properties had the funds to construct the building shell. The applicant did not provide any documentation to support the financial ability of Hookie Bones Properties to construct the proposed building shell.
- A search on the Mecklenburg County GIS system at http://polaris3g.mecklenburgcountync.gov/ shows that Hookie Bones Properties does not own any properties, including the three sites identified in Section XI.
- Please see Attachment I.

Proposed Primary Site – 100 Judson Avenue

- A search on the Mecklenburg County GIS system at http://polaris3g.mecklenburgcountync.gov/ shows that the proposed primary site, 100 Judson Avenue, is currently a vacant lot that is owned by Hemingway Joan, LLC. The applicant did not provide any documentation, such as a Letter of Intent, indicating that Hemingway Joan, LLC has agreed to make this property available to Hookie Bones Properties such that Hookie Bones Properties could, in turn, lease the property to the applicant. The blank "lease" in Exhibit 1 is between Hookie Bones Properties and the applicant. But in order for Hookie Bones Properties to be in a position to lease 100 Judson Avenue to the applicant, the application needs to include documentation showing that Hemingway Joan, LLC has agreed to make this property available to Hookie Bones Properties. The applicant failed to provide this essential information. There is simply no way to know whether 100 Judson Avenue is available to the applicant and the applicant cannot provide additional information after the submission of the CON application. See 10A NCAC 14C .0204. This is in contrast to the CCAD application, which *does* provide documentation showing that the property is available. See Exhibit 1 to CCAD application.
- Please see Attachment J.

Alternate Secondary Site – 1918 Randolph Road, Suite 175

- A search on the Mecklenburg County GIS system at http://polaris3g.mecklenburgcountync.gov/ shows that the building located on the alternate secondary site, 1918 Randolph Road, is owned by LLC CHP Midtown-Charlotte North Carolina MOB, Inc. The applicant did not provide any documentation indicating that Hookie Bones Properties has control of the alternate secondary site either through acquisition, lease, or other agreement.
- A search on the Mecklenburg County GIS system at http://polaris3g.mecklenburgcountync.gov/ shows that the alternate secondary site, 1918 Randolph Road, Suite 175, is currently occupied by the Novant Health Urgent Care & Occupational Medicine – Charlotte and that the suite is owned by Novant Health, Inc. The applicant did not provide any documentation indicating that Hookie Bones Properties has control of the alternate secondary site either through acquisition, lease, or other agreement.
- The Novant Health website at http://www.novanthealth.org/clinic-locations shows that Novant Health Urgent Care & Occupational Medicine – Charlotte still operates at the alternate secondary site. The applicant did not provide any documentation showing that the Novant Health service will relocate if the proposed primary site is not available.
- Please see Attachment K.

Alternate Tertiary Site – 2711 Randolph Road, Suite 305

- A search on the Mecklenburg County GIS system at http://polaris3g.mecklenburgcountync.gov/ shows that the alternate tertiary site, 2711 Randolph Road, Suite 305, is currently occupied by the Carolina Hand Center and that the suite is owned by CHC Holdings, LLC. The applicant did not provide any documentation indicating that Hookie Bones Properties has control of the alternate tertiary site either through acquisition, lease, or other agreement.
- The Carolinas Healthcare System website at http://www.carolinashealthcare.org shows that the Carolina Hand Center and Dr. Steven Byron Sanford still operates at the alternate tertiary site. The applicant did not provide any documentation showing that the Dr. Sanford's practice will relocate if the proposed primary site or the alternate secondary site are not available.
- Please see Attachment L.

In response to Section XI.5, on page 205 of the application, the applicant responds in a footnote that:

> *"SCDP of Charlotte will upfit 9,868 SF of leased space in a building to be constructed by a third party developer. As noted in Section II.1, construction of the shell of the building will be completed prior to development of the proposed project; as such, SCDP of Charlotte refers to the building as "existing" in various sections of this application."*

The applicant assumes that because it states a "third party developer" will be constructing the building shell and leasing to the applicant, the applicant can just identify three addresses in the application and include no other supporting documentation. This is incorrect. The applicant must demonstrate that either it or the third party developer has the right to use the property. The applicant cannot hide behind Hookie Bones Properties and claim it was unable to get the information. Hookie Bones Properties, the "third party developer," has the same principal office address, 746 East Franklin Street, Chapel Hill, North Carolina 27514, as Papillion Management, LLC; the proposed management company identified in Section I.10(c). Laura Reebye, the wife of Dr. Uday Reebye, is also the registered agent for both LLCs and is also located at the address of the LLC's principal office. Please see Attachment M. Dr. Uday Reebye is also located at 746 East Franklin Street, Chapel Hill, North Carolina 27514. As of the CON application's submission, Dr. Reebye is the majority owner (18%) of Surgical Center for Dental Professionals of North Carolina, LLC, which is the sole member of Surgical Center for Dental Professionals of Charlotte, LLC; the applicant. Given the relationships between these entities, the applicant does have access to the "third party developer's" information.

Based on the fact that neither the applicant nor the "third party developer" has control of the proposed sites or the financial capability to fund the acquisition of the site or construction of the building shell, the application is non-conforming with Criterion (12).

(18a) 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 a service on which competition will not have a favorable impact.

The applicant failed to adequately demonstrate that its proposal will have a positive impact upon the cost effectiveness, access, and quality of the proposed services. See also Criteria (1), (3), (4), (5), (6), (7), (8) and (12) for discussion.

DEMONSTRATION PROJECT REQUIREMENTS

The applicant's project also fails to meet at least two of the requirements for this demonstration project:

> **10. For each of the first three full federal fiscal years of operation, the applicant(s) shall provide the projected number of patients for the following payor types, broken down by age (under 21, 21 and older): (i) charity care; (ii) Medicaid; (iii) TRICARE; (iv) private insurance; (v) self-pay; and (vi) payment from other sources.**

The applicant spends six pages (pages 139-145) discussing Region 2's age mix and payor mix by age mix. However, where it previously believed that Region 1 was more similar to Region 2, now it believes that Region 3 is more similar to Region 2. The applicant provides no valid reasons to base the age mix or payor mix by age mix in the 8-county Region 2 by slightly adjusting the age mix and payor mix by age mix in the 44-county Region 3.

The applicant's entire age mix and payor mix by age mix are based on unreasonable assumptions and unrelated data. Thus, the applicant fails to meet this requirement of the demonstration project.

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

The applicant's utilization methodology on page 116 states the following assumption:

> *"...most of its projected cases would be appropriate to be performed in either the two operating rooms of in the two proposed procedure rooms. Patients will be priority scheduled in the operating rooms based on the request of the user."*

Based on this statement, the applicant sees no difference between the operating rooms and the procedure rooms. The applicant believes that any of its projected dental cases that require sedation can be performed in a non-licensed procedure room, which is where they are currently being performed at the convenience of the patients. The applicant believes it is reasonable to estimate that each operating room will provide 1,000 cases annually, leaving the procedure rooms with 607 cases annually, for a total of 3,214 cases in Year 3. However, this distribution of cases is not reasonable or supported by any program, staffing, or clinical information and will most likely not be how the ASC operates. Since the applicant believes that the procedure rooms are no different from the operating rooms, it is more likely that the four rooms will be scheduled in a manner that equalizes the annual volumes or 803 cases per operating and procedure room annually, which does not meet the 900 cases per operating room performance standard. See also the discussion under Criteria (3) and (8) for more information.

The applicant's projections by operating room and procedure room are based on unreasonable assumptions. Thus, the applicant fails to meet this requirement of the demonstration project.

Comparative Analysis

Facility Ownership

The following table identifies the ownership of the proposed CCAD ASF and the applicant ASC:

CCAD	Ownership
Dale J. Misiek, DMD	8.0%
Brian B. Farrell, DDS, MD	8.0%
Bart C. Farrell, DDS, MD	8.0%
Waheed Mohamed, DDS, MD	7.0%
John C. Nale, DMD, MD	7.0%
Daniel R. Cook, DDS, MD	7.0%
Rick Kapitan, DDS, MD	7.0%
Valleygate Dental Surgery Center of Charlotte, LLC (7 Dentists)	48.0%

SCDP of Charlotte	Ownership
SCDP of North Carolina, LLC	100.0%
SCDP of North Carolina	
Dr. Uday Reebye	18.000%
Initial Facility Dental Directors	2.000%
S. Rouse	1.000%
K. Richards	0.400%
M. Hayes	0.250%
Dr. F. Lee	0.125%
Dr. D. Kornstein	0.125%
Dr. S. DeAngelo	0.125%
Dr. K. Henderson	0.125%
Dr. B. Hollowell	0.125%
Dr. A. Horalek	0.125%
Dr. E. Hoverstad	0.125%
Dr. R. Pillai	0.125%
No Current Investor	77.350%

CCAD has dentist and oral surgeon investors equal to 100.0 percent of the ASF facility; whereas, the applicant through the ownership of SCDP of North Carolina can only identify the ownership of 20.65 percent of the ASC, since 77.35 percent is not identified and 2.000 percent is for unidentified Initial Facility Dental Directors.

Access by Underserved Groups

The following table shows the number of dental cases projected to be provided to Medicaid and Charity Care recipients as stated in the applications:

Combined Ages	% of Dental Cases		
	Medicaid	Charity Care	Total
CCAD	79.5%	3.8%	83.3%
SCDP of Charlotte	51.5%	4.5%	57.0%

As shown in the table, CCAD propose to serve a higher percentage of underserved individuals, especially Medicaid recipients.

Revenues

The third full fiscal year of operation (Project Year 3) for CCAD is October 1, 2020 to September 30, 2021. Project Year 3 for the applicant is January 1, 2020 to December 31, 2020.

The average gross revenue per case for Project Year 3 was calculated by dividing total gross revenue by total cases. See the following table:

Project Year 3

Average Gross Revenue per Case

	Total Gross Revenue	# of Cases	Average Gross Revenue per Case
CCAD	$5,543,523	3,232	$1,715
SCDP of Charlotte	$6,298,958	3,214	$1,960

As shown in the previous table, CCAD projects the lowest average gross revenue per case by $245.

The average net revenue per case for Project Year 3 was calculated by dividing total net revenue by total cases. See the following table:

Project Year 3

Average Net Revenue per Case

	Total Net Revenue	# of Cases	Average Net Revenue per Case
CCAD	$2,943,748	3,232	$911
SCDP of Charlotte	$4,220,940	3,214	$1,313

As shown in the previous table, CCAD projects the lowest average net revenue per case by $402.

Moreover, the average gross revenue per case and average net revenue per case for the applicant's application are both questionable because projected utilization is not based on reasonable, credible and supported assumptions.

Conversely, the average gross revenue per case and average net revenue per case for CCAD's application are not questionable because the projected utilization is based on reasonable, credible and supported assumptions.

Operating Costs

The average operating cost per case for Project Year 3 was calculated by dividing total operating expenses by total cases.

Project Year 3

Average Operating Cost per Case

	Total Operating Cost	# of Cases	Average Operating Cost per Case
CCAD	$2,484,005	3,232	$769
SCDP of Charlotte	$3,020,669	3,214	$940

As shown in the previous table, CCAD projects the lowest average operating cost per case by $171. Moreover, these data are skewed. SCDP of Charlotte overestimates the number of cases in its facility and underestimates cost (see discussion on management agreement under CON Review Criterion 7.)

CONCLUSION

The SCDP application is non-conforming with multiple CON and demonstration project criteria and must be disapproved. A comparative analysis shows that the CCAD application is comparatively superior.

Attachment A

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 B

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.

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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.

ADA American Dental Association®
America's leading advocate for oral health

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 proceoure 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).

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- 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.

Attachment C

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 D

Corporate practice of medicine

It is the position of the Board that, except as discussed below, businesses practicing medicine in North Carolina must be owned in their entirety by persons holding active North Carolina licenses. The owners of a business engaged in the practice of medicine must be licensees of this Board or one of the combinations permitted in N.C. Gen. Stat. § 55B-14. Licensees of the Board providing medical services on behalf of businesses engaged in the corporate practice of medicine may be subject to disciplinary action by the Board. Whether a licensee of the Board is an employee or independent contractor is not determinative of whether a physician is aiding and abetting the corporate practice of medicine. In addition, the Board may seek injunctive relief against lay owners of businesses engaged in the corporate practice of medicine.

The Board does recognize certain exceptions to the corporate practice of medicine, including hospitals and health maintenance organizations. Such exceptions are premised on the notion that these entities are statutory creations intended for the public welfare and regulated by the government, thus ameliorating the inherent conflict between profit-making and good medical care. Under a similar rationale, public health clinics and charitable nonprofits are also considered exceptions to the prohibition on the corporate practice of medicine.

Hospital-owned practices

As mentioned above, the Board recognizes an exception to the prohibition on the corporate practice of medicine for non-profit hospitals and in turn medical practices that are owned by such hospitals. The policy underlying this exception is that non-profit hospitals are charged with the same mission as the Board in protecting the well-being of the citizens of North Carolina. In keeping with this policy, it is the Board's expectation that hospital-owned practices will recognize the ethical obligations that their physician employees have to their patients and allow them to discharge such obligations. For example, it is the position of the Board that physicians who depart such practices for reasons other than safety concerns be permitted to provide appropriate notice to their patients, ensure continuity of care, and allow patient selection.

(Adopted March 2016)

Attachment E

July 20, 2016

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

RE: Retraction of Support for SCDP of Charlotte CON Application

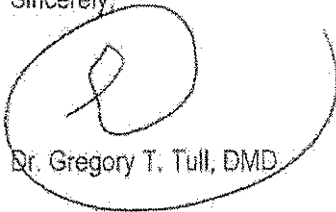
Dear Ms. Frisone:

I would like to retract my letter of support that was included in the SCDP of Charlotte CON Application (Project ID # F-11195-16). I am an oral surgeon with Carolinas Center for Oral & Facial Surgery and the oral surgeons in my practice have also submitted a CON application (Carolinas Center for Ambulatory Surgery, Project ID # F-11202-16) for the two operating rooms available in Region 2.

I erroneously responded to an email that was sent to my work email address assuming it was for our Carolinas Center for Ambulatory Surgery CON application. If I had realized that the letter with no identifying name on it was for the SCDP of Charlotte CON application, I would not have completed and signed the letter. Please accept this letter as documentation of my request to have the letter rescinded.

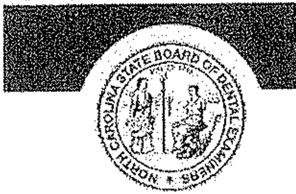
Please let me know if you have any other questions. Thank you for your time and attention.

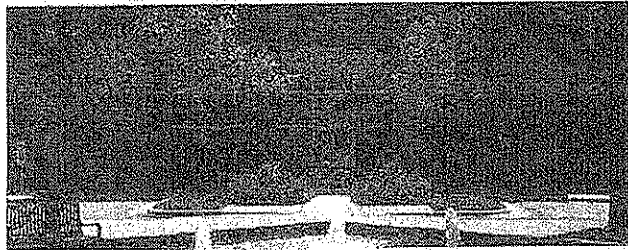
Sincerely,

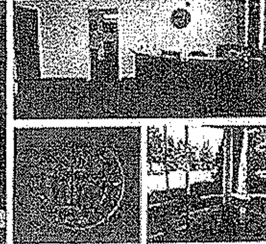


Dr. Gregory T. Tull, DMD

Attachment F







search results

DENTISTS	
Dr. William S. Kirk, Jr.	License # : 4501 (Licensed Dentist)
City : Goldsboro	License Issued : 7/10/1979
State : NC	Expiration : 3/31/2017
Board Action : Y	Status : Good Standing
Anesthesia: N	Sedation: Y
View Disciplinary Actions	
New Search	

Functions of the Board of Dental Examiners

- The administration of licensure examinations for dentists and dental hygienists
- The promulgation of rules and enforcement of laws and regulations governing the practice of dentistry and dental hygiene in this state
- The issuance and renewal of licenses to dentists and dental hygienists

info@ncdentalboard.org ©2012 North Carolina State Board of Dental Examiners | 507 Airport Blvd., Suite 105, Morrisville, NC 27560 | Tel: 919.678.8223 | Fax: 919.678.8472

Attachment G

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.

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. Medicaid
   None Apply.
b. NCHC
   None Apply.

CDT 2015 (including procedure codes, descriptions, and other data) is copyrighted by the American Dental Association. © 2014 American Dental Association. All rights reserved.
Applicable FARS/DFARS apply.

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.

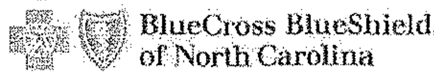
D7285	D7465	D7740	D7872	D7948
D7286	D7490	D7750	D7873	D7949
D7288	D7540	D7760	D7910	D7950
D7410	D7610	D7780	D7911	D7955
D7411	D7620	D7810	D7912	D7980
D7412	D7630	D7820	D7920	D7981
D7413	D7640	D7830	D7940	D7982
D7414	D7650	D7840	D7941	D7983
D7415	D7660	D7850	D7943	D7990
D7440	D7680	D7858	D7944	D7991
D7441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



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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

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

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

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

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

c) Postoperative complications following outpatient dental/oral surgery.

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

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

In the absence of the medical criteria shown above.

For the dentist's or patient's convenience.

Policy Guidelines

Claims should be reviewed for documentation of medical necessity.

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

Billing/Coding/Physician Documentation Information

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

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

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

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual

Medical Policy Advisory Group Review - 3/99

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

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

MEDLINE and MD Consult literature search from 1995 to present.

Specialty Matched Consultant Advisory Panel - 5/2001

Specialty Matched Consultant Advisory Panel - 5/2003

Specialty Matched Consultant Advisory Panel - 5/2005

Specialty Matched Consultant Advisory Panel - 5/2007

Specialty Matched Consultant Advisory Panel- 11/2009

Senior Medical Director Review- 8/2010

Specialty Matched Consultant Advisory Panel- 10/2011

Specialty Matched Consultant Advisory Panel- 9/2012

Specialty Matched Consultant Advisory Panel- 10/2013

Specialty Matched Consultant Advisory Panel- 10/2014

Medical Director Review- 10/2014

Specialty Matched Consultant Advisory Panel 10/2015

Medical Director Review 10/2015

Policy Implementation/Update Information

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

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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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

Cigna Medical Coverage Policy

Subject **Anesthesia and Facility Services for Dental Treatment**

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

Table of Contents

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General Background 2
Coding/Billing Information 7
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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

***Current Procedural Terminology (CPT®) ©2014 American Medical Association: Chicago, IL.**
****Current Dental Terminology (CDT®) ©2011—2012 American Dental Association, Chicago, IL.**

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Attachment H

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: September 27, 2011
FINDINGS DATE: October 4, 2011

PROJECT ANALYST: Michael J. McKillip
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER:

J-8660-11/WakeMed/Add 79 acute care beds on the WakeMed Raleigh Campus/Wake County

J-8661-11/WakeMed/Add 22 acute care beds at WakeMed Cary Hospital/Wake County

J-8667-11/Rex Hospital, Inc./Add 11 acute care beds and construct a new beds tower to replace 115 acute care beds in a change of scope for Project I.D. # J-8532-10 (heart and vascular renovation and expansion project)/Wake County

J-8669-11/Rex Hospital, Inc./Develop a new separately licensed 50-bed hospital in Holly Springs/Wake County

J-8670-11/Rex Hospital, Inc./Develop a new separately licensed 40-bed hospital in Wakefield/Wake County

J-8673-11/Holly Springs Hospital II, LLC/Develop a new 50-bed hospital in Holly Springs/Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(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

"Please see the physician letters provided in Exhibit 62 which document their support for the proposed project and indicate their interest in providing coverage and admitting patients to the facility. Because Rex Hospital Wakefield will be a new hospital, there is currently no Medical Director or Chief of Staff. Pursuant to the medical staff bylaws, the medical staff of the facility is charged with electing the Chief of Staff for the hospital. Since the medical staff does not currently exist, no Chief of Staff can be elected at this time."

The applicant demonstrates the availability of adequate health manpower and administrative personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

Novant Holly Springs. In Section VII.1, page 267, the applicant projects a total of 316 FTE positions at Novant Holly Springs in the second full operating year of the proposed project. In Section VII.6, pages 275-277, the applicant describes its experience and procedures for recruiting and retaining personnel. In Section VII.8, page 279, the applicant identifies Dr. James Stevens as the Chief of the Medical Staff for Novant Holly Springs, and Exhibit 14 contains a letter indicating Dr. Stevens' agreement to serve as the Chief of the Medical Staff. Exhibit 14 also contains letters from other physicians expressing their willingness to serve as medical directors for various hospital departments, including neonatal, radiology, pathology, emergency, anesthesia, surgical, obstetrics, and intensive care services. The applicant demonstrates the availability of adequate health manpower and administrative personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

(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.

C
WakeMed Raleigh
WakeMed Cary
Rex Hospital
Rex Holly Springs
Rex Wakefield

NC
Novant Holly Springs

WakeMed Raleigh. In Section II.2, page 18, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at WakeMed Raleigh Campus. In Section V.2, pages 102-103, the applicant provides a list of healthcare facilities with which WakeMed has transfer agreements, and Exhibit 35 contains copies of sample transfer agreements. Exhibit 49 contains letters from physicians supporting the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system and that the necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

WakeMed Cary. In Section II.2, page 15, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at WakeMed Cary Hospital. In Section V.2, pages 91-92, the applicant provides a list of healthcare facilities with which WakeMed has transfer agreements, and Exhibit 35 contains copies of sample transfer agreements. Exhibit 49 contains letters from physicians supporting the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system and that the necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

Rex Hospital. In Section II.2, pages 40-41, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at Rex Hospital. In Exhibit 8, the applicant provides a list of healthcare facilities with which Rex Hospital has transfer agreements, and an example of a transfer agreement. Exhibit 54 contains letters from physicians supporting the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system and that the necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

Rex Holly Springs. In Section II.2, pages 40-41, the applicant states that the majority of the necessary ancillary and support services for the proposed services will be provided at the proposed hospital, and a few support services will be provided at the *"corporate level for economies of scale for system-wide functions such as finance, payroll, human resources and others."* In Section V.2, page 274, the applicant states, *"As a part of Rex Healthcare, Rex Hospital Holly Springs will have a transfer agreement with Rex Hospital and UNC Hospitals in Chapel Hill."* In Exhibit 58, the applicant provides a list of healthcare facilities with which Rex Hospital has transfer agreements, and an example of a transfer agreement. Exhibit 66 contains letters from physicians supporting the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system and that the necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

Rex Wakefield. In Section II.2, pages 40-41, the applicant states that the majority of the necessary ancillary and support services for the proposed services will be provided at the proposed hospital, and a few support services will be provided at the *"corporate level for economies of scale for system-wide functions such as finance, payroll, human resources and others."* In Section V.2, page 239, the applicant states, *"As a part of Rex Healthcare, Rex Hospital Wakefield will have a transfer agreement with Rex Hospital and UNC Hospitals in Chapel Hill."* In Exhibit 5, the applicant provides a list of healthcare facilities with which Rex Hospital has transfer agreements, and an example of a transfer agreement. Exhibit 62 contains letters from physicians supporting the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system and that the necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

Novant Holly Springs. In Section II.2, pages 36-38, the applicant states that all of the necessary ancillary and support services for the proposed services will be provided at the proposed hospital. In Section V.2, page 224 the applicant states, *"Prior to opening Holly Springs Hospital will make every reasonable effort to ensure that appropriate transfer agreements are in place with Triangle area tertiary hospitals such as Rex Hospital, WakeMed Raleigh, UNC Hospitals in Chapel Hill, and Duke University Medical Center."* In Exhibit 13, the applicant provides copies of letters of interest to Wake County hospitals regarding the development of transfer agreements, a list of healthcare facilities with which Novant Health has transfer agreements, and an example of a transfer agreement. Exhibit 14 contains letters from physicians supporting the proposed project. However, the applicant did not provide sufficient documentation from obstetricians practicing in Wake County and surrounding areas to demonstrate the proposed services will be coordinated with the existing health care system. Exhibit 14 does not contain any letters of support from obstetricians practicing in applicant's proposed service area, or from any other Wake County obstetricians. Exhibit 14 contains only one letter an obstetrician in the local area expressing support for the proposed hospital, and that obstetrician practices in Durham. Exhibit 14 also contains a letter of support from the obstetrician who the applicant identifies as the medical director for obstetrical services, however that physician practices in Winston-Salem. In Section V.3(b), page 228, the applicant provides a list of physicians by medical and surgical specialty that support the proposed hospital, but the list does not include obstetricians. Similarly, in Section V.4, page 229, the applicant provides a list of the Novant Medical Group *"Triangle physician network"* physicians by medical and surgical specialty that support the proposed hospital, but the list does not include obstetricians. Therefore, the applicant did not adequately demonstrate that the proposed project will be coordinated with the existing health care system. Consequently, the application is not conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or

Attachment I

SOSID: 1517770
Date Filed: 5/17/2016 2:08:00 PM
Elaine F. Marshall
North Carolina Secretary of State
C2016 137 00857

ARTICLES OF ORGANIZATION
OF
PAPILLION MANAGEMENT SERVICES 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: Papillion Management Services 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, 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, 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 13th day of May, 2016.

SPRUILLCO, LLC, Organizer

By: ______________________
Christopher Dwight, Vice President

3077665

Elaine F. Marshall
Secretary

North Carolina
DEPARTMENT OF THE SECRETARY OF STATE

PO Box 29622 Raleigh, NC 27626-0622 (919)807-2000

Account
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Register

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Print a Pre-Populated Annual Report form

Corporate Names

Legal: Hookie Bones Properties LLC

Limited Liability Company Information

SosId:	1521894
Status:	Current-Active
Annual Report Status:	Current
Citizenship:	Domestic
Date Formed:	6/3/2016
Fiscal Month:	January
State of Incorporation:	NC
Registered Agent:	Reebye, Laura

Corporate Addresses

Mailing:	746 East Franklin Street Chapel Hill, NC 27514
Principal Office:	746 East Franklin Street Chapel Hill, NC 27514
Reg Office:	746 East Franklin Street Chapel Hill, NC 27514
Reg Mailing:	746 East Franklin Street Chapel Hill, NC 27514

Company Officials

All LLCs are managed by their managers pursuant to N.C.G.S. 57D-3-20.

SOSID: 1521894
Date Filed: 6/3/2016 11:27:00 AM
Elaine F. Marshall
North Carolina Secretary of State
C2016 155 00219

ARTICLES OF ORGANIZATION
OF
HOOKIE BONES 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: Hookie Bones 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

Attachment J

Tutorials Quick Tips Report Issues GIS Data Store

Search Results Layers/Labels Property Report Zoom To

Property Key

Parcel ID	GIS ID
06904135	06904135

Address located on Property

NA

Owner Name	Mailing Address
HEMINGWAY JOAN LLC	2730 ROZZELLES FERRY RD SUITE A CHARLOTTE NC 28208

Unselect Property

Link To

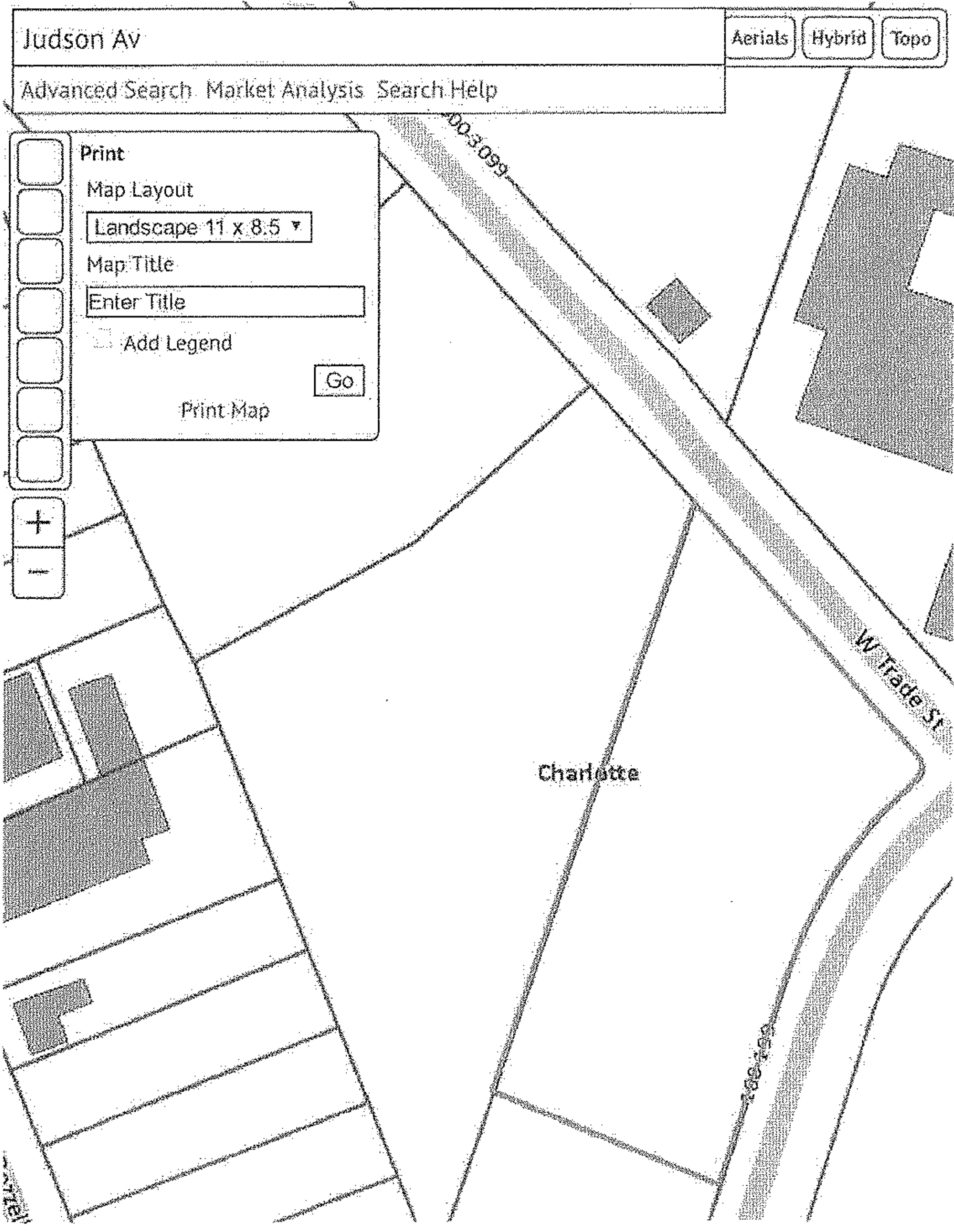
Google Street View

Birdseye View maintained by Mecklenburg County

Associated Information

Legal Desc	L2 M54-737
Land Area	1.305 AC
Fire District	City Of Charlotte
Special District	NA
Account Type	Nc Corp
Municipality	Charlotte
Land Use	Industrial

Tax Information



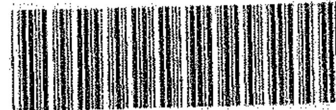
Polaris 3G Map – Mecklenburg County, North Carolina

Date Printed: 7/11/2016 2:22:21 PM

0 0.005 0.01 0.02 Miles

This map or report is prepared for the inventory of real property within Mecklenburg County and is compiled from recorded deeds, plats, tax maps, surveys, planimetric maps, and other public records and data. Users of this map or report are hereby notified that the aforementioned public primary information sources should be consulted for verification. Mecklenburg County and its mapping contractors assume no legal responsibility for the information contained herein.

FOR REGISTRATION
J. David Granberry
REGISTER OF DEEDS
Mecklenburg County, NC
2014 JUN 27 02:23:30 PM
BK:29276 PG:282-283
FEE:$26.00
EXCISE TAX: $433.00
INSTRUMENT # 2014072972
BAKERFR



2014072972

RETURNED TO CUSTOMER

NORTH CAROLINA SPECIAL WARRANTY DEED

Excise Tax: $ 433.00

Parcel Identifier No. ____________ Verified by ______________ County on the ____ day of ______________, 20________
By: ____

Mail/Box to: Grantee (13505.312 (CDS/tr))

This instrument was prepared by: Cheryl D. Steele, Horack Talley Pharr & Lowndes, 301 S. College St., Charlotte, NC 28202

Brief description for the Index: 4.326 acres, The Greenway Business Center, Mecklenburg County, NC

THIS DEED made this 26 day of June, 2014, by and between

GRANTOR	GRANTEE
CMHP DEVELOPMENT LLC, a North Carolina limited liability company <u>ADDRESS:</u> 4601 Charlotte Park Drive, Suite 350 Charlotte, NC 28217-1915	**HEMINGWAY JOAN, LLC,** a North Carolina limited liability company <u>ADDRESS:</u> 421 Penman Street, Suite 100 Charlotte, NC 28203

Enter in appropriate block for each Grantor and Grantee: name, mailing address, and, if appropriate, character of entity, e.g. corporation or partnership.

The designation Grantor and Grantee as used herein shall include said parties, their heirs, successors, and assigns, and shall include singular, plural, masculine, feminine or neuter as required by context.

WITNESSETH, that the Grantor, for a valuable consideration paid by the Grantee, the receipt of which is hereby acknowledged, has and by these presents does grant, bargain, sell and convey unto the Grantee in fee simple, all that certain lot, parcel of land or condominium unit situated in the City of Charlotte, Mecklenburg County, North Carolina and more particularly described as follows:

> BEING all of Parcels 1, 2 and 3 on that plat of Greenway Business Center recorded in Map Book 54, Page 737 in the Mecklenburg County Public Registry.

The property hereinabove described was acquired by Grantor by instrument recorded in Book 29008, page 112.

All or a portion of the property herein conveyed does not include the primary residence of a Grantor.

A map showing the above described property is recorded in Plat Book 54, page 737.

TO HAVE AND TO HOLD the aforesaid lot or parcel of land and all privileges and appurtenances thereto belonging to the Grantee in fee simple.

And the Grantor covenants with the Grantee, that Grantor has done nothing to impair such title as Grantor received, and Grantor will warrant and defend the title against the lawful claims of all persons claiming by, under or through Grantor, other than the following exceptions:

1. Declaration of Protective Covenants for The Greenway Business Center;
2. Record Plat for The Greenway Business Center;
3. All other matters of public record;
4. Zoning ordinances applicable to the Property;
5. Such other matters of title, if any, contained in Schedule B I of the title insurance policy; and
6. Such matters as would be revealed by a current and accurate survey of the Property.

IN WITNESS WHEREOF, the Grantor has duly executed the foregoing as of the day and year first above written.

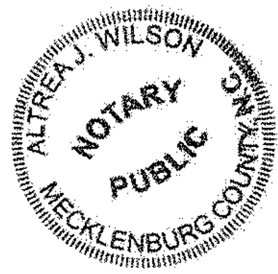
CMHP DEVELOPMENT LLC,
a North Carolina limited liability company
By: CHARLOTTE-MECKLENBURG HOUSING PARTNERSHIP, INC.,
its Sole Member and Manager

By: [signature]
Name: JULIE A. PORTER
Title: PRESIDENT

State of North Carolina – County of Mecklenburg

I, the undersigned Notary Public of the County or City of Charlotte and State aforesaid, certify that Julie A. Porter personally came before me this day and acknowledged that s/he is the President of * CMHP DEVELOPMENT LLC, a North Carolina limited liability company, and that by authority duly given and as the act of such entity, she signed the foregoing instrument in its name on its behalf as its act and deed. Witness my hand and Notarial stamp or seal, this 25th day of June, 2014. *CHARLOTTE-MECKLENBURG HOUSING PARTNERSHIP, INC. the sole Member and Manager of

My Commission Expires: March 2, 2015
(Affix Seal)



[signature] Notary Public
Altrea J. Wilson
Notary's Printed or Typed Name

HTPL 574015v1

Attachment K

Tutorials Quick Tips Report Issues GIS Data Store

Search Results Layers/Labels Property Report Zoom To

Property Key

Parcel ID	GIS ID
15501222	15501222

Address located on Property

NA

Owner Name	Mailing Address
OWNER LLC CHP MIDTOWN-CHARLOTTE NC MOB	450 S ORANGE AVE ORLANDO FL 32801
INC C/O CNL LIFESTYLE PROPERTIES	450 S ORANGE AVE ORLANDO FL 32801

Unselect Property

Photo: 1 / 1

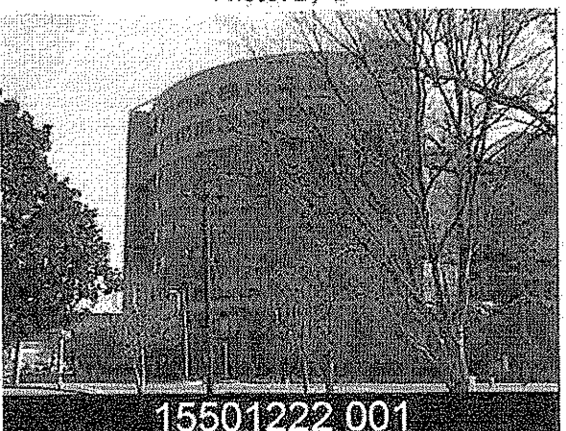


Photo Date: 11/15/2006 Source: Mecklenburg County

1918 RANDOLPH RD CHARLOTTE NC 28207

Advanced Search Market Analysis Search Help

Aerials Hybrid Topo

N Caswell

S Caswell Rd

Randolph Rd

Tutorials Quick Tips Report Issues GIS Data Store

Search Results Layers/Labels Property Report Zoom To

Property Key

Parcel ID	GIS ID
15501219	15501219

Addresses located on Property

1918 RANDOLPH RD CHARLOTTE NC 28207

Owner Name	Mailing Address
NOVANT HEALTH INC	P O BOX 33549 CHARLOTTE NC 28233
ATTN: PROPERTY MANAGEMENT	P O BOX 33549 CHARLOTTE NC 28233

Unselect Property

Photo: 1 / 1

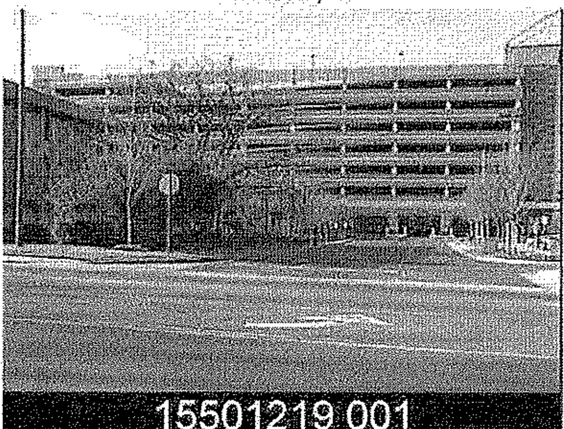


Photo Date: 01/30/2007 Source: Mecklenburg County

1918 RANDOLPH RD CHARLOTTE NC 28207

Aerials Hybrid Topo

Advanced Search Market Analysis Search Help

S Caswell Rd

Randolph R

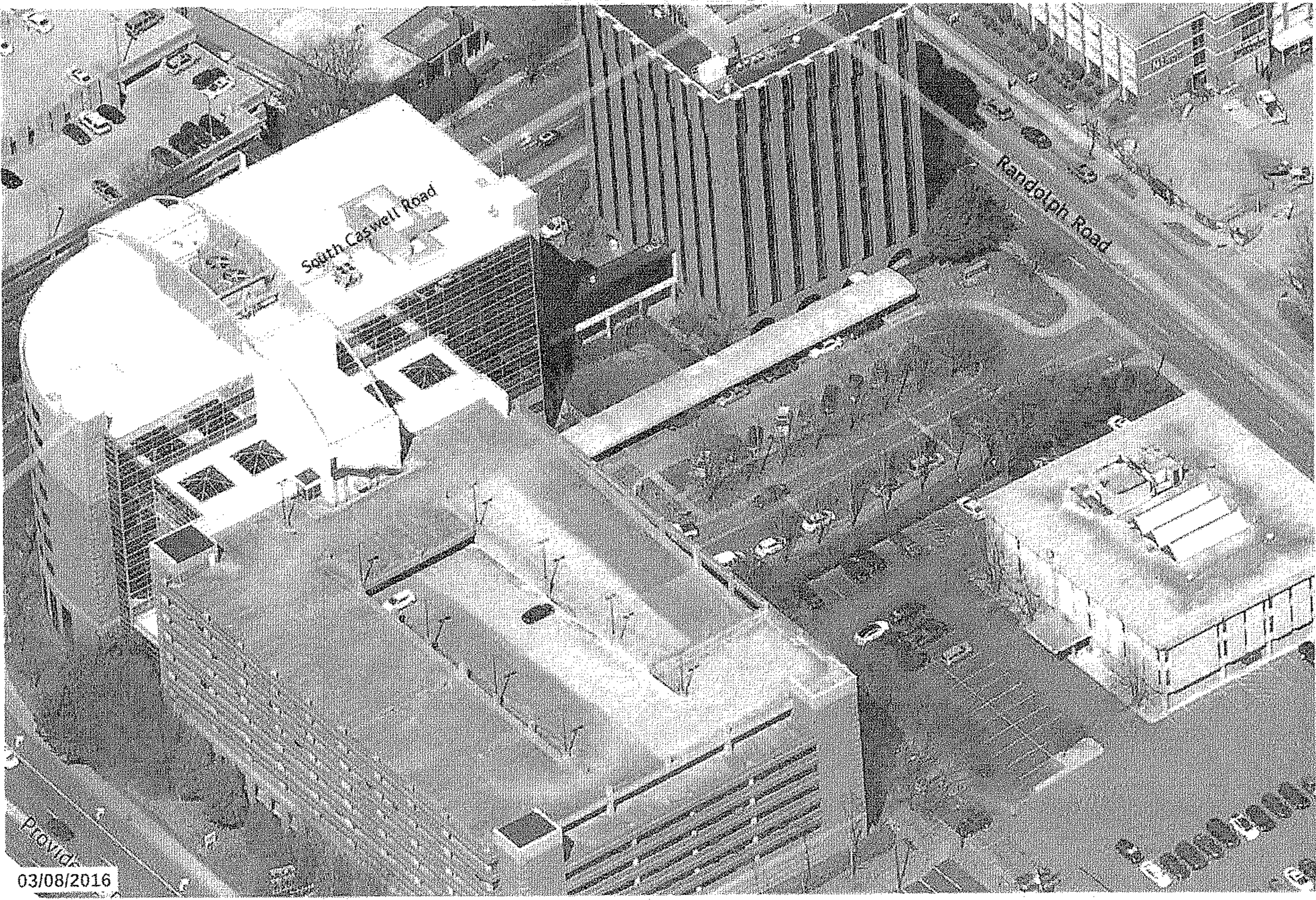
16

Charlotte

100-151

Providence Rd

Secondary

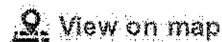


Urgent Care & Occupational Medicine - Charlotte

Select Language ▼

Novant Health Urgent Care & Occupational Medicine – Charlotte

1918 Randolph Road, Suite 175
Charlotte, NC 28207



704-316-1050

Office hours

Monday to Friday:
8 a.m. to 8 p.m.
Saturday:
10 a.m. to 6 p.m.
Sunday:
1 p.m. to 6 p.m.

Location

Attachment L

Tutorials Quick Tips Report Issues GIS Data Store

Search Results Layers/Labels Property Report Zoom To

Property Key

Parcel ID	GIS ID
12712158	12712C98

Address located on Property

2711 RANDOLPH RD 305 CHARLOTTE NC 28207

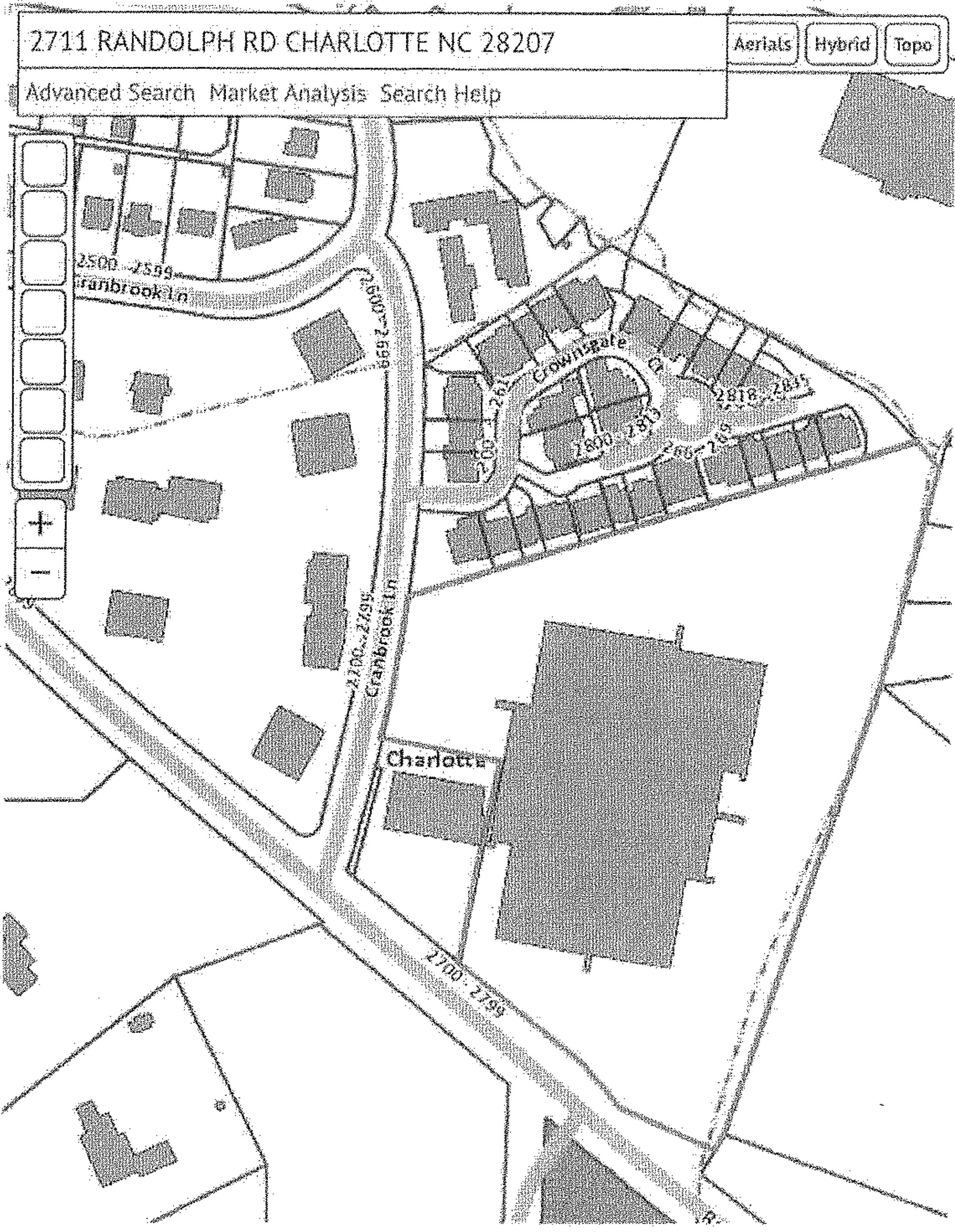
Owner Name	Mailing Address
CHC HOLDINGS LLC	9874 AMBER DR MARSHFIELD WI 54449
C/O STEVEN SANFORD	9874 AMBER DR MARSHFIELD WI 54449

Supplementary Information

Additional Owners, Leaseholds, Condo Complex Areas may be present on this selected Tax Parcel.

Other Owners tied to Parcel

Photo: 1 / 1

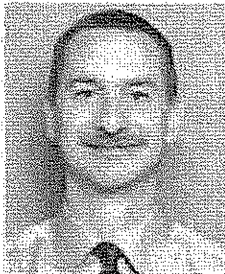


Tertiary

Menu ☰

(http://www.carolinashealthcare.org/default_levine.cfm?id=17713)

‹ Back to Team Listing



Steven Byron Sanford, MD

Surgery

LOCATIONS
Carolina Hand Center
2711 Randolph Road, Suite 305
Charlotte, NC 28207
Phone: (704) 375-3397
Get Directions (http://maps.google.com/maps?

SPECIALTIES
Surgery

EDUCATION
Medical School
Wayne State University
Completion Year: 1991

Attachment M

Elaine F. Marshall
Secretary

North Carolina
DEPARTMENT OF THE SECRETARY OF STATE
PO Box 29622 Raleigh, NC 27626-0622 (919)807-2000

Account
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Register

Click Here To:

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Corporate Names

Legal:	Papillion Management LLC
Prev Legal:	Papillion Management Services LLC

Limited Liability Company Information

SosId:	1517770
Status:	Current-Active
Annual Report Status:	Current
Citizenship:	Domestic
Date Formed:	5/17/2016
Fiscal Month:	January
State of Incorporation:	NC
Registered Agent:	Reebye, Laura

Corporate Addresses

Mailing:	746 Esat Franklin Street Chapel Hill, NC 27514
Principal Office:	746 Esat Franklin Street Chapel Hill, NC 27514
Reg Office:	746 Esat Franklin Street Chapel Hill, NC 27514
Reg Mailing:	746 Esat Franklin Street Chapel Hill, NC 27514

Company Officials

All LLCs are managed by their managers pursuant to N.C.G.S. 57D-3-20.

Elaine F. Marshall
Secretary

North Carolina
DEPARTMENT OF THE SECRETARY OF STATE
PO Box 29622 Raleigh, NC 27626-0622 (919)807-2000

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Click Here To:

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Corporate Names

Legal: Surgical Center For Dental Professionals of NC LLC

Limited Liability Company Information

SosId:	1481029
Status:	Current-Active
Annual Report Status:	Current
Citizenship:	Domestic
Date Formed:	11/13/2015
Fiscal Month:	January
State of Incorporation:	NC
Registered Agent:	National Corporate Research, Ltd.

Corporate Addresses

Reg Office:	212 South Tryon Street Suite 1000 Charlotte, NC 28281-0001
Reg Mailing:	212 South Tryon Street Suite 1000 Charlotte, NC 28281-0001
Mailing:	9650 Strickland Road, Suite 103-177 Raleigh, NC 27615-1902
Principal Office:	9650 Strickland Road, Suite 103-177 Raleigh, NC 27615-1902

Company Officials

All LLCs are managed by their managers pursuant to N.C.G.S. 57D-3-20.

Member: Uday Reebye
746 East Franklin St.
Chapel Hill NC 27514

SOSID: 1481029
Date Filed: 11/13/2015 3:58:00 PM
Elaine F. Marshall
North Carolina Secretary of State
C2015 317 00216

ARTICLES OF ORGANIZATION
OF
SURGICAL CENTER FOR DENTAL PROFESSIONALS OF NC 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: Surgical Center for Dental Professionals of NC LLC

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

   Spruillco, LLC, Organizer
   301 Fayetteville Street, Suite 1900
   Raleigh, NC 27601

3. The street address, mailing address and county of the initial registered office of the limited liability company are:

   212 South Tryon Street, Suite 100
   Charlotte, NC 28281
   Mecklenburg County

4. The name of the initial registered agent is: National Corporate Research, Ltd.

5. There is no principal office of the limited liability company at this time.

6. To the fullest extent permitted by the North Carolina Limited Liability Company Act as it exists or may hereafter be amended, but subject to the provisions of the limited liability company's operating agreement as in effect from time to time, 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.

7. These articles will be effective upon filing.

This the 13th day of November, 2015.

SPRUILLCO, LLC, Organizer

By:
David R. Krosner
Vice President

4826594

LIMITED LIABILITY COMPANY ANNUAL REPORT

NAME OF LIMITED LIABILITY COMPANY: Surgical Center For Dental Professionals of NC LLC

SECRETARY OF STATE ID NUMBER: 1481029 STATE OF FORMATION: NC

REPORT FOR THE YEAR: 2016

Filing Office Use Only
E-Filed Annual Report
1481029
CA201606100267
3/1/2016 09:57
☐ Changes

SECTION A: REGISTERED AGENT'S INFORMATION

1. NAME OF REGISTERED AGENT: National Corporate Research, Ltd.

2. SIGNATURE OF THE NEW REGISTERED AGENT: ____________________

SIGNATURE CONSTITUTES CONSENT TO THE APPOINTMENT.

3. REGISTERED OFFICE STREET ADDRESS & COUNTY
212 South Tryon Street Suite 1000
Charlotte, NC 28281-0001 Mecklenburg County

4. REGISTERED OFFICE MAILING ADDRESS
212 South Tryon Street Suite 1000
Charlotte, NC 28281-0001

SECTION B: PRINCIPAL OFFICE INFORMATION

1. DESCRIPTION OF NATURE OF BUSINESS: Surgery Center

2. PRINCIPAL OFFICE PHONE NUMBER: 9198411000

3. PRINCIPAL OFFICE EMAIL: Privacy Redaction

4. PRINCIPAL OFFICE STREET ADDRESS & COUNTY
9650 Strickland Road, Suite 103-177
Raleigh, NC 27615-1902

5. PRINCIPAL OFFICE MAILING ADDRESS
9650 Strickland Road, Suite 103-177
Raleigh, NC 27615-1902

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

NAME: Uday Reebye	NAME:	NAME:
TITLE: Member	TITLE:	TITLE:
ADDRESS:	ADDRESS:	ADDRESS:
746 East Franklin Street		
Chapel Hill, NC 27514		

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

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

3/1/2016
DATE

Uday Reebye
Print or Type Name of Company Official

Member
Print or Type The Title of the Company Official

This Annual Report has been filed electronically.
MAIL TO: Secretary of State, Corporations Division, Post Office Box 29525, Raleigh, NC 27626-0525

SOSID: 1522027
Date Filed: 6/3/2016 2:40:00 PM
Elaine F. Marshall
North Carolina Secretary of State
C2016 155 00200

ARTICLES OF ORGANIZATION
OF
SURGICAL CENTER FOR DENTAL PROFESSIONALS OF CHARLOTTE 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: Surgical Center for Dental Professionals of Charlotte LLC

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

   Spruillco, LLC, Organizer
   301 Fayetteville Street, Suite 1900
   Raleigh, NC 27601

3. The street address, mailing address and county of the initial registered office of the limited liability company are:

   212 South Tryon Street, Suite 1000
   Charlotte, NC 28281
   Mecklenburg County

4. The name of the initial registered agent is: National Corporate Research, Ltd.

5. There is no principal office of the limited liability company at this time.

6. To the fullest extent permitted by the North Carolina Limited Liability Company Act as it exists or may hereafter be amended, but subject to the provisions of the limited liability company's operating agreement as in effect from time to time, 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.

7. These articles will be effective upon filing.

This the 3rd day of June, 2016.

SPRUILLCO, LLC, Organizer

By: ______________________
David R. Krosner
Vice President

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