

ALABAMA STATE COMMITTEE OF PUBLIC HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
DIVISION OF LICENSURE AND CERTIFICATION
ADMINISTRATIVE CODE

CHAPTER 420-5-18
SLEEP DISORDERS FACILITIES

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420-5-18-.01 General.

(1) Legal Authority for Adoption of Regulations. Pursuant to the authority granted by Code of Ala. 1975, §§22-21-20 to §22-21-33, and in accordance with the Alabama Administrative Procedures Act, Code of Ala. 1975, §§41-22-1 to §41-22-27, the State Board of Health does hereby adopt and promulgate rules governing all free-standing sleep disorders facilities in Alabama except these exempt by law from licensure.

(2) Definition.

(a) "AAC Rules" means Alabama Administrative Code Rules.

(b) "Applicant" means a person or public agency that applies for Sleep Disorders Facility Licensure.

(c) "Advisory Board". See Section 22-21-27 of Appendix A.

(d) "Board or State Board of Health" means the Alabama State Board of Health.

(e) "License" means the document issued by the State Board of Health and signed by the State Health Officer. The license shall constitute the authority to receive patients and perform the services included within the scope of the applicable rules. The license shall be posted in a conspicuous place on the premises.

(f) "Licensee" means the individual owner, partnership, corporation, association, city, county, or other organization to whom the license is issued and upon whom rests the responsibility for compliance with these rules.

(g) "May" indicates permission.

(h) "Medical Director". The Medical Director of a facility must be a physician who has been granted a certificate by the American Board of Sleep Medicine or an individual who is boarded or board-eligible in another primary specialty of medicine. This physician must be able to show that he/she is knowledgeable not only concerning sleep related breathing disorders, but also able to recognize other sleep disorders.

(i) "Patient" means any person who is referred to or presents him/herself to a licensed sleep disorders facility for evaluation or treatment.

(j) "Physician". A person currently licensed to practice medicine in accordance with Title 34, Chapter 24, Article 8, Code of Ala. 1975.

(k) "Shall" indicates a mandatory requirement.

(l) "Sleep Disorders Facility". A free-standing outpatient medical facility that evaluates and treats patients with sleep disorders.

(m) "Technical Personnel". Sleep Disorders facility personnel that are basic CPR Certified and have at least one of the following credentials: (a) Be registered by the Board of Polysomnographic Technologists, (b) Formal training in any Allied health area, (c) Verifiable training in the field of Sleep Disorders.

(n) "Polysomnographic Technologist". An individual who is currently registered by the Board of Polysomnographic Technologists.

Author:

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: New Rule: Filed November 20, 1996; effective December 24, 1996.

420-5-18-.02

Licensing And Administrative Procedures.

(1) Types of License. All licenses are issued for the calendar year and shall expire December 31 unless renewed by the owner for the succeeding year.

(a) Regular license. A regular license shall be issued by the State Board of Health after the Board has determined that the sleep disorders facility is in substantial compliance with rules herein adopted.

(b) Probational license. The State Board of Health may, in its discretion and in lieu of license revocation, issue a probational license to a facility when inspection shows that the maintenance and operation of the facility are such that the sleep disorders facility no longer substantially complies with the rules adopted herein. However, the Board may issue a probational license only after determining that the health and safety of patients are adequately protected despite non-compliance, and that the facility has submitted an adequate written plan to correct the non-compliance in a timely manner.

(2) Application and Fee.

(a) Every sleep disorders facility shall be required to submit an application for license accompanied by the required statutory fee in accordance with the provisions of Section 22-21-24 of the Code of Ala. 1975. Every application must be submitted on a form supplied by the Board and must contain all the information requested on said form in order for the application to be processed and considered.

(b) Name of sleep disorders facility. Every sleep disorders facility shall be designated by a permanent and distinctive name which shall be used in applying for a license and shall not be changed without prior written notice to the Board specifying the name to be discontinued as well as the new name.

(3) Licensing.

(a) Issuance of license. The license document issued by the State Board of Health shall set forth the name and location of the sleep disorders facility, the type of facility, the area of operation, the bed capacity, if applicable, and the type of license (temporary, regular, provisional).

(b) Separate licenses. A separate license shall be required for each sleep disorders facility when more than one sleep disorders facility is operated under the same management, at a different location, and has a separate professional staff and patient load.

(4) Basis for Denial of License.

(a) The State Board of Health may deny a license to any corporation, partnership or individual making application to own or operate any sleep disorders facility if said corporation, partnership or individual:

1. Has falsified any information or record required by the application for license;
2. Has been found by a court or by a state or federal agency after the provision of appropriate due process to have committed abuse or neglect of any individual or to have misappropriated the property of a patient or resident of a health care facility.
3. Has been convicted of fraud in this or any state, or in any federal jurisdiction within the past five years.
4. Has previously been the subject of license revocation proceedings and does not demonstrate a present ability and willingness to fully comply with State Board of Health rules; or
5. Is unable to demonstrate sufficient ability and resources to fully comply with State Board of Health rules.

(b) Basis for license revocation. The State Board of Health may revoke a license to operate a sleep disorders facility if the owner and/or operator of said facility:

1. Violates any of the provisions of these rules and regulations.
2. Permits, aids or abets the commission of any illegal act in such sleep disorders facility; or
3. Engages in conduct or practices deemed by the State Board of Health to be detrimental to the welfare of the patients of such sleep disorders facility.

(5) Right of Review. Whenever a license is denied or revoked, the applicant or licensee will be afforded an opportunity for a hearing in accordance with the requirements for contested case proceedings under the Alabama Administrative Procedures Act, Code of Ala. 1975, §41-22-17, and Chapter 420-1-3 of the Alabama Administrative Code.

(6) Research Projects. Any licensee who is, or contemplates being, engaged in a bona fide research program which may be in conflict with one or more specific provisions of these rules may make application for waiver of the specific provisions in conflict. Application for waiver shall be made in writing to the Licensure Advisory Board who shall, upon completion of its investigation, send its findings, conclusions, and recommendation to the State Board of Health for final action.

(7) Reissuance of License. The following changes in the status of the sleep disorders facility will require issuance of a new license, upon application and payment of a licensing fee:

(a) Change in sleep disorders facility ownership. A change of ownership occurs whenever there is a change in the legal form under which the controlling entity is organized. Transaction constituting a change of ownership include, but are not limited to, the following:

1. Sale or donation of the sleep disorders facility's legal title.
2. Lease of the entire sleep disorders facility's real and personal property.
3. A sole proprietor becomes a member of a partnership or corporation, succeeding him as the new operator.
4. A partnership dissolves.
5. One partnership is replaced by another through the removal, addition or substitution of a partner.
6. A general partnership becomes a limited partnership, or a limited partnership becomes general.
7. Two (2) or more corporations merge and the originally licensed corporation does not survive.
8. Corporations consolidate.
9. A non-profit corporation becomes a general corporation, or a for-profit corporation becomes non-profit.
10. Transfers between levels of government.

(b) The following status changes require issuance of a new license without payment of licensure fee:

1. Change in name or address of the sleep disorders facility.

(c) The governing authority shall file with the State Board of Health an application for license 30 days before any proposed change requiring a new license in order to permit processing of the application and issuance of the license prior to the desired effective date of the change.

(8) Compliance Exceptions. At its discretion, the State Board of Health may grant an exception to or modify the application of one or more provisions of these rules or referenced codes for a period

and under conditions, if any, determined by the Board. The exceptions or modifications shall be based on hardship, impracticability, or economic infeasibility in complying with the rules. The sleep disorders facility's request shall be in writing, shall state the specific provisions for which the exception or modification is requested, and reasons for each requested exception or modification.

(9) Compliance with State and Local Laws.

(a) Licensing of staff. Staff of the sleep disorders facility shall be licensed or registered in accordance with applicable laws.

(b) Compliance with other laws. The sleep disorders facility shall be in compliance with state and local laws relating to fire and safety, sanitation, communicable and reportable diseases, certificate of need, if applicable, and other relevant health and safety requirements.

(10) Inspections. Failure or refusal to submit to a survey will result in initiation of license revocation proceedings. Findings noted during any survey shall be corrected by execution of a plan of correction. The plan of correction shall be succinctly written to address identified problems in a timely manner not to exceed 60 days of such other time as may be required by the director.

Author:

Statutory Authority: Code of Ala. 1975, Title 22, Chapter 21, and Article 2.

History: New Rule: Filed November 20, 1996; effective December 24, 1996.

420-5-18-.03 Governing Body.

(1) The overall conduct and operation of the sleep disorders facility shall be the full legal responsibility of a clearly defined, organized governing body which shall perform the following functions.

(a) Establish and review policies for the management, operation, and evaluation of the sleep disorders facility program, including establishing qualifications of employees and independent contractors;

(b) Arrange for a physician to serve as medical director for the sleep disorders facility.

(c) Appoints in writing an individual who is responsible for the day to day management of the sleep disorders facility.

(2) There is an individual authorized in writing to act for the manager during absences.

(a) The manager serves as liaison between the governing body and the professional staff, consultants, and other agencies and organizations.

(b) The manager acts upon recommendations of the sleep disorders facility's committees, department heads and consultants.

(c) Written notification shall be made to the Alabama Department of Public Health, Division of Licensure and Certification within 15 days of the manager's appointment.

(3) Financial. The accounting method and procedures used shall be sufficient to permit an annual audit, accurate determination of the cost of operation, and the cost per patient day.

Author:

Statutory Authority: Code of Ala. 1975, Title 22, Chapter 21.

History: New Rule: Filed November 20, 1996; effective December 24, 1996.

420-5-18-.04 Administration and Organization.

(1) Medical Supervision. Sleep disorders facilities are medical units and the core responsibility must be medical. While other health care professionals may participate in a patient's evaluation, each patient must have a clearly-identifiable staff physician who is responsible for his/her care throughout the patient's active status at the sleep disorders facility.

(2) Medical Director. Every facility must have a physician who is designated as the medical director who must perform all the following duties on site:

(a) Assure and document that each patient has an appropriate diagnostic evaluation.

(b) Be involved with all phases of the facility's functions, including patient care decisions.

(c) Review and certify the accuracy of polysomnographic scoring and interpretations.

(d) Supervise the training and performance of the technical personnel.

(e) Be responsible for quality assurance review, and

(3) Staffing. The facility must have sufficient staff to enable it to effectively carry out its function. The staffing pattern must be clearly defined, particularly in regard to safety, comfort and well being of its patients.

Author:

Statutory Authority: Code of Ala. 1975, Title 22, Chapter 21.

History: New Rule: Filed November 20, 1996; effective December 24, 1996.

420-5-18-.05 Patient Evaluation.

(1) Outside Information. Any available outside information must be properly obtained with suitable releases. The receipt of this information by the facility must be reflected in the patient's chart.

(2) Medical and Sleep History, Physical Examination, Laboratory Tests. Evidence of a recent general clinical work-up obtained sleep evaluation must be contained in the chart, as well as evidence that this information was reviewed by a staff physician prior to testing. Laboratory test results must always be available in the patient records. An evaluation at a sleep disorders facility is a medical evaluation and appropriate medical procedures must be followed.

(3) Consultative Evaluations and Procedures. Sleep disorders require careful and total evaluation. Such evaluation often requires utilization of knowledgeable consultants. Evidence should appear in the charts that appropriate consultants have been consistently utilized. Prompt communications between the facility's professional and technical personnel and consultants is crucial to an integrated clinical effort.

(4) Scoring and Interpretation of Polysomnographic Data. A facility must have evidence that its recordings are adequate and have been properly scored and interpreted. An appropriate technical monitoring log regarding nocturnal patient activity, position, and events must be maintained throughout the night of recording. An oximetry strip chart may be used for this purpose. Scoring may be performed by technologists or staff physician, but interpretation of polysomnograms is the responsibility of the Medical Director or staff physician who must submit a signed and dated report for each separate polysomnographic procedure. In addition, a written and signed assessment of the clinical significance of these results is the role of the physician responsible for the case and must be a component of the patient's chart.

Author:

Statutory Authority: Code of Ala. 1975, Title 22, Chapter 21.

History: New Rule: Filed November 20, 1996; effective December 24, 1996.

420-5-18-.06 Medical Records.

(1) Patient Charts. Charts should be well-organized and the information in them easily accessible. Materials such as questionnaires, sleep and temperature logs, and psychological tests should be made part of the patient's chart.

(2) Narrative Entries. Narrative entries must be included in the patient chart to document all patient contacts, to review results, and to record diagnosis, treatment plan, and mode of implementation. Patient intake information must be included in each chart and include appropriate histories and physicals.

(3) Diagnostic Information. All diagnostic information, regardless of its state of development during the course of the work-up, should be in written form. A consulting cardiologist, for example, should be required to submit a written report. All clinical information relative to a patient's sleep study and treatment shall be documented in a single patient chart and stored in the sleep disorder facility until the file becomes inactive. Active patient charts should be readily available at all times.

(4) Summary. A written summary of each case must be placed in the chart by the responsible physician at the time that treatment recommendations or procedures are undertaken. Summaries should include not only a description of the procedure performed, but also a soundly reasoned analysis of the clinical significance of these procedures and their implications for the management of the patient.

(5) Statement of Follow-up Plan. The patient's record must contain a description of follow-up procedures, whether or not the treatment is executed by the facility. If the facility is not providing the treatment, the record must be explicit as to how contact will be maintained with the patient or referring source. In order to ensure that the highest quality care is being provided, a formal, efficient, and effective vehicle must be used by staff physicians to convey the results of the evaluation and treatment options to the patient and the physician or others who referred the patient to the facility. Consequently, each patient's chart should have a copy of the correspondence which states the diagnostic assessment of the patient and a recommended treatment plan if the disorder has a known treatment. This communication should be sent with a reasonable time after the completion of the evaluation.

(6) Final Diagnosis. All final Diagnoses must be made using ASDA nosology as established in a current International Classification of Sleep Disorders Diagnostic and Coding Manual.

(7) Storage and Safety. Provisions shall be made for the safe storage and confidentiality of records.

(8) Retention of Records. Medical records must be retained in their original or legally reproduced form for a period of at least five years.

(9) Proposed Plan for Disposition for Medical Records. When a sleep disorders facility ceases to operate, either voluntarily or by revocation of its license, the governing body (licensee) at or prior to such action shall develop a proposed plan for the disposition of its medical records. Such plan shall be submitted for review and approval to the Division of Licensure and Certification and shall contain provision for the proper storage, safeguarding and confidentiality, transfer and/or disposal of patient medical records.

Author:

Statutory Authority: Code of Ala. 1975, Title 22, Chapter 21.

History: New Rule: Filed November 20, 1996; effective December 24, 1996.

420-5-18-.07 Physical Plant.

(1) Local Restrictions. The location and construction of sleep disorders facilities shall comply with all local zoning and building codes and fire or other emergency ordinances.

(2) Personal Amenities. A facility must demonstrate a high sense of responsibility toward and sensitivity to the dignity and comfort of the patient. The patient's surroundings should be similar to a comfortable bedroom at home.

(3) Bedrooms. Certain minimum space requirements are essential. The overall concept of a sleep disorders facility includes a private bedroom for each patient and a centralized control room for equipment and for staff to perform on-line monitoring of polysomnographic data.

(a) The bedrooms must conform to local standards with regard to entrances, exits, fire precautions, and other building codes. They must be sound and light attenuated and should possess either effective insulation or independent temperature controls to avoid variations in sleep parameters secondary to seasonal variations in temperature. White noise background sound is acceptable. The rooms should be isolated to ensure minimal interaction with the external environment.

(b) The bedroom should be a minimum of eight by ten feet and be a single room. A sleep disorders facility will determine the appropriate number of bedrooms equipped for polysomnographic recording based on space availability and

patient demand. The rooms must be within easy access to the polysomnographic technologists.

(c) Each bedroom must be furnished with a bed and mattress in good repair. The patient should be able to hang his/her clothes, dress, and sit comfortably while waiting to get into bed. Bathroom and shower facilities must be conveniently located to the patient's room. Cleanliness and tidiness must be apparent.

(4) Control Room. The control room must be large enough to comfortably house working space for the polysomnographic technologist(s) and the required equipment. An easy way for the patient to call whoever is monitoring the tests must be available.

Author:

Statutory Authority: Code of Ala. 1975, Title 22, Chapter 21.

History: New Rule: Filed November 20, 1996; effective December 24, 1996.

420-5-18-.08

Storage, Preparation And Handling Of Drugs And Medicines.

(1) Administering Drugs and Medicines. Drugs and medicines shall not be administered to individual patients nor to anyone within or outside the facility unless ordered by a physician duly licensed to prescribe drugs. Such order shall be in writing and signed personally by the physician who prescribes the drug or medicine.

(2) Medicine Storage. Medicines, drugs and biologicals maintained in the sleep disorders facility for administration shall be properly stored and safeguarded in enclosures of sufficient size and which are not accessible to unauthorized persons. Only authorized personnel shall have access to storage enclosures. Any controlled substances and ethyl alcohol maintained on the premises shall be stored under double locks and in accordance with applicable State and Federal laws.

(3) Controlled Substances Permit. If controlled substances are maintained in the sleep disorders facility for patient use, appropriate permits shall be obtained or maintenance and usage shall be under the controlled substances permit of the prescribing physician.

(4) Records. If controlled substances are maintained and used in the sleep disorder facility, records shall be maintained that account for all items and received and administered.

(5) Medication Orders. All oral or telephone orders for medication shall be received by a licensed nurse or a physician and shall be reduced to writing on the physician's order sheet with an indication as to the prescribing physician and who wrote the

order. Telephone or oral orders shall be signed by the prescribing physician within 48 hours. Patients requiring prescription legend drugs outside of the facility shall be given "a written prescription where those drugs can be obtained from a licensed pharmacy, except in cases where the sleep disorders facility has a licensed pharmacy on the premises."

(6) Pharmacy. If the facility has a pharmacy, it shall meet the requirements of the Title 34, Chapter 23, Practice of Pharmacy Act 205, Code of Ala. 1975.

(7) Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration.

(8) Emergency Kit or Emergency Drugs. Upon the advice and written approval of the facility's medical director, an emergency kit or an emergency supply of drugs or medicines may be maintained to be used by the physician in treating the emergency needs of the patients. Those medications shall be stored in such a manner as to limit its access to unauthorized personnel but in such a manner as to allow quick retrieval. Records or usage must be maintained and periodic inventories accomplished to prevent diversion.

(9) Drug Referenced Sources. Each sleep disorders facility shall maintain reference sources for identifying and describing drugs and medicines.

Author:

Statutory Authority: Code of Ala. 1975, Title 22, Chapter 21.

History: New Rule: Filed November 20, 1996; effective December 24, 1996.