TITLE 440 DIVISION OF MENTAL HEALTH AND ADDICTION

Proposed Rule
LSA Document #07-875

DIGEST

Amends 440 IAC 1.5-1-2 and 440 IAC 1.5-1-3 to revise definitions specific to the rule. Adds 440 IAC 1.5-1-3.5, 440 IAC 1.5-1-4.5, 440 IAC 1.5-1-5.1, 440 IAC 1.5-1-5.2, 440 IAC 1.5-1-7.5, 440 IAC 1.5-1-10, and 440 IAC 1.5-1-11 to add new definitions specific to the rule. Amends 440 IAC 1.5-2-2 through 440 IAC 1.5-2-8 to revise and clarify matters concerning the licensure process for private mental health institutions, to update the names of state agencies, and to include specific reporting of a consumer death occurring in or around the time in which the consumer was in restraint or seclusion. Amends 440 IAC 1.5-3-1 through 440 IAC 1.5-3-9, 440 IAC 1.5-3-11, and 440 IAC 1.5-3-12 to revise and clarify matters concerning the organizational standards for and required components of a private mental health institution and to update the names of state agencies. Adds 440 IAC 1.5-3-13 to establish specific procedures and requirements for the use of restraint or seclusion, or the simultaneous use of restraint and seclusion. Effective 30 days after filing with the Publisher.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

440 IAC 1.5-1-2; 440 IAC 1.5-1-3; 440 IAC 1.5-1-3.5; 440 IAC 1.5-1-4.5; 440 IAC 1.5-1-5.1; 440 IAC 1.5-1-5.2; 440 IAC 1.5-1-7.5; 440 IAC 1.5-1-10; 440 IAC 1.5-1-11; 440 IAC 1.5-2-2; 440 IAC 1.5-2-3; 440 IAC 1.5-2-4; 440 IAC 1.5-2-5; 440 IAC 1.5-2-6; 440 IAC 1.5-2-7; 440 IAC 1.5-2-8; 440 IAC 1.5-3-1; 440 IAC 1.5-3-2; 440 IAC 1.5-3-3; 440 IAC 1.5-3-4; 440 IAC 1.5-3-5; 440 IAC 1.5-3-6; 440 IAC 1.5-3-7; 440 IAC 1.5-3-8; 440 IAC 1.5-3-9; 440 IAC 1.5-3-11; 440 IAC 1.5-3-12; 440 IAC 1.5-3-13

SECTION 1. 440 IAC 1.5-1-2 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-1-2 "Accreditation" defined

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

Sec. 2. "Accreditation" means **that** 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)

SECTION 2. 440 IAC 1.5-1-3 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
Affected: IC 12-25

Sec. 3. "Accrediting agency" means an organization ~~included on a list of accrediting organizations~~ **that:**
(1) has been approved **as an accrediting agency** by the division; ~~which~~
(2) has developed clinical, financial, and organizational standards for the operation of a provider of mental health services; ~~and which~~
(3) evaluates a private mental health institution's compliance with ~~its~~ **the accrediting agency's** established standards on a regularly scheduled basis; **and**
(4) has been approved by the Centers for Medicare and Medicaid Services for deeming authority for Medicare requirements under 24 CFR 488.5 or 24 CFR 488.6.

(Division of Mental Health and Addiction; 440 IAC 1.5-1-3; filed Oct 11, 2002, 11:26 a.m.: 26 IR 733)

SECTION 3. 440 IAC 1.5-1-3.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 1.5-1-3.5 "Attending physician" defined

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

Sec. 3.5. "Attending physician" means the licensed physician who has the overall responsibility and authority for the management and care of a consumer. The term includes another physician to whom the attending physician has delegated responsibility when the attending physician is unavailable.

(Division of Mental Health and Addiction; 440 IAC 1.5-1-3.5)

SECTION 4. 440 IAC 1.5-1-4.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 1.5-1-4.5 "Director" defined

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

Sec. 4.5. "Director" means the director of the division.

(Division of Mental Health and Addiction; 440 IAC 1.5-1-4.5)

SECTION 5. 440 IAC 1.5-1-5.1 IS ADDED TO READ AS FOLLOWS:

440 IAC 1.5-1-5.1 "Facility" defined

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

Sec. 5.1. "Facility" means a private mental health institution licensed under IC 12-25-1.

(Division of Mental Health and Addiction; 440 IAC 1.5-1-5.1)

SECTION 6. 440 IAC 1.5-1-5.2 IS ADDED TO READ AS FOLLOWS:

440 IAC 1.5-1-5.2 "Licensed independent practitioner" or "LIP" defined

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

Sec. 5.2. "Licensed independent practitioner" or "LIP" means an individual permitted by state law and by the policy of a facility to order restraint or seclusion for consumers independently within the scope of the individual's license and consistent with the clinical privileges granted to that individual.

(Division of Mental Health and Addiction; 440 IAC 1.5-1-5.2)

SECTION 7. 440 IAC 1.5-1-7.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 1.5-1-7.5 "Physician" defined

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2; IC 12-25-1-4
Affected: IC 12-25; IC 25-22.5

Sec. 7.5. "Physician" means an individual who holds an unlimited license to practice medicine under IC 25-22.5.

(Division of Mental Health and Addiction; 440 IAC 1.5-1-7.5)

SECTION 8. 440 IAC 1.5-1-10 IS ADDED TO READ AS FOLLOWS:

440 IAC 1.5-1-10 "Restraint" defined

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

Sec. 10. (a) "Restraint" means:
(1) any:
(A) manual method;
(B) physical or mechanical device;
(C) material; or
(D) equipment;
that immobilizes or reduces the ability of a consumer to move his or her arms, legs, body, or head freely; or
(2) a drug or medication when it is:
(A) used as a restriction to manage the consumer's behavior or restrict the consumer's freedom of movement; and
(B) not a standard treatment or dosage for the consumer's condition.

(b) The term does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods, that involve the physical holding of a consumer for:
(1) conducting routine physical examinations or tests;
(2) protecting the consumer from falling out of bed; or
(3) permitting the consumer to participate in activities without the risk of physical harm, excluding, however, the provision of a physical escort.

(Division of Mental Health and Addiction; 440 IAC 1.5-1-10)

SECTION 9. 440 IAC 1.5-1-11 IS ADDED TO READ AS FOLLOWS:

440 IAC 1.5-1-11 "Seclusion" defined

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

Sec. 11. "Seclusion" means the involuntary confinement of a consumer alone in a room or an area from which the consumer is physically prevented from leaving. Seclusion may be used only for the management of violent or self-destructive behavior.

(Division of Mental Health and Addiction; 440 IAC 1.5-1-11)

SECTION 10. 440 IAC 1.5-2-2 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
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) **A** governing board.

(2) Medical or professional staff organization.
(3) **A** quality assessment and improvement program.
(4) Dietetic service.
(5) **An** 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) **A** plan for special procedures.

(d) The private mental health institution shall have a written plan that clearly defines ~~their~~ **the facility's** 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 **an** occurrence of any of the following:
(1) **The** death or ~~kidnaping~~ **kidnapping** of **a** consumer occurring after admission.
(2) Any consumer death that occurs while the consumer is in restraint or seclusion.
(3) Any death of a consumer that occurs within twenty-four (24) hours after the consumer has been removed from restraint or seclusion.
(4) Any death of a consumer known to the facility that occurs within one (1) week after restraint or seclusion where it is reasonable to assume that the use of restraint or placement in seclusion contributed directly or indirectly to that consumer's death. For purposes of this subdivision, "reasonable to assume" includes, but is not limited to, deaths related to:
(A) restrictions of movement for prolonged periods of time;
(B) chest compression;
(C) restriction of breathing; or
(D) asphyxiation.
(5) The admission of a child, fourteen (14) years of age or younger, to an adult unit, as prescribed by 440 IAC 1.5-3-9(g) and 440 IAC 1.5-3-9(h).
~~(2)~~ **(6)** A disruption, exceeding four (4) hours, in the continued safe operation of the facility or in the provision of consumer care, caused by:
(A) internal or external disasters;
(B) strikes by health care workers; or
(C) unscheduled revocation of vital services.
~~(3)~~ **(7)** Any fire or explosion.

(f) In addition, **a facility shall submit** a written report, ~~on occurrences~~ **as required in subsection (h), to the division within ten (10) working days of any occurrence** listed in subsection (e). ~~shall be submitted to the division within ten (10) working days.~~

(g) The facility shall ~~make~~ **also submit** a written report, **as required in subsection (h), to the division** within ten (10) working days of the occurrence of any of the following:
(1) **A** serious **injury to a** consumer ~~injuries~~ with the **actual or** potential ~~of a~~ loss of function or **a** marked deterioration ~~of~~ **in** a consumer's condition occurring under unanticipated or unexpected circumstances.
(2) Chemical poisoning occurring within the facility resulting in **actual or potential harm to** a ~~negative~~ consumer. ~~outcome.~~
(3) **An** unexplained loss ~~of~~ or theft of a controlled substance.
(4) ~~Missing~~ **A** consumer ~~whose whereabouts are unknown~~ **who:**
(A) is missing; or
(B) cannot be located;
for ~~over~~ **more than** twenty-four (24) hours.

(h) ~~All~~ **A** written ~~reports~~ **report required under subsection (f) or (g)** shall include the following **information:**
(1) An explanation of the circumstances surrounding the incident.
(2) Summaries of all findings, conclusions, and recommendations associated with ~~the~~ **a** review of the incident.
(3) A summary of actions taken to:
(A) resolve identified problems; ~~to~~

(B) prevent recurrence of the incident; and ~~to~~
(C) 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~~ **an affected** 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, **or an affected part thereof,** after ~~it is inspected~~ **an inspection** and ~~approved as safe~~ **approval for reoccupation of the facility** by the:
(1) Indiana state department of health; or ~~the department~~
(2) division of fire ~~prevention~~ and building safety, ~~commission, or both.~~ **department of homeland security; as applicable.**

(j) A private mental health institution that has:
(1) applied for ~~licensure~~ **a license;** or ~~has~~
(2) been licensed; ~~must~~
shall supply any information **reasonably** requested by the division. ~~as fully as it is capable.~~ **A facility's** failure to comply with ~~a request from~~ the ~~division~~ **division's request** may result in revocation or denial of a private mental health institution's ~~licensure.~~ **license.**

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

(l) A private mental health institution's license shall be posted in a conspicuous place in **an area of** the facility open **and accessible** to consumers and **to** 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)

SECTION 11. 440 IAC 1.5-2-3 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
Affected: IC 4-21.5-3; IC 12-25-1-6; IC 12-25-3-1

Sec. 3. (a) An entity seeking ~~licensure~~ **a license** 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:
(A) consumer population to be served; and ~~the~~
(B) program focus.
(4) **A** 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) **Written** evidence of **the following:**
(A) An on-site review and inspection by the:
(i) Indiana state department of health; and ~~the correction of any deficiencies.~~
~~(7) Evidence of an on-site review and inspection by the department~~ **(ii) division** of fire ~~prevention~~ and building safety ~~commission and~~ **of the department of homeland security.**
(B) The correction of any deficiencies.
~~(8)~~ **(7)** Other materials as requested by the division to assist in the evaluation of the application.

(c) An applicant that is accredited ~~must forward~~ **shall submit the following** to the division:
(1) Proof of accreditation in all services provided by the applicant.
(2) Site survey recommendations from the accrediting agency. ~~and~~
(3) 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~~ **an applicant** is not yet accredited in all services provided by the applicant, **but provides proof of application to an accrediting agency approved by the division, the division may issue** a temporary license ~~may be issued~~ for **a period of** six (6) months. ~~if the entity provides proof of application to an accrediting body approved by the division.~~

(f) **At the end of the six (6) month period of a temporary license granted under subsection (e), the division may extend the temporary license for not longer than six (6) additional months,** if the nonaccredited ~~entity~~ **applicant** continues to meet ~~the~~ **all** other requirements for ~~licensure, temporary licensure may be extended for no more than six (6) additional months.~~ **a license except for accreditation.**

(g) ~~Before~~ **Prior to** the **expiration of an** extended temporary license ~~expires,~~ **under subsection (f),** the applicant ~~must forward to~~ **shall provide** the division **with** 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) **If required by** the division, ~~may require the applicant to correct~~ **proof of the correction of** any ~~deficiencies~~ **deficiency** described in the site survey.
(5) Any other materials requested by the division as a part of the application process.

(h) If ~~the~~ **an** applicant fails to achieve accreditation within **a period of** twelve (12) months **from the date of application,** the applicant may not reapply for ~~licensure~~ **a license** until twelve (12) months after ~~the~~ **an** extended temporary license ~~ends.~~ **expires.**

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

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

(k) ~~Relicensure of~~ A facility ~~is required~~ **must obtain a new license** when any of the following ~~occur:~~ **occurs:**

(1) **A** change in **any of the following:**
  (A) Ownership **as determined by the division in conjunction with the requirements of the accrediting agency.**
  ~~(2) Change in~~ **(B)** The location of the physical plant.
  ~~(3) Change in~~ **(C)** The primary program focus.
~~(4) When~~ **(2)** 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~~ **Under** IC 12-25-1-6, **the director may do either of the following:**

(1) Issue a license upon an application without further evidence.
(2) Conduct:
  (A) a hearing on the application; and
  (B) an investigation to determine whether a license should be granted.

(m) If an applicant is denied a license, or is otherwise aggrieved by an action of the director, after a hearing under subsection (l), the applicant may do either of the following:

(1) Seek administrative review of that determination under IC 4-21.5-3.
(2) File an action under IC 12-25-3-1.

~~(m)~~ **(n)** If an applicant is denied ~~licensure,~~ a ~~new application for licensure~~ **license, the applicant** may not ~~be submitted until~~ **submit a new application for a license for a period of** twelve (12) months ~~have passed.~~ **from the effective date of the division's denial of a license.**

(Division of Mental Health and Addiction; 440 IAC 1.5-2-3; filed Oct 11, 2002, 11:26 a.m.: 26 IR 735)

SECTION 12. 440 IAC 1.5-2-4 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
Affected: IC 12-25; IC 12-27

Sec. 4. ~~Maintenance of~~ **To maintain** licensure, ~~is dependent upon~~ **a private mental health institution shall do** 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:

(A) health;

(B) building;

(C) fire; and

(D) 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)~~ **(4)** 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)~~ **(5)** Post the written statement of rights **in a conspicuous place** in ~~the reception~~ **an** area of the facility **open and accessible to consumers and to the public.**

~~(C)~~ **(6)** Document **in the consumer's record** that staff ~~provides~~ **provided** both a written and an oral explanation of these rights to each consumer.

~~(D) Each private mental health institution shall~~ **(7)** 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)

SECTION 13. 440 IAC 1.5-2-5 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
Affected: IC 12-25; IC 12-27

Sec. 5. (a) A private mental health institution ~~must~~ **shall** notify the division, in writing, **in the manner designated in subsection (b), within** thirty (30) days prior to any of the following:

(1) **A** change in **any of the following:**

(A) Ownership.

(B) The location of **any operational site of** the private mental health ~~institution's operational site.~~ **institution.**

~~(2) Change in~~ **(C)** The primary program focus **of the private mental health institution.**

(2) The effective date of a change in subdivision (1).

(3) **The:**

(A) date of ~~the~~ **a** scheduled accreditation survey; and ~~the~~

(B) name of the accrediting agency. ~~to provide accreditation.~~

(b) The facility shall submit to the division the written notice required in subsection (a) in the following manner:

(1) For subsection (a)(1) and (a)(2), on a form designated by the division.

(2) For subsection (a)(3), on the facility's letterhead.

(c) If a facility does not provide the division with at least thirty (30) days advance written notice of the

information required in subsection (a)(1), the division shall record such information on the facility's license effective on the date when the division receives written notice of a change under subsection (a)(1)(A) or (a)(2)(B) or the effective date of the change under subsection (a)(1)(C).

~~(b)~~ **(d)** A private mental health institution ~~must~~ **shall** notify the division, in writing **on the facility's letterhead,** within ten (10) working days after any of the following:

(1) **A** change in **any of the following:**
  (A) The accreditation status of the private mental health institution.
  ~~(2) Change in~~ **(B)** The president of the governing board.
  ~~(3) Change in~~ **(C)** The chief executive officer of the private mental health institution.
~~(4)~~ **(2) An** unannounced accreditation ~~surveys.~~ **survey.**
~~(5)~~ **(3)** The initiation of bankruptcy proceedings.
~~(6)~~ **(4) An** adverse action against the ~~entity~~ **facility** as the result of ~~the~~ **a** violation of:
  (A) health;
  (B) building;
  (C) fire; or
  (D) safety;

codes as prescribed by federal, state, or local law.

~~(7)~~ **(5) A** 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)

SECTION 14. 440 IAC 1.5-2-6 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-2-6 Conditional licensing

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

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

(b) The division may change the ~~licensure~~ **licensing** status of a private mental health institution to that of **a** conditional ~~licensure~~ **license** 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 **do any of the following:**
(1) Require that the facility stop all new admissions.
(2) Grant an extension of the conditional ~~licensure;~~ **license.**
(3) Reinstate the regular license of the private mental health institution if the ~~division~~ **division's** requirements are met within the imposed deadline. ~~or~~
(4) Take action to suspend or revoke the ~~entity's licensure~~ **facility's license** as a private mental health institution if the ~~division~~ **division's** requirements are not met within the imposed deadline.

(d) The division shall ~~notify~~ **give written notice to** the chief executive officer of the private mental health institution of ~~the~~ **any** change in **the facility's** certification status. ~~in writing.~~ The notice shall include the following:
(1) The:
  (A) standards not met; and ~~the~~
  (B) 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;~~ **license;** however, a conditional ~~licensure~~ **license** plus any extensions **thereof** may not exceed **a total period of** twelve (12) months.

(f) Extension requirements shall include the following:
(1) If the division grants an extension of a conditional ~~licensure,~~ **license,** 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:
(i) standards not met; and ~~the~~
(ii) actions the private mental health institution must take to meet those standards.
(C) **The** 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)

SECTION 15. 440 IAC 1.5-2-7 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-2-7 Revocation of a license

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

Sec. 7. (a) The division may revoke ~~the licensure~~ **a license** 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 **facility's** 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 **either** the:
(A) health **or** safety **of consumers;** or
(B) continuity of services to consumers.
~~(6) The private mental health institution or its corporate owner files for bankruptcy.~~

(b) **In order** to revoke a license, the director shall follow the requirements in IC 12-25-2.

(c) If the division revokes an entity's ~~licensure~~ **license** as a private mental health institution, the entity may not **do the following:**
(1) Continue to operate.
~~(d) If the division revokes an entity's licensure as a private mental health institution, the entity may not~~ **(2)** 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)

SECTION 16. 440 IAC 1.5-2-8 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-2-8 Appeal rights

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2; IC 12-25-1-4
Affected: IC 4-21.5-3; IC 12-25-3-1

Sec. 8. A private mental health institution **licensee or applicant** that is aggrieved by any adverse action taken under this rule may ~~appeal the action under IC 12-25-3.~~ **do either of the following:**

(1) Appeal the action under IC 12-25-3-1.

(2) Seek administrative review under IC 4-21.5-3.

(Division of Mental Health and Addiction; 440 IAC 1.5-2-8; filed Oct 11, 2002, 11:26 a.m.: 26 IR 737)

SECTION 17. 440 IAC 1.5-3-1 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-3-1 Governing board

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2; IC 12-25-1-4
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:
(1) make policy; and ~~to~~
(2) assure the effective implementation of the policy.

(c) The duties of the governing board include the following:
(1) ~~Meet~~ **Meeting** on a regular basis.
(2) ~~Employ~~ **Employing** 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~~ **Delineating** in writing the responsibility and authority of the chief executive officer.
(4) ~~Ensure that~~ **Ensuring the following:**
(A) All workers, including contract and agency personnel, for whom a license, registration, or certification is required, maintain **their** current license, registration, or certification. ~~and keep documentation of same so that it can be made available within a reasonable period of time.~~
(B) The facility retains the documentation of the same.
(C) The documentation is available within a reasonable period of time.
~~(5) Ensure that~~ **(D)** Orientation and training programs are provided to all employees, and ~~that~~ each employee has a periodic performance evaluation, ~~that~~ **which** includes **the following:**
(i) A competency evaluation. ~~and~~
(ii) An individualized education plan.
~~(6) Evaluate~~ **(5) Evaluating** the performance of the chief executive officer. ~~Evaluations~~ **An evaluation** must be conducted **at least** every other year. ~~at a minimum.~~
~~(7) Establish~~ **(6) Establishing** and ~~enforce~~ **enforcing** prudent business and fiscal policies for the private mental health institution.
~~(8) Develop~~ **(7) Developing** and ~~enforce~~ **enforcing** written policies governing private mental health institution operations.
~~(9) Develop~~ **(8) Developing** and ~~implement~~ **implementing** an ongoing strategic plan that:
(A) identifies the priorities of the governing board; and
(B) considers community input and consumer assessment of programs and services offered.
~~(10) Assure~~ **(9) Assuring** that minutes of all meetings:
(A) are maintained; and
(B) accurately reflect the actions taken.
~~(11) Conduct~~ **(10) Conducting** an annual assessment that includes the following:
(A) A review of the business practices of the private mental health institution to ensure ~~that:~~ **the following:**
(i) Appropriate risk management procedures are in place.
(ii) Prudent financial practices ~~occur; and~~ **are used.**
(iii) Professional practices are maintained in regard to **the following:**
(AA) Information systems.
(BB) Accounts receivable. ~~and~~
(CC) 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~~ **shall assess** whether the programs are:
(i) well-utilized;
(ii) cost-effective; and
(iii) 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~~ **recommendations** of the medical or professional staff, and in accordance with state law, ~~which~~ **determine the** categories of practitioners **who** are eligible candidates for appointment to the medical or professional staff.
(2) Ensure ~~that:~~ **the following:**
(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~~ **The above processes are accomplished** within a reasonable period of time, as specified by the medical or professional staff bylaws.
~~(3) Ensure that~~ **(E)** The medical or professional staff has approved bylaws and rules, ~~and that the bylaws and rules~~ **which** are reviewed and approved at least triennially. **The** governing board **shall not unreasonably withhold** approval of medical or professional staff bylaws and rules. ~~shall not be unreasonably withheld.~~
~~(4) Ensure that~~ **(F)** The medical or professional staff is accountable and responsible to the governing board for the quality of care provided to consumers.
~~(5) Ensure that~~ **(G) The** criteria for **the** selection ~~for~~ **of the** medical ~~or~~ **and** professional staff ~~membership are~~ **members include** individual:
(i) character;
(ii) competence;
(iii) education;
(iv) training;
(v) experience; and
(vi) judgment.
~~(6) Ensure that~~ **(H)** 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)

SECTION 18. 440 IAC 1.5-3-2 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
Affected: IC 12-25

Sec. 2. (a) ~~There~~ **A facility** shall ~~be~~ **have** a single organized medical or professional staff that has the overall responsibility for **the following:**
(1) The quality of all clinical care provided to consumers. ~~and for~~
(2) The professional practices of its members. ~~as well as for~~
(3) 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~~ **a determination** can ~~satisfactorily~~ be ~~determined~~ **made** that ~~the~~ **an** individual is:
(1) appropriately:
(A) licensed;
(B) certified;

(C) registered; or
(D) experienced; and ~~is~~
(2) qualified for **the** privileges and responsibilities sought.

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

(d) The facility shall:
(1) provide clinical supervision when required or indicated; **and**
~~(e) There shall be~~ **(2) have** a physician on call twenty-four (24) hours a day.

~~(f)~~ **(e)** The private mental health institution shall have on staff a medical services director who **meets the following criteria:**
(1) **The medical services director** has responsibility for the oversight and provision of all medical services. ~~and~~
(2) **The medical services director** 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)

SECTION 19. 440 IAC 1.5-3-3 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
Affected: IC 12-25

Sec. 3. (a) The facility shall establish a planned, systematic, **and** 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~~ **is** sustained, and ~~reduce~~ **reduces** the risk of sentinel events.

(b) The process analyzes and makes necessary improvements to the following:
(1) All services, including ~~service by~~ **the services of any** 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 **shall ensure the following:**
(1) The action shall be documented. ~~and~~
(2) The outcome of the action shall be documented as to ~~its~~ **the action's** effectiveness, continued follow-up, and **the** 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)

SECTION 20. 440 IAC 1.5-3-4 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-3-4 Dietetic services

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2; IC 12-25-1-4
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 **staff:**
(1) A full-time employee who **shall perform the following duties:**
(A) ~~serves~~ **Serve** as **the** director of ~~the~~ food and dietetic services. ~~and~~
(B) ~~is~~ **Be** 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~~ **the consultant** shall **perform the following tasks:**
(A) Submit periodic written reports on the dietary services provided.
(B) Provide the number of on-site dietitian hours commensurate with the **following:**
(i) **The** type of dietary supervision required.
(ii) Bed capacity. ~~and~~
(iii) **The** 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~~ **the functions** of other consumer care personnel ~~that include,~~ **including,** but ~~are~~ not limited to, the following **functions:**
(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 **the following:**
(A) Recognized dietary standards of practice. ~~and in accordance with~~
(B) 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)

SECTION 21. 440 IAC 1.5-3-5 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-3-5 Infection control

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

Sec. 5. (a) The facility shall provide a safe and healthful environment that minimizes infection exposure and risk to: ~~consumer~~
(1) consumers;
(2) health care workers; and
(3) visitors.

This is completed in a coordinated process that recognizes the risk of ~~the~~ endemic and epidemic nosocomial infections.

(b) ~~There~~ **The facility** shall ~~be an active, effective~~ **have a** written **policy for a** facility wide infection control program. ~~Included in~~ The program shall:

(1) be **active and effective; and**

(2) include a system designed for the:

(A) identification;

(B) surveillance;

(C) investigation;

(D) control;

(E) reporting of information, **both** internally and to health agencies; and

(F) prevention;

of infection and communicable diseases in ~~the consumer~~ **consumers** and health care ~~worker.~~ **workers.**

(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~~ **shall involve** 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:

(1) ongoing infection control activities; and ~~the~~

(2) 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 following:**

(1) The individual responsible for the infection control program.

(2) A member of the medical or professional staff.

(3) A representative from **the** nursing staff. ~~and~~

(4) Other appropriate individuals as needed.

The committee will meet quarterly, and minutes of meeting will be taken **and retained.**

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

(1) Writing policies and procedures in regard to **the following:**

(A) Sanitation.

(B) Universal precautions.

(C) Cleaning.

(D) Disinfection.

(E) Aseptic technique.

(F) Linen management.

(G) Employee health.

(H) Personal hygiene. ~~and~~

(I) Attire.

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

(3) Providing information regarding infection control for the following:

(A) Plans for renovation and new construction to ensure awareness of federal, state, and local rules that affect infection control practices.

(B) Plans for appropriate protection of consumers and employees during construction or renovation.

(h) Facility management shall:

(1) be responsible to assure implementation and corrective actions as necessary to ensure that infection control policies are followed; **and**

~~(i) Management shall~~ **(2)** provide **input concerning** 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)

SECTION 22. 440 IAC 1.5-3-6 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
Affected: IC 12-25

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

(b) The services must be directed by:
(1) a registered health information administrator (RHIA); or
(2) 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) **A** face sheet (identification data).
(2) Referral information.
(3) **A** database (assessment information).
(4) **An** individual treatment plan.
(5) History and physical exams.
(6) ~~Physician's or~~ **Orders of a physician,** licensed mental health ~~professional's orders.~~ **professional, and LIP.**
(7) Medication and treatment record.
(8) Progress notes.
(9) Treatment plan reviews.
(10) Special dietetic information.
(11) Consultation reports.
(12) Correspondence.
(13) Legal **or** commitment ~~papers.~~ **documents.**
(14) **A** discharge **or** separation summary.
(15) Release **or** 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) **The** 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:
(1) if they have been approved by the medical or professional staff; and ~~only~~
(2) when ~~there is~~ an explanatory legend ~~and~~ **is provided.**
Symbols and abbreviations shall not be used in the recording of a diagnosis.

(h) The facility shall be responsible ~~to~~ **for the following:**
(1) ~~maintain,~~ **Maintenance,** control, and ~~supervise~~ **supervision of** consumer records. ~~and~~
(2) ~~maintain~~ **Maintaining the** quality **of medical record services.**

(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:
(1) govern the:
(A) compilation;
(B) storage;
(C) dissemination; and
(D) accessibility;
of consumer records; and
(2) be so designed as to assure that the facility fulfills its responsibility to protect the records against:
(A) loss;
(B) unauthorized alteration; or
(C) 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:
(1) protect the confidentiality of consumer records; and
(2) govern the disclosure of information in the records.
The ~~record~~ **records** 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:
(1) maintained by the facility for a period of seven (7) years; ~~must be~~
(2) readily accessible, in accordance with the facility policy; and ~~must be~~
(3) 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)

SECTION 23. 440 IAC 1.5-3-7 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-3-7 Nursing service

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2; IC 12-25-1-4
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 **following** authority and responsibility: ~~to~~
(1) The nursing executive shall ensure that the:
(A) nursing standards of consumer care; and
(B) standards of nursing practice;
are consistent with professional standards.
(2) The nursing executive or designee shall approve all:
(A) nursing policies;
(B) procedures;
(C) nursing standards of consumer care; and
(D) standards of nursing practice.
(3) The nurse executive is also responsible for **the following:**

(A) Determining **the** number and type of nursing personnel needed. ~~as well as~~

(B) Maintaining a nursing organizational chart and job description for all positions.

(4) 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 **throughout the organization.**

(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:~~ **including the following:**

(1) Monitoring ~~of~~ each consumer's status. ~~and coordinates~~

(2) Coordinating the provision of nursing care. ~~while~~

(3) Assisting other professional **staff in** implementing ~~their~~ **the** plans of care **for consumers.**

(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 **the following:**

(A) Assessing consumer nursing needs.

(B) Planning and providing nursing care interventions.

(C) Preventing complications.

(D) Providing and improving ~~on~~ consumer comfort and wellness.

(2) ~~The service shall have~~ A procedure to ensure that ~~private mental health institution~~ **the facility's** nursing personnel, including nurse registry personnel for whom ~~licensure~~ **a license** is required, have valid and current ~~licensure.~~ **licenses.**

(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)

SECTION 24. 440 IAC 1.5-3-8 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
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:~~ **meet the following requirements:**

(A) **Be** staffed to meet the scope of the services provided. ~~and~~

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

(2) ~~There~~ **The facility** shall ~~be~~ **have** a **designated** safety officer ~~designated~~ to assume responsibility for the safety program.

(3) The facility shall ~~provide~~ **have** a physical plant and equipment that ~~meets~~ **meet** 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:

(A) insects;

(B) rodents; or

(C) other vermin.

(2) No condition shall be created or maintained ~~which~~ **that** may result in a hazard to:
(A) consumers; ~~public, or~~
(B) employees; **or**
(C) the public.
(3) ~~There~~ **The facility** shall ~~be~~ **have** 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:
(i) established; ~~and~~
(ii) retained;
(iii) analyzed periodically; ~~These records shall be~~ **and**
(iv) readily available on the premises.
(C) Maintenance and repairs shall be carried out in accordance with applicable codes, rules, standards, and requirements of:
(i) local jurisdictions;
(ii) the ~~administrative building council, the state fire marshal,~~ **fire prevention and building safety commission;** and
(iii) the Indiana state department of health.
(5) The food service of the private mental health institution shall comply with ~~410 IAC 7-20.~~ **the administrative rules of the Indiana state department of health contained in 410 IAC 7-24.**

(c) ~~In new construction, renovations, and additions, the facilities~~ **A facility** shall ~~meet~~ **comply with** the following **provisions regarding new construction, a renovation, or an addition to the facility:**
(1) The **standards contained in the** 2001 edition of the national "Guideline for Construction and Equipment of Private Mental Health Institution and Medical Facilities" (Guidelines) **shall apply to all facilities covered by this rule, except as provided in subdivision (2).**
(2) ~~All building, fire safety, and handicapped accessibility~~ Codes and rules adopted by the fire prevention and building safety commission **that pertain to building requirements, fire safety, and access for individuals with disabilities** shall:
(A) apply to all facilities covered by this rule; and
(B) take precedence over ~~any building, fire safety, or handicapped accessibility~~ **the** requirements of the Guidelines **on those topics.**
(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:
(A) be located away from detrimental nuisances;
(B) be well drained; and
(C) not **be** subject to flooding.
A site survey and recommendations shall be obtained from the **Indiana state** 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 **per day** 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 **potable** 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,~~ **include at least** the following:
(A) **A** functional program narrative as ~~established~~ **required** in the Guidelines.
(B) Schematics, based upon the functional program, **and** 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~~ **Before beginning a** construction, addition, ~~and/or~~ **or** renovation ~~projects, detailed architectural and operational plans for construction~~ **project, the facility** shall ~~be submitted to the plan review division of the department of~~ **submit all documentation required under the rules of the** fire **prevention** and

building ~~services and~~ **safety commission** to the division of ~~sanitary engineering of the Indiana state~~ **fire and building safety, plan review section of the** department of ~~health as follows:~~ **homeland security, including the following documentation:**

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

(B) Prior to **the** 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.~~ **under section 5(g)(3) of this rule.**

(C) All required construction design releases shall be obtained from the ~~state~~ **division of fire and** building ~~commissioner and final approval from the division~~ **safety, plan review section,** of ~~sanitary engineering of~~ the ~~Indiana state~~ department of ~~health prior to issuance of the occupancy letter by the division.~~ **homeland security.**

(9) Before the division's issuance of a letter of occupancy, the facility shall provide the division with any final approval required from the division of sanitary engineering of the Indiana state department of health.

~~(9)~~ **(10)** All backflow 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)~~ **(11)** Upon receipt of a construction design release from the ~~state~~ **division of fire and** building ~~commissioner~~ **safety, plan review section of the department of homeland security** and documentation of a completed plan review by the division of sanitary engineering of the Indiana state department of health, ~~a licensure application~~ **an entity, which is not yet licensed by the division under this article,** shall ~~be submitted~~ **submit a license application** to the division on ~~the~~ **a** form approved and provided by the division.

(d) The equipment requirements are as follows:

(1) All equipment shall be:

(A) in good working order; and

(B) regularly serviced and maintained.

(2) ~~There~~ **The facility** shall ~~be~~ **have** 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~~ **The facility** shall ~~be~~ **retain the following:**

(i) Evidence of preventive maintenance on all equipment.

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

(3) Defibrillators shall be discharged at ~~least~~ **a minimum** 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 **the** transmission of disease to consumers, health care workers, the public, and visitors by using the current principles of **the following:**

(A) Asepsis.

(B) Cross infection. ~~and~~

(C) Safe practice.

(2) Refuse and garbage shall be:

(A) collected;

(B) transported;

(C) sorted; and

(D) 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:

(A) administration;

(B) consumer services; and

(C) 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 **complies with the provisions of the Indiana Fire Code and** contains provisions for the following:
~~(i) Prompt reporting of fires, as required under the provisions of the Indiana Fire Code.~~
~~(ii)~~ **(i) The** extinguishing of fires.
~~(iii)~~ **(ii)** Protection of consumers, personnel, and guests.
~~(iv)~~ **(iii)** Evacuation.
~~(v)~~ **(iv)** Cooperation with firefighting authorities.
(F) Maintenance of written evidence of regular inspection and approval by state or local fire ~~control agencies.~~ **inspection authorities.**
(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)

SECTION 25. 440 IAC 1.5-3-9 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
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~~ **a** consumer shall be appropriate to the facility and the professional expertise of the staff.

(c) **A consumer may be admitted if** alternatives for less intensive and restrictive treatment are not available in the community.

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

(e) An initial:
(1) emotional;
(2) behavioral;
(3) social; and
(4) legal;
assessment of each consumer shall be completed upon admission.

(f) ~~When~~ **If** the **consumer being** admitted ~~consumer~~ is ~~a child or adolescent under~~ **less than** eighteen (18) years of age, then the initial assessment shall also include **the following:**
(1) An evaluation of school progress.
(2) A report of involvement with other social **or** legal services agencies. ~~and~~
(3) 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 **who is** fourteen (14) years of age ~~and under)~~ **or younger** may be admitted to a nonsegregated

unit, **that is, an** adult unit, only ~~under~~ **in** an emergency. ~~situation.~~ The **facility shall:**

(1) specify in advance the criteria for such an emergency admission; ~~must be specified in advance~~ and ~~must include plans for~~

(2) require an evaluation **of the child** by a child psychiatrist within sixty (60) hours of admission.

(h) **A facility shall do the following:**

(1) Verbally report to the division an admission under subsection (g) ~~shall be verbally reported to the division~~ within twenty-four (24) hours of the admission **as required under 440 IAC 1.5-2-2(e)(5).**

(2) Submit a written report ~~shall be submitted~~ to the division within ten (10) working days **as required under 440 IAC 1.5-2-2(f) in the form specified in 440 IAC 1.5-2-2(h).**

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

(j) ~~Consumers~~ **Each consumer** shall **be encouraged and allowed to** participate in the development and review of ~~their~~ **the consumer's** own treatment ~~plans.~~ **plan.** If the consumer:

(1) agrees to family participation; and

(2) 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~~ **A consumer's choice** not to participate in the **consumer's** treatment planning process ~~it~~ shall be documented in the clinical record.

(l) The treatment plan shall:

(1) specify the services necessary to meet the consumer's needs; and ~~shall~~

(2) 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:

(1) entered in an integrated chronological order in the record;

(2) signed; and

(3) dated.

(n) ~~At a minimum of every seven (7) days, the~~ **Each consumer's** treatment plan shall be:

(1) reviewed **at least every seven (7) days;** and

(2) 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)

SECTION 26. 440 IAC 1.5-3-11 IS AMENDED TO READ AS FOLLOWS:

440 IAC 1.5-3-11 Pharmacy services

Authority: IC 12-8-8-4; IC 12-21-2-3; IC 12-25-1-2; IC 12-25-1-4
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.~~ **facility.** The following requirements apply:

(1) The ~~organization~~ **facility** shall **do the following:**

(A) Identify an appropriate selection or formulary of medications available for prescribing or ordering.

~~(2) The private mental health institution shall~~ **(B)** Address **the** prescribing or ordering and ~~procuring~~ **the procurement** of medications not available within the formulary.

~~(3)~~ **(2)** Policies and procedures shall be in place to:

(A) support safe ~~medication~~ prescription ordering and storage; and

(B) address such issues as:

(i) pain management medication; and

(ii) PRN medications.

~~(4)~~ **(3)** The ~~preparation and dispensing of medication(s)~~ **facility** shall adhere to law, regulation, licensure, and professional standards of practice **regarding the preparation and dispensing of medication.**

~~(5)~~ **(4)** The preparation and dispensing of ~~medication(s) is~~ **medication shall be** appropriately controlled **as follows:**

(A) ~~There~~ **The facility** shall ~~be~~ **have** an individual patient dose system in place.

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

(C) ~~There shall be~~ A system **shall be** in place ~~for considering important~~ **to assure that** consumer medication information **is considered** when ~~a medication(s)~~ **medication** is prepared and dispensed for a consumer.

(D) ~~There~~ **The facility** shall ~~be~~ **have** a procedure in place for ~~pharmacy service~~ **the** availability **of pharmacy services** at any ~~times~~ **time** 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~~ **The facility** shall ~~be~~ **have** a medication recall system ~~providing~~ for the retrieval and safe disposal of:

(i) expired;

(ii) discontinued; and

(iii) recalled;

medications.

~~(6) There~~ **(5) The facility** shall ~~be~~ **have** a system in place to ~~insure~~ **ensure** that:

(A) prescriptions or orders are verified; and

(B) consumers are properly identified;

before any medication is administered or dispensed.

~~(7)~~ **(6)** Any investigational ~~medication(s)~~ **medication** shall be safely:

(A) controlled and administered during **any** experimental ~~trials,~~ **or investigational trial;** and ~~safely~~

(B) destroyed at the conclusion of any ~~such~~ **experimental or** investigational trial.

~~(8) There~~ **(7) A facility** shall ~~be~~ **have the following in place:**

(A) A written policy ~~in place~~ that assures the routine inspection of the storage of all medications.

~~(9) There shall be~~ **(B)** 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)

SECTION 27. 440 IAC 1.5-3-12 IS AMENDED TO READ AS FOLLOWS:

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; IC 12-25-1-4
Affected: IC 12-25; IC 16-36-1

Sec. 12. (a) ~~The facility~~ **A private mental health institution** shall have policies and a written plan in place that shall include clinical justification for **the use of** any of the following special procedures:

(1) ~~The use of~~ Restraint or seclusion or ~~both.~~ **the simultaneous use of restraint and seclusion.**

(2) ~~The use~~ Electro-convulsive therapy.

(3) ~~The use of~~ **An** investigational ~~and~~ **drug or an** experimental ~~drugs.~~ **drug.**

(b) The use of restraint or seclusion or the simultaneous use of restraint and seclusion shall be governed by the provisions of section 13 of this rule.

~~(b)~~ **(c)** If any procedure **listed** in ~~this section~~ **subsection (a)** is ~~utilized,~~ **used, the facility shall clearly state** the rationale for the use ~~shall be clearly stated~~ in the ~~consumer~~ **consumer's** 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~~ **(d) Prior to using** electro-convulsive therapy, ~~or~~ **an** investigational **drug,** or **an** experimental ~~drugs are used,~~ **drug, the facility shall obtain** the written informed consent ~~of~~ **for the use as follows:**

(1) From the consumer, ~~or legal guardian shall be obtained.~~ **if** the **consumer has the legal capacity to make such decision.**

(2) If the consumer does not have the legal capacity to make such decision, from either of the following:

(A) An individual appointed:

(i) by the consumer under IC 16-36-1-7; or

(ii) for the consumer under IC 16-36-1-8.

(B) An individual legally authorized to make such decision for the consumer under IC 16-36-1-5 if clause (A) does not apply.

(e) A consumer **with the legal capacity to make such decision** or ~~legal guardian~~ **an individual acting on behalf of the consumer under subsection (d)(2)** may withdraw consent at any time.

~~(r)~~ **(f)** The facility shall comply with all federal regulations regarding **the use of** any of the following special procedures:

(1) ~~The use of~~ Restraint or seclusion or ~~both.~~ **the simultaneous use of restraint and seclusion.**
(2) ~~The use~~ Electro-convulsive therapy.
(3) ~~The use of~~ **An** investigational ~~and~~ **drug or an** experimental ~~drugs.~~ **drug.**

(Division of Mental Health and Addiction; 440 IAC 1.5-3-12; filed Oct 11, 2002, 11:26 a.m.: 26 IR 744)

SECTION 28. 440 IAC 1.5-3-13 IS ADDED TO READ AS FOLLOWS:

440 IAC 1.5-3-13 Requirements and procedures for the use of restraint or seclusion

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

Sec. 13. The following provisions apply to the use of restraint or seclusion:
(1) A private mental health institution shall have a written plan and written policies in place that shall include the clinical justification for the:
(A) use of restraint or seclusion; or
(B) simultaneous use of both restraint and seclusion.
(2) A facility shall not use restraint or seclusion of any form imposed as a means of:
(A) coercion;
(B) discipline;
(C) convenience; or
(D) retaliation;
by staff. Restraint or seclusion may be imposed only to ensure the immediate physical safety of the consumer, a staff member, or others and must be discontinued at the earliest possible time.
(3) Restraint or seclusion may be used only when less restrictive interventions have been determined to be ineffective to protect the consumer, a staff member, or others from harm.
(4) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the consumer, a staff member, or others from harm.
(5) The use of restraint or seclusion must meet the following requirements:
(A) Be in accordance with a written modification to the consumer's plan of care.
(B) Be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by the facility's policy and in accordance with state law.
(6) The use of restraint or seclusion must be in accordance with the order of a physician or other LIP who is:
(A) responsible for the care of the consumer; and
(B) authorized to order restraint or seclusion by facility policy and in accordance with state law.
An order shall contain behavioral criteria for the consumer's release from restraint or seclusion.
(7) An order for the use of restraint or seclusion shall not be written:
(A) as a standing order; or
(B) on an as needed basis (PRN).
(8) The attending physician must be consulted as soon as possible after implementation of the restraint or seclusion if that physician did not order the restraint or seclusion.
(9) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the consumer, a staff member, or others may be renewed only in accordance with the following limits for up to a total of twenty-four (24) hours:
(A) Four (4) hours for adults eighteen (18) years of age or older.
(B) Two (2) hours for children and adolescents nine (9) to seventeen (17) years of age.
(C) One (1) hour for children under nine (9) years of age.
(10) After the twenty-four (24) hour period described in subdivision (9), and before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other LIP, who is:
(A) responsible for the care of the consumer; and
(B) authorized to order restraint or seclusion by facility policy and in accordance with state law;
must see and assess the consumer.
(11) Each order for restraint used to ensure the physical safety of a nonviolent or nonself-destructive consumer may be renewed as authorized by the facility's policy.
(12) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order. In particular, the use of restraint or seclusion shall be discontinued when the consumer meets the behavioral criteria specified in the order for restraint or seclusion.

(13) The condition of the consumer who is restrained or secluded must be monitored by a physician, other LIP, or trained staff that have completed the training criteria specified in subdivision (23) at an interval determined in accordance with the facility's policy.

(14) The facility's policy shall specify the training requirements, including the use of restraint or seclusion, for physicians and other LIPs. At a minimum, physicians and other LIPs authorized to order restraint or seclusion by facility policy in accordance with state law must have a working knowledge of the facility's policy regarding the use of restraint or seclusion.

(15) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the consumer, a staff member, or others, the consumer must be seen face-to-face within one (1) hour after the initiation of the intervention as follows:

(A) By either a:

(i) physician or other LIP; or

(ii) registered nurse or physician assistant who has been trained in accordance with the requirements specified in subdivision (23).

(B) For an evaluation of the following:

(i) The consumer's immediate situation.

(ii) The consumer's reaction to the intervention.

(iii) The consumer's medical and behavioral condition.

(iv) The need to continue or terminate the restraint or seclusion.

(16) By written policy, a facility may implement requirements that are more restrictive than the requirements contained in subdivision (15)(A).

(17) If the face-to-face evaluation specified in subdivision (15) is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other LIP who is responsible for the care of the consumer as soon as possible after the completion of the one (1) hour face-to-face evaluation.

(18) Staff must assess and monitor a consumer in restraint or seclusion in accordance with the following requirements:

(A) Except as provided in clause (C), a consumer placed in restraint or seclusion shall be assessed and monitored continuously through a face-to-face observation by an assigned, trained staff member who has been trained in accordance with the requirements of subdivision (23).

(B) If a staff member restrains a consumer by means of physically holding the consumer, another trained staff member shall assess and monitor the restraint continuously through a face-to-face observation.

(C) After the first hour, a consumer placed in seclusion or restraint may be monitored by trained staff using video and audio equipment. However, such monitoring must be in close proximity to the consumer.

(19) All requirements specified under this subdivision are applicable to the simultaneous use of restraint and seclusion. The use of simultaneous restraint and seclusion is permitted only if the consumer is continually monitored by either of the following:

(A) Face-to-face by an assigned, trained staff member.

(B) By trained staff using both video and audio equipment, provided, however, that such monitoring must be in close proximity to the consumer.

(20) The use of restraint or seclusion must be documented in accordance with the following requirements:

(A) When restraint or seclusion is used, the facility shall retain documentation in the consumer's medical record of the following:

(i) The one (1) hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of a consumer, a staff member, or others.

(ii) A description of the consumer's behavior and the intervention used.

(iii) Alternatives or other less restrictive interventions attempted (as applicable).

(iv) The consumer's condition, symptom, or symptoms that warranted the use of restraint or seclusion.

(v) The consumer's response to the intervention or interventions used, including the rationale for the continued use of the intervention.

(B) The consumer's response to the intervention or interventions used shall be documented every fifteen (15) minutes throughout the duration of the restraint or seclusion. The fifteen (15) minute monitoring must include the monitoring of the consumer's physical and psychological condition including, but not limited to:

(i) respiratory and circulatory status;

(ii) skin integrity;
(iii) vital signs; and
(iv) any additional special requirements specified in a facility's written policy for the face-to-face assessment;
within one (1) hour after the initiation of seclusion or restraint required in subdivision (15).

(21) After the termination of an incident of the:
(A) use of restraint or seclusion; or
(B) simultaneous use of restraint and seclusion;
facility staff and the consumer shall participate in debriefing about the intervention.

(22) A facility shall collect data regarding each incident of the facility's use of restraint or seclusion in order to monitor and to improve the facility's practices and procedures regarding the use of restraint or seclusion.

(23) Facility staff shall be trained in the safe implementation of restraint or seclusion in accordance with the following requirements:
(A) Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a consumer in restraint or seclusion at each of the following times:
(i) Before performing any of the actions specified in this section.
(ii) As part of orientation.
(iii) Subsequently on a periodic basis consistent with the facility's policy.
(B) The facility must require appropriate staff to have education and training in, and to demonstrate knowledge regarding, the specific needs of the consumer population in the facility in at least the following:
(i) Techniques to identify staff and consumer behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.
(ii) The use of nonphysical intervention skills.
(iii) Choosing the least restrictive intervention based on an individualized assessment of the consumer's medical or behavioral status or condition.
(iv) The safe application and use of all types of restraint or seclusion used in the facility, including training in how to recognize and respond to signs of physical and psychological distress, for example, positional asphyxia.
(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.
(vi) Monitoring the physical and psychological well-being of the consumer who is restrained or secluded, including, but not limited to, the following:
(AA) Respiratory and circulatory status.
(BB) Skin integrity.
(CC) Vital signs.
(DD) Any special requirements specified by facility policy associated with the one (1) hour face-to-face evaluation.
(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.
(C) Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address consumers' behaviors.
(D) The facility must document in staff personnel records that the training and the demonstration of competency were successfully completed.

(24) A private mental health institution shall report a death associated with the use of seclusion or restraint to the division in accordance with the following provisions:
(A) The facility shall make a verbal report to the division within twenty-four (24) hours of the facility's knowledge of the occurrence of any of the following:
(i) Each death that occurs while a consumer is in restraint or seclusion.
(ii) Each death that occurs within twenty-four (24) hours after a consumer has been removed from restraint or seclusion.
(iii) Each death known to the facility that occurs within one (1) week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a consumer's death. For purposes of this item, "reasonable to assume" includes, but is not limited to, deaths related to:
(AA) restrictions of movement for prolonged periods of time;
(BB) chest compression;
(CC) restriction of breathing; or
(DD) asphyxiation.

(B) In addition, a facility shall submit to the division a written report of any occurrence listed in clause (A) within ten (10) working days of the facility's knowledge of the occurrence.

(25) Staff shall document in the consumer's medical record the date and time when a consumer's death was reported to the division.

(26) A facility shall comply with all requirements of federal laws regarding the:

(A) use of restraint or seclusion; and

(B) simultaneous use of restraint and seclusion.

(Division of Mental Health and Addiction; 440 IAC 1.5-3-13)

Notice of Public Hearing

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