Starting a Sleep Center

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CHEST Postgraduate Education Corner

CONTEMPORARY REVIEWS IN SLEEP MEDICINE

Starting a Sleep Center

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The demand for sleep medicine services has grown tremendously during the last decade and will likely continue. To date, growth in demand has been met by growth in the number of new sleep centers. The need for more new centers will be dependent on market drivers that include increasing regulatory requirements, personnel shortages, integration of home sleep testing, changes in reimbursement, a shift in emphasis from diagnostics to treatment, and an increased consumer focus on sleep. The decision to open a new center should be based on understanding the market dynamics, completing a market analysis, and developing a business plan. The business plan should include an overview of the facility, a personnel and organizational structure, an evaluation of the business environment, a financial plan, a description of services provided, and a strategy for obtaining, managing, and extending a referral base. Implementation of the business plan and successful operation require ongoing planning and monitoring of operational parameters. The need for new sleep centers will likely continue, but the shifting market dynamics indicate a greater need for understanding the marketplace and careful planning. ***CHEST 2010; 137(5):1217–1224***

Abbreviations: AASM = American Academy of Sleep Medicine; CMS = Center for Medicare and Medicaid Services; CPAP = continuous positive airway pressure; DME = durable medical equipment; IDTFs = independent diagnostic testing facilities; OSA = obstructive sleep apnea; PAP = positive airway pressure; PSG = polysomnography

The practice of sleep medicine and the demand for sleep medicine services have grown tremendously in the last decade. Multiple factors are driving this growth, including recognition of an increasing number of sleep disorders, identification of the link between sleep disorders and other medical disorders, increased training of medical professionals about sleep disorders, and increased understanding in the general population of the presence and consequences of sleep disorders.

The most recent International Classification of Sleep Disorders lists >70 sleep disorders.[1] Current estimates are that between 50 and 70 million Americans suffer from sleep-related problems.[2] In addition to the morbidity and mortality from sleep disorders themselves, including higher rates of workplace and automobile accidents,[3,4] sleep disorders have been linked to higher rates of hypertension,[5] cardiovascular disease,[6] obesity,[7] diabetes[8] and depression.[9] To address the increased clinical demand, formal Accreditation Council on Graduate Medical Education-approved training programs in sleep medicine have been established, and competency in sleep medicine can be demonstrated by passage of an American Board of Medical Specialties board examination in sleep medicine. This constitutes recognition of sleep medicine as an independent subspecialty.[10]

Diagnosis of sleep disorders is based on a combination of history and physical examination, monitoring of the sleep/wake pattern, and physiologic testing. The most common sleep study is overnight polysomnography (PSG), the monitoring of multiple physiologic parameters during sleep. This study is indicated for the diagnosis of obstructive sleep apnea (OSA), periodic limb movements of sleep, narcolepsy, and parasomnias, and to assess response to therapies for these disorders.[11] In-laboratory PSG requires an overnight stay at a sleep center with attendance by a technologist trained in sleep technology.

There is sufficient demand to increase the number of available sleep centers, laboratories, and related

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operations. The number of sleep centers and laboratories accredited by the American Academy of Sleep Medicine (AASM) has increased 400% in the last 10 years (Fig 1), and they are thought to represent about one-third of the centers and laboratories in the United States.[12,13] For accreditation purposes, a sleep center comprises a clinic and a diagnostic section for sleep testing and is directed by a board-certified sleep specialist, while a sleep laboratory has the same setup, focuses predominantly on sleep-disordered breathing patients, and may be directed by a pulmonologist with training in sleep medicine in lieu of a sleep specialist.[14,15]

Reflecting the increase in capacity, there has been an increase in the amount of testing conducted. The Center for Medicare and Medicaid Services (CMS) reported that the number of sleep studies performed more than doubled from 2000 to 2004 (Fig 2).[16] In addition, the number of continuous positive airway pressure (CPAP) devices, considered a marker for the growth in sleep diagnostic services, has continued to rise at an annual rate of 10% to 15% per year.[17]

Despite the large increase in the number of centers and sleep studies performed, there still may be a shortage of sleep medicine facilities. In 1997, Young et al[17] evaluated a population of middle-aged state employees with no barrier to health care and found that 82% of men and 93% of women with moderate-to-severe OSA had not yet been clinically diagnosed. In 2004, Flemons et al[19] used this information to estimate that 2,310 PSGs per 100,000 people per year would be needed to diagnose and treat patients with suspected moderate-to-severe OSA, a figure >10 times their estimate of capacity. The authors felt this indicated a potential problem with access to care. To date, problems with access have not been widespread. Several surveys have found that wait times for studies have not increased despite the increased demand, most likely because the number of available facilities continues to grow.[13,20] A recent survey found that existing sleep centers expected to increase bed capacity 10% to 20% in the next year.[21]

Recent developments may affect the structure of the industry, but will likely continue to drive the need for more sleep medicine operations and new sleep centers. This article is designed to assist those interested in opening new sleep programs in understanding the process involved in starting a sleep center.

Market Dynamics

When investigating new practice opportunities, it is critical to first understand the market dynamics affecting the profession that influence the growth or contraction of the need for sleep medicine services (Table 1). Identification of these drivers will help those considering opening a center make an educated guess about the direction the local market is heading. The key drivers are outlined in the following sections.

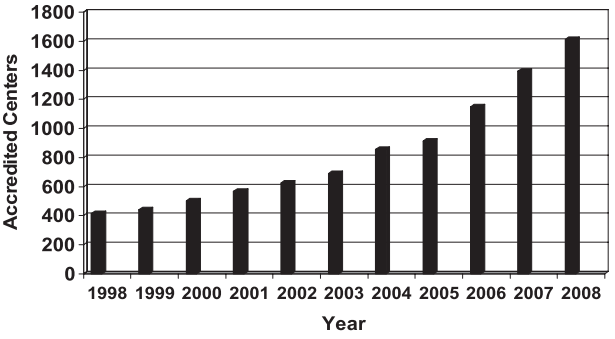

Figure 1. Increase in American Academy of Sleep Medicine-accredited sleep centers and laboratories. (Adapted from data from the American Academy of Sleep Medicine with permission.)

Integration of Home Sleep Testing

Improvements in portable monitoring technology have made home sleep testing more feasible. While this may reduce the cost per study and improve some patients' tolerance of sleep testing, there is also the potential for more widespread testing and increased overall cost. New CMS guidelines allow coverage for CPAP devices to treat OSA when the diagnosis is made using a portable monitor as well as in-laboratory PSG.[22] This policy might drive down the need for sleep bedrooms and decrease the profitability of sleep centers if the site of study shifts from the laboratory to the home.

Shift in Emphasis from Diagnostics to Treatment

CMS guidelines require demonstration of objective adherence to CPAP therapy and benefit from use.[23-26] Other third-party payers will likely establish

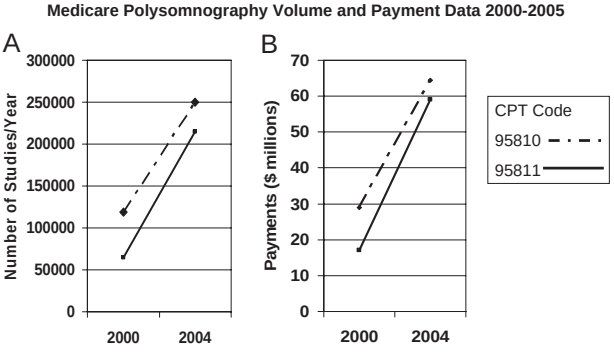

Figure 2. Increase in the number of sleep studies performed. There was a 111% increase in the number of diagnostic sleep studies (CPT code 95810) and a 238% increase in the number of split-night and titration studies (CPT code 95811) from 2000 to 2004 (*A*). There was a similar rise in payments of 222% for 95810 and 340% for 95811 (*B*). CPT = Current Procedural Terminology.[16]

similar guidelines. Sleep centers will need to shift their focus to providing long-term care for patients with OSA.

Increasing Regulatory, Payer, and Accreditation Requirements

Payers are establishing additional internal guidelines to control testing and treatment. Many require preauthorization prior to testing, potentially limiting patient eligibility. The CMS, as well as other third-party payers, is adding requirements that sleep studies be performed under the supervision of board-certified sleep specialists and in accredited facilities.[23-26] The AASM accreditation standards focus on providing longitudinal care, maintaining quality improvement programs, and raising the qualifications of the clinical and technical staff. While improving quality, these standards may also increase cost. New CMS regulations bar independent diagnostic testing facilities (IDTFs), but not hospitals or physician-owned centers, from performing sleep studies in hotels or motels and prevent positive airway pressure (PAP) providers from conducting home sleep testing.[27]

Finally, the Office of Inspector General's 2009 Work Plan includes a proposal to investigate the appropriateness of Medicare payments for both sleep studies and CPAP devices.[28] In response to the increase in Medicare payments from $62 million in 2001 to $215 million in 2005, the Office of Inspector General "will examine the appropriateness of Medicare payments for sleep studies" and "assess provider compliance with Federal program requirements." The appropriateness of Medicare payments for CPAP devices will also be reviewed. Developers of new sleep centers need to ensure that appropriate compliance programs are put in place.

Personnel Shortages

Sleep centers must have trained and qualified personnel to staff those centers, including sleep specialists, behavioral sleep specialists, nurses, sleep technologists, respiratory therapists, and other allied health personnel. The 68 Accreditation Council for Graduate Medical Education-accredited sleep medicine fellowship programs graduate approximately 200 new sleep specialists per year on top of the almost 1,400 physicians who have passed the American Board of Medical Specialties sleep medicine board certification examination. In addition, 3,445 practitioners passed the previous sleep board certification examination given by the American Board of Sleep Medicine. Formal workforce assessments have not been performed, but many communities are still underserved by board-certified sleep specialists. The greatest bottleneck is with trained and certified sleep technologists. Multiple states have established training and licensing requirements for sleep technologists. CMS IDTF regulations[29] require that in-laboratory sleep studies on Medicare patients be performed by technicians with appropriate certification: registered PSG technologists, registered EEG technologists, or registered or certified respiratory therapists. This requirement most likely also extends to Medicaid sleep studies. Traditionally, tech training has been on-the-job training, but recent initiatives have led to the establishment of college-based sleep technology training programs and the formalization of on-the-job training through the AASM-sponsored Accredited Sleep Technologist Education Program. Planning for a new center must include an assessment of the availability of sleep technologists and a strategy for obtaining or training new technologists.

Anticipated Decline in Sleep Study Reimbursement

Health-care reform and the enhanced scrutiny of costs will likely lead to a decrease in sleep study reimbursement. Already, the CMS has planned a 6% decrease in the reimbursement rates for sleep studies starting in 2010. Similar cuts are likely to be implemented by other third-party payers. This will impact a new center's budget and necessitate the need to identify opportunities for efficiency and cost containment.

Continued Search for Alternate Treatments

Despite effective therapies for most sleep disorders, the search continues for more effective and better-tolerated therapies. In particular, CPAP is highly effective, but not all patients are adherent.[30] Current alternative therapies include different PAP modalities (bilevel and autotitrating PAP), oral appliances, and upper airway surgery. On the horizon, flow resistance valves, electrical muscle stimulation, and even pharmacological agents may be available. The emergence of new therapies will affect the volume of titration studies and the need for new center services.

Table 1—*Sleep Market Dynamics*

Dynamic
Integration of home sleep testing
Shift in emphasis from diagnostics to treatment
Increasing regulatory, payer, and accreditation requirements
Personnel (eg, sleep technologists, respiratory therapists, sleep specialists) shortages
Anticipated decline in sleep study reimbursement
Continued search for alternate treatments
Increased consumer focus on sleep

Increased Consumer Focus on Sleep

Recent publications have stressed the need to increase public awareness about the negative health consequences of untreated sleep disorders,[31] and professional medical organizations spend a great deal of effort to educate the general public. However, obesity rates in adults and children continue to increase.[32] In addition, regulatory agencies are becoming more aware of the impact of sleep deprivation and sleep disorders on performance, absenteeism, and accident rates, further increasing the demand for sleep medicine services. For instance, the Federal Motor Carrier Safety Administration is considering regulations to require sleep studies for all truck drivers over a certain BMI to screen for OSA. Finally, consumers want to play a greater role in their own health care. Understanding consumer perspectives, attitudes, and needs is a critical success factor. An active educational outreach program should be a planned component of a new center.

Does An Opportunity Exist?

Multiple factors go into the decision to open a new sleep center. Is there sufficient need for a new center? Are there other centers, and if so, how does a new center compete with them? What financial resources are required to start and maintain a new operation? Can the barriers for entry into the marketplace be overcome?

The first step is completing a market analysis to assess the current situation in the prospective catchment area. This will determine if there is sufficient need for a new center. The analysis should include an assessment of the local competition, the demographics of the catchment area, the regulatory environment, the reimbursement structure for that area, the composition and patterns of the local health-care community, and financial requirements.

A competitive analysis should include details on the number of centers and laboratories in the catchment area, the number of sleep beds, whether the competitors provide comprehensive care, the use of laboratory testing only and/or home monitoring, whether the centers provide durable medical equipment (DME) or rely on DME companies, what institutions the centers are affiliated with, and the major referring provider relationships. This information will aid in positioning a new center and contribute to the ease of establishing a steady referral pattern.

The demographics of the catchment area may influence the type and size of the new center. Items to consider include total population, age distribution, recent and predicted population growth, population density, local average income, and area type (eg, urban, suburban, rural). Any factor affecting prospective patients' health-care decision making should be investigated. For instance, while population density may be enough to justify opening a center in a suburb, it is possible this patient base may prefer to travel into the city for its health care.

Federal regulations are uniform throughout the country. However, their application as well as state and local regulations can vary tremendously. Understanding all the relevant regulations is important for a smooth opening and continued operation. Both federal and local regulations tend to be different, depending on whether the center will be in a hospital, a physician practice, or an IDTF. An IDTF is a facility where diagnostic testing is performed independent of a physician's office or hospital and can be a fixed location, a mobile entity, or run by an individual nonphysician practitioner. CMS IDTF regulations describe rules for physician and nonphysician qualifications and responsibilities, procedures for ordering tests, and billing procedures.[29] These rules also apply when an IDTF supplies diagnostic procedures in a physician's office. It is important to determine the requirements for licensing, if necessary, and whether the state requires a certificate of need or some other license to open this type of health-care facility.

Reimbursement structures vary widely from location to location and even between different payers in the same location. Reimbursement tends to be higher for hospital-based centers than for IDTFs and physician practices. Reimbursement analysis should identify the different payers, the reimbursement rates by payer, and the rate differentiation between hospitals, IDTFs, and physician practices. In addition, each payer's reimbursement requirements for the services offered in the new center must be determined.

Those establishing a new center must also review the number of and relationships between area hospitals, physician organizations, and likely referring provider groups. The relationships between doctors, their employers, local hospitals, and health-care systems may define a level of loyalty that cannot be easily penetrated.

A complete understanding of the key financial requirements such as salaries for sleep specialists, sleep technologists, and other personnel is also necessary. These often differ significantly across the country. In addition, space costs, such as rent, construction, and parking should be identified.

The market analysis may provide enough information to aid someone in deciding against opening a new sleep center. If not, and the market analysis has provided a sufficient level of comfort, the next step is to draft a business plan.

The Business Plan and Implementation

The business plan is "a selling document that conveys the excitement and promise of your business to any potential backers or stakeholders".[33] Although not everyone will need to resort to others for financial support, the concept of underlining the excitement and promise of an opportunity is integral to business planning. A business plan should help determine if the opportunity is worthy of time and resources, uncover relevant business aspects that would not otherwise have been considered, and focus efforts on specific tactical actions necessary to operate a successful enterprise.

A completed business plan can run from 10 pages to 100 pages. Length is related to the intended use of the document. Usually, the most important part is the executive summary. This very short segment (maximum two pages) should highlight all critical aspects of the business plan, from start to finish. Business plan writing can either start or end with the executive summary. Some people find it easier to draft the executive summary up-front, layering the details in as they develop the plan, then going back to finalize it. Others may find it easier to dig into the details first, consolidating the plan into a short summary afterward.

The business plan itself should incorporate the items (Table 2) outlined in the sections that follow. Implementation recommendations are also included.

Company Overview

This typically defines the strategy, management team, and ownership. If desired, it can include the vision, mission, and values as well.

Business Environment

The market analysis will influence and aid in drafting this section of the plan. This is a good opportunity to identify strengths, weaknesses, opportunities, and threats to the new proposed organization.

Service Description

The sleep center model should be defined in this section. Is the center intended to be hospital-based or physician practice-owned and operated? Will it be operated internally, or will a management company be hired? Will there be a hospital or physician practice affiliation? If so, will the facility be located on the premises of the affiliated organization? Will this be a comprehensive center with a clinic, an integrated center with a clinic and DME, or simply a laboratory? Will the center conduct research trials, either investigator-initiated or industry-sponsored, and what is needed to provide for patient safety and protection and to meet institutional requirements for conducting human clinical trials?

Table 2—*Components of the Business Plan*

Business Plan Section
Company overview
Business environment
Service description
Population served
Customer value strategy
Competitive strategy
Operational strategy and implementation
Financial plan

Population Served

Most sleep centers are geared to adult patients because clinical work and research has focused on this population. However, there is growing awareness of the prevalence of sleep disorders in children and the negative impact of these disorders on proper functioning and development. Sleep centers serving pediatric populations have different requirements for facilities, equipment, and staffing. Pediatric centers must have child-friendly rooms that accommodate parents as well as children. Different sensors are required for small children, and there is a difference in the measurement of carbon dioxide levels to detect hypoventilation. Small children or special-needs children require one-to-one tech-to-patient ratios more frequently than adults. These differences drive up the cost of caring for children while reimbursement remains the same. Provisions must also be made for the inclusion and financial impact of providing indigent care, access for the disabled, and translation services for non-English-speaking patients. The center's business plan must take all these into account.

Customer Value Strategy

Why will customers (ie, patients, referring providers, hospitals, payers) want to work at the new facility? This is the place to discuss the experience of the key individuals who will be treating patients and the relationships with other specialists, such as otolaryngologists, dentists, and behavioral psychologists, if they are not part of the center. The market analysis may have indicated interest in a specific referral method (eg, integrated care vs sleep study only) or the need for quick turnaround time.

Competitive Strategy

What differentiates the center from the other players in the marketplace? Accreditation for sleep centers is becoming more and more important and should be highlighted in the marketing strategy.

Starting in 2010, all sleep studies on Medicare patients must be performed in an accredited center or interpreted by a board-certified sleep specialist.[23-26] Other third-party payers are also adopting this standard. Accrediting entities include the AASM and the Joint Commission (formerly the Joint Commission on the Accreditation of Healthcare Organizations). DME accreditation will also be necessary for centers interested in providing integrated care, including PAP device set-up and long-term compliance programs as part of the center's clinical services.

Operational Strategy and Implementation

This section defines how the business will operate and how the strategies and decisions discussed in the business plan will be implemented. Areas of focus should include:

Personnel: What does the organization look like, both initially as well as over time? What types of people are needed (eg, sleep specialists, physician extenders, sleep technologists, respiratory therapists, clinic administrators, billing/collection personnel), and what are each of their roles? How will training be accomplished, and how will 24-hour physician coverage be provided? The benefits, policies, and procedures required for personnel management must also be taken into account.

Facility: The size of the facility will depend heavily on the decisions outlined in earlier sections. It is important to note how many bedrooms, exam rooms, and offices are needed. Space costs, lease vs purchase, the length of the lease if applicable, other common area costs, and any build-out investments should be addressed. What furniture and other furnishings are required? How long will it take to set up the facility?

Equipment: What are the equipment needs including sleep diagnostic devices, PAP devices, and other devices? Information technology plays a large role because it affects data storage needs, communication capabilities if there are multiple sites, use of computerized work-flow and reporting programs, and whether to use an electronic medical record program. Implementation requirements should be identified.

Regulations: A plan for adherence to regulatory requirements for facility licensure, patient and worker safety, Medicare enrollment and payment rules, and antikickback and Stark regulations should be outlined.

Reimbursement: Will billing occur through a hospital relationship or using the physician fee schedule? What is needed with regard to payer contracts? Is it possible to bill on day 1? If not, the time it will take to contract with the payers in the marketplace should be taken into account.

Affiliation: A new center may be affiliated with an existing hospital or physician organization. This can provide a built-in referral network from day 1 and an advertising advantage but can also add restrictions depending on the rules of the affiliated organization. The affiliation legal agreement should consider space needs, use of trademarks, provision of clinical and technical staff, administrative obligations, insurance verification, billing, staffing privileges, marketing support, equipment, insurance, terms, noncompetition, and other aspects. Royalty expenses tied to this affiliation should be factored into financial planning.

Marketing: How will services be communicated to customers? Are there sales and/or marketing personnel? Does the center have a logo? How will the Web site, brochures, and other signage be developed? Other communication methods include periodic newsletters to referring providers or patients, advertisements, press releases, or writing a newspaper column. Are there opportunities for patient or physician educational talks and local radio and television talk shows?

Financial Plan

The preliminary review of the market should provide relevant information for the financial plan. The plan should consider start-up costs, financing requirements (eg, working capital needs, equipment funding), and financing sources. Typically, financial plans look ahead 3 to 5 years. Financial statements have three components. The profit/loss statement outlines expected revenue and expenses, typically on a monthly basis for the first year or two, then annually. The balance sheet highlights the health of the business by reflecting the status of assets (things that are owned or owed), liabilities (items owed by the business), and equity (investments into the company) at a specific point in time. Finally, the cash-flow statement reflects the lifeline of most organizations: cash. Some companies are successful in providing a positive profit, but poor cash management runs them out of business.

At the completion of the business plan, the factors that will determine the likelihood of success for the new venture and the steps to bring it about should be in place. With this information, one can make an informed decision of whether to start a new center. If that decision is yes, the business plan will provide a useful roadmap.

Table 3—*Potential Performance Parameters*

Parameter
Referrals
By referring provider, group, or hospital
Conversion to visit rate
Reasons for nonconversion
Patients
Demographics
Satisfaction
Referring providers
Satisfaction
Sleep studies/clinics
Capacity utilization
No-show rate
Average revenue
Type of visit or study
Cancellation reasons
Technical staffing
Cost per study
Certification
Profitability
By center
By provider
By business segment (laboratory, clinic, DME)

DME = durable medical equipment.

Subsequent Planning and Analysis

Ongoing planning is necessary to ensure the organization responds to the changing environment. This involves both strategic and tactical planning.

Strategic planning typically focuses on the big picture: Where is the market going, and how do businesses respond to the market? Managers should hold meetings at all levels of the organization (eg, board, and medical, technical, and administrative staffs). Planning should consider sources of revenue growth as well as the resources required to accomplish this growth. If analysis shows that a center is in an underserved market, one might consider expanding the number of beds in the center or starting new centers. If a center is in a highly competitive market, it is important to seek a competitive advantage. This can include adding services, improving the quality of services, or creating affiliations with new practice groups.

Tactical planning identifies the actions an organization will undertake to accomplish the strategic plan. For each project, responsible personnel should be identified, a step-by-step plan created, and deadlines for completion established. Upon completion, the process followed, the performance of personnel, and the final outcome should all be evaluated. New ideas should be tried as long as there is a process to evaluate outcome measures that will show if the program is a success.

It is also helpful to identify key operational parameters to watch on a daily, weekly, and monthly basis. These parameters provide a sense of the progress (or lack thereof) of the company ahead of the publication of periodic financial statements. Dozens of parameters exist; it is critical to identify those that mean something to the specific organization (Table 3). Once the best parameters are identified, they must be reviewed on a trend basis as opposed to as "snapshots." Here are some parameter considerations:

- Numbers should always be put into context; what spells success for this center?
- The timing for each parameter should be predetermined; how frequently should this information be provided?
- It is important to limit the number of parameters that are watched and focus on those that matter most to the center.
- When the environment changes, the parameters should change.

Conclusions

Sleep medicine is a new, independent field of medicine. New technologies, changes in the health-care system, and increased regulatory scrutiny pose challenges to continued growth of the field. However, an increase in the appreciation of the importance of good sleep to good health, an increase in the understanding and recognition of new sleep disorders, and a continued rise in the prevalence of obesity and sleep deprivation suggest a continued growth in the need for sleep medicine services and new sleep centers. Deciding to open a new sleep center requires analysis of the existing marketplace and market dynamics and careful evaluation of available resources. Once the decision is made to open a new center, careful planning of the type of center and the required equipment and personnel is needed. Once established, successful operation is dependent on continued evaluation and planning in order to maintain and grow a referral base.

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