OBTAINING OR ACCESS FOR PEDIATRIC DENTAL PROCEDURES:

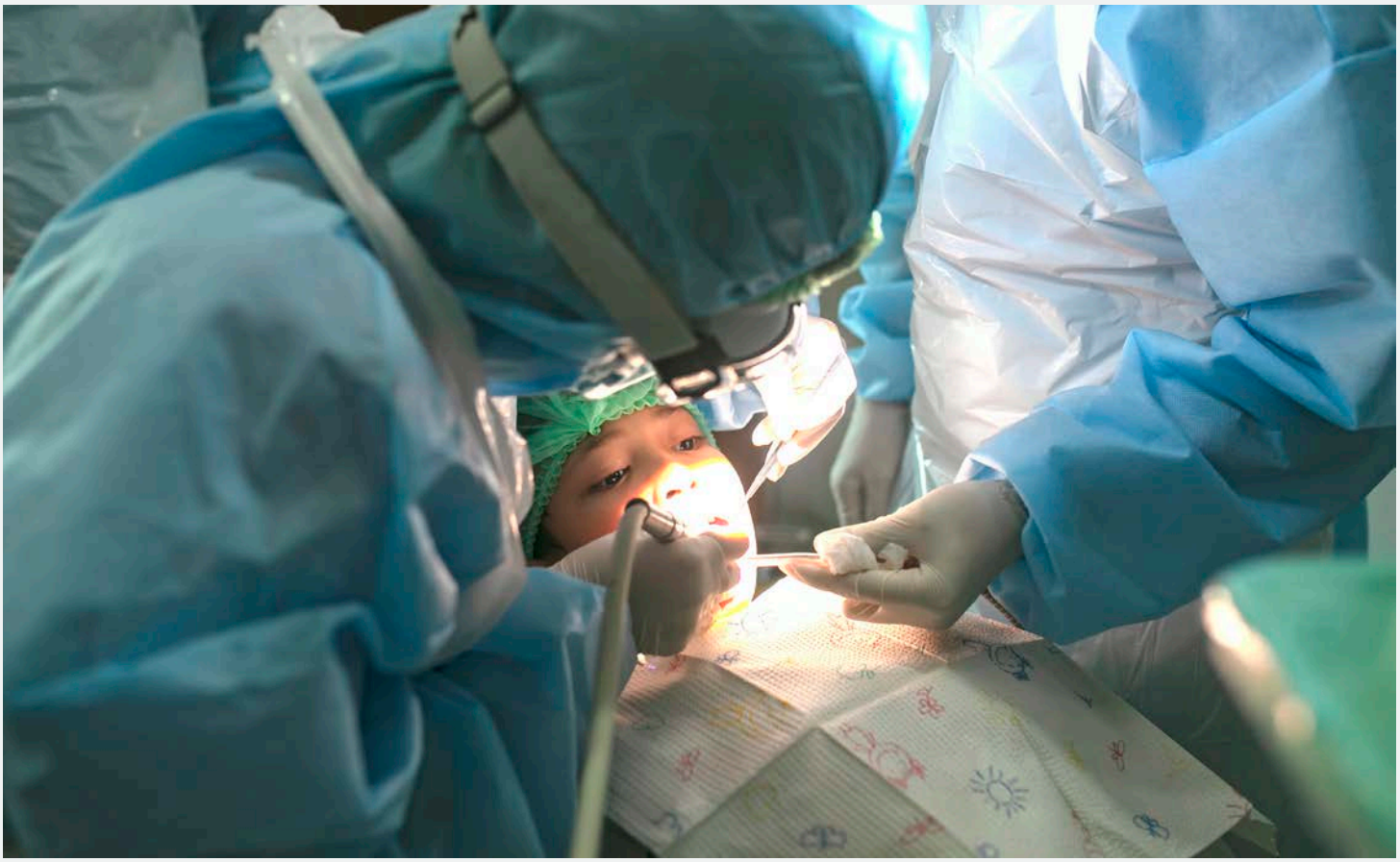
Making Your Practice Do "Double Duty" as an Ambulatory Surgical Center

by Diane Millman and C. Scott Litch

It is well documented that 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. The establishment of ambulatory surgical centers (ASCs) equipped to perform dental procedures has the potential to alleviate this pressing need. As the result of concerted advocacy efforts by a coalition of dental organizations led by the AAPD, in 2024 the Medicare Program began to add dental procedures (including dental rehabilitation (HCPCS G0330), a code created the prior year to report OR dental procedures performed for pediatric patients) to the list of procedures that Medicare covers in ASC settings (the Covered Procedures List or CPL). While Medicare is not a significant payer for the pediatric patient population, many other payers (including many Medicaid programs and private payers) utilize the Medicare CPL to determine which procedures are eligible for ASC coverage These payers generally require that an ASC be state-licensed and Medicare-certified to be eligible to receive payment for their equipment, supply, clinical personnel, and overhead costs (facility costs). While Medicaid programs establish their own payment rates, as the result of the Medicare program's recognition of the dental OR access crisis, an increasing number of states are authorizing Medicaid payment to ASCs for dental procedures for the first time or increasing the applicable rates. For this reason, there is increasing interest in using ASCs to help fill the continuing unmet need for OR access for pediatric dental procedures that require general anesthesia, particularly for patients classified as ASA I or II. This article explores the organizational and operational issues that should be considered by any pediatric dental practice that is considering establishing a single specialty dental ASC to address the unmet need for dental OR access in its community.[1]

DENTAL PRACTICES OPERATED AS PART-TIME ASCS

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. Likewise, the Medicare certification regulations make it possible for dentists 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. Specifically, while Medicare regulations require that an ASC be a "distinct entity" from other healthcare



operations, this requirement is interpreted broadly in CMS Interpretive Guidelines found in Appendix L of the State Operations Manual:

> *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.*

Because of this interpretation, a single specialty dental ASC may be established in a space adjacent to (or within) a pediatric dentist's office, so long as the practice is closed when the ASC is in use or there is no overlapping space and the facility otherwise meets all state licensure and Medicare certification (including Life-Safety Code) requirements.

CMS' 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. Dental ASCs operated in unused space owned by hospitals or hospital clinics may wish to consider joint venturing with the hospital entities involved to spread financial and operational risk.

The same shared space concept may be used by otherwise unaffiliated dentists in an area to establish a single-specialty ASC in office space that is not utilized by one of them or that is set aside for ASC purposes during designated periods of time. While such a joint arrangement is somewhat more complex (insofar as a new legal entity likely would be required), a joint arrangement may also help ensure that the ASC is more fully utilized than if the ASC is operated by a single dental practice.

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 "deemed" to be in compliance with Medicare certification requirements. The organizations that have achieved deemed status for ASCs are listed by CMS.[2] 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 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, as applied by 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.[3]

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 or to obtain Medicaid payment. In addition, temperature, humidity, and airflow requirement must be met, special Life Safety Code requirements are applicable, and the facility must have a separate recovery room and waiting room that is separate from the OR/procedure room and separate 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 relating to personnel that may pose a challenge for some single specialty ASCs. For example, the Medicare Conditions of Coverage include requirements related to the provision of anesthesia, nursing services, and post-operative examinations that may require the involvement of a medical doctor, anesthesiologist or CRNA, 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. Several of the personnel requirements that may warrant consideration accompany this article.

ASC ORGANIZATIONAL AND OPERATIONAL STRUCTURES

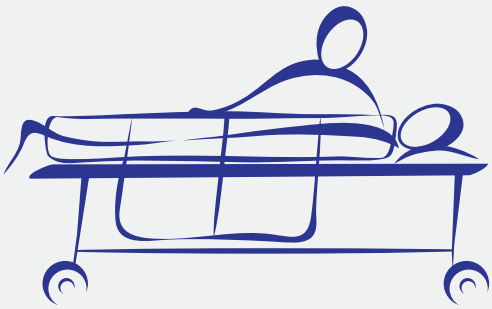
A number of legal structures can be utilized for the organization of an ASC. For example, the ASC may be owned by a dental practice, a single dentist, a for-profit joint venture, a not-for-profit organization, or another entity or individual. Under Medicare rules, a single individual can function as 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 qualifying 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 that times that 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. 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, for pediatric dental practices that 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.

CONCLUSION

A number of organizational and operational models can be used to establish facilities that provide OR/procedure room access for the performance of pediatric dental procedures.It is likely that no single model will work in all areas of the country, and that creativity and initiative will be required for those pursuing any of these options. But physicians in a number of specialty areas have successfully negotiated the hurdles involved and, as a result, have established safe, cost- effective settings for the performance of surgery within ASC settings that are accessible to their patients on a timely basis; that meet high quality standards of care; and that are financially viable. While the dominance of Medicaid as the primary payer for dental procedures makes these solutions more challenging for pediatric dentists, pediatric dentists in need of OR access are well advised to explore the many ASC options that are available. The authors recognize that such options may include seeking OR time with an existing ASC that primarily or solely accommodates dental cases and has engaged pediatric dentists.



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Accompanying Material

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 that

    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 RN, 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), 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.

1. *A more detailed analysis of this topic was prepared for the AAPD in 2021 by Diane Millman and Julie Allen of Powers, and is available on the AAPD website at: https://www.aapd.org/advocacy/legislative-and-regulatory-issues/latest-advocacy-news/obtaining-operating-room-access-for-pediatric-dental-procedures-via-ambulatory-surgery-centers/*

2. *See: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf.*

3. *See: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_l_ambulatory.pdf*