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Obtaining Operating Room Access for Pediatric Dental Procedures via Ambulatory Surgery Centers: Organizational and Operational Issues and Options

A Primer for Pediatric Dentists

Prepared for the AAPD by Julie Allen and Diane Millman of Powers Pyles Sutter & Verville PC

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There are significant financial, reimbursement, and other barriers that limit hospital Operating Room (OR) access for the performance of pediatric dental procedures that require general anesthesia.[1] The purpose of this White Paper is to explore the organizational and operational options for pediatric dentists to gain OR access in Ambulatory Surgical Center (ASC) settings. Specifically, this White Paper addresses three options for obtaining OR access in an ASC:

- Establishing a single-specialty dental ASC by a single practice or through joint venture arrangements among otherwise unaffiliated dentists;
- Leasing an existing ASC on an intermittent or part-time basis; and
- Obtaining block schedule OR time in an existing ASC.

Given that Medicaid is a primary payer for pediatric dental procedures, it is important to understand that Medicaid requirements for ASCs may or may not require Medicare certification as a condition of providing ASC facility payment. This White Paper assumes that, as a general matter, Medicaid programs provide facility payment only to state licensed, Medicare-certified ASCs; that Medicaid programs otherwise generally follow Medicare rules regarding the types of procedures for which facility payment is available; and that Medicaid programs establish their own payment rates, which may or may not be based in whole or in part on Medicare rates.

I. Establishing a Single-specialty Dental ASC

While ASCs are commonly viewed as mini-hospitals, a significant number of Medicare-certified ASCs are in fact extensions of physicians' offices—physicians' offices that are utilized as ASCs on a part-time basis. In particular, the Medicare certification regulations make it possible for physicians who perform surgical procedures to obtain Medicare certification for their practices as ASCs, so long as Medicare certification and any applicable state certificate of need and state licensure requirements are met.

A. Physicians' Offices that Function as ASCs

The Medicare certification requirements (Conditions of Coverage) for ASCs are included in Part 416 of 42 CFR. These regulations, at 42 CFR §416.2**,** define an ASC as follows:

> *Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. . . .*

While this definition on its face would appear to preclude the office of a physician or other practitioner from qualifying as an ASC, the Interpretive Guidelines used by state personnel that conduct Medicare certification ASC surveys on behalf of CMS (State Operations Manual, Appendix L) interpret this definition broadly. Because this point is critical to understanding how a pediatric dental practice (or a group of otherwise unaffiliated pediatric or other dentists) might establish their own single-specialty ASC, the relevant section of the Interpretive Guidelines is quoted at length below:

> *An ASC satisfies the criterion of being a "distinct" entity when it is wholly separate and clearly distinguishable from any other healthcare facility or office-based physician practice. The ASC is not required to be housed in a separate building*

from other healthcare facilities or physician practices, but, in accordance with National Fire Protection Association (NFPA) Life Safety Code requirements (incorporated by cross-reference at §416.44(b)), it must be separated from other facilities or operations within the same building by walls with at least a one-hour separation. If there are State licensure requirements for more permanent separations, the ASC must comply with the more stringent requirement.

An ASC does not have to be completely separate and distinct physically from another entity, if, and only if, it is temporally distinct. In other words, the same physical premises may be used by the ASC and other entities, so long as they are separated in their usage by time. *For example: •Adjacent physician office: Some ASCs may be adjacent to the office(s) of the physicians who practice in the ASC.* ***Where permitted under State law, CMS permits certain common, non-clinical spaces, such as a reception area, waiting room, or restrooms to be shared between an ASC and another entity, as long as they are never used by more than one of the entities at any given time, and as long as this practice does not conflict with State licensure or other State law requirements****. In other words, if a physician owns an ASC that is located adjacent to the physician's office, the physician's office may, for example, use the same waiting area, as long as the physician's office is closed while the ASC is open and vice-versa. The common space may not be used during concurrent or overlapping hours of operation of the ASC and the physician office. Furthermore, care must be taken when such an arrangement is in use to ensure that the ASC's medical and administrative records are physically separate. During the hours that the ASC is closed, its records must be secure and not accessible by non-ASC personnel.*

*Permitting use of common, non-clinical space by distinct entities separated temporally does not mean that the ASC is relieved of the obligation to comply with the NFPA Life Safety Code standards for ASCs, in accordance with§416.44(b), that require, among other things, a one-hour separation around all physical space that is used by the ASC and fire alarms in the ASC. (****Emphasis added****)*

Because of this interpretation, a single-specialty dental ASC may be established in space adjacent to (or within) a pediatric dentist's office, so long as the practice is closed when the ASC is in use, Life Safety Code requirements can be met, and the facility otherwise meets all state licensure and Medicare certification requirements. The separate records requirement does not mean that there cannot be duplicative patient information maintained by the ASC and the pediatric dental office. For example, the ASC records would maintain details of the general anesthesia cases while the pediatric dental office would maintain regular dental records and could also indicate that the patient received care under general anesthesia in the ASC.

Please note that CMS's recognition of space sharing arrangements also may facilitate the establishment of single-specialty dental ASCs in space otherwise used as a hospital clinic, during periods when the clinic otherwise would be closed. Under this model, a pediatric dentist would lease the space from the hospital or clinic entity during otherwise-unused hours of operation and outfit one of the rooms in a manner that meets any applicable requirements for OR/procedure rooms. Such a model may be particularly attractive for integrated delivery systems that own and operate dental clinics that already have the necessary specialized equipment.

B. Dental Rehabilitation as Surgical Procedures

In order to qualify for certification, an ASC must provide only surgical procedures that ordinarily would not take more than 24 hours, including pre-op preparation and recovery time. Pediatric dental rehabilitation procedures generally do not exceed this time limitation, and it appears clear that dental rehabilitation procedures that require the administration of general anesthesia meet the definition of "surgical services" set forth in the Interpretive Guidelines:

Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system, is also considered to be surgery. (This does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician.) All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

Despite the requirement that an ASC perform only surgical services, it may provide radiological services ancillary to surgery: Therefore, a single-specialty dental ASC can provide x-ray and other imaging services that may be necessary for the safe and effective provision of dental rehabilitation, without violating the requirement that the ASC perform "only" surgical services.

C. Dentists and Physicians

For the purposes of the ASC certification requirements, dentists and physicians are specifically recognized as equivalent. The regulations, at 42 CFR §416.42 - Condition for Coverage: Surgical Services, provides that "surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC." For the purpose of this requirement, the Interpretive Guidelines define a qualified physician with respect to ASCs to include:

a ***doctor of dental surgery or dental medicine****, and a doctor of podiatric medicine. In all cases, the physician must be licensed in the State in which the ASC is located and practicing within the scope of his/her license.*[2] *(****Emphasis Added****)*

D. Meeting the ASC Conditions of Coverage

A single-specialty ASC seeking Medicare certification has the option to either (a) undergo a survey by state surveyors under contract with the Medicare Program, who inspect ASCs for compliance with the ASC Conditions of Coverage using the survey methodology and standards described in the Interpretive Guidelines; or (b) become accredited by an organization that has obtained "deemed status" from CMS. Because the standards applied by "deemed status" organizations have been reviewed by CMS and have been found to be at least as stringent as Medicare conditions of coverage, ASCs that attain accreditation by an organization that has "deemed status" are considered compliant with Medicare certification requirements. The organizations that have achieved deemed status for ASCs are set forth on the CMS website.[3]

Each deemed status organization has slightly different accreditation requirements, and, for those pediatric dental practices interested in attaining Medicare certification through deemed status, each organization's standards should be reviewed before a choice is made. In addition, some third-party payers require accreditation by one or another of these organizations as a condition of payment, so it is advisable to check the payment policies for the major third party payers in the area, and in some states, accredited ASCs may be deemed to be in compliance with state licensure requirements.

Those dental practices that seek Medicare certification through a state survey will need to meet the requirements set forth in the Medicare regulations, per state surveyors, applying the interpretations and survey procedures in the Interpretive Guidelines, including:

- **§416.40 —Compliance with State licensure law.**
- **§416.41 —Governing body and management.**
- **§416.42 —Surgical services.**
- **§416.43 —Quality assessment and performance improvement.**
- **§416.44 —Environment.**
- **§416.45 —Medical staff.**
- **§416.46 —Nursing services.**
- **§416.47 —Medical records.**
- **§416.48 —Pharmaceutical services.**
- **§416.49 —Laboratory and radiologic services.**
- **§416.50 —Patient rights.**
- **§416.51 —Infection control.**

More details are available on the CMS website.[4]

While the ASC Conditions of Coverage may appear intimidating on their face, in fact many of them can be satisfied with the adoption and implementation of written policies and procedures that can be obtained from consultants and other sources and tailored as appropriate to meet particular needs. The two ASC Conditions of Coverage that may pose the greatest challenges for a pediatric dental practice seeking to operate as an ASC on a part-time basis are those pertaining to physical plant and personnel.

The requirements related to physical plant are set forth in 42 CFR § 416.44 Condition for Coverage: Environment. To meet Medicare certification requirements, procedure rooms that are used for the performance of non-sterile surgical procedures need not meet the "same design and equipment standards as traditional operating rooms;" however, if state licensure laws (which vary based on the state involved) require that procedure rooms must meet OR standards, those state requirements must be met for the facility to be Medicare-certified. In addition, temperature, humidity, and airflow requirements must be met, special Life Safety Code requirements must be applicable, and the facility must have recovery and waiting rooms that are separate from the OR/procedure room and from each other. These physical facility requirements may make some dental offices impracticable for conversion to ASCs, even on a part-time basis.

In addition, there are a number of ASC Conditions of Coverage that require the involvement of a medical doctor, anesthesiologist, or other qualified personnel in the operations of an ASC; therefore, obtaining Medicare certification for a single-specialty dental ASC operated as a component of a dental practice likely will not be possible without the participation of other physicians or practitioners, such as physician or dentist anesthesiologists. *See Attachment A*.

E. ASC Organizational and Operational Structures

Any of a number of legal structures can be utilized for the organization of an ASC. For example, the ASC may be owned by a dental practice, a for-profit joint venture, or a not-for-profit organization. An ASC can even be owned by a single dentist or other individual. Under Medicare rules, a single individual can function as the ASC's "governing body." Moreover, Medicare rules do not preclude an ASC from being owned and operated as a component of a dentist's professional corporation or other professional practice. Alternatively, a separate legal entity may be established, and ownership may be held individually or shared with others. Depending upon how the ASC is organized and operated, it may qualify for tax exemption, with contributions to its support qualified as charitable donations for tax purposes. However, if a separate legal entity is established for an ASC that is co-located with a dental practice, the ASC entity will need to enter into a formal lease (or sublease) agreement with the dental practice specifying when the facility will be operated as an ASC and providing compensation for any shared personnel.

Assuming that a dental practice in a community is physically configured in a manner that makes it practicable for conversion to a part-time ASC and compliance with other Medicare Conditions of Coverage and state licensure requirements

is achievable, access to the ASC need not be limited to the patients of the dental practice involved or patients of other dentists in the area that may also be part-owners of the facility. Unless access is required to be restricted in order to maintain an exemption from state certificate of need or licensure requirements, the ASC facility can be made available to other dentists, who may be granted staff privileges in much the same way a hospital might grant staff privileges to physicians and other practitioners.

Finally, please note that ASCs are generally subject to state licensure laws that may impose requirements that differ from those imposed by the Medicare program or accreditation organizations. In addition, in some states, ASCs may be subject to certificate of need laws. The applicability of state licensure (and, where they exist, certificate of need requirements) in some states may depend upon whether the ASC is organized as a component of a dentist's professional practice or is organized and operated as a separate legal entity, so state laws should be examined before the legal structure of the ASC is determined. In addition, state licensure laws in some states may be triggered by Medicare certification of a facility. For this reason, since pediatric dental practices do not rely on Medicare as a primary source of revenue, it is important to check whether Medicaid or area payers require Medicare certification as a condition of payment before beginning the process.

II. Leasing an Existing ASC on an Intermittent or Part-Time Basis

Another option for pediatric dentists to obtain OR access may involve leasing (or subleasing) space in an existing Medicare-certified ASC during otherwise unused or available hours of operation. Under this option, the dentists/lessor would obtain separate Medicare/Medicaid certification for the facility that would apply for those periods when it operates as a dental ASC. The Interpretive Guidelines specifically contemplate this type of facility sharing arrangement:

> *Separately Certified ASCs Sharing Space: Where permitted under State law, several different ASCs, including ones that participate in Medicare and ones that do not, may use the same physical space, including the same operating rooms, so long as they are temporally distinct, i.e., they do not have concurrent or overlapping hours of operation…*
>
> *Each of the different ASCs that utilize the same space is separately and individually responsible for compliance with all ASC Conditions for Coverage (CfCs).*

This type of shared space arrangement may be attractive, for example, if there is an underutilized ASC in the community; if a dental group's physical space is not configured in a manner that makes conversion into a part-time ASC practicable; or if a group of otherwise unaffiliated dentists (or dental groups) wish to have access to OR facilities in a "neutral" location (i.e., in a location that is not affiliated with any one of them).

One consideration, however, is whether the performance of dental rehabilitation procedures requires highly specialized equipment of the kind that typically might be found in a well-equipped dental office. It is relatively uncommon for either multi-specialty ASCs or the typical single-specialty ASC (which tend to be established by ophthalmologists and GIs) to have the necessary equipment. To the extent that this equipment is relatively immobile, the type of space sharing arrangement described here may be practicable only if there is an ASC in the community that is not only willing to lease itself out during otherwise unused hours of operation but that also has unused space that is appropriate to be outfitted as a dental procedure room/OR. If additional specialized equipment is necessary in order for dental rehabilitation to be performed in shared space leased from an ASC, the dentist(s) leasing the space (not the ASC-lessor) will be responsible for obtaining and maintaining the equipment.

III. Obtaining Block Schedule OR Time In An Existing ASC

Another option for pediatric dentists to obtain OR access is to obtain block time at an existing ASC for the performance of dental rehabilitation. A number of barriers to this approach have thus far made block time unavailable–or available to only a limited extent. Because the Medicare regulations preclude coverage to ASCs for procedures reported using the "miscellaneous" CPT code that is currently applicable to dental rehabilitation, ASCs are not a non-viable or very limited option in those states that use Medicare coverage rules for services provided to Medicaid patients. And even if dental rehabilitation were payable in ASC settings, the amount that would be paid is completely inadequate to cover costs. Unless and until these reimbursement issues are addressed, it appears unlikely that ASCs will be willing to make OR block time available to pediatric dentists for the performance of dental rehabilitation. The problem is likely to be particularly intractable if the performance of these procedures requires specialized dental equipment that is relatively immobile and that requires dedicated floorspace.

Once reimbursement-related obstacles are removed, however, dentists may wish to consider investing in area ASCs in order to increase the possibility of obtaining block time. ASCs are typically owned by referring physicians who often also serve on their governing boards, and physician-owners typically determine the scope of services to be provided as well as resource allocation. Holding an investment interest in an ASC may in some cases provide access to block schedule time that otherwise may be inaccessible.

Other documents describe the current advocacy efforts by AAPD, ADA, and AAOMS to obtain a specific dental rehabilitation code under the CMS Healthcare Common Procedure Coding System (HCPCS) and thereby improve the facility fee for such hospital and ASC cases.

Attachment A

Selected ASC Personnel Requirements

The Conditions of Coverage that implicate the services of other physicians or practitioners include the following:

- 42 CFR §416.42(a) Standard: Anesthetic Risk and Evaluation provides:
    1. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.
    2. Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

To the extent that the evaluation of the risk of general anesthesia falls outside of the scope of a dentist's licensure under state law, an anesthesiologist would need to be engaged to provide this service as well as other anesthesia-related services required under the Medicare certification regulations. In addition, a single-specialty dental ASC would have to contract with a physician or anesthetist to provide the post-surgical discharge evaluation.

- 42 CFR §416.42(b) Standard: Administration of Anesthesia requires that, with certain exceptions, anesthesia be administered by a qualified anesthesiologist, a physician qualified to administer anesthesia, a certified registered nurse anesthetist under the supervision of the operating surgeon, or anesthesiologist assistant under supervision of a qualified anesthesiologist.
- 42 CFR §416.46 Condition for Coverage: Nursing Service requires that the nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met. The applicable Interpretive Guidelines require that nursing services be under the direction and leadership of a Registered Nurse and there must be a Registered Nurse available for emergency treatment whenever there is a patient in the ASC.
- 42 CFR §416.48 Condition for Coverage: Pharmaceutical Services. The ASC must designate a specific licensed healthcare professional to provide direction to the ASC's pharmaceutical service (i.e., any drugs dispensed at the ASC), and that individual must be routinely present when the ASC is open for business, but a consulting pharmacist is not required unless the ASC is performing activities which under State law may only be performed by a licensed pharmacist.
- 42 CFR §416.49(a) Standard: Laboratory Services. If the ASC performs laboratory services, it must meet any applicable CLIA requirements, and if the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory.
- Under 42 CFR §416.49(b)(2) Standard: Radiologic Services. If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with Medicare certification requirements.

References

1. Vo AT, Casamassimo PS, Peng J, Amini H, Litch CS, Hammersmith K. Denial of operating room access for pediatric dental treatment: A national survey. Pediatr Dent 2021;43(1):33-8.E14-E16.
2. Chapter 5 of the Provider Reimbursement Manual (§70.2) states, in relevant part: A dentist qualifies as a physician if he/she is a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he/she performs such function and who is acting within the scope of his/her license when he/she performs such functions. Such services include any otherwise covered service that may legally and alternatively be performed by doctors of medicine, osteopathy and dentistry; e.g., dental examinations to detect infections prior to certain surgical procedures, treatment of oral infections and interpretations of diagnostic X-ray examinations in connection with covered services.
3. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf.
4. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_l_ambulatory.pdf.