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TITLE 440 DIVISION OF MENTAL HEALTH AND ADDICTION

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DIGEST

Adds 440 IAC 1.5 concerning the licensure of private mental health institutions. Repeals 440 IAC 1-1.5. Effective 30 days after filing with the secretary of state.

440 IAC 1-1.5
440 IAC 1.5

SECTION 1. 440 IAC 1.5 IS ADDED TO READ AS FOLLOWS:

ARTICLE 1.5. LICENSURE OF PRIVATE MENTAL HEALTH INSTITUTIONS

Rule 1. Definitions

440 IAC 1.5-1-1 Applicability
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 1. The definitions in this rule apply throughout this article. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-1; filed Oct 11, 2002, 11:26 a.m.: 26 IR 733)*

440 IAC 1.5-1-2 "Accreditation" defined
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 2. "Accreditation" means an accrediting agency has determined that a private mental health institution has met specific requirements of the accrediting agency. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-2; filed Oct 11, 2002, 11:26 a.m.: 26 IR 733)*

440 IAC 1.5-1-3 "Accrediting agency" defined
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 3. "Accrediting agency" means an organization, included on a list of accrediting organizations approved by the division, which has developed clinical, financial, and organizational standards for the operation of a provider of mental health services and which evaluates a private mental health institution's compliance with its established standards on a regularly scheduled basis. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-3; filed Oct 11, 2002, 11:26 a.m.: 26 IR 733)*

440 IAC 1.5-1-4 "Consumer" defined
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 4. "Consumer" means an individual who is receiving assessment or mental health services from the private

mental health institution. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-4; filed Oct 11, 2002, 11:26 a.m.: 26 IR 733)*

440 IAC 1.5-1-5 "Division" defined
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 5. "Division" means the division of mental health and addiction. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-5; filed Oct 11, 2002, 11:26 a.m.: 26 IR 733)*

440 IAC 1.5-1-6 "Licensed mental health professional" defined
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 6. "Licensed mental health professional" means a mental health professional whose scope of practice under Indiana licensure encompasses the expertise involved in writing orders for treatment and who is appropriately credentialed under the private mental health institution's bylaws and policies to write such orders. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-6; filed Oct 11, 2002, 11:26 a.m.: 26 IR 734)*

440 IAC 1.5-1-7 "Mental health services" defined
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 7. "Mental health services" means psychological services, counseling services, case management services, residential services, and other social services for the treatment and care of individuals with psychiatric disorders or chronic addictive disorders, or both. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-7; filed Oct 11, 2002, 11:26 a.m.: 26 IR 734)*

440 IAC 1.5-1-8 "Private mental health institution" defined
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25; IC 16

Sec. 8. "Private mental health institution" means an inpatient hospital setting, including inpatient and outpatient services provided in that setting, for the treatment and care of individuals with psychiatric disorders or chronic addictive disorders, or both, that is physically, organizationally, and programmatically independent of any hospital or health facility licensed by the Indiana state department of health under IC 16. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-8; filed Oct 11, 2002, 11:26 a.m.: 26 IR 734)*

440 IAC 1.5-1-9 "PRN" defined
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 9. "PRN" means as needed. *(Division of Mental Health and Addiction; 440 IAC 1.5-1-9; filed Oct 11, 2002, 11:26 a.m.: 26 IR 734)*

Rule 2. General Provisions

440 IAC 1.5-2-1 Applicability
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25; IC 16

Sec. 1. This article applies to any inpatient, hospital setting, including inpatient and outpatient services provided in that setting, for the treatment and care of individuals with psychiatric disorders or chronic addictive disorders, or both, that is physically, organizationally, and programmatically independent of any hospital or health facility licensed by the Indiana state department of health under IC 16. *(Division of Mental*

Health and Addiction; 440 IAC 1.5-2-1; filed Oct 11, 2002, 11:26 a.m.: 26 IR 734)

440 IAC 1.5-2-2 Licensure by the division
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 2. (a) Before an entity may operate as a private mental health institution, the entity must be licensed by the division under this article.

(b) A private mental health institution shall be accredited by an accrediting agency approved by the division.

(c) The following components are required to be present for licensure as a private mental health institution:
(1) Governing board.
(2) Medical or professional staff organization.
(3) Quality assessment and improvement program.
(4) Dietetic service.
(5) Infection control program.
(6) Medical record services.
(7) Nursing service.
(8) Physical plant, maintenance, and environmental services.
(9) Intake and treatment services.
(10) Discharge planning services.
(11) Pharmacy services.
(12) Plan for special procedures.

(d) The private mental health institution shall have a written plan that clearly defines their course of action and arrangements for emergency services.

(e) The facility shall make a verbal report to the division within twenty-four (24) hours of occurrence of any of the following:
(1) Death or kidnaping of consumer occurring after admission.
(2) A disruption, exceeding four (4) hours, in the continued safe operation of the facility or in the provision of consumer care, caused by internal or external disasters, strikes by health care workers, or unscheduled revocation of vital services.
(3) Any fire or explosion.

(f) In addition, a written report on occurrences listed in subsection (e) shall be submitted to the division within ten (10) working days.

(g) The facility shall make a written report within ten (10) working days of the occurrence of any of the following:
(1) Serious consumer injuries with the potential of a loss of function or marked deterioration of a consumer's condition occurring under unanticipated or unexpected circumstances.
(2) Chemical poisoning occurring within the facility resulting in a negative consumer outcome.
(3) Unexplained loss of or theft of a controlled substance.
(4) Missing consumer whose whereabouts are unknown for over twenty-four (24) hours.

(h) All written reports shall include the following:
(1) An explanation of the circumstances surrounding the incident.
(2) Summaries of all findings, conclusions, and recommendations associated with the review of the incident.

(3) A summary of actions taken to resolve identified problems, to prevent recurrence of the incident, and to improve overall consumer care.

(i) In the event of flood, fire, or other disaster, when significant damage has occurred to the facility, the governing board, or the governing board's designee, or the director of the division shall suspend the use of all or that part of the facility as may be necessary to ensure the safety and well being of consumers. The director of the division shall issue a permit to reoccupy the facility after it is inspected and approved as safe by the Indiana state department of health or the department of fire prevention and building safety commission, or both.

(j) A private mental health institution that has applied for licensure or has been licensed must supply any information requested by the division as fully as it is capable. Failure to comply with a request from the division may result in revocation or denial of a private mental health institution's licensure.

(k) As the licensing body, the division may conduct inspections and investigate complaints and incidents in any private mental health institution.

(l) A private mental health institution's license shall be posted in a conspicuous place in the facility open to consumers and the public. *(Division of Mental Health and Addiction; 440 IAC 1.5-2-2; filed Oct 11, 2002, 11:26 a.m.: 26 IR 734)*

440 IAC 1.5-2-3 Application for licensure
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25-1-6

Sec. 3. (a) An entity seeking licensure as a private mental health institution shall file an application with the division.

(b) The application shall contain the following:
(1) A description of the organizational structure and mission of the applicant.
(2) The location of all operational sites of the applicant.
(3) The consumer population to be served and the program focus.
(4) List of governing board members and executive staff.
(5) A copy of the applicant's procedures to ensure protection of consumer rights and confidentiality.
(6) Evidence of an on-site review and inspection by the Indiana state department of health and the correction of any deficiencies.
(7) Evidence of an on-site review and inspection by the department of fire prevention and building safety commission and the correction of any deficiencies.
(8) Other materials as requested by the division to assist in the evaluation of the application.

(c) An applicant that is accredited must forward to the division proof of accreditation in all services provided by the applicant, site survey recommendations from the accrediting agency, and the applicant's responses to the site survey recommendations.

(d) The division may require the applicant to correct any deficiencies described in the site survey.

(e) If the entity is not yet accredited in all services provided by the applicant, a temporary license may be issued for six (6) months, if the entity provides proof of application to an accrediting body approved by the division.

(f) If the nonaccredited entity continues to meet the other requirements for licensure, temporary licensure may be extended for no more than six (6) additional months.

(g) Before the extended temporary license expires, the applicant must forward to the division the following:

(1) Proof of accreditation.

(2) Site survey recommendations from the accrediting agency.

(3) The applicant's responses to the site survey recommendations.

(4) The division may require the applicant to correct any deficiencies described in the site survey.

(5) Any other materials requested by the division as a part of the application process.

(h) If the applicant fails to achieve accreditation within twelve (12) months, the applicant may not reapply for licensure until twelve (12) months after the extended temporary license ends.

(i) The division may issue a license as a private mental health institution to the applicant after the division has determined that the applicant meets all criteria for a private mental health institution set forth in this rule and in federal and state law.

(j) The regular licensure shall expire one (1) year after the date of issuance.

(k) Relicensure of a facility is required when any of the following occur:

(1) Change in ownership.

(2) Change in the location of the physical plant.

(3) Change in the primary program focus.

(4) When the existing license expires.

(l) The applicant has the right to a hearing conducted by the director of the division or the director's designee, pursuant to IC 12-25-1-6.

(m) If an applicant is denied licensure, a new application for licensure may not be submitted until twelve (12) months have passed. *(Division of Mental Health and Addiction; 440 IAC 1.5-2-3; filed Oct 11, 2002, 11:26 a.m.: 26 IR 735)*

440 IAC 1.5-2-4 Maintenance of licensure

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25; IC 12-27

Sec. 4. Maintenance of licensure is dependent upon the following:

(1) The private mental health institution shall maintain accreditation from an accrediting agency approved by the division. The division shall annually provide all private mental health institutions with a list of accrediting agencies approved by the division.

(2) The private mental health institution shall maintain compliance with required health, fire, and safety codes as prescribed by federal, state, and local law.

(3) Each private mental health institution shall have written policies and enforce these policies to support and protect the fundamental human, civil, constitutional, and statutory rights of each consumer.

(4) Each private mental health institution shall do the following:

(A) Give a written statement of rights under IC 12-27 to each consumer. The statement shall include the toll free consumer service line number and the telephone number for Indiana protection and advocacy services.

(B) Post the written statement of rights in the reception area of the facility.

(C) Document that staff provides both a written and an oral explanation of these rights to each consumer.

(D) Each private mental health institution shall respond to complaints from the consumer service line in a timely manner.

(Division of Mental Health and Addiction; 440 IAC 1.5-2-4; filed Oct 11, 2002, 11:26 a.m.: 26 IR 736)

440 IAC 1.5-2-5 Notification of changes

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25; IC 12-27

Sec. 5. (a) A private mental health institution must notify the division, in writing, thirty (30) days prior to any of the following:

(1) Change in the location of the private mental health institution's operational site.

(2) Change in the primary program focus.

(3) Date of the scheduled accreditation survey and the name of the accrediting agency to provide accreditation.

(b) A private mental health institution must notify the division, in writing, within ten (10) working days after any of the following:

(1) Change in the accreditation status of the private mental health institution.

(2) Change in the president of the governing board.

(3) Change in the chief executive officer of the private mental health institution.

(4) Unannounced accreditation surveys.

(5) The initiation of bankruptcy proceedings.

(6) Adverse action against the entity as the result of the violation of health, fire, or safety codes as prescribed by federal, state, or local law.

(7) Documented violation of the rights of an individual being treated in the private mental health institution under IC 12-27.

(Division of Mental Health and Addiction; 440 IAC 1.5-2-5; filed Oct 11, 2002, 11:26 a.m.: 26 IR 736)

440 IAC 1.5-2-6 Conditional licensure

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25-2

Sec. 6. (a) The division shall change the licensure status of a private mental health institution to that of conditional licensure if the division determines that the private mental health institution has received conditional accreditation status.

(b) The division may change the licensure status of a private mental health institution to that of conditional licensure if the division determines that the private mental health institution no longer meets the requirements in this article.

(c) Within a conditional licensure period, the division may:

(1) require that the facility stop all new admissions;

(2) grant an extension of the conditional licensure;

(3) reinstate the regular license of the private mental health institution if the division requirements are met within the imposed deadline; or

(4) take action to suspend or revoke the entity's licensure as a private mental health institution if the division requirements are not met within the imposed deadline.

(d) The division shall notify the chief executive officer of the private mental health institution of the change in certification status in writing. The notice shall include the following:

(1) The standards not met and the actions the private mental health institution must take to meet those standards.

(2) The amount of time granted the private mental health institution to meet the required standard.

(3) Actions to be taken by the private mental health institution during the time period of the extension.

(e) The division has the discretion to determine the time period and frequency of a conditional licensure; however, a conditional licensure plus any extensions may not exceed twelve (12) months.

(f) Extension requirements shall include the following:

(1) If the division grants an extension of a conditional licensure, the division shall notify the private mental health institution in writing.

(2) The notice shall include the following:

(A) The time period of the extension.

(B) The standards not met and the actions the private mental health institution must take to meet those standards.

(C) Actions to be taken by the private mental health institution during the time period of the extension.

(g) If the private mental health institution does not attain the improvements required by the division within the period of time required, the division shall take action to suspend or revoke the private mental health institution's license in accordance with IC 12-25-2. *(Division of Mental Health and Addiction; 440 IAC 1.5-2-6; filed Oct 11, 2002, 11:26 a.m.: 26 IR 736)*

440 IAC 1.5-2-7 Revocation of licensure

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25-2

Sec. 7. (a) The division may revoke the licensure issued under this article after the division's investigation and determination of the following:

(1) A substantive change in the operation of the private mental health institution, which, under the standards for accreditation, would cause the accrediting agency to revoke the accreditation.

(2) Failure of the private mental health institution to regain accreditation within ninety (90) days following expiration of the private mental health institution's current accreditation by the private mental health institution's accrediting agency.

(3) Failure to comply with this article.

(4) That the physical safety of the consumers or staff of the private mental health institution is compromised by a physical or sanitary condition of a physical facility of a private mental health institution.

(5) Violation of a federal, state, or local statute, ordinance, rule, or regulation in the course of the operation of the private mental health institution that endangers the health, safety, or continuity of services to consumers.

(6) The private mental health institution or its corporate owner files for bankruptcy.

(b) To revoke a license, the director shall follow the requirements in IC 12-25-2.

(c) If the division revokes an entity's licensure as a private mental health institution, the entity may not continue to operate.

(d) If the division revokes an entity's licensure as a private mental health institution, the entity may not reapply to become a private mental health institution until a lapse of twelve (12) months from the date of the revocation. *(Division of Mental Health and Addiction; 440 IAC 1.5-2-7; filed Oct 11, 2002, 11:26 a.m.: 26 IR 737)*

440 IAC 1.5-2-8 Appeal rights

Authority: IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25-3

Sec. 8. A private mental health institution that is aggrieved by any adverse action taken under this rule may appeal the action under IC 12-25-3. *(Division of Mental Health and Addiction; 440 IAC 1.5-2-8; filed Oct 11, 2002, 11:26 a.m.: 26 IR 737)*

Rule 3. Organizational Standards and Requirements

440 IAC 1.5-3-1 Governing board

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 1. (a) The private mental health institution shall have a governing board.

(b) The purpose of the governing board is to make policy and to assure the effective implementation of the policy.

(c) The duties of the governing board include the following:

(1) Meet on a regular basis.

(2) Employ a chief executive officer for the private mental health institution who is delegated the authority and responsibility for managing the private mental health institution.

(3) Delineate in writing the responsibility and authority of the chief executive officer.

(4) Ensure that all workers, including contract and agency personnel, for whom a license, registration, or certification is required, maintain current license, registration, or certification and keep documentation of same so that it can be made available within a reasonable period of time.

(5) Ensure that orientation and training programs are provided to all employees and that each employee has a periodic performance evaluation that includes competency evaluation and an individualized education plan.

(6) Evaluate the performance of the chief executive officer. Evaluations must be conducted every other year, at a minimum.

(7) Establish and enforce prudent business and fiscal policies for the private mental health institution.

(8) Develop and enforce written policies governing private mental health institution operations.

(9) Develop and implement an ongoing strategic plan that identifies the priorities of the governing board and considers community input and consumer assessment of programs and services offered.

(10) Assure that minutes of all meetings are maintained and accurately reflect the actions taken.

(11) Conduct an annual assessment that includes the following:

(A) A review of the business practices of the private mental health institution to ensure that:

(i) appropriate risk management procedures are in place;

(ii) prudent financial practices occur; and

(iii) professional practices are maintained in regard to information systems, accounts receivable, and accounts payable.

A plan of corrective action shall be implemented for any identified deficiencies in the private mental health institution's business practices.

(B) A review of the programs of the private mental health institution, assessing whether the programs are well utilized, cost effective, and clinically effective. A plan of corrective action shall be implemented for any identified deficiencies in the private mental health institution's current program practices.

(d) The governing board is responsible for the conduct of the medical or professional staff. The governing board shall do the following:

(1) Determine, with the advice and recommendation of the medical or professional staff, and in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical or professional staff.

(2) Ensure that:

(A) the requests of practitioners, for appointment or reappointment to practice in the private mental health institution, are acted upon, with the advice and recommendation of the medical or professional staff;

(B) reappointments are acted upon at least biennially;

(C) practitioners are granted privileges consistent with their individual training, experience, and other qualifications; and

(D) this process occurs within a reasonable period of time, as specified by the medical or professional staff bylaws.

(3) Ensure that the medical or professional staff has approved bylaws and rules and that the bylaws and rules are reviewed and approved at least triennially. Governing board approval of medical or professional staff bylaws and rules shall not be unreasonably withheld.

(4) Ensure that the medical or professional staff is accountable and responsible to the governing board for the quality of care provided to consumers.

(5) Ensure that criteria for selection for medical or professional staff membership are individual character, competence, education, training, experience, and judgment.

(6) Ensure that the granting of medical or professional staff membership or professional privileges in the private mental health institution is not solely dependent upon certification, fellowship, or membership in a specialty body or society.

(Division of Mental Health and Addiction; 440 IAC 1.5-3-1; filed Oct 11, 2002, 11:26 a.m.: 26 IR 737)

440 IAC 1.5-3-2 Medical or professional staff organization

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 2. (a) There shall be a single organized medical or professional staff that has the overall responsibility for the quality of all clinical care provided to consumers and for the professional practices of its members as well as for accounting to the governing board.

(b) The appointment and reappointment of medical or professional staff shall be based on well-defined, written criteria whereby it can satisfactorily be determined that the individual is appropriately licensed, certified, registered, or experienced and is qualified for privileges and responsibilities sought.

(c) Clinical privileges shall be facility specific and based on an individual's demonstrated current competency.

(d) The facility shall provide clinical supervision when required or indicated.

(e) There shall be a physician on call twenty-four (24) hours a day.

(f) The private mental health institution shall have on staff a medical services director who:

(1) has responsibility for the oversight and provision of all medical services; and

(2) is a physician licensed to practice medicine in Indiana.

(Division of Mental Health and Addiction; 440 IAC 1.5-3-2; filed Oct 11, 2002, 11:26 a.m.: 26 IR 738)

440 IAC 1.5-3-3 Quality assessment and improvement

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 3. (a) The facility shall establish a planned, systematic, organizational approach to process design, performance, analysis, and improvement. The plan must be interdisciplinary and involve all areas of the facility. Performance expectations shall be established, measured, aggregated, and analyzed on an ongoing basis, comparing performance over time and with other sources. Through this process, the facility identifies changes that will lead to improved performance that is achieved and sustained and reduce the risk of sentinel events.

(b) The process analyzes and makes necessary improvements to the following:

(1) All services, including service by contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge and transfer.

(B) Infection control.

(C) Medication use.

(D) Response to emergencies.
(E) Restraint and seclusion.
(F) Consumer injury.
(G) Staff injury.
(H) Any other areas that are high risk, problem prone, or high volume incidents.
(3) All medical and treatment services performed in the facility with regard to appropriateness of diagnosis and treatments related to a standard of care and anticipated or expected outcomes.

(c) The facility shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement plan, and:
(1) the action shall be documented; and
(2) the outcome of the action shall be documented as to its effectiveness, continued follow-up, and impact on consumer care.
(Division of Mental Health and Addiction; 440 IAC 1.5-3-3; filed Oct 11, 2002, 11:26 a.m.: 26 IR 739)

440 IAC 1.5-3-4 Dietetic services
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 4. (a) The private mental health institution shall have organized food and dietary services that are directed and staffed by adequate, qualified personnel, or a contract with an outside food management company that meets the minimum standards specified in this section.

(b) The food and dietetic service shall have the following:
(1) A full-time employee who:
(A) serves as director of the food and dietetic services; and
(B) is responsible for the daily management of the dietary services.
(2) A registered dietitian, full time, part time, or on a consulting basis. If a consultant is used, he or she shall:
(A) submit periodic written reports on the dietary services provided;
(B) provide the number of on-site dietitian hours commensurate with the:
(i) type of dietary supervision required;
(ii) bed capacity; and
(iii) complexity of the consumer care services;
(C) complete nutritional assessments; and
(D) approve menus.
(3) Administrative and technical personnel competent in their respective duties.

(c) The dietary service shall do the following:
(1) Provide for liaison with the private mental health institution medical or professional staff for recommendations on dietetic policies affecting consumer treatment.
(2) Correlate and integrate dietary care functions with those of other consumer care personnel that include, but are not limited to, the following:
(A) Consumer nutritional assessment and intervention.
(B) Recording pertinent information on the consumer's chart.
(C) Conferring with and sharing specialized knowledge with other members of the consumer care team.

(d) Menus shall meet the needs of the consumers as follows:
(1) Therapeutic diets shall be prescribed by the practitioner responsible for the care of the consumer.
(2) Nutritional needs shall be met in accordance with recognized dietary standards of practice and in accordance with the orders of the responsible practitioner.
(3) A current therapeutic diet manual approved by the dietitian and medical or professional staff shall be readily available to all medical, nursing, and food service personnel.

(4) Menus shall be followed and posted in the food preparation and serving area.

(5) Menus served shall be maintained on file for at least thirty (30) days.

(Division of Mental Health and Addiction; 440 IAC 1.5-3-4; filed Oct 11, 2002, 11:26 a.m.: 26 IR 739)

440 IAC 1.5-3-5 Infection control

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 5. (a) The facility shall provide a safe and healthful environment that minimizes infection exposure and risk to consumer, health care workers, and visitors. This is completed in a coordinated process that recognizes the risk of the endemic and epidemic nosocomial infections.

(b) There shall be an active, effective written facility-wide infection control program. Included in the program shall be a system designed for the identification, surveillance, investigation, control, reporting of information (internally and to health agencies), and prevention of infection and communicable diseases in the consumer and health care worker.

(c) The infection control program shall have a method for identifying and evaluating trends or clusters of nosocomial infections or communicable diseases. The infection control process involves universal precautions and other activities aimed at preventing the transmission of communicable diseases significant between consumer and health care workers.

(d) The facility shall have as part of the infection control program a needlestick prevention and exposure plan.

(e) A person, who has the support of facility management and is qualified by training or experience, shall be designated as responsible for the ongoing infection control activities and the development and implementation of the policies governing the control of infection and the communicable diseases.

(f) The facility shall have a functioning infection control committee that includes the individual responsible for the infection control program, a member of the medical or professional staff, a representative from nursing staff, and other appropriate individuals as needed. The committee will meet quarterly and minutes of meeting will be taken.

(g) The duties of the committee include the following:

(1) Writing policies and procedures in regard to sanitation, universal precautions, cleaning, disinfection, aseptic technique, linen management, employee health, personal hygiene, and attire.

(2) Assuring the system complies with state and federal laws to monitor the immune status of consumers and staff exposed to communicable diseases.

(h) Facility management shall be responsible to assure implementation and corrective actions as necessary to ensure that infection control policies are followed.

(i) Management shall provide appropriate infection control input into plans during any renovation or construction. *(Division of Mental Health and Addiction; 440 IAC 1.5-3-5; filed Oct 11, 2002, 11:26 a.m.: 26 IR 739)*

440 IAC 1.5-3-6 Medical record services

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 6. (a) The facility shall maintain a written clinical record on every consumer and shall have policies and procedures for clinical record organization and content.

(b) The services must be directed by a registered health information administrator (RHIA) or an accredited health information technician (RHIT). If a full-time or part-time RHIA or RHIT is not employed, then a consultant RHIA or RHIT must be provided to assist the person in charge. Documentation of the findings and recommendations of the consultant must be maintained.

(c) The unit record system shall be used to assure that the maximum possible information about a consumer is available. The consumer's record shall contain pertinent information, which, at a minimum, shall consist of the following:
(1) Face sheet (identification data).
(2) Referral information.
(3) Data base (assessment information).
(4) Individual treatment plan.
(5) History and physical exams.
(6) Physician's or licensed mental health professional's orders.
(7) Medication and treatment record.
(8) Progress notes.
(9) Treatment plan reviews.
(10) Special dietetic information.
(11) Consultation reports.
(12) Correspondence.
(13) Legal/commitment papers.
(14) Discharge/separation summary.
(15) Release/aftercare plans.

(d) The record shall contain identifying data in accordance with the policy of the facility.

(e) The consumer record shall contain information of any unusual occurrences, such as the following:
(1) Treatment complications.
(2) Accidents or injuries to the consumer.
(3) Morbidity.
(4) Death of a consumer.
(5) Procedures that place a consumer at risk or cause unusual pain.

(f) All entries in the consumer record shall be signed and dated.

(g) Symbols and abbreviations shall be used only if they have been approved by the medical or professional staff and only when there is an explanatory legend and shall not be used in the recording of a diagnosis.

(h) The facility shall be responsible to:
(1) maintain, control, and supervise consumer records; and
(2) maintain quality.

(i) The consumer record service shall establish, maintain, and control record completeness systems and mechanisms to ensure the quality and appropriateness of all documentation.

(j) Written policies and procedures shall govern the compilation, storage, dissemination, and accessibility of consumer records and be so designed as to assure that the facility fulfills its responsibility to protect the records against loss, unauthorized alteration, or disclosure of information.

(k) The consumer record shall be considered both a medical and legal document with careful consideration given to each entry in advance; therefore, the record may not be changed unless an error has been made or

omission discovered with the correction process identified by policy and procedure.

(l) The facility shall maintain an indexing or referencing system that can be used to locate a consumer record that has been removed from the central file area.

(m) The facility shall have written policies and procedures that protect the confidentiality of consumer records and govern the disclosure of information in the records. The record shall comply with all applicable federal, state, and local laws, rules, and regulations.

(n) All original medical records or legally reproduced medical records must be maintained by the facility for a period of seven (7) years, must be readily accessible, in accordance with the facility policy, and must be kept in a fire resistive structure. *(Division of Mental Health and Addiction; 440 IAC 1.5-3-6; filed Oct 11, 2002, 11:26 a.m.: 26 IR 740)*

440 IAC 1.5-3-7 Nursing service
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 7. (a) The private mental health institution shall have an organized nursing service led by a nurse executive, who has the authority and responsibility to ensure that the nursing standards of consumer care, and standards of nursing practice are consistent with professional standards. The nursing executive or designee shall approve all nursing policies, procedures, nursing standards of consumer care and standards of nursing practice. The nurse executive is also responsible for determining number and type of nursing personnel needed as well as maintaining a nursing organizational chart and job description for all positions. The nurse executive participates with leaders of the governing body, management and medical or professional staff, and other clinical areas in planning and promoting and conducting organizational wide performance improvement activities.

(b) The private mental health institution shall have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse.

(c) The service shall have an organized plan that delineates the responsibilities for consumer care, which includes monitoring of each consumer's status and coordinates the provision of nursing care while assisting other professional implementing their plans of care.

(d) The nursing service shall have the following:
(1) Adequate numbers of licensed registered nurses and licensed practical nurses for the provision of appropriate care to all consumers which may include assessing consumer nursing needs, planning, and providing nursing care interventions, preventing complications, providing and improving on consumer comfort and wellness.
(2) The service shall have a procedure to ensure that private mental health institution nursing personnel, including nurse registry personnel for whom licensure is required, have valid and current licensure.

(e) All nursing personnel shall demonstrate and document competency in fulfilling their assigned responsibilities. *(Division of Mental Health and Addiction; 440 IAC 1.5-3-7; filed Oct 11, 2002, 11:26 a.m.: 26 IR 741)*

440 IAC 1.5-3-8 Physical plant; maintenance and environmental services
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 8. (a) The private mental health institution shall be constructed, arranged, and maintained to ensure the safety of the consumer and to provide facilities for services authorized under the private mental health

institution license as follows:

(1) The plant operations and maintenance service, equipment maintenance, and environmental service shall be:

(A) staffed to meet the scope of the services provided; and

(B) under the direction of a person or persons qualified by education, training, or experience.

(2) There shall be a safety officer designated to assume responsibility for the safety program.

(3) The facility shall provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the rules of the fire prevention and building safety commission, including 675 IAC 22, Indiana fire codes, and 675 IAC 13, Indiana building codes.

(b) The condition of the physical plant and the overall environment shall be developed and maintained in such a manner that the safety and well being of consumers are assured as follows:

(1) No condition in the facility or on the grounds shall be maintained that may be conducive to the harborage or breeding of insects, rodents, or other vermin.

(2) No condition shall be created or maintained which may result in a hazard to consumers, public, or employees.

(3) There shall be a plan for emergency fuel and water supply.

(4) Provision shall be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:

(A) Operation, maintenance, and spare parts manuals shall be available, along with training or instruction of the appropriate personnel, in the maintenance and operation of the fixed and movable equipment.

(B) Operational and maintenance control records shall be established and analyzed periodically. These records shall be readily available on the premises.

(C) Maintenance and repairs shall be carried out in accordance with applicable codes, rules, standards, and requirements of local jurisdictions, the administrative building council, the state fire marshal, and the Indiana state department of health.

(5) The food service of the private mental health institution shall comply with 410 IAC 7-20.

(c) In new construction, renovations, and additions, the facilities shall meet the following:

(1) The 2001 edition of the national "Guideline for Construction and Equipment of Private Mental Health Institution and Medical Facilities" (Guidelines).

(2) All building, fire safety, and handicapped accessibility codes and rules adopted by the fire prevention and building safety commission shall apply to all facilities covered by this rule and take precedence over any building, fire safety, or handicapped accessibility requirements of the Guidelines.

(3) When renovation or replacement work is done within an existing facility, all new work or addition, or both, shall comply, insofar as practical, with applicable sections of the Guidelines and for certification with appropriate parts of National Fire Protection Association (NFPA) 101 and the applicable rules of the fire prevention and building safety commission.

(4) Proposed sites shall be located away from detrimental nuisances, well drained, and not subject to flooding. A site survey and recommendations shall be obtained from the department of health prior to site development.

(5) Water supply and sewage disposal services shall be obtained from municipal or community services. Outpatient facilities caring for consumers less than twenty-four (24) hours that do not provide surgery, laboratory, or renal dialysis services may be served by approved private on-site septic tank absorption field systems.

(6) Site utility installations for water, sprinkler, sanitary, and storm sewer systems, and wells for potable emergency water supplies shall comply with applicable sections of Bulletin S.E. 13, "On-Site Water Supply and Wastewater Disposal for Public and Commercial Establishments", 1988 edition.

(7) As early in the construction, addition, or renovation project as possible, the functional and operational description shall be submitted to the division. This submission shall consist of, but not be limited to, the following:

(A) Functional program narrative as established in the Guidelines.

(B) Schematics, based upon the functional program, consisting of drawings (as single-line plans), outline specifications, and other documents illustrating the scale and relationship of project components.

(8) Prior to the start of construction, addition, and/or renovation projects, detailed architectural and operational plans for construction shall be submitted to the plan review division of the department of fire and building services and to the division of sanitary engineering of the Indiana state department of health as follows:

(A) Working drawings, project manual, and specifications shall be included.

(B) Prior to submission of final plans and specifications, recognized standards, and codes, including infection control standards, shall be reviewed as required in section 2(f)(2) of this rule.

(C) All required construction design releases shall be obtained from the state building commissioner and final approval from the division of sanitary engineering of the Indiana state department of health prior to issuance of the occupancy letter by the division.

(9) All back flow prevention devices shall be installed as required by 327 IAC 8-10 and the current edition of the Indiana plumbing code. Such devices shall be listed as approved by the Indiana state department of health.

(10) Upon receipt of a construction design release from the state building commissioner and documentation of a completed plan review by the division of sanitary engineering of the Indiana state department of health, a licensure application shall be submitted to the division on the form approved and provided by the division.

(d) The equipment requirements are as follows:

(1) All equipment shall be in good working order and regularly serviced and maintained.

(2) There shall be sufficient equipment and space to assure the safe, effective, and timely provision of the available services to consumers as follows:

(A) All mechanical equipment (pneumatic, electric, or other) shall be on a documented maintenance schedule of appropriate frequency and with the manufacturer's recommended maintenance schedule.

(B) There shall be evidence of preventive maintenance on all equipment.

(C) Appropriate records shall be kept pertaining to equipment maintenance, repairs, and current leakage checks.

(3) Defibrillators shall be discharged at least in accordance with manufacturers recommendations and a discharge log with initialed entries shall be maintained.

(4) Electrical safety shall be practiced in all areas.

(e) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, shall be kept clean and orderly in accordance with current standards of practice as follows:

(1) Environmental services shall be provided in such a way as to guard against transmission of disease to consumers, health care workers, the public, and visitors by using the current principles of:

(A) asepsis;

(B) cross-infection; and

(C) safe practice.

(2) Refuse and garbage shall be collected, transported, sorted, and disposed of by methods that will minimize nuisances or hazards.

(f) The safety management program shall include, but not be limited to, the following:

(1) An ongoing facility-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the safety committee.

(2) A safety committee appointed by the chief executive officer that includes representatives from administration, consumer services, and support services.

(3) The safety program that includes, but is not limited to, the following:

(A) Consumer safety.

(B) Health care worker safety.

(C) Public and visitor safety.

(D) Hazardous materials and wastes management in accordance with federal and state rules.

(E) A written fire control plan that contains provisions for the following:

(i) Prompt reporting of fires, as required under the provisions of the Indiana Fire Code.

(ii) Extinguishing of fires.

(iii) Protection of consumers, personnel, and guests.

(iv) Evacuation.

(v) Cooperation with firefighting authorities.

(F) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies.

(G) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.

(Division of Mental Health and Addiction; 440 IAC 1.5-3-8; filed Oct 11, 2002, 11:26 a.m.: 26 IR 741)

440 IAC 1.5-3-9 Intake and treatment

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 9. (a) The facility shall have policies and procedures that govern the intake and assessment process to determine eligibility for services.

(b) Treatment required by the consumer shall be appropriate to the facility and the professional expertise of the staff.

(c) Alternatives for less intensive and restrictive treatment are not available in the community.

(d) A physical examination shall be completed by a licensed physician, an advanced practice nurse, or physician's assistant within twenty-four (24) hours after admission.

(e) An initial emotional, behavioral, social, and legal assessment of each consumer shall be completed upon admission.

(f) When the admitted consumer is a child or adolescent under eighteen (18) years of age, then the initial assessment shall also include an evaluation of school progress, a report of involvement with other social/legal services agencies, and an assessment of family functioning and relationships. Family input and advice shall be considered in the diagnosis, treatment planning, and discharge planning process.

(g) A child (fourteen (14) years of age and under) may be admitted to a nonsegregated unit (adult unit) only under an emergency situation. The criteria for such an emergency admission must be specified in advance and must include plans for an evaluation by a child psychiatrist within sixty (60) hours of admission.

(h) An admission under subsection (g) shall be verbally reported to the division within twenty-four (24) hours of the admission. A written report shall be submitted to the division within ten (10) working days.

(i) A preliminary treatment plan shall be formulated within sixty (60) hours of admission on the basis of the intake assessment done at the time of admission.

(j) Consumers shall participate in the development and review of their own treatment plans. If the consumer agrees to family participation and signs a release of information, the facility shall consider input from and participate with the family in the diagnosis and treatment process.

(k) If a consumer chooses not to participate in the treatment planning process, it shall be documented in

the clinical record.

(l) The treatment plan shall specify the services necessary to meet the consumer's needs and shall contain discharge or release criteria and the discharge plan.

(m) Progress notes shall be entered daily in the consumer's record by staff having knowledge of the consumer and responsibility for implementing the treatment plan. The notes from all sources shall be entered in an integrated chronological order in the record, signed, and dated.

(n) At a minimum of every seven (7) days, the treatment plan shall be reviewed and revised as necessary.
(Division of Mental Health and Addiction; 440 IAC 1.5-3-9; filed Oct 11, 2002, 11:26 a.m.: 26 IR 743)

440 IAC 1.5-3-10 Discharge planning services
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 10. To facilitate discharge as soon as an inpatient level of care is no longer required, the private mental health institution shall have effective, ongoing discharge planning initiated at admission that does the following:

(1) Facilitates the provision of follow-up care.

(2) Transfers or refers consumers, along with necessary medical information and records, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care. The information shall include, but not be limited to, the following:

(A) Medical history.

(B) Current medications.

(C) Available social, psychological, and educational services to meet the needs of the consumer.

(D) Nutritional needs.

(E) Outpatient service needs.

(F) Follow-up care needs.

(3) Utilizes available community and private mental health institution resources to provide appropriate referrals or make available social, psychological, and educational services to meet the needs of the consumer.
(Division of Mental Health and Addiction; 440 IAC 1.5-3-10; filed Oct 11, 2002, 11:26 a.m.: 26 IR 744)

440 IAC 1.5-3-11 Pharmacy services
Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 11. The private mental health institution shall have a pharmacy service that ensures that medication use processes are organized and systematic throughout the private mental health institution. The following requirements apply:

(1) The organization shall identify an appropriate selection or formulary of medications available for prescribing or ordering.

(2) The private mental health institution shall address prescribing or ordering and procuring of medications not available within the formulary.

(3) Policies and procedures shall be in place to support safe medication prescription ordering and storage, and address such issues as pain management medication and PRN medications.

(4) The preparation and dispensing of medication(s) shall adhere to law, regulation, licensure, and professional standards of practice.

(5) The preparation and dispensing of medication(s) is appropriately controlled.

(A) There shall be an individual patient dose system in place.

(B) A pharmacist shall review all medication prescriptions or orders, including reviewing for interactions and adverse effects.

(C) There shall be a system in place for considering important consumer medication information when a medication(s) is prepared and dispensed for a consumer.

(D) There shall be a procedure in place for pharmacy service availability at any times when the pharmacy is closed or otherwise unavailable.

(E) Emergency medications shall be consistently available, controlled, and secure in the pharmacy and consumer care areas.

(F) There shall be a medication recall system providing for the retrieval and safe disposal of discontinued and recalled medications.

(6) There shall be a system in place to insure that prescriptions or orders are verified and consumers are properly identified before any medication is administered or dispensed.

(7) Any investigational medication(s) shall be safely controlled and administered during experimental trials, and safely destroyed at the conclusion of any such investigational trial.

(8) There shall be a written policy in place that assures the routine inspection of the storage of all medications.

(9) There shall be a written system in place to address appropriate storage and dispensing of sample medications.

(Division of Mental Health and Addiction; 440 IAC 1.5-3-11; filed Oct 11, 2002, 11:26 a.m.: 26 IR 744)

440 IAC 1.5-3-12 Plan for special procedures

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2
Affected: IC 12-25

Sec. 12. (a) The facility shall have policies and a written plan in place that shall include clinical justification for any of the following special procedures:

(1) The use of restraint or seclusion, or both.

(2) The use electro-convulsive therapy.

(3) The use of investigational and experimental drugs.

(b) If any procedure in this section is utilized, the rationale for the use shall be clearly stated in the consumer record.

(c) The use of restraint or seclusion shall be limited through plans, priorities, human resource planning, staff orientation and education, assessment process that identify and prevent behavioral risk factors. The process shall involve the consumer and, with the consent of the consumer, the family.

(d) Restraint or seclusion use within the facility is limited to incidents and those situations, with adequate appropriate clinical justification, that are required due to dangerousness to the consumer or others.

(e) The use of restraint or seclusion shall be utilized using the least restrictive alternative.

(f) A licensed independent practitioner shall conduct a clinical assessment of the consumer prior to writing an order for seclusion or restraint or within one (1) hour of the initiation of the seclusion or restraint.

(g) The licensed independent practitioner's orders should be limited to four (4) hours for individuals eighteen (18) years of age and older, two (2) hours for individuals nine (9) years of age through seventeen (17) years of age and one (1) hour for individuals under the nine (9) years of age. The orders shall contain behavioral criteria for release.

(h) In an emergency, restraint or seclusion, or both, may only be utilized by trained, clinically privileged staff, and shall be documented in the consumer's record and an order obtained. The licensed independent practitioner must complete a face-to-face evaluation within one (1) hour.

(i) PRN orders shall not be used to authorize seclusion or restraint.

(j) A consumer in restraint or seclusion shall be assessed and monitored continuously through face-to-face observation by an assigned staff member who is trained in correct procedures and competent.

(k) After the first hour, an individual in seclusion only may be monitored by video and audio equipment.

(l) If the individual is put in a physical hold a second staff member shall be assigned to observe.

(m) Documentation shall occur every fifteen (15) minutes in the consumer's record, consistent with the organizational policies.

(n) The use of restraint and seclusion shall be discontinued when the individual meets the behavior criteria set forth in the orders.

(o) Staff and the consumer will participate in debriefing about the restraint and seclusion episode.

(p) The organization shall collect data on the use of restraint and seclusion in order to monitor and improve its performance.

(q) When electro-convulsive therapy or investigational or experimental drugs are used, the written informed consent of the consumer or legal guardian shall be obtained. The consumer or legal guardian may withdraw consent at any time.

(r) The facility shall comply with all federal regulations regarding any of the following special procedures:
(1) The use of restraint or seclusion, or both.
(2) The use electro-convulsive therapy.
(3) The use of investigational and experimental drugs.
(Division of Mental Health and Addiction; 440 IAC 1.5-3-12; filed Oct 11, 2002, 11:26 a.m.: 26 IR 744)

SECTION 2. 440 IAC 1-1.5 IS REPEALED.

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