

**RULES
OF
ALABAMA BOARD OF HEALTH
DIVISION OF LICENSURE AND CERTIFICATION**

CHAPTER 420-5-18

SLEEP DISORDERS FACILITIES



**With
LICENSURE LAW**

EFFECTIVE DECEMBER 25, 1996

**STATE OF ALABAMA
DEPARTMENT OF PUBLIC HEALTH
MONTGOMERY, ALABAMA**

**RULES
OF
ALABAMA BOARD OF HEALTH
DIVISION OF LICENSURE AND CERTIFICATION**

CHAPTER 420-5-18

SLEEP DISORDERS FACILITIES

TABLE OF CONTENTS

420-5-18-.01	General	1
420-5-18-.02	Licensing and Administrative Procedures.	2
420-5-18-.03	Governing Body	5
420-5-18-.04	Administration and Organization.....	6
420-5-18-.05	Patient Evaluation	7
420-5-18-.06	Medical Records	8
420-5-18-.07	Physical Plant.....	9
420-5-18-.08	Storage, Preparation and Handling of Drugs and Medicines.....	10

420-5-18-.01 General.

- (1) **Legal Authority for Adoption of Regulations.** Pursuant to the authority granted by *Code of Alabama* §§22-21-20 to §22-21-33, and in accordance with the Alabama Administrative Procedures Act, *Code of Alabama* §§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) **Definitions.**
- (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: Jimmy D. Prince

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Original Rules Effective December 26, 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 Alabama*. 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 Alabama* §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 or such other time as may be required by the director.

Author: Jimmy D. Prince

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Original Rules Effective December 26, 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: Jimmy D. Prince

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Original Rules Effective December 26, 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: Jimmy D. Prince

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Original Rules Effective December 26, 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: Jimmy D. Prince

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Original Rules Effective December 26, 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 of 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: Jimmy D. Prince

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Original Rules Effective December 26, 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: Jimmy D. Prince

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Original Rules Effective December 26, 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 orders 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 Title 34, Chapter 23, Practice of Pharmacy Act 205, *Code of Alabama, 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: Jimmy D. Prince

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Original Rules Effective December 26, 1996.

APPENDIX A
CODE OF ALA. 1975, SECTIONS 22-21-20, ET SEQ.

Code of Alabama

Title 22. Health, Mental Health, and Environmental Control.

Subtitle 1. Health and Environmental Control Generally

Chapter 21 Hospitals and Other Health Care Facilities Generally.

Article 2 Licensing of Hospitals, Nursing Homes, and Other Health Care Institutions.

§ 22-21-20. Definitions.

For the purpose of this article, the following terms shall have the meanings respectively ascribed to them by this section:

(1) HOSPITALS. General and specialized hospitals, including ancillary services; independent clinical laboratories; rehabilitation centers; ambulatory surgical treatment facilities for patients not requiring hospitalization; end stage renal disease treatment and transplant centers, including free-standing hemodialysis units; abortion or reproductive health centers; hospices; health maintenance organizations; and other related health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for the diagnosis and/or treatment of injury, deformity, disease, surgical or obstetrical care. Also included within the term are long term care facilities such as, but not limited to, skilled nursing facilities, intermediate care facilities, assisted living facilities, and specialty care assisted living facilities rising to the level of intermediate care. The term "hospitals" relates to health care institutions and shall not include the private offices of physicians or dentists, whether in individual, group, professional corporation or professional association practice. This section shall not apply to county or district health departments.

(2) PERSON. The term includes individuals, partnerships, corporations, and associations.

§ 22-21-21. Purpose of article.

The purpose of this article is to promote the public health, safety and welfare by providing for the development, establishment and enforcement of standards for the treatment and care of individuals in institutions within the purview of this article and the establishment, construction, maintenance and operation of such institutions which will promote safe and adequate treatment and care of individuals in such institutions.

§ 22-21-22. License -- Required; exceptions.

No person shall establish, conduct or maintain any hospital as defined in Section 22-21-20 without first obtaining the license provided in this article. Hospitals operated by the federal government and mental hospitals under the supervision of the board of trustees of the Alabama state hospitals shall be exempt from the provisions of this article.

§ 22-21-23. License -- Application.

Any person desiring licensing under this article shall apply to the State Board of Health therefor. The applicant shall state the name of the applicant and whether an individual, partnership, corporation or other entity, the type of institution for which a license is desired, the

Appendix A

location thereof and the name of the person in direct supervision and charge thereof. The person in charge of such hospital must be at least 19 years of age and of reputable and responsible character. The applicant shall submit evidence of ability to comply with the minimum standards provided in this article or by regulations issued under its authority.

§ 22-21-24. License -- Fees; expiration and renewal; accreditation.

The application for a license to operate a hospital other than an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care shall be accompanied by a standard fee of two hundred dollars (\$200), plus a fee of five dollars (\$5) per bed for each bed over 10 beds to be licensed in accordance with regulations promulgated under Section 22-21-28. Increase in a hospital's bed capacity during the calendar year is assessed at the standard fee of two hundred dollars (\$200) plus five dollars (\$5) each for the net gain in beds. The initial licensure fee and subsequent annual licensure renewal fee for an assisted living facility and for a specialty care assisted living facility rising to the level of intermediate care shall be two hundred dollars (\$200) plus fifteen dollars (\$15) for each bed. A license renewal application for any hospital, as defined by this article, which is not received by the expiration date in a properly completed form and accompanied by the appropriate renewal fee shall be subject to a late penalty equal to two hundred fifty dollars (\$250) or 100 percent of the renewal fee, whichever is greater. No fee shall be refunded. All fees received by the State Board of Health under the provision of this article shall be paid into the State Treasury to the credit of the State Board of Health and shall be used for carrying out the provisions of this article. A license granted under this article shall expire on December 31 of the year in which it was granted. A license certificate shall be on a form prescribed by the department, and shall be posted in a conspicuous place on the licensed premises. Licenses shall not be transferable or assignable and shall be granted only for the premises named in the application. Licenses may be renewed from year to year upon application, investigation, and payment of the required license fee, as in the case of procurement of the original license. All fees collected under this article are hereby appropriated for expenditure by the State Health Department. All hospitals which are accredited by the joint commission on accreditation of hospitals shall be deemed by the State Health Department to be licensable without further inspection or survey by the personnel of the State Department of Health. Further accreditation by the joint commission on accreditation of hospitals shall in no way relieve that hospital of the responsibility of applying for licensure and remitting the appropriate licensure fee as specified in this article.

§ 22-21-25. License -- Issuance; suspension or revocation; new applications after revocation.

- (a) The State Board of Health may grant licenses for the operation of hospitals which are found to comply with the provisions of this article and any regulations lawfully promulgated by the State Board of Health.
- (b) The State Board of Health may suspend or revoke a license granted under this article on any of the following grounds:
 - (1) Violation of any of the provisions of this article or the rules and regulations issued pursuant thereto.
 - (2) Permitting, aiding or abetting the commission of any illegal act in the institution.
 - (3) Conduct or practices deemed by the State Board of Health to be detrimental to the welfare of the patients of the institution.

Appendix A

(c) Before any license granted under this article is suspended or revoked, written notice shall be given the licensee, stating the grounds of the complaint, and the date, time, and place set for the hearing of the complaint, which date of hearing shall be not less than 30 days from the date of the notice. The notice shall be sent by registered or certified mail to the licensee at the address where the institution concerned is located. The licensee shall be entitled to be represented by legal counsel at the hearing.

(d) If a license is revoked as provided in this section, a new application for license shall be considered by the State Board of Health if, when, and after the conditions upon which revocation was based have been corrected and evidence of this fact has been furnished. A new license shall then be granted after proper inspection has been made and all provisions of this article and rules and regulations promulgated under this article have been satisfied.

§ 22-21-26. License -- Judicial review of suspension or revocation.

Any party aggrieved by a final decision or order of the Board of Health suspending or revoking a license is entitled to a review of such decision or order by taking an appeal to the circuit court of the county in which the hospital is located or is to be located.

§ 22-21-27. Advisory board.

(a) There shall be an advisory board of 17 members to assist in the establishment of rules, regulations, and standards necessary to carry out the provisions of this article and to serve as consultants to the State Health Officer. The board shall meet at least twice each year and at the call of the State Health Officer. The members of the board shall annually elect one of its members to serve as chairman.

(b) The advisory board shall be constituted in the following manner:

(1) Four representatives of hospitals, who shall be appointed by the Board of Trustees of the Alabama Hospital Association as follows:

- a. One administrator of a governmental hospital.
- b. One administrator of a nongovernmental nonprofit hospital.
- c. One owner or administrator of a proprietary hospital.
- d. One member of a managing board of a nonprofit hospital.

(2) Three representatives who shall be doctors of medicine appointed by the Board of Censors of the Medical Association of the State of Alabama.

(3) One representative who shall be a registered nurse appointed by the Executive Board of the Alabama State Nurses Association.

(4) One representative from the State Board of Human Resources who shall be appointed by the board.

(5) One registered pharmacist actively engaged in the practices of pharmacy in the State of

Appendix A

Alabama, to be appointed by the Executive Committee of the Alabama Pharmacy Association.

(6) Three members who shall be appointed by the Executive Committee of the Alabama Nursing Home Association, each of whom shall be the operator of a duly qualified licensed nursing home.

(7) One member who shall be appointed by the Alabama Hospice Association.

(8) Two members who shall be appointed by the Assisted Living Association of Alabama, one of whom shall be the operator of a licensed assisted living facility or licensed specialty care assisted living facility rising to the level of intermediate care with 16 or fewer beds, and one of whom shall be the operator of an assisted living facility or licensed specialty care assisted living facility rising to the level of intermediate care with more than 16 beds.

(9) One member who shall be appointed by the Governor to represent the interests of consumers. The consumer representative shall be at least 65 years of age and shall have no financial interest in any facility licensed under this article.

Each new appointee shall serve for five years or until his or her successor is appointed, whichever is later. Any vacancy caused by a member leaving the position before the expiration of his or her term shall be filled by the organization selecting the original member. The replacement member appointed shall serve for the remainder of the unexpired term.

(c) A member of the advisory board shall not be eligible to succeed himself or herself after serving one full five-year term, but shall be eligible for reappointment if he or she has served only a portion of a five-year term or if he or she has not served immediately preceding the reappointment.

(d) Members of the advisory board shall serve without compensation, but shall be entitled to reimbursement for expenses incurred in the performance of the duties of the office at the same rate allowed state employees pursuant to general law.

§ 22-21-28. Rules and regulations.

(a) In the manner provided in this section, the State Board of Health, with the advice and after approval by the advisory board, shall have the power to make and enforce, and may modify, amend, and rescind, reasonable rules and regulations governing the operation and conduct of hospitals as defined in Section 22-21-20. All such regulations shall set uniform minimum standards applicable alike to all hospitals of like kind and purpose in view of the type of institutional care being offered there and shall be confined to setting minimum standards of sanitation and equipment found to be necessary and prohibiting conduct and practices inimical to the public interest and the public health. The board shall not have power to promulgate any regulation in conflict with law nor power to interfere with the internal government and operation of any hospital on matters of policy. The procedure for adopting, amending, or rescinding any rules authorized by this article shall conform to the Alabama Administrative Procedure Act. At any public hearing called for the purpose of soliciting public comment on proposed rules, any interested hospital or any member of the public may be heard.

(b) Any person affected by any regulation, amendment, or rescission thereof may appeal consideration thereof to the circuit court of the county of that person's residence or in which that person does business or to the Circuit Court of Montgomery County, pursuant to the

Appendix A

Alabama Administrative Procedure Act. And upon appeal the question of the reasonableness of such regulation shall be a question of fact for the court to determine, and no presumption shall be indulged that the regulation adopted was and is a reasonable regulation.

(c) Regulations adopted under this section shall become effective as provided in the Alabama Administrative Procedure Act.

§ 22-21-29. Inspections.

(a) Every hospital licensed under this article shall be open to inspection to the extent authorized in this section by employees and agents of the State Board of Health, under rules as shall be promulgated by the board with the advice and consent of the advisory board. Employees and agents of the board shall also inspect unlicensed and suspected unlicensed facilities. Nothing in this section shall authorize the board to inspect quarters therein occupied by members of any religious group or nurses engaged in work in any hospital or places of refuge for members of religious orders for whom care is provided, but any inspection shall be limited and confined to the parts and portions of the hospital as are used for the care and treatment of the patients and the general facilities for their care and treatment. No hospital shall, by reason of this section, be relieved from any other types of inspections authorized by law.

(b) All inspections undertaken by the State Board of Health shall be conducted without prior notice to the facility and its staff. Notwithstanding the foregoing, an inspection of a hospital or other health care facility, prior to its licensure, may be scheduled in advance. An employee or contract employee of the state shall not disclose in advance the date or the time of an inspection of a hospital or other health care facility to any person with a financial interest in any licensed health care facility, to any employee or agent of a licensed health care facility, to any consultant or contractor who performs services for or on behalf of licensed health care facilities, or to any person related by blood or marriage to an owner, employee, agent, consultant, or contractor of a licensed health care facility. For purposes of this section, the term inspection shall include periodic and follow-up compliance inspections and surveys on behalf of the State Board of Health, complaint investigations and follow-up investigations conducted by the State Board of Health, and compliance inspections and surveys, complaint investigations, and follow-up visits conducted on behalf of the United States Department of Health and Human Services, Health Care Financing Administration, or its successors. The board may prescribe by rule exceptions to the prohibition where considerations of public health or safety make advance disclosure of inspection dates or times reasonable. Disclosure in advance of inspection dates when such disclosure is required or authorized pursuant to federal law or regulation shall not be a violation of this section. Scheduling inspections of hospitals or other health care facilities by the board at regular, periodic intervals which may be predictable shall not be a violation of this section.

(c) Any employee or contract employee of the state who discloses in advance the date or time of an inspection in violation of subsection (b) shall be guilty of a Class A misdemeanor. Any person who solicits an employee or contract employee of the state to disclose in advance the date or time of an inspection in violation of subsection (b) for the purpose of disclosing the information to others shall be guilty of a Class A misdemeanor.

§ 22-21-30. Disclosure of information.

Information received by the State Board of Health through on-site inspections conducted by the state licensing agency is subject to public disclosure and may be disclosed upon written request. Information received through means other than inspection will be treated as confidential and

Appendix A

shall not be directed publicly except in a proceeding involving the question of licensure or revocation of license.

§ 22-21-31. Practice of medicine, etc., not authorized; child placing.

Nothing in this article shall be construed as authorizing any person to engage in any manner in the practice of medicine or any other profession nor to authorize any person to engage in the business of child placing. Any child born in any such institution whose mother is unable to care for such child or any child who, for any reason, will be left destitute of parental support shall be reported to the Department of Human Resources or to any agency authorized or licensed by the Department of Human Resources to engage in child placing for such service as the child and the mother may require. In the rendering of service, representatives of the Department of Human Resources and agencies authorized or licensed by the Department of Human Resources shall have free access to visit the child and the mother concerned.

§ 22-21-32. State board not empowered to prohibit erection and operation of hospitals. Repealed by Acts 1977, 1st Ex. Sess., No. 82, p. 1509, § 19, effective June 16, 1977.

§ 22-21-33. Penalties for operation of or referring persons to unlicensed hospital.

(a) Any individual, association, corporation, partnership, limited liability company, or other business entity who operates or causes to be operated a hospital of any kind as defined in this article or any regulations promulgated hereunder, without having been granted a license therefor by the State Board of Health shall be guilty of a Class B misdemeanor upon conviction, except that any individual, association, corporation, partnership, limited liability company, or other business entity who operates or causes to be operated a hospital of any kind as defined in this article or any regulations promulgated hereunder without having been granted a license therefor by the State Board of Health shall be guilty of a Class A misdemeanor upon conviction of a second or any subsequent offense. The State Board of Health, upon determination that a facility or business is operating as a hospital, within the meaning of this article or any rules promulgated hereunder, and that the facility or business does not have a current and valid license granted by the State Board of Health, may apply to the circuit court of the county in which the unlicensed facility or business is located for declaratory and injunctive relief. The proceedings shall be expedited. The sole evidentiary questions before the court in a proceeding shall be whether the facility or business that is the subject of the action meets the definition of a hospital, within the meaning of this article and any rules promulgated hereunder, and whether the facility or business has been granted a current and valid license to operate by the State Board of Health. If the State Board of Health prevails on these questions, then the court shall, upon request of the State Board of Health, forthwith grant declaratory and injunctive relief requiring the operator or operators to close the facility or business and requiring the operator or operators to move all residents or patients to appropriate placements. Any individual failing to obey an injunction to close a hospital shall be guilty of a Class A misdemeanor. Any individual, after having once been subject to such an injunction, who shall later operate or cause to be operated a hospital, as defined in this article or any regulations promulgated hereunder, without having been granted a license therefor by the State Board of Health shall be guilty of a Class A misdemeanor. The State Board of Health may, upon the advice of the Attorney General, maintain an action in the name of the state for an injunction to restrain any state, county, or local governmental unit, or any division, department, board, or agency thereof, or any individual, association, corporation, partnership, limited liability company, or other business entity, from operating, conducting, or managing a hospital in violation of any provisions of this article, or any regulation promulgated hereunder. Evidence

Appendix A

that a person who is a licensed health care professional is or has been operating an unlicensed hospital or knowingly is or has been an employee of an unlicensed hospital shall be grounds for license revocation by the applicable professional licensing board or boards. No county or municipality shall grant a business license to a hospital, as defined in this article, unless the facility holds a current license to operate granted by the State Board of Health. In any action to collect a fee for services brought against a resident or patient by a hospital, as defined in this article or regulations promulgated hereunder, it shall be a defense to the action to demonstrate that the operator of the hospital did not have a current and valid license to operate pursuant to this article at the time the services in question were rendered.

(b) A licensed inpatient hospital acting through an authorized agent of the licensed inpatient hospital shall not knowingly refer to an unlicensed hospital any person who is in need of care rendered by a licensed hospital. A licensed hospice or certified home health agency acting through an authorized agent of the licensed hospice or certified home health agency shall not knowingly provide treatment or services in an unlicensed hospital to a person who is in need of care rendered by a licensed hospital. The Department of Public Health shall maintain, in electronic format and available on the Internet, a current directory of all licensed hospitals. The department, shall publish and mail to licensed inpatient hospitals, licensed hospices, and certified home health agencies every three months a listing of licensed hospitals. A determination of actual knowledge that a facility or business was unlicensed shall be supported by evidence that the unlicensed hospital had not been listed in either the printed or electronic directory during the 12 months immediately prior to the time the referral was made or treatment provided. In any action to levy a fine or revoke a license under this section, it shall be a defense to the action to demonstrate that the unlicensed inpatient hospital appeared in the list published by the department, either electronically or in print format, as a licensed inpatient hospital during the 12 months immediately prior to the time the referral was made or the treatment was provided. Any licensed inpatient hospital acting through an authorized agent of the licensed inpatient hospital that knowingly makes a referral to an unlicensed hospital of a person in need of care rendered by a licensed hospital, or any licensed hospice or any certified home health agency acting through an authorized agent of the licensed hospice or certified home health agency that knowingly provides treatment in an unlicensed hospital to a person in need of care rendered by a licensed hospital, may be subject to a civil penalty imposed by the Board of Health not to exceed one thousand five hundred dollars (\$1,500) per instance. All civil monetary penalties collected pursuant to this section or Section 22-21-34 shall be paid to the Department of Human Resources and held in a dedicated fund for the sole purpose of making grants or disbursements to assist protected persons, as this term is defined in Section 38-9-2 et seq. with appropriate placement or relocation from an unlicensed facility into a licensed facility or relocation from a facility undergoing license termination, suspension, or revocation, pursuant to Section 22-21-25, to an appropriate setting. The Department of Human Resources is hereby authorized to make grants or disbursements from this fund to protected persons or to individuals or public or private organizations acting on behalf of a protected person.

(c)(1) For the purposes of this section, the term “licensed inpatient hospital” shall mean a licensed acute care hospital, long-term acute care hospital, rehabilitation hospital, inpatient hospice, skilled nursing facility, intermediate care facility, assisted living facility, or specialized care assisted living facility.

(2) For the purposes of this section, the term “knowingly” shall mean actual knowledge by a licensed inpatient hospital, licensed hospice, or certified home health agency acting through an authorized agent making a referral or providing services, that the unlicensed hospital to which the referral is made or services rendered is unlicensed within the meaning of this section.

§ 22-21-34. Assisted living facility, etc., rising to level of intermediate care.

Under the circumstances listed below, an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care may be subject to a civil money penalty imposed by the Board of Health not to exceed ten thousand dollars (\$10,000) per instance. The imposition of the penalty may be appealed pursuant to the Alabama Administrative Procedure Act. All money penalties imposed pursuant to this section shall be remitted to the Department of Public Health and shall be deposited in the State General Fund. The penalties shall be deposited in the General Fund and shall not be earmarked for the Department of Public Health. Failure of an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care to pay a civil money penalty within 30 days after its imposition or within 30 days after the final disposition of any appeal shall be grounds for license revocation unless arrangements for payment are made that are satisfactory to the State Board of Health. No assisted living facility or specialty care assisted living facility rising to the level of intermediate care may renew its license to operate if it has any unpaid civil money penalties which were imposed more than 30 days prior to the facility's license expiration date, except for any penalties imposed which are still subject to appeal and except for penalties for which arrangements for payment have been made that are satisfactory to the State Board of Health.

(1) A civil money penalty may be imposed for falsification of any record kept by an assisted living facility or specialty care assisted living facility rising to the level of intermediate care, including a medication administration record or any record or document submitted to the State Board of Health, by an employee or agent of the facility, where such falsification is deliberate and undertaken with intent to mislead the Board of Health, or its agents or employees, or residents, sponsors, family members, another state, county, or municipal government agency, or the public, about any matter of legal compliance, regulatory compliance, compliance with fire or life safety codes, or quality of care.

(2) A civil money penalty may be imposed as a result of a false statement made by an employee or agent of an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care to an employee or agent of the State Board of Health, if the statement is made with intent to deceive or mislead the Board of Health, its agents or employees, about any matter of legal compliance, regulatory compliance, compliance with fire or life safety codes, or quality of care. A civil money penalty shall not be imposed if the facility's employee or agent makes a false statement when he or she has no reason to believe the false statement is authorized by the administrator or operator of the facility and if it is likely that the facility's employee or agent made the statement with the intent to cause damage to the facility.

**Alabama Department of Public Health
Bureau of Health Provider Standards
Division of Provider Services
201 Monroe Street
P.O. Box 303017
Montgomery, AL 36130-3017
334-206-5175
www.adph.org/providers**