

**Final Rule**  
LSA Document #08-412(F)

**DIGEST**

Adds [440 IAC 10](#) to implement rules based on Senate Enrolled Act 157 (P.L.130-2007), including establishing definitions, establishing certification standards and procedures for opioid treatment facilities, establishing specific approval standards and procedures for opioid treatment programs, establishing operational standards for opioid treatment programs, and establishing standards of competent practice for opioid treatment programs. Effective 30 days after filing with the Publisher.

**[440 IAC 10](#)**

SECTION 1. [440 IAC 10](#) IS ADDED TO READ AS FOLLOWS:

**ARTICLE 10. MINIMUM STANDARDS FOR THE PROVISION OF SERVICES BY OPIOID TREATMENT FACILITIES AND PROGRAMS**

**Rule 1. Definitions**

**[440 IAC 10-1-1](#) Applicability**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 1. The definitions in this rule apply throughout this article.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-1](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-2](#) "Accreditation" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 2. "Accreditation" means that an accreditation body has granted approval to an entity to provide specific services after the entity has met specific requirements of the accreditation body.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-2](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-3](#) "Accreditation body" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 3. "Accreditation body" means a body that has been approved by both the division and the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration under 42 CFR §8.3.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-3](#); filed Dec 30, 2009, 2:00 p.m.:  
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**[440 IAC 10-1-4](#) "Addiction credential" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 4. "Addiction credential" means a credential approved by the division from a nationally recognized credentialing body approved by the division.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-4](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-5](#) "Addiction treatment facility" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 5. "Addiction treatment facility" means a facility:**

- (1) certified by the division as an adjunct to an opioid treatment facility; and**
- (2) where an OTP shall:**
  - (A) not administer opioid treatment medication; and**
  - (B) provide:**
    - (i) nonmedical services; and**
    - (ii) recovery services.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-5](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-6](#) "Addiction treatment services" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 6. "Addiction treatment services" means a broad range of planned and continuing care, treatment, rehabilitation, and recovery, including, but not limited to, counseling, psychological, medical, and social services, designed to influence the behavior of an individual who abuses alcohol or drugs based on an individual treatment plan.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-6](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-7](#) "Administration of a drug" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 7. "Administration of a drug" means the direct application of a drug to the body of a person.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-7](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-8](#) "Assessment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 8. "Assessment" means procedures by which a counselor and other clinical staff identify and evaluate an individual patient's:**

- (1) strengths;
- (2) weaknesses;
- (3) problems; and
- (4) needs;

in the development and review of the individualized treatment plan that guides treatment.

(Division of Mental Health and Addiction; [440 IAC 10-1-8](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### **[440 IAC 10-1-9](#) "Authorized health care professional" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 9. "Authorized health care professional" means a physician assistant, a nurse practitioner, or a clinical nurse specialist performing duties within the scope of the individual's license and under the supervision of, or under a supervisory agreement with, a licensed physician.**

(Division of Mental Health and Addiction; [440 IAC 10-1-9](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### **[440 IAC 10-1-10](#) "Biopsychosocial history" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 10. "Biopsychosocial history" means information from a patient in areas of physical, psychological, and social health and well-being used to assist in the development of an individualized treatment plan.**

(Division of Mental Health and Addiction; [440 IAC 10-1-10](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### **[440 IAC 10-1-11](#) "Case management" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 11. "Case management" means the management of patient activities identified in the individualized treatment plan that assist in patient goal attainment, including referrals to other service providers, such as mental health, physical health, housing, education, vocational rehabilitation and other employment services providers, and linking patients to recovery support groups.**

(Division of Mental Health and Addiction; [440 IAC 10-1-11](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### **[440 IAC 10-1-12](#) "Central registry" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-5.6](#)

**Sec. 12. "Central registry" means the registry created under [IC 12-23-18-5.6](#).**

(Division of Mental Health and Addiction; [440 IAC 10-1-12](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-13](#) "Certification" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 13. "Certification" means the process used by the division to document an entity's compliance with the statutory and regulatory requirements for operating as a provider of services, including the issuance of a certificate if the entity is found to comply with this article.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-13](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-14](#) "Clinical assessment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 14. "Clinical assessment" means an assessment of the effectiveness, safety, and proper dosing of a patient's opioid treatment medication.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-14](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-15](#) "Counseling" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 15. "Counseling" means the utilization of skills to assist individuals, families, or groups to achieve objectives through the following:**

- (1) The exploration of a problem and its ramifications.**
- (2) The examination of attitudes and feelings.**
- (3) The consideration of alternative solutions.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-15](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-16](#) "Detoxification treatment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 16. "Detoxification treatment" means the administering of an opioid treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-16](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-17](#) "Division" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-7-2-69](#); [IC 12-23-18](#)

**Sec. 17. "Division" means the Indiana family and social services administration, division of mental**

**health and addiction.**

(Division of Mental Health and Addiction; [440 IAC 10-1-17](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-18](#) "Educational services" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 18. "Educational services" means services providing information to patients, their families, and other groups concerning topics, including the treatment of opioid addiction, relevant to:**

- (1) OTP patients;**
- (2) their families;**
- (3) significant others; and**
- (4) the community.**

(Division of Mental Health and Addiction; [440 IAC 10-1-18](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-19](#) "Employee" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 19. "Employee" means an individual hired by an OTP to work for either of the following:**

- (1) Wages or salary.**
- (2) Pursuant to a contract.**

(Division of Mental Health and Addiction; [440 IAC 10-1-19](#); filed Dec 30, 2009, 2:00 p.m.:  
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**[440 IAC 10-1-20](#) "Entity" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 20. "Entity" means:**

- (1) an individual;**
- (2) a firm;**
- (3) a corporation;**
- (4) a partnership;**
- (5) an association;**
- (6) a foundation;**
- (7) a governmental unit;**
- (8) a private agency; or**
- (9) a public agency.**

(Division of Mental Health and Addiction; [440 IAC 10-1-20](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-21](#) "Facility" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 21. "Facility" means the physical structure, or a subdivision thereof, and the location of the physical structure, or a subdivision thereof, in which opioid treatment services are provided.**

(Division of Mental Health and Addiction; [440 IAC 10-1-21](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

**[440 IAC 10-1-22](#) "Full-time equivalent" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 22. "Full-time equivalent" means an employee or contracted employee working forty (40) hours per week.**

(Division of Mental Health and Addiction; [440 IAC 10-1-22](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

**[440 IAC 10-1-23](#) "Fund" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-4](#)

**Sec. 23. "Fund" means the opioid treatment program fund established under [IC 12-23-18-4\(b\)](#).**

(Division of Mental Health and Addiction; [440 IAC 10-1-23](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

**[440 IAC 10-1-24](#) "Incident reporting" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 24. "Incident reporting" means an OTP's reporting to the division of an event specified in [440 IAC 10-4-35](#).**

(Division of Mental Health and Addiction; [440 IAC 10-1-24](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

**[440 IAC 10-1-25](#) "Induction" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 25. "Induction" means the introduction of the initial dose of opioid treatment medication.**

(Division of Mental Health and Addiction; [440 IAC 10-1-25](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

**[440 IAC 10-1-26](#) "Legitimate treatment use" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 26. "Legitimate treatment use" means the use of opioid treatment medication as ordered by a physician.**

(Division of Mental Health and Addiction; [440 IAC 10-1-26](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-27](#) "Maintenance treatment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 27. "Maintenance treatment" means the administering of an opioid treatment medication at stable dosage levels for a period in excess of twenty-one (21) days in the treatment of an individual for opioid addiction.**

(Division of Mental Health and Addiction; [440 IAC 10-1-27](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-28](#) "Opiate drug" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 28. "Opiate drug" refers only to natural opium alkaloids, for example, morphine and codeine, and the semisynthetic drugs derived therefrom, such as heroin, that is, diacetylmorphine.**

(Division of Mental Health and Addiction; [440 IAC 10-1-28](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-29](#) "Opioid addiction treatment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 29. "Opioid addiction treatment" means a comprehensive range of medical and recovery services, as clinically indicated, for an individual to alleviate the adverse medical, psychological, or physical effects incident to opioid addiction. The term encompasses the following:**

- (1) Detoxification treatment.
- (2) Short-term detoxification treatment.
- (3) Long-term detoxification treatment.
- (4) Maintenance treatment.

(Division of Mental Health and Addiction; [440 IAC 10-1-29](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-30](#) "Opioid drug" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 30. "Opioid drug" means a natural or synthetic drug that has the following:**

- (1) A similar mechanism of action and effects to opium alkaloids, such as morphine and codeine, and to the semisynthetic drugs derived from them, such as heroin.
- (2) A similar addiction-forming or addiction-sustaining liability.

(Division of Mental Health and Addiction; [440 IAC 10-1-30](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-31](#) "Opioid treatment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 31. "Opioid treatment" means the administering of opioid treatment medication, along with a comprehensive range of medical and recovery services, as clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opioid addiction.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-31](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-32](#) "Opioid treatment facility" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 32. "Opioid treatment facility" means the building and the location at which an OTP provides the following services:**

- (1) The administering of an opioid treatment medication.**
- (2) A comprehensive range of medical and recovery services to alleviate the adverse medical, psychological, or physical effects incident to opioid addiction.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-32](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-33](#) "Opioid treatment medication" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 33. "Opioid treatment medication" means any opioid treatment medication approved by the Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355) for use in the treatment of opioid addiction.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-33](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-34](#) "Opioid treatment program" or "OTP" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-7-2-135.6](#); [IC 12-23-18](#)

**Sec. 34. "Opioid treatment program" or "OTP" means a program as follows:**

- (1) Through which opioid treatment medication is administered to an individual in the treatment of opioid addiction.**
- (2) For which certification is required under 42 CFR Part 8.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-34](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-35](#) "Opioid treatment services" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)



**Sec. 35. "Opioid treatment services" means any and all services provided by an OTP, including, but not limited to, the following:**

- (1) Medical services.**
- (2) Educational services.**
- (3) Counseling services.**
- (4) Treatment planning.**
- (5) Treatment plan review.**
- (6) Referral services for any service not provided by the OTP.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-35](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-36](#) "Orientation" defined**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#)

**Sec. 36. "Orientation" means a structured session provided to a patient enrolling in an OTP including the following:**

- (1) Information on the following:**
  - (A) Services provided by the OTP.**
  - (B) Patient rights and responsibilities.**
- (2) The provision of written materials on relevant topics.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-36](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-37](#) "Outcome measures" defined**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#)

**Sec. 37. "Outcome measures" means measures that indicate the effect of treatment upon an individual receiving treatment in an OTP.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-37](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-38](#) "Patient" defined**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#)

**Sec. 38. "Patient" means an individual who has received or is receiving treatment from an OTP in Indiana.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-38](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-39](#) "Patient record" defined**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#)

**Sec. 39. "Patient record" means a compilation of all documents and information, including recorded, written, and electronic formats that pertain to a patient's care in an OTP.**

(Division of Mental Health and Addiction; [440 IAC 10-1-39](#); filed Dec 30, 2009, 2:00 p.m.:  
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**[440 IAC 10-1-40](#) "Physical evaluation" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 40. "Physical evaluation" means an evaluation carried out by an OTP physician to determine an applicant's eligibility for admission to an OTP.**

(Division of Mental Health and Addiction; [440 IAC 10-1-40](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-41](#) "Physical examination" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 41. "Physical examination" means a full medical examination, including laboratory analyses.**

(Division of Mental Health and Addiction; [440 IAC 10-1-41](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-42](#) "Program sponsor" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 42. "Program sponsor" has the meaning provided in 42 CFR §8.2.**

(Division of Mental Health and Addiction; [440 IAC 10-1-42](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-43](#) "Recovery indicators" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 43. "Recovery indicators" means information regarding an OTP patient's response to treatment as collected in the central registry and used in legislatively mandated reports.**

(Division of Mental Health and Addiction; [440 IAC 10-1-43](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-44](#) "Recovery services" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 44. "Recovery services" means, for purposes of [440 IAC 10-3](#), nonmedical services provided by an OTP and specifically excluding the administration of opioid treatment medication.**

(Division of Mental Health and Addiction; [440 IAC 10-1-44](#); filed Dec 30, 2009, 2:00 p.m.:  
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**[440 IAC 10-1-45](#) "Recovery support services" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 45. "Recovery support services" means supportive services provided in the community by formal and informal organizations and resources designed to assist patients, their family members, and significant others to initiate and sustain the patient's recovery.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-45](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-46](#) "Referral" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 46. "Referral" means the process of assisting a patient to find and use resources that:**

- (1) meet the patient's needs for services; and**
- (2) are not provided directly by an OTP.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-46](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-47](#) "Regular attendance" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 47. "Regular attendance" means the attendance requirements set forth in the following:**

- (1) An agreement between an OTP and a patient of the OTP.**
- (2) A patient's individualized treatment plan.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-47](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-48](#) "Safe storage capacity" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 48. "Safe storage capacity" means a portable, lockable container:**

- (1) for storing an OTP patient's self-administered medication; and**
- (2) designed to reduce the risk of accidental ingestion of a patient's self-administered medication.**

*(Division of Mental Health and Addiction; [440 IAC 10-1-48](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-1-49](#) "Self-administration" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 49. "Self-administration" means the direct application of a drug to the body of a patient by the patient and also referred to as unsupervised doses or take-home medications.**

(Division of Mental Health and Addiction; [440 IAC 10-1-49](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-50](#) "Serious behavior problems" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 50. "Serious behavior problems" means either of the following:

(1) Problems indicating that a patient is failing to benefit from opioid addiction treatment.

(2) Problems that would interfere with other patients' treatment or staff safety, including, but not limited to, the following:

(A) Physical fighting on the program premises.

(B) Aggression toward other patients or staff.

(C) The repeated use of nonprescribed drugs or alcohol on the program premises and failure to comply with the patient's treatment plan.

(D) Verbal or physical threats to staff or other patients.

(E) Falsifying information to program staff.

(F) Bringing a firearm onto the premises of an OTP.

(G) Criminal behavior, including, but not limited to, attempts to complete or the completion of a sale of illicit drugs.

(H) The diversion of opioid treatment medication from therapeutic use.

(Division of Mental Health and Addiction; [440 IAC 10-1-50](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-51](#) "Short-term detoxification treatment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 51. "Short-term detoxification treatment" means detoxification treatment for a period not exceeding thirty (30) days.

(Division of Mental Health and Addiction; [440 IAC 10-1-51](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-52](#) "Specific approval" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-0.5](#)

Sec. 52. "Specific approval" means the division's approval of an OTP under [IC 12-23-18-0.5](#) and [440 IAC 10-4](#).

(Division of Mental Health and Addiction; [440 IAC 10-1-52](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-53](#) "Stable home environment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 53. "Stable home environment" means a criterion based on a judgment made by OTP clinical staff on the basis of knowledge of a patient's lifestyle at admission and the patient's movement toward

**increased stability in living arrangements and health-promoting social relationships.**

(Division of Mental Health and Addiction; [440 IAC 10-1-53](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-54](#) "State authority" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 54. "State authority" means the government agency designated by the governor, or other appropriate official designated by the governor, to exercise the responsibility and authority within the state for governing the treatment of opioid addiction with an opioid drug.**

(Division of Mental Health and Addiction; [440 IAC 10-1-54](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-55](#) "Substance abuse assessment" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 55. "Substance abuse assessment" means an assessment using a standardized tool that meets the following requirements:**

- (1) Has proven reliable and valid in measuring an individual's severity of substance use disorder.**
- (2) Assists a clinician in:**
  - (A) identifying treatment needs; and**
  - (B) developing an individualized treatment plan.**

(Division of Mental Health and Addiction; [440 IAC 10-1-55](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-56](#) "Tapering" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 56. "Tapering" means a directed reduction of medication dosage over time with the goal of reducing the dosage or eliminating the dosage as clinically determined based on the:**

- (1) known pharmacology of the medication; and**
- (2) clinical responsiveness of the patient.**

(Division of Mental Health and Addiction; [440 IAC 10-1-56](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**[440 IAC 10-1-57](#) "Titration" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)  
Affected: [IC 12-23-18](#)

**Sec. 57. "Titration" means the induction of opioid treatment medication in which initial low doses are used to test patient tolerance with the goal of achieving the correct dosage as clinically determined on an individualized basis given the:**

- (1) known pharmacology of the medication; and**
- (2) clinical responsiveness of the patient.**

(Division of Mental Health and Addiction; [440 IAC 10-1-57](#); filed Dec 30, 2009, 2:00 p.m.):

**[440 IAC 10-1-58](#) "Treatment planning" defined**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 58. "Treatment planning" means the process by which a counselor or clinical staff and a patient do the following:

- (1) Identify and rank problems needing resolution.
- (2) Establish agreed-upon individualized immediate and longer term treatment goals.
- (3) Decide upon a treatment process and the resources to be used.

(Division of Mental Health and Addiction; [440 IAC 10-1-58](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**Rule 2. General Requirements**

**[440 IAC 10-2-1](#) Purpose and authority of rules for operation of opioid treatment programs**

Authority: [IC 12-23-18-0.5](#); [IC 12-23-18-5.5](#)

Affected: [IC 12-23-18-0.5](#)

Sec. 1. (a) The purpose of this article is to establish standards by which an OTP shall operate in Indiana, including the following:

- (1) An opioid treatment facility and, if applicable, an addiction treatment facility shall be certified by the division.
- (2) An OTP shall be specifically approved by the division.
- (3) An OTP shall be in compliance with state and federal law.
- (4) Separate specific approval and certification under this article is required for each location at which an OTP is operated.

(b) The division may not grant specific approval for a new OTP unless specifically permitted and authorized by Indiana law.

(Division of Mental Health and Addiction; [440 IAC 10-2-1](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

**Rule 3. Certification of Opioid Treatment Facilities**

**[440 IAC 10-3-1](#) Certification of opioid treatment facilities and addiction treatment facilities**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-0.5](#)

Sec. 1. (a) An OTP shall apply to the division annually for the following:

- (1) Certification of an opioid treatment facility under this rule.
- (2) If applicable, certification of an addiction treatment facility under this rule.

(b) In addition, an opioid treatment facility and an addiction treatment facility shall obtain and maintain certification to provide addiction treatment services under [440 IAC 4.4](#).

(c) An OTP shall use forms provided by the division to apply for certifications under subsections (a) and (b).

(d) If an OTP requires more space than available in the opioid treatment facility, the OTP may provide nonadministering of opioid treatment medication and nonmedical recovery services at a maximum of one (1) additional addiction treatment facility. Before providing services at that location, the OTP shall obtain certifications under subsections (a) and (b).

(e) The division shall assess the OTP's compliance with the certification requirements for an opioid treatment facility and an addiction treatment facility through:

- (1) a review of application materials; and
- (2) an on-site monitoring inspection.

(f) An OTP shall apply for annual facility recertification not later than sixty (60) days prior to the expiration of the previous year's certification.

(g) The opioid treatment facility and, if applicable, one (1) additional addiction treatment facility shall be in compliance with all applicable federal, state, and local laws and rules.

(h) An OTP must be a federally certified OTP that is the subject of a current, valid certification under 42 CFR Part 8.

(i) The opioid treatment facility and any additional addiction treatment facility shall do the following:

- (1) Attain certification from the division prior to providing services.
- (2) Attain specific approval from the division prior to providing services.
- (3) Be located in the same county.
- (4) Remain in the same county in which the opioid treatment facility was situated on July 1, 2008.

(j) An OTP that has applied for opioid treatment facility certification, or that the division has previously certified, shall do the following:

- (1) Provide information requested by the division.
- (2) Respond to a request from the division as fully as reasonably possible.
- (3) Participate in the division's quality assurance program.

(k) An OTP's failure to comply with a request from the division may result in termination of the opioid treatment facility's certification under section 8 of this rule.

(l) A copy of the most recent opioid treatment facility certification issued by the division shall be available to the public upon request.

*(Division of Mental Health and Addiction; [440 IAC 10-3-1](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-3-2](#) Requirements for facility certification**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 2. (a)** Before commencing services, an OTP applicant shall have the opioid treatment facility and, if applicable, a maximum of one (1) addiction treatment facility certified by the division.

**(b)** An OTP applicant shall file an application with the division. The application shall contain the following:

- (1) The legal name of the OTP applicant.
- (2) A description of the following:
  - (A) The organizational structure.
  - (B) The applicant's mission statement.



- (C) The services to be provided.
- (D) The population to be served.
- (3) The location of the following:
  - (A) The opioid treatment facility.
  - (B) The addiction treatment facility, if applicable.
  - (C) The county where both clauses (A) and (B) are located.
- (4) Documentation showing that the applicant is accredited by an accreditation body approved by the division and by the United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), including a copy of the following:
  - (A) The accreditation report.
  - (B) Any response to the report required by the accreditation body.
  - (C) The final disposition issued by the accreditation body.
- (5) Documentation of any license and inspection for each facility, including the following:
  - (A) Any business license, certificate of occupancy, zoning permit, or any other documentation required by local laws for the facility and location.
  - (B) A periodic inspection of security equipment.
  - (C) A periodic inspection of emergency equipment.
  - (D) The applicant's procedures for emergency or disaster preparation.
  - (E) The most recent annual fire inspection report from the appropriate department of jurisdiction.
- (6) Documentation showing the following:
  - (A) The applicant has met the requirements of SAMHSA.
  - (B) The applicant has a current certification from SAMHSA.
  - (C) The applicant has the most current federal notification form or forms on file with SAMHSA specifying the names of the following:
    - (i) The current sponsor.
    - (ii) The current medical director of the OTP.
- (7) Documentation showing the following:
  - (A) The applicant has met the requirements of the federal Drug Enforcement Agency (DEA).
  - (B) The applicant has a current controlled substances registration certificate from the DEA.
  - (C) The applicant's medical director has met the DEA requirements.
  - (D) The applicant's medical director has a current controlled substances registration certificate from the DEA.
- (8) Documentation showing the following:
  - (A) The applicant has a current controlled substances registration certificate issued by the Indiana board of pharmacy.
  - (B) The applicant's medical director is a licensed physician.
  - (C) The applicant's medical director has a current license issued by the medical licensing board of Indiana.
  - (D) The applicant's medical director has a current controlled substances registration issued by the Indiana board of pharmacy.
- (9) Any other materials required by statute.

*(Division of Mental Health and Addiction; [440 IAC 10-3-2](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-3-3](#) Requirements for opioid treatment facilities and addiction treatment facilities**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 3. (a) An OTP applicant shall be in compliance with the following requirements for an opioid treatment facility and, if applicable, an addiction treatment facility:**

- (1) The OTP shall maintain the facility in a sanitary condition.
- (2) In common or waiting areas, the OTP shall display educational materials pertinent to the following:
  - (A) Opioid addiction treatment.
  - (B) Recovery support services.
- (3) The OTP shall provide adequate ventilation and lighting in the following:
  - (A) Waiting areas.
  - (B) Counseling areas.
  - (C) All other facility areas.



- (4) The OTP shall have adequate soundproofing so that confidentiality shall be maintained in the following:
  - (A) Patient counseling rooms.
  - (B) Physical examination rooms.
  - (C) Other rooms or areas in the facility used to meet with patients.
- (5) The OTP shall provide adequate security both inside and outside the facility:
  - (A) for the safety of the patients, staff, and others; and
  - (B) to prevent loitering and illegal activities.
- (6) Separate toilet facilities shall be provided for use by patients and staff.
- (7) The facility and areas within the facility shall be accessible to persons with physical disabilities.
- (8) The physical environment within the facility shall be conducive to promoting improved functioning and recovery.
- (9) The facility shall:
  - (A) meet all local, state, and federal requirements; and
  - (B) post an annual inspection report from appropriate officials.
- (10) The facility shall maintain stocked first aid kits for emergency use.
- (11) The facility shall:
  - (A) have a disaster plan and facility evacuation plan;
  - (B) annually update and approve the plan in clause (A); and
  - (C) post the plan in clause (A) in an area accessible to staff and to the public.
- (12) The facility shall meet physical facility standards established by the OTP's accreditation body.

(b) In addition, an OTP applicant shall be in compliance with the following requirements for the opioid treatment facility:

- (1) Medication administration stations and all other medical service areas shall be adequately ventilated and lighted.
- (2) Privacy and confidentiality shall be protected and maintained in the following:
  - (A) Medication administering stations.
  - (B) Areas adjacent to medication administering stations.
  - (C) All other areas where medical services are provided.
- (3) The opioid treatment facility shall maintain universal precaution spill kits.
- (4) The facility shall maintain infection control procedures consistent with the requirements of the state and federal occupational safety and health administrations.

(c) Compliance with certification requirements shall be assessed through the following:

- (1) A review of application materials.
- (2) An on-site monitoring inspection.

(d) The division shall conduct an on-site inspection of each facility to assess the OTP's compliance with this section at the following times:

- (1) Upon receipt of an initial application.
- (2) Annually thereafter.

*(Division of Mental Health and Addiction; [440 IAC 10-3-3](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-3-4](#) Temporary certification**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 4. (a) The division may issue a temporary certification if the applicant:**

- (1) has applied for, but has not yet obtained, a current certification from the United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) under 42 CFR Part 8; and
- (2) meets the requirements of this section.

**(b) To obtain temporary certification, the OTP applicant shall provide the following:**

- (1) A copy of the application for accreditation.
- (2) Documentation of licenses and inspections for each facility or location, including the following:
  - (A) The local business license, certificate of occupancy, and other documentation required by local law for the facility or location.
  - (B) An inspection of security equipment.
  - (C) Any periodic inspection of emergency equipment.
  - (D) The OTP applicant's emergency procedures.
  - (E) The latest annual fire inspection report from a department of jurisdiction.
- (3) Documentation showing that the applicant has either:
  - (A) filed for SAMHSA certification; or
  - (B) met SAMHSA requirements and has a current certification.
- (4) The most current federal notification form or forms on file with SAMHSA specifying the names of the following:
  - (A) The OTP applicant's current sponsor.
  - (B) The current medical director.
- (5) Documentation showing that the applicant has:
  - (A) filed an application with the Drug Enforcement Agency (DEA) for a controlled substances registration certificate; or
  - (B) met DEA requirements and has a current controlled substances registration certificate.
- (6) Documentation showing that the applicant's medical director has:
  - (A) met DEA requirements; and
  - (B) a current controlled substances registration certificate.
- (7) Documentation showing the following:
  - (A) The applicant has either:
    - (i) filed an application with the Indiana board of pharmacy for a controlled substances registration certificate; or
    - (ii) met the requirements and has been issued a controlled substances registration certificate by the Indiana board of pharmacy.
  - (B) The medical director has a current physician's license issued by the medical licensing board of Indiana.
  - (C) The applicant's medical director has done the following:
    - (i) Met the requirements of the Indiana board of pharmacy.
    - (ii) Received a controlled substances registration certificate issued by the Indiana board of pharmacy.
- (8) Any other materials required by statute.

(c) Temporary certification may be issued for a period of twelve (12) months. Prior to the expiration of a temporary certification, the OTP shall provide the following:

- (1) Documentation that the applicant has:
  - (A) a current, still pending application for accreditation; or
  - (B) achieved accreditation, which shall include a copy of:
    - (i) the accreditation report;
    - (ii) any response to the report required by the accreditation body; and
    - (iii) the final disposition issued by the accreditation body.
- (2) Current, updated documentation required under subsections [subsection] (b)(2) through (b)(8).

(d) Upon the verification of the required licenses and certifications or correspondence specified above in this section, the temporary certification may be extended for not more than twelve (12) additional months.

(e) Before an extended temporary certification expires, the applicant shall forward to the division the following:

- (1) Documentation that accreditation has been achieved, including a copy of the following:
  - (A) The accreditation report.
  - (B) Any response to the report required by the accreditation body.
  - (C) The final disposition issued by the accreditation body.
- (2) Documentation of licenses and inspections for each facility, including a copy of the items listed in subsections [subsection] (b)(2) through (b)(8).

(Division of Mental Health and Addiction; [440 IAC 10-3-4](#); filed Dec 30, 2009, 2:00 p.m.):

**[440 IAC 10-3-5](#) Maintenance of certification**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#); [IC 12-27](#)

Sec. 5. (a) An OTP certified under this article shall notify the division in writing not later than sixty (60) days prior to any of the following:

- (1) A change in the location within the same county of an:
  - (A) opioid treatment facility; or
  - (B) addiction treatment facility.
- (2) A change in the services provided at an opioid treatment facility.
- (3) A change in ownership of an OTP.
- (4) The closing of an opioid treatment facility.

(b) An OTP certified under this article shall notify the division in writing within twenty-four (24) hours of the following:

- (1) An alleged violation of health, fire, or safety codes as prescribed by local, state, or federal laws.
- (2) A documented violation of a patient's rights under either of the following:
  - (A) [IC 12-27](#).
  - (B) 42 CFR Part 2.

(c) An OTP certified under this rule shall notify the division in writing within thirty (30) days of a change in any of the following:

- (1) The accreditation body to provide accreditation.
- (2) The accreditation status of the entity.
- (3) The licensing and inspection documentation required under this rule.
- (4) The federal documentation required under this rule.
- (5) The Indiana state documentation required under this rule.

*(Division of Mental Health and Addiction; [440 IAC 10-3-5](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))*

**[440 IAC 10-3-6](#) Relocation of an opioid treatment facility or addiction treatment facility**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 6. (a) Certification of any opioid treatment facility shall not be transferred from one (1) location to another location.

(b) An OTP may not relocate either an opioid treatment facility or an addiction treatment facility to a location outside of the county in which the OTP has obtained the following:

- (1) Certification from the division under this rule.
- (2) Specific approval from the division under [440 IAC 10-4](#).

(c) An OTP certified under this article shall notify the division in writing not later than sixty (60) days prior to any of the following:

- (1) A change in the location within the same county of an:
  - (A) opioid treatment facility; or
  - (B) addiction treatment facility.
- (2) Any change in the treatment services provided at an opioid treatment facility.
- (3) The closing of an opioid treatment facility.

(d) Before commencing services, an OTP applicant shall obtain certification and specific approval for

the following:

- (1) An opioid treatment facility.
- (2) A maximum of one (1) addiction treatment facility.

(e) For the relocation within the same county of an opioid treatment facility or an addiction treatment facility, the applicant shall file a separate required form with the division for each facility. The form shall contain the following:

- (1) The legal name of the OTP applicant.
- (2) The name under which the OTP applicant does business.
- (3) The location of the following:
  - (A) The opioid treatment facility.
  - (B) The addiction treatment facility.
  - (C) The county where both are located.
- (4) Information regarding fire and safety inspections.
- (5) The services to be provided.
- (6) The population or populations to be served.

(f) Documentation that the applicant has notified the accreditation body approved by the division and by the United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) of the change in the facility's location.

(g) For the relocation within the same county of an opioid treatment facility, additional documentation shall include the following:

- (1) Any license and inspection for the opioid treatment facility, including the following:
  - (A) Any business license, certificate of occupancy, zoning permit, or any other documentation required by local laws for the facility and location.
  - (B) A periodic inspection of security equipment.
  - (C) A periodic inspection of emergency equipment.
  - (D) The OTP applicant's procedures for emergency or disaster preparation.
  - (E) The most recent annual fire inspection report from the appropriate department of jurisdiction.
- (2) Documentation showing that the opioid treatment facility has met the requirements of SAMHSA as follows:
  - (A) Has a current certification from SAMHSA.
  - (B) Has the most current federal notification form or forms on file with SAMHSA specifying the following:
    - (i) The address of the new location.
    - (ii) The name of the current sponsor.
    - (iii) The name of the current medical director of the OTP.
- (3) Documentation showing that the opioid treatment facility has:
  - (A) met the requirements of the Drug Enforcement Agency (DEA); and
  - (B) a current controlled substances registration certificate from the DEA.
- (4) Documentation showing that the opioid treatment facility has a current controlled substance registration certificate issued by the Indiana board of pharmacy.
- (5) Any other materials required by statute.

(h) For the addition or relocation of an addiction treatment facility, documentation shall be provided of any license and inspection for the location, including the following:

- (1) Any business license, certificate of occupancy, zoning permit, or any other documentation required by local laws for the facility and location.
- (2) A periodic inspection of security equipment.
- (3) A periodic inspection of emergency equipment.
- (4) The OTP applicant's procedures for emergency or disaster preparation.
- (5) The most recent annual fire inspection report from the appropriate department of jurisdiction.

*(Division of Mental Health and Addiction; [440 IAC 10-3-6](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-3-7](#) Conditional status of certification**

Sec. 7. (a) The division shall issue a conditional status under this article upon the division's investigation and determination of any of the following conditions:

- (1) A substantive change in the entity's accreditation status other than revocation of the accreditation.
- (2) Failure of the entity to renew accreditation within ninety (90) days following expiration of the entity's current accreditation by the entity's accrediting agency.
- (3) Failure to comply with this article.
- (4) Any conduct or practice in the operations of the entity that is found by the division to be detrimental to the welfare of persons served by the entity or organization.
- (5) The physical safety of the patients or staff of the entity is compromised by a physical or sanitary condition of a physical facility of the entity.
- (6) Violation of, or failure to comply with, a federal or state statute, rule, or regulation in the course of the operation of the entity.

(b) The time period of a conditional status is determined by the division but may not exceed twelve (12) months from the date the conditional status was effective.

(c) The division shall notify the entity of the following:

- (1) The requirements not met and the intermediate steps required by the division that the entity shall take to meet the requirements.
- (2) The time period granted by the division for the entity to meet the requirements.

(d) The division shall terminate the entity's certification if the entity fails to meet the requirements within the allotted time period.

*(Division of Mental Health and Addiction; [440 IAC 10-3-7](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### [440 IAC 10-3-8](#) Penalties and appeals

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 4-21.5](#); [IC 12-23-18-5.8](#)

Sec. 8. (a) The division director may take action if any of the following occurs:

- (1) A failure to comply with any local, state, or federal statute, rule, or regulation pertaining to the certification of an opioid treatment facility.
- (2) A violation of a local, state, or federal statute, rule, or regulation in the course of the operation of an opioid treatment facility.
- (3) A substantive change in the OTP's addiction services provider certification under [440 IAC 4.4](#).
- (4) A substantive change in or termination of an OTP's accreditation.
- (5) A substantive change in the OTP's certification under this rule.
- (6) A substantive change in or termination of an OTP's specific approval by the division.
- (7) Permitting, aiding, or abetting the commission of any illegal act in an OTP facility.
- (8) Conduct or practice found by the director to be detrimental to the welfare of an OTP patient.

(b) The division director may take any of the following actions:

- (1) Issue a letter of correction to an OTP.
- (2) Require the reinspection of an opioid treatment facility.
- (3) Issue a notice of conditional status of certification under this rule, as follows:
  - (A) The time period of a conditional status shall be determined by the division but may not exceed twelve (12) months from the effective date of the conditional status.
  - (B) The division shall notify the OTP of the following:
    - (i) The requirements not met.
    - (ii) The intermediate steps required by the division to meet the requirements in item (i).
    - (iii) The time period granted by the division to meet the requirements in item (i).

- (4) Deny renewal of, or terminate the certification of, an opioid treatment facility.
- (5) Impose a civil penalty not exceeding ten thousand dollars (\$10,000).

(c) If an opioid treatment facility's certification has been terminated, the division shall notify the following:

- (1) The Indiana family and social services administration.
- (2) The Indiana department of administration.

(d) [IC 4-21.5](#) applies to an action under this section.

*(Division of Mental Health and Addiction; [440 IAC 10-3-8](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### Rule 4. Specific Approval of Opioid Treatment Programs

##### [440 IAC 10-4-1](#) Specific approval of an opioid treatment program

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-0.5](#); [IC 12-23-18-5.5](#)

Sec. 1. (a) In order to obtain and maintain specific approval to operate as an OTP, an OTP shall comply with the requirements of this rule.

(b) The division may not grant specific approval to be a new OTP unless permitted by Indiana law.

*(Division of Mental Health and Addiction; [440 IAC 10-4-1](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

##### [440 IAC 10-4-2](#) Diversion control

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 2. (a) Each OTP shall develop, implement, update, and submit to the division by February 28 of each year a diversion control plan for the following purposes:

- (1) To identify individuals who divert opioid treatment medications from legitimate treatment use.
- (2) To terminate the opioid treatment of those individuals.

(b) The diversion control plan shall meet the requirements of 42 CFR Part 8, including 42 CFR §8.12(c)(2).

(c) The diversion control plan shall include a consideration of at least the following provisions:

- (1) Regular OTP attendance by the patient.
- (2) Counseling requirements for the program.
- (3) Serious behavior problems of the patient.
- (4) Stable home environment of the patient.
- (5) Safe storage capacity of opioid treatment medications within the patient's home.
- (6) Medically recognized testing protocols to determine legitimate opioid treatment medication use.
- (7) The responsibilities of the medical director and the administrative staff for preparing and implementing the plan.

(d) The diversion control plan shall include the OTP's drug testing procedure for testing a patient during the patient's treatment by the OTP.

(e) The division shall review and either approve or disapprove the diversion control plan of each OTP



by May 1 of each year. If the division disapproves an OTP's diversion control plan, the OTP shall submit a plan revision to the division not later than sixty (60) days after the disapproval of the plan.

(f) If the OTP fails to submit an acceptable plan within the required time frame, the division shall consider following the procedures for penalties in section 41 of this rule.

*(Division of Mental Health and Addiction; [440 IAC 10-4-2](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-3](#) Written program policies and procedures**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 3. (a) An OTP shall maintain a policy and procedure manual (manual) that does the following:**

- (1) Addresses all areas of program operation.**
- (2) Contains all program protocols.**
- (3) Clearly identifies the staff responsible for each function.**

**(b) The manual shall be reviewed and approved annually by the following:**

- (1) The program sponsor.**
- (2) The medical director.**
- (3) Authorized administrative staff.**

**(c) The OTP shall make the manual available to the division and its representatives upon request.**

*(Division of Mental Health and Addiction; [440 IAC 10-4-3](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-4](#) Required services**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 4. (a) The program shall establish and implement policies, procedures, and practices that do the following:**

- (1) Ensure access to a range of opioid addiction treatment services.**
- (2) Address the safety and health care needs of its patients.**

**(b) Services shall include, but not be limited to, the following:**

- (1) Medical services.**
- (2) Educational services.**
- (3) Counseling.**
- (4) Treatment planning and treatment plan review.**
- (5) Referrals to services not provided by the OTP, including recovery support, medical, mental health, vocational, educational, and employment services.**
- (6) Referrals to services when the provision of services at the OTP is prevented or interrupted in the event of an emergency or natural disaster.**

**(c) An OTP shall ensure the continued provision of opioid medication treatment in the event of an emergency or natural disaster that interrupts the OTP's provision of services.**

**(d) An OTP shall maintain an up-to-date and appropriately signed disaster planning agreement or memorandum of understanding with all other Indiana OTPs and other appropriate OTPs to assure the provision of services to enrolled patients if a disaster results in an OTP's inability to serve its patient population.**

(Division of Mental Health and Addiction; [440 IAC 10-4-4](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### **[440 IAC 10-4-5](#) Medical services**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 5. Medical services include the following:**

- (1) An evaluation of physiological addiction to opioid drugs.
- (2) The determination of the appropriate dose of treatment medication to eliminate symptoms of opioid withdrawal.
- (3) The administering of treatment medication to the patient.
- (4) The management of treatment medication reduction initiated by either the patient or clinical staff.
- (5) Drug testing as required in section 22 of this rule.
- (6) Physical examination services, including an annual physical examination.
- (7) Consultation with other medical service providers to coordinate medical care.
- (8) Referral for medical services not provided by the OTP.

(Division of Mental Health and Addiction; [440 IAC 10-4-5](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### **[440 IAC 10-4-6](#) Counseling services**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-1](#)

**Sec. 6. (a)** The objective for opioid addiction treatment is to improve the overall functioning of patients through the provision of opioid treatment medication at medically appropriate levels. In addition, counseling services shall be provided to support the following:

- (1) A patient's elimination of illicit drug use and other destructive behaviors.
- (2) The elimination of a patient's opioid treatment medication as medically appropriate.
- (3) Establishing a sound basis for a patient's ongoing recovery after treatment is concluded.

**(b)** Key goals for the patient shall include, but not be limited to, the following as appropriate to the individual patient:

- (1) The elimination of the following:
  - (A) The use of illicitly obtained prescription opioid drugs.
  - (B) The illicit use of nonprescription opioid drugs.
  - (C) The illicit use of drugs other than opioids.
  - (D) Criminal behavior.
  - (E) Behavior related to the spread of infectious diseases.
  - (F) Alcohol abuse.
- (2) An improvement in the following:
  - (A) Education or vocational training.
  - (B) Employment status.
  - (C) Family and other social relationships.

**(c)** An OTP shall use the following:

- (1) A structured approach in providing treatment and recovery-oriented services.
- (2) Established criteria for determining patient progress.

**(d)** Factors relevant to a patient's progress in treatment shall include, but not be limited to, the following:

- (1) Absence of the abuse of alcohol and the use of other drugs, except as medically prescribed.
- (2) Stable:



- (A) social;
  - (B) vocational;
  - (C) legal;
  - (D) family;
  - (E) emotional; and
  - (F) behavioral;
- functioning.
- (3) Program attendance as scheduled by the OTP in the individualized treatment plan.
  - (4) Other individual goals identified in the patient's individualized treatment plan.
- (e) An OTP shall provide counseling services, including individual, group, and family counseling.
- (f) Counseling topics shall include, but not be limited to, the following:
- (1) Health education and stabilization on opioid treatment medication.
  - (2) The patient's need for mental health services and other social services, as well as referral resources for those services.
  - (3) Encouraging the involvement of:
    - (A) family members;
    - (B) significant others; and
    - (C) supportive persons;in the patient's recovery process.
  - (4) Preventing exposure to, and transmission of, the following:
    - (A) Hepatitis C.
    - (B) Tuberculosis.
    - (C) HIV/AIDS.
    - (D) Other sexually transmitted and communicable diseases.
  - (5) Employment.
  - (6) Further education or vocational training.
  - (7) Family dynamics.
- (g) Counseling services shall include the provision of the following:
- (1) A comprehensive substance abuse assessment using a standardized addiction assessment instrument.
  - (2) Individualized treatment planning.
  - (3) Periodic treatment plan review.
  - (4) Interactions with the patient to assist the patient in reaching the patient's goals for recovery.
  - (5) Case management.
  - (6) Aftercare planning including the following:
    - (A) Referrals to recovery support services for the patient.
    - (B) Postdischarge sessions with an OTP counselor in support of continued recovery.
- (h) Based on the patient's time in treatment, counseling shall be provided on the following schedule:
- (1) During the first three (3) months of treatment, at least four (4) hours of counseling per month, of which at least two (2) hours shall be in individual counseling.
  - (2) From three (3) months to six (6) months in treatment, at least two (2) hours of counseling per month, including one (1) hour of individual counseling.
  - (3) From six (6) months to one (1) year in treatment, at least one (1) hour of counseling per month.
  - (4) After one (1) year in treatment, based on the results of drug testing and other relevant indicators, the counselor shall determine the following:
    - (A) The patient's need for counseling.
    - (B) The frequency of counseling.

*(Division of Mental Health and Addiction; [440 IAC 10-4-6](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-7](#) Educational services**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#)

**Sec. 7. An OTP shall provide and document the education of patients during program orientation and annually on at least the following:**

- (1) The prevention, treatment, and transmission of the following:**
  - (A) HIV and AIDS.**
  - (B) Hepatitis C.**
  - (C) Tuberculosis.**
  - (D) Other sexually transmitted and communicable diseases.**
- (2) For pregnant women, prenatal care for the fetus while the patient is receiving opioid addiction treatment.**

*(Division of Mental Health and Addiction; [440 IAC 10-4-7](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-8](#) Referral services**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#)

**Sec. 8. (a) An OTP shall have written, dated, and properly signed memoranda of understanding, qualified service organization agreements, or other types of formal agreements that assure the referral of patients to all services not provided by the OTP, including, but not limited to, the following:**

- (1) Vocational rehabilitation.**
- (2) Education.**
- (3) Employment.**
- (4) Housing.**
- (5) Other medical services not provided by the OTP.**
- (6) Prenatal care or other gender-specific services for pregnant patients.**
- (7) Testing for the following:**
  - (A) HIV.**
  - (B) AIDS.**
  - (C) Hepatitis C.**
  - (D) Tuberculosis.**
- (8) Mental health services.**

**(b) For individuals who test positive for HIV, AIDS, hepatitis C, or tuberculosis, the referral agreements shall include provisions for pretest and posttest counseling.**

*(Division of Mental Health and Addiction; [440 IAC 10-4-8](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-9](#) Record keeping requirements**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#); [IC 16-39-7-1](#)

**Sec. 9. (a) An OTP shall maintain a master patient record for each current patient at the OTP medication administering site.**

**(b) If any OTP patient services are provided at a certified addiction treatment facility, the OTP shall have written policies and procedures requiring the inclusion of, and time frame for inclusion of, copies of all chart notes and records of patient services in the master patient record at the OTP medication administering site.**

**(c) The content and format of patient records shall be uniform. Entries shall be signed and dated by the staff member making the entry.**

(d) Patient records shall be:

- (1) kept confidential; and
- (2) protected against:
  - (A) loss;
  - (B) tampering; or
  - (C) unauthorized disclosure.

(e) Records of discharged patients shall be retained for a period of at least seven (7) years after the patient's last contact with the OTP.

(f) An OTP that ceases to provide treatment services shall do the following:

- (1) Retain patient records for at least seven (7) years from the date of facility closure.
- (2) Notify the division of the following:
  - (A) The location of the records.
  - (B) The name of the person responsible for maintaining the records.

(g) An OTP shall establish a written record for each patient to include at least the following:

- (1) The patient's written informed consent to treatment.
- (2) Documentation showing that the patient was given information on the following:
  - (A) Patient rights, including the right to confidentiality.
  - (B) Patient responsibilities.
  - (C) The OTP's grievance procedures.
- (3) Medication dose history, including current dose.
- (4) Results of medical tests, including drug testing.
- (5) The current treatment plan.
- (6) Progress addressing treatment plan goals.
- (7) Documentation of each contact with the patient and patient's family.
- (8) Referrals to services not provided by the OTP.

(h) The OTP shall make all patient information contained in patient records available to the division and its agents upon request.

*(Division of Mental Health and Addiction; [440 IAC 10-4-9](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-10](#) OTP days of operation**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 10. (a) An OTP shall offer opioid treatment services sufficient to meet the needs of patients seven (7) days per week.**

**(b) Service provision on Sundays and on federal and state holidays shall, at a minimum, include opioid medication administration services for patients not eligible to receive unsupervised medication; provided, however, if all patients of an OTP are eligible to receive unsupervised medication, the OTP may be closed for business on that Sunday or federal or state holiday.**

**(c) An OTP may provide services on Sundays and on federal and state holidays through a contract with a qualified service provider if the contract assures that all the provisions of this rule will be met.**

*(Division of Mental Health and Addiction; [440 IAC 10-4-10](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-11](#) Security of medications**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Sec. 11. An OTP shall do the following:**

- (1) Ensure the security of its treatment medication supply.
- (2) Account for all treatment medication in the facility.
- (3) Meet the requirements of [440 IAC 10-3-2\(b\)\(7\)](#).
- (4) Meet the requirements of the federal Drug Enforcement Agency (DEA), including securing and retaining a valid DEA registration.
- (5) Maintain a DEA acceptable security system that meets the requirements of 21 CFR §1301.71 through §1301.76 as applicable. The system shall be checked on a quarterly basis to ensure its continued safe operation.
- (6) Physically separate the areas for the storage of, and administration of, treatment medication from other parts of the facility where patients are present.
- (7) Implement written policies and procedures to ensure the positive identification of a patient before treatment medication is administered.
- (8) Implement written policies and procedures regarding the recording of the following:
  - (A) Patient medication intake.
  - (B) A daily treatment medication inventory.
- (9) The OTP shall develop and implement procedures for assuring the following:
  - (A) The safety and security of the OTP and persons working at or visiting the OTP, including the provision of alarm protection and on-site security protection.
  - (B) The clinic patients or others are not using the clinic to identify potential drug sale clients or for the transfer of medications from patient to patient.
  - (C) Safety and security in the facility parking lot and grounds.

*(Division of Mental Health and Addiction; [440 IAC 10-4-11](#); filed Dec 30, 2009, 2:00 p.m.:  
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**[440 IAC 10-4-12](#) OTP administrative structure; general staff requirements**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 12. (a) An OTP shall have an administrative structure that includes the following:**

- (1) A program sponsor identified in the application for certification under 42 CFR Part 8 as responsible for the operation of the program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, counseling, educational, or referral services at the program or by contract with the program.
- (2) A medical director who assumes responsibility for administering all medical services performed by the program, either by:
  - (A) performing the services directly; or
  - (B) delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's direct supervision.
- (3) A program director who is responsible for the following:
  - (A) Managing the day-to-day operation of the program.
  - (B) Assuming responsibilities delegated by the program sponsor.
- (4) A clinical supervisor who is responsible for overseeing the work of the counseling staff at the proportionate equivalent of one (1) full-time clinical supervisor for every ten (10) counselors or portion thereof.

**(b) The staff of an OTP shall meet the following general requirements:**

- (1) All individuals working for an OTP shall have experience and training to:
  - (A) safely manage therapeutic services to patients; and
  - (B) provide therapeutic services to patients receiving opioid treatment medication.
- (2) All OTP employees shall have a documented orientation in opioid addiction treatment and shall meet the goals and objectives of the training prior to assuming their job functions, unless an employee's personnel record contains documentation showing that the employee has had sufficient experience in opioid addiction treatment to forgo this session.

- (3) All individuals employed by the OTP shall undergo a criminal background check prior to employment to assure that individuals with convictions for drug-related offenses are not hired in any capacity with access to controlled substances.
  - (4) An OTP shall require an individual seeking employment with the OTP to have a preemployment drug screening for any of the substances itemized in section 22(c) of this rule.
  - (5) An OTP shall not employ any individual who has a positive drug test in a screening before employment for any of the substances itemized in section 22(c) of this rule, for which substance the individual does not have a prescription.
  - (6) Individuals in recovery employed in any capacity with access to controlled substances shall have a documented recovery from substance abuse for a minimum of three (3) years prior to hiring. An OTP shall have written policies and procedures concerning the following:
    - (A) The employment of individuals in recovery.
    - (B) The acceptable documentation of recovery required by the OTP.
    - (C) Substance abuse by current employees.
  - (7) The OTP shall have the following:
    - (A) Written job descriptions specifying the following:
      - (i) The qualifications for hiring.
      - (ii) The position responsibilities.
      - (iii) The degree of authority to execute job responsibilities.
    - (B) An annually reviewed and approved chart or description of the organizational structure of the OTP that indicates lines of authority and responsibility.
  - (8) Separate personnel files shall be maintained for each staff member containing at least the following:
    - (A) An employment application containing the staff member's qualifications for employment.
    - (B) Documentation showing that the individual meets the qualifications for the position held.
    - (C) Documentation of updated credentials required for the position.
    - (D) Documentation demonstrating completion of in-service training requirements.
    - (E) The results of a preemployment criminal background check.
    - (F) The results of a preemployment drug screening.
- (c) The OTP shall provide and maintain a drug-free workplace by complying with the following:
- (1) Publishing and providing to all employees a statement notifying them that the unlawful:
    - (A) manufacture;
    - (B) distribution;
    - (C) administering;
    - (D) possession; or
    - (E) use;of a controlled substance is prohibited in the OTP.
  - (2) Specifying the actions that shall be taken against employees for a violation of the prohibitions in subdivision (1).
  - (3) Establishing a drug-free awareness program to inform the OTP's employees of the following:
    - (A) The dangers of drug abuse in the workplace.
    - (B) The OTP's policy of maintaining a drug-free workplace.
    - (C) Any available drug counseling, rehabilitation, and employee assistance programs.
    - (D) The penalties that may be imposed upon an employee for drug abuse violations occurring in the workplace.
  - (4) Notifying all employees in the statement required by subdivision (1) that, as a condition of continued employment, an employee shall do the following:
    - (A) Abide by the terms of the statement.
    - (B) Notify the OTP of an employee's conviction under any criminal drug statute for a violation occurring in the workplace not later than five (5) days after the conviction.
  - (5) Notifying the division in writing within ten (10) days after receiving a notice as follows:
    - (A) From an employee under subdivision (4)(B).
    - (B) Otherwise receiving actual notice of such conviction.
  - (6) Within thirty (30) days after receiving a notice under subdivision (4)(B) of an employee's conviction, imposing the following sanctions or remedial measures on any employee who is convicted of drug abuse violations occurring in the workplace:
    - (A) Taking appropriate personnel action against an employee, up to and including termination.
    - (B) Requiring an employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a federal, state, or local health, law enforcement, or other

appropriate agency.

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**[440 IAC 10-4-13](#) OTP staff positions**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#); [IC 25-22.5-2](#); [IC 25-23-1](#); [IC 25-23.6](#); [IC 25-27.5](#); [IC 25-33](#)

**Sec. 13. (a) Each OTP shall employ qualified individuals to fill the staff functions in this section.**

**(b) An OTP shall have a medical director who shall meet the following requirements:**

**(1) The medical director shall have the following qualifications:**

**(A) Be licensed as a physician in Indiana.**

**(B) Meet at least one (1) of the following requirements:**

**(i) Have a minimum of one (1) year's experience as a physician in an OTP.**

**(ii) Be employed as a medical director of an OTP as of the effective date of this article; or**

**(iii) Within one (1) year of the date of hiring, obtain ten (10) hours of training in opioid addiction treatment.**

**(2) Within thirty (30) days of the date of hiring, the medical director shall have or obtain admitting privileges at one (1) local hospital.**

**(3) The responsibilities of the medical director include, but are not limited to, the following:**

**(A) Ensuring that all medical protocols are:**

**(i) in writing; and**

**(ii) reviewed and approved by appropriate program officials on an annual basis.**

**(B) Ensuring that the manner in which medical functions may be delegated to other staff is clearly articulated in the protocols.**

**(C) Ensuring that individuals seeking admission to the OTP meet the admission criteria in 42 CFR Part 8 and in section 15 of this rule.**

**(D) Establishing clinical standards for the following:**

**(i) The induction of treatment medication for a patient upon admission.**

**(ii) The titration of a patient on treatment medication.**

**(iii) The tapering of a patient off of a treatment medication.**

**(E) Ensuring the following:**

**(i) Patients admitted to the OTP shall have a complete physical examination.**

**(ii) The results of the physical examination shall be documented in the patient's record.**

**(iii) Referrals are made for identified services not provided by the OTP.**

**(F) Ensuring the following:**

**(i) All patients voluntarily choose maintenance opioid addiction treatment.**

**(ii) All relevant facts concerning the use of a treatment medication are clearly and adequately explained to the patient.**

**(iii) Each patient provides written informed consent to treatment.**

**(G) Ensuring the signing or countersigning and dating of all medical orders as required by federal or state law.**

**(H) Ensuring that each patient's dose of treatment medication is appropriate for the patient's needs.**

**(I) Ensuring that appropriate laboratory tests or studies have been performed and reviewed.**

**(J) Ensuring that a justification is recorded in the patient's record for the following:**

**(i) Reducing the frequency of visits to the program for observed medication ingestion.**

**(ii) The prescribing of medication to address other problems.**

**(iii) Approving a patient's receipt of unsupervised doses of opioid treatment medication.**

**(iv) Approving exception requests for patients' unsupervised doses of opioid treatment medication.**

**(K) Ensuring that treatment plans are:**

**(i) reviewed at least every six (6) months; and**

**(ii) signed or countersigned and dated when reviewed.**

**(L) Ensuring that a clinical evaluation of a patient is conducted within ten (10) days of any positive drug screening.**

**(M) Ensuring that a face-to-face clinical evaluation of the patient's progress in treatment is conducted at least every six (6) months regarding the patient's need for the following:**

- (i) Continuing maintenance treatment with treatment medication.
- (ii) A medication reduction protocol.
- (N) Ensuring the administering of all medical services provided by the program, including an annual physical examination.
- (O) Ensuring that the program complies with all federal, state, and local statutes, ordinances, and regulations regarding the treatment of opioid addiction.
- (P) Ensuring that the core principle of OTP treatment is to work with each patient as follows:
  - (i) To arrive at the clinically appropriate dose of medication.
  - (ii) To eliminate the use of treatment medication as clinically appropriate.
- (Q) When either the patient or the OTP determines that the reduction and elimination of treatment medication is in the best interest of the patient or the OTP, ensuring supervision as follows:
  - (i) To alleviate adverse effects incidental to withdrawal from medication.
  - (ii) To bring the individual to recovery.

(c) An OTP shall have a program physician, who may also be the medical director. A program physician shall meet the following requirements:

- (1) All OTP physicians shall:
  - (A) be licensed in the state of Indiana; and
  - (B) work under the supervision of the medical director.
- (2) OTP physicians, who are not the medical director, are responsible for OTP medical services as delegated by the medical director.
- (3) Each OTP shall have one (1) program physician physically present in the facility for a minimum of one (1) full-time equivalent of forty (40) hours per week for every one thousand (1,000) enrolled patients; provided, however, that except for services required under this rule to be performed by a physician, fifty percent (50%) of the services of a program physician may be performed by an authorized health care professional.

(d) An OTP shall have a program director who meets the following requirements:

- (1) The program director shall have at least one (1) of the following qualifications:
  - (A) One (1) year of work experience providing services to individuals with addiction problems.
  - (B) A minimum of a bachelor's degree.
  - (C) Three (3) years of work experience in administration or personnel supervision in human services.
  - (D) A division-approved credential in addiction counseling under [440 IAC 4.4](#).
- (2) The program director is responsible for the following:
  - (A) The:
    - (i) day-to-day operations of the OTP; and
    - (ii) delivery of treatment services.
  - (B) The supervision of OTP staff.
  - (C) Managing all other functions delegated by the medical director.

(e) An OTP shall have nurses that meet the following requirements:

- (1) All nurses are required to maintain appropriate licenses to perform delegated and assigned nursing functions.
- (2) A nurse qualified by education, training, and experience shall do the following:
  - (A) Supervise the administering of medication to OTP patients.
  - (B) Perform other functions delegated by the medical director or an OTP physician.
- (3) A registered nurse or licensed practical nurse may administer opioid treatment medication only under the following circumstances:
  - (A) When acting as the agent of a practitioner licensed under state law and registered under the appropriate state and federal laws to administer opioid treatment medication.
  - (B) When supervised by, and under the order of, a practitioner licensed under state law and registered under the appropriate state and federal laws to administer opioid treatment medication.
- (4) An OTP shall employ one (1) nurse for a minimum of one (1) full-time equivalent of forty (40) hours per week for every two hundred (200) enrolled patients.

(f) An OTP shall have counselors that meet the following requirements:

- (1) An OTP counselor shall be qualified by education, training, or experience to do the following:
  - (A) Assess the psychological and sociological background of patients.



- (B) Contribute to the appropriate treatment plan for the patient.
- (C) Monitor patient progress toward identified treatment goals.
- (2) OTP counselors shall be provided an orientation to opioid addiction treatment, including the diversion control plan. The orientation shall be documented in the counselor's personnel record and shall meet the following requirements:
  - (A) Be for not less than four (4) hours prior to assuming counseling duties for counseling staff lacking experience in opioid addiction treatment.
  - (B) Be for a minimum of one (1) hour prior to assuming counseling duties for counseling staff experienced in opioid addiction treatment.
- (3) Counselors shall be credentialed as any of the following:
  - (A) A licensed clinical social worker ([IC 25-23.6-5](#)).
  - (B) A licensed mental health counselor ([IC 25-23.6-8.5](#)).
  - (C) A licensed marriage and family therapist ([IC 25-23.6-8](#)).
  - (D) A psychologist ([IC 25-33](#)).
  - (E) A physician ([IC 25-22.5-2](#)).
  - (F) A physician assistant ([IC 25-27.5](#)), a nurse practitioner ([IC 25-23-1](#)), or a clinical nurse specialist ([IC 25-23-1](#)).
  - (G) An individual credentialed in addictions counseling by a nationally recognized credentialing body approved by the division.
- (4) A counselor who lacks a credential shall obtain a credential listed in subdivision (3) within three (3) years of the effective date of this article.
- (5) Counselors are responsible for providing counseling, educational, and referral services to enrolled patients and their families as defined by OTP protocols. Counseling services shall include individual, group, and family counseling.
- (6) An OTP shall employ one (1) full-time counselor for a minimum of forty (40) hours per week for every fifty-five (55) enrolled patients.
- (g) An OTP shall have a clinical supervisor that meets the following requirements:
  - (1) A clinical supervisor shall have either of the following qualifications:
    - (A) Have a division-approved credential under subsection (f)(3).
    - (B) Be licensed by the state in any of the following:
      - (i) Social work ([IC 25-23.6-5](#)).
      - (ii) Marriage and family therapy ([IC 25-23.6-8](#)).
      - (iii) Mental health counseling ([IC 25-23.6-8.5](#)).
  - (2) A clinical supervisor shall have a minimum of three (3) years of experience in providing addiction treatment services.
  - (3) A clinical supervisor is responsible for supervising the work of the counselors.
  - (4) For every ten (10) counselors or portion thereof, an OTP shall employ the proportionate equivalent of one (1) full-time clinical supervisor for a minimum of forty (40) hours per week.
  - (5) A clinical supervisor may carry a patient caseload proportionate to the number of counselors supervised.

*(Division of Mental Health and Addiction; [440 IAC 10-4-13](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-14](#) Continuing education of OTP staff**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 14. (a) Each OTP shall designate a staff person to serve as the staff training coordinator.**

**(b) All clinical and medical staff shall annually receive a minimum of one (1) two-hour training session relevant to service delivery in an opioid treatment setting.**

**(c) In addition to subsection (b), each OTP shall establish an in-service training curriculum for counselors for at least ten (10) hours annually. The training curriculum shall:**

- (1) be based on an annual evaluation of staff training needs; and**



(2) include a refresher course on the program's diversion control plan as part of the training curriculum each year.

(d) The OTP shall maintain documentation in each employee's personnel file of all training completed by the employee. Evidence of training obtained outside of OTP-provided workshops is acceptable as proof of training.

(e) For counselors who do not have a credential, the OTP shall provide information and training for the employee that will lead toward credentialing or licensure in addiction treatment.

(f) Each OTP shall send appropriate staff to all division-sponsored OTP workshops.

*(Division of Mental Health and Addiction; [440 IAC 10-4-14](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-15](#) Patient admission criteria**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 15. (a) An individual applying for admission to an OTP shall:**

- (1) present a government-issued photographic identification card to assure that the individual is providing accurate identity information;**
- (2) be addicted to an opioid drug;**
- (3) have become addicted at least one (1) year before admission;**
- (4) voluntarily choose treatment; and**
- (5) provide written informed consent to treatment.**

**(b) If an applicant lacking a laboratory study confirmation of addiction to an opioid drug is admitted to an OTP, the reason for the admission shall be documented in the patient's record.**

**(c) An OTP physician may waive the requirement of a one-year history of addiction for the following individuals:**

- (1) An individual released from a penal institution within the previous six (6) months.**
- (2) A pregnant woman of any age if the pregnancy is certified by an OTP physician.**
- (3) A patient previously treated within two (2) years of the current admission.**

**(d) An individual under eighteen (18) years of age may be admitted to an OTP only under the following circumstances:**

- (1) The individual has had two (2) unsuccessful attempts at short-term detoxification treatment or drug-free treatment within the twelve (12) month period preceding admission, as documented in records provided to the OTP.**
- (2) The individual shall meet one (1) of the following requirements:**
  - (A) The individual's parent or legal guardian consents in writing to the admission and treatment.**
  - (B) The individual is an emancipated minor.**

**(e) The medical director may refuse the admission of an applicant if, in the medical director's reasonable clinical judgment, the applicant would not benefit from the treatment. The medical director shall record the reason or reasons for a decision to refuse admission in an admissions denied log kept for this purpose.**

**(f) An admitting OTP shall verify that an individual meeting admission criteria is not currently enrolled in another OTP as provided as follows:**

- (1) An admitting OTP shall obtain this information via the following:**
  - (A) The division's central registry for Indiana dual enrollment.**
  - (B) Other processes that ensure that an individual who seeks treatment is not enrolled in another**

**OTP in Indiana.**

(2) The admitting OTP shall make good faith efforts, using available resources and mechanisms, to assure that an individual who seeks treatment is not enrolled in another OTP outside of the state of Indiana.

(3) To support the actions in subdivisions (1) and (2), an admitting OTP shall obtain appropriate written authorizations for the release of information from an individual who seeks enrollment.

(g) An OTP shall give written notice to an individual seeking treatment that, if the individual refuses or fails to give the written authorizations for the release of information required under subsection (f), the OTP may refuse to admit the individual.

(h) The OTP shall document in the individual's record the giving of the notice in subsection (g).

*(Division of Mental Health and Addiction; [440 IAC 10-4-15](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

**[440 IAC 10-4-16](#) Physical evaluation**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 16. (a) A physical evaluation shall be made upon admission to an OTP and shall meet the following requirements:**

- (1) Be fully documented in the patient's record.
- (2) Be conducted by a program physician.
- (3) Include all measures and procedures necessary to determine opioid addiction.

**(b) The physical evaluation shall include the following:**

- (1) Observation of the signs and symptoms of opioid withdrawal.
- (2) Obtaining an opioid use history and addiction history.
- (3) Drug testing, which shall include testing for the presence of the following:
  - (A) Methadone.
  - (B) Cocaine.
  - (C) Opiates.
  - (D) Amphetamines.
  - (E) Barbiturates.
  - (F) Tetrahydrocannabinol.
  - (G) Benzodiazepines.
  - (H) Any other suspected or known drug that may have been abused by the patient.
- (4) Pregnancy testing as medically appropriate.

**(c) The risks and benefits of treatment medication shall be explained to the applicant. Documentation that this explanation was made shall be included in an admitted patient's record.**

**(d) Documentation of the following shall be retained in a patient's record:**

- (1) Individuals applying for admission to an OTP shall voluntarily choose opioid addiction treatment.
- (2) All relevant facts concerning the use of opioid treatment medication shall be clearly and adequately explained to the individual.
- (3) Each patient being admitted to treatment shall provide written informed consent to treatment.

**(e) All psychoactive prescription medications detected by drug testing shall be documented in the patient's record.**

**(f) With appropriate written authorization for the release of information, the program staff shall do the following:**

- (1) Make contact with the physician prescribing the psychoactive prescription medications in subsection (e).

(2) Explore the need for the medication.

(3) Document in the patient's record the justification for the continued use of the medication if the use is contraindicated with the use of opioid treatment medication.

(g) Enrolled patients who are taking prescription medication or medications that may adversely interact with opioid treatment medication shall be advised of the following:

(1) The contraindications for the use of prescription medications with opioid treatment medication.

(2) The need to consider the following:

(A) Alternative prescriptions.

(B) Over-the-counter medication or medications.

(C) Alternative treatment protocols.

(h) An OTP shall give written notice to an individual seeking treatment that, if the individual refuses or fails to give the written authorization for release of information required under subsection (f), the OTP may refuse to admit the individual.

(i) The OTP shall document in the patient's record the OTP's request for written authorization for the release of information in subsection (f).

*(Division of Mental Health and Addiction; [440 IAC 10-4-16](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-17](#) Individuals not meeting admission criteria**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 17. (a) All individuals not meeting admission criteria shall be counseled regarding a need for a referral to another:

(1) service provider; or

(2) level of care.

(b) A written authorization for the release of information shall be obtained as needed.

(c) The OTP shall maintain a referral log showing the following:

(1) Referrals made by the OTP.

(2) The reason for the referral of individuals not meeting OTP admission criteria.

*(Division of Mental Health and Addiction; [440 IAC 10-4-17](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-18](#) Patient admission procedures**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 18. (a) An OTP shall maintain current written policies, procedures, and protocols designed to ensure that patients are admitted to opioid treatment by qualified personnel.

(b) To admit a patient to an OTP, qualified OTP personnel shall make a determination, using accepted medical criteria, that the patient meets the following criteria:

(1) The individual is currently addicted to an opioid drug.

(2) Based on available evidence documented in the patient record, the individual has been addicted for a minimum of one (1) year before admission for treatment.

(3) The admission criteria in 42 CFR §8.12(e) have been met.

(c) The OTP shall record the following information in the patient's record:

- (1) Clinical signs of addiction.
- (2) Past drug use patterns.
- (3) Prior treatment history.
- (4) Other relevant information supporting the admission.

(d) Admission to an OTP shall involve the following three (3) steps:

- (1) A physical evaluation conducted by a program physician prior to admission.
- (2) A medical history and a physical examination conducted by either of the following:
  - (A) A program physician.
  - (B) An authorized health care professional or professionals under the supervision of a program physician.
- (3) A substance abuse assessment conducted by appropriate OTP personnel.

(Division of Mental Health and Addiction; [440 IAC 10-4-18](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### [440 IAC 10-4-19](#) Initial opioid treatment medication

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 19. (a) An OTP shall use only opioid treatment medications approved by the Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355) for use in the treatment of opioid addiction.

(b) An OTP shall maintain current procedures adequate to ensure that each treatment medication used by the program is administered in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures shall ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(c) Before the patient may receive the initial dose of medication, the OTP shall document the following in the patient's record:

- (1) Evidence of current addiction to an opioid drug or drugs, including, but not limited to, drug testing results.
- (2) Length of history of addiction to opioid drug or drugs.
- (3) Any exception to the criteria for admission under section 15 of this rule.

(d) For patients deemed clinically appropriate for admission, medication is titrated to a dose with the rate of increase indicated based on a clinical assessment of the following:

- (1) The patient's tolerance.
- (2) The patient's withdrawal symptoms.
- (3) The elimination of craving.

(e) The rate of titration and dose achieved shall be determined on a case-by-case basis through the course of multiple clinical assessments. These assessments shall also monitor for the following:

- (1) To assure the optimum effective dose to prevent withdrawal.
- (2) To adequately block euphoric effects of other opioid drugs.
- (3) To minimize or eliminate craving and dosing regimens too high for a given patient that may result in a clinically significant level of intoxication.

(f) The initial dose of the following medications shall be as follows:

- (1) For methadone, the program physician may order the following:
  - (A) Up to thirty (30) milligrams of methadone as an initial dose for an incoming patient.
  - (B) After at least one (1) hour observation, up to ten (10) milligrams of additional methadone for an

incoming patient if the symptoms of withdrawal have persisted.

(2) For buprenorphine, an initial dose as determined in the reasonable medical judgment of the program physician in light of the patient's circumstances.

(g) Precautions shall be taken in the induction of the opioid treatment medication to assure that an individual can tolerate the dosage of medication prescribed.

(h) A patient's initial dose of opioid treatment medication shall be administered under the direction of a program physician.

(i) A patient admitted to an OTP shall not be provided with doses of opioid treatment medication for self-administration until clinical staff has observed the patient after the administration of medication at clinic visits for a minimum of five (5) days.

*(Division of Mental Health and Addiction; [440 IAC 10-4-19](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-20](#) Medical history and physical examination**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 20. (a) An OTP shall conduct a physical examination of each patient at the following times:**

- (1) Prior to admission to an OTP.
- (2) Annually thereafter.

(b) The OTP shall fully document the nature, extent, and results of the physical examination in the patient's record.

(c) The physical examination shall be performed by either of the following:

- (1) A program physician.
- (2) An authorized health care professional.

(d) The physical examination shall include at least the following:

- (1) A health history, including the following:
  - (A) Surgeries.
  - (B) Allergies.
  - (C) Significant medical problems.
  - (D) Review of current prescriptions and over-the-counter medications.
  - (E) Personal and family history of alcohol, drug, psychiatric, and medical conditions and treatment.
- (2) A review of all major physical systems, including the following:
  - (A) Neurological.
  - (B) Respiratory.
  - (C) Cardiac.
  - (D) Gastrointestinal.
  - (E) Endocrine.
  - (F) Musculoskeletal.
  - (G) Urogenital.
- (3) For women, the following:
  - (A) The date of the last menstrual period.
  - (B) Pregnancy history.
  - (C) Current pregnancy status, including the following:
    - (i) Breastfeeding.
    - (ii) Current menses status.
    - (iii) Childbearing status.
- (4) A pain evaluation using a standard pain scale.
- (5) Vital signs, including the following:

- (A) Temperature.
- (B) Pulse.
- (C) Respiration.
- (D) Blood pressure.
- (6) An exploration of symptoms of communicable disease, including the following:
  - (A) Tuberculosis.
  - (B) Hepatitis A, B, and C.
  - (C) Sexually-transmitted diseases.
  - (D) HIV and AIDS.
- (7) A tuberculosis skin test, such as the intradermal Purified Protein Derivative (PPD) test.
- (8) Screening for syphilis and, for positive screens, referral for further evaluation.
- (9) A complete blood count.

(e) Documentation of the full medical examination, including the results of serology and other tests, shall be recorded in the patient medical record not later than fourteen (14) days following the patient's admission.

(Division of Mental Health and Addiction; [440 IAC 10-4-20](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### [440 IAC 10-4-21](#) Substance abuse assessment

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 21. (a) A comprehensive substance abuse assessment shall be:

- (1) conducted with each admitted patient; and
- (2) documented in the patient's record.

(b) The substance abuse assessment shall include, but not be limited to, the following:

- (1) Completion of a comprehensive substance abuse assessment using a standardized instrument as required in section 6(g)(1) of this rule that indicates the following:
  - (A) The level of addiction.
  - (B) The level of care needs.
  - (C) The intensity of services needed for a patient's recovery.
- (2) Completion of a biopsychosocial history, including documentation of other treatment that the patient is currently receiving.

(Division of Mental Health and Addiction; [440 IAC 10-4-21](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### [440 IAC 10-4-22](#) Drug testing

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-1](#); [IC 12-23-18-2.5](#)

Sec. 22. (a) An OTP shall do the following:

- (1) Use medically recognized drug testing protocols:
  - (A) to determine legitimate treatment use; and
  - (B) as a clinical tool for the purpose of diagnosis and treatment planning.
- (2) Perform all drug testing as specified in this section.
- (3) Have written procedures for drug testing, including protocols to assure the chain of custody of bodily fluid samples.
- (4) Contract for drug testing only with a laboratory that is in compliance with all applicable federal proficiency testing and licensing standards.
- (5) Require an OTP staff person to observe each patient's provision of a bodily fluid sample for drug testing to assure that a false sample is not provided by the patient.

(b) The results of all drug tests shall be recorded in the patient's record.

(c) An OTP shall periodically and randomly test a patient, including before receiving treatment, for the following:

- (1) Methadone.
- (2) Cocaine.
- (3) Opiates.
- (4) Amphetamines.
- (5) Barbiturates.
- (6) Tetrahydrocannabinol.
- (7) Benzodiazepines.
- (8) Any other suspected or known drug that may have been abused by the patient.

(d) A patient shall have a drug test under this section at the following times:

- (1) After admission but before the patient receives treatment medication.
- (2) At least eight (8) times during each twelve (12) month period after the patient's admission.
- (3) As required under subsection (f) following a positive drug test.

(e) The OTP and a patient shall comply with the requirements of subsection (f) if the patient tests positive for any of the following:

- (1) A controlled substance for which the patient does not have a prescription.
- (2) A controlled substance that is not part of the patient's treatment plan at the OTP.
- (3) An illegal drug other than a drug that is part of the patient's treatment plan at the OTP.

(f) If a patient tests positive under a test for a controlled substance or an illegal drug that is not allowed under subsection (e), the following provisions shall be met:

- (1) The OTP shall refer the patient to the on-site physician for a clinical evaluation that shall be conducted not more than ten (10) days after the date of the patient's positive test.
- (2) The physician shall consult with medical and behavioral staff at the OTP to conduct the evaluation.
- (3) The clinical evaluation shall recommend a remedial action for the patient that may include either of the following:
  - (A) Discharge from the OTP.
  - (B) Amending the patient's treatment plan to require a higher level of supervision.
- (4) The OTP may not allow the patient to take any opioid treatment medications from the facility for self-administration until the patient has:
  - (A) completed the clinical evaluation under this subdivision; and
  - (B) passed a random test.
- (5) The patient shall do the following:
  - (A) Attend the OTP daily until the on-site physician, after consultation with the medical and behavioral staff, determines that daily treatment is no longer necessary.
  - (B) Take a weekly random test until the patient passes a test under this subdivision.

(g) The results of a single drug test shall not be the sole basis for making significant treatment decisions; provided, however, that this subsection shall not exempt an OTP from complying with the requirements of this section.

*(Division of Mental Health and Addiction; [440 IAC 10-4-22](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-23](#) Treatment plan**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 23. (a)** An initial individualized treatment plan, based on information obtained during the admission process, shall:

- (1) be established following a patient's admission to the OTP;



- (2) guide the first three (3) months of the patient's treatment;
- (3) be completed within fourteen (14) days following the patient's admission;
- (4) identify the:
  - (A) goals on which the patient shall work;
  - (B) time frames for goal attainment; and
  - (C) strategies to be used by the OTP to facilitate the patient's goal attainment;
- (5) include goals to address the patient's needs as identified in the:
  - (A) physical evaluation;
  - (B) substance abuse assessment;
  - (C) physical examination; and
  - (D) results of drug testing of the patient; and
- (6) include the following goals:
  - (A) the stabilization of the patient on treatment medication;
  - (B) an assessment of the patient's readiness to discontinue treatment medication;
  - (C) a discontinuation of treatment medication, as clinically indicated; and
  - (D) at least one (1) of the goals in subsection (b).

(b) The initial treatment plan may include the following goals as appropriate for the patient:

- (1) An elimination of the following:
  - (A) The use of illicitly obtained prescription opioid drugs.
  - (B) The illicit use of nonprescription opioid drugs.
  - (C) The illicit use of drugs other than opioids.
  - (D) Criminal behavior.
  - (E) Risky behavior related to the transmission of infectious disease.
  - (F) Alcohol abuse.
- (2) An improvement in the following:
  - (A) Education or vocational training status.
  - (B) Employment status.
  - (C) Family and other social relationships.

(c) The initial treatment plan shall include referrals for the following services, as appropriate:

- (1) Mental health services.
- (2) Other medical services.
- (3) Vocational training.
- (4) Education services.
- (5) Employment services.

(d) The patient's treatment plan shall be reviewed and updated at the following times:

- (1) At least monthly during the first three (3) months of treatment.
- (2) Thereafter, as clinically appropriate, but not less frequently than annually.

*(Division of Mental Health and Addiction; [440 IAC 10-4-23](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-24](#) Patient orientation**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 24. (a) Within seven (7) days of admission, a patient admitted to the OTP shall receive an orientation to OTP services providing information on the following:**

- (1) The mission and goals of the OTP.
- (2) The hours during which services are provided.
- (3) Treatment costs.
- (4) Patient rights and responsibilities.
- (5) Counseling services.
- (6) Federal confidentiality requirements.
- (7) Attendance expectations.



(8) The OTP's treatment philosophy and program structure.

(9) The:

(A) attainment of self-administered dose privileges; and

(B) requirements to maintain the privileges.

(10) Referral to services not provided by the OTP.

(11) Rules governing patient conduct and infractions that can lead to disciplinary action or discharge from the OTP.

(12) Information about initiating a discontinuation of medication.

(b) Information provided in the orientation shall be accompanied by the provision of written materials on all covered topics.

(c) The OTP shall require a new patient to acknowledge in writing that the patient has received a full orientation to all requirements and responsibilities associated with program enrollment.

(d) For pregnant women, the OTP shall explain the following:

(1) The risks and benefits of opioid treatment medication during pregnancy.

(2) The program requirement for prenatal medical care.

(e) Documentation of the provision of the above information shall be included in the patient's record.

*(Division of Mental Health and Addiction; [440 IAC 10-4-24](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-25](#) Patient compliance with program rules**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 25. (a) To remain enrolled in the program, a patient shall do the following:**

(1) Comply with program rules and expectations.

(2) Demonstrate progress toward identified goals.

(b) A violation of program rules by a patient may result in either of the following:

(1) A medically supervised reduction of opioid treatment medication.

(2) The patient's termination from the program.

However, a patient's continued use of an illicit drug or drugs or a patient's nonpayment of fees is not a sufficient justification for termination or discharge of the patient from the OTP, unless the patient refuses to cooperate with the patient's treatment plan.

(c) Violations of OTP rules for which a patient may be subject to discharge from the OTP include, but are not limited to, the following:

(1) Threats of violence or actual violence toward staff or another patient.

(2) Other disruptive behavior.

(3) Community incidents, including, but not limited to, any of the following:

(A) Loitering near the OTP.

(B) The diversion of opioid treatment medication.

(C) The sale or purchase of illicit drugs.

(4) Continued unexcused absences from counseling and other OTP services.

(5) An involvement in criminal activities.

(6) Any other OTP rule violation.

(d) At the discretion of the medical director, a patient may be moved to a level of treatment necessary to reestablish stability if the patient does any of the following:

(1) Relapses to the illicit use of controlled substances.

(2) Abuses alcohol.

(3) Ceases to progress in treatment.

(e) The OTP shall have written policies and procedures that address the consequences of a patient testing positive for the following:

- (1) A drug for which the patient does not have a prescription.
- (2) A drug which is not part of the patient's treatment plan.

(f) The OTP shall provide its written policies and procedures to a patient within seven (7) days of admission.

*(Division of Mental Health and Addiction; [440 IAC 10-4-25](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-26](#) Self-administered medication**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-5](#)

**Sec. 26. (a) An OTP shall do the following:**

- (1) Comply with the requirements in this section for a patient's self-administration of opioid treatment medication.
- (2) Implement practices in accordance with the principle that obtaining unsupervised doses of opioid treatment medication is a privilege given only to a patient who:
  - (A) will benefit from obtaining unsupervised doses; and
  - (B) has demonstrated responsibility in taking opioid treatment medication as prescribed and toward the patient's overall recovery program.
- (3) Not provide an enrolled patient with any dose of opioid treatment medication for self-administration until the clinical staff has observed the patient's ingestion of opioid treatment medication for at least five (5) days.

(b) Treatment program decisions regarding the administering of opioid treatment medications to patients for unsupervised use, beyond the requirement in subsection (d), shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the take-home criteria in subsection (e).

(c) The determinations made under subsection (b) and the basis for the determinations, consistent with the criteria under subsection (e), shall be documented in the patient's medical record.

(d) An OTP may provide unsupervised opioid treatment medication based on the patient's time in treatment pursuant to 42 CFR §8.12(i)(3) unless the patient does not qualify under, and subject to the provisions of, the following:

- (1) Subsection (a)(3).
- (2) Subsection (k).
- (3) Section 22(f)(4) of this rule.

(e) In determining whether a patient may be permitted the unsupervised use of opioid treatment medication, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid treatment medication for unsupervised use:

- (1) The absence of recent abuse of drugs (opioid or non-narcotic), including alcohol.
- (2) Regularity of clinic attendance and compliance with the patient's treatment plan.
- (3) The absence of serious behavioral problems at the clinic.
- (4) The absence of known recent criminal activity, for example, drug dealing.
- (5) Stability of the patient's home environment and social relationships.
- (6) The length of time in opioid treatment.
- (7) Assurance that take-home medication can be safely and securely stored within the patient's home.
- (8) Whether the patient will derive a benefit from decreasing the frequency of clinic attendance that outweighs the potential risks of diversion.

(f) Before self-administration privileges are granted:

(1) an OTP shall educate the patient regarding:

(A) the safe transportation of opioid treatment medication;

(B) storage requirements for opioid treatment medication; and

(C) emergency procedures in case of the accidental ingestion of opioid treatment medication; and

(2) the patient is required to provide:

(A) an opaque, childproof locked container for transportation of opioid treatment medication; and

(B) safe and secure home storage.

(g) The OTP shall prepare bottles for the self-administration of medication with labels containing the following information:

(1) The patient's name.

(2) The name of the OTP physician.

(3) The medication name.

(4) The medication dose.

(5) The date the bottle was filled.

(6) The date or dates when the medication is to be ingested.

(7) Directions for ingesting the medication.

(8) The name, address, and telephone number of the OTP.

(9) Appropriate cautionary statements, including "Caution: Federal law prohibits the transfer of this drug to a person other than the patient for whom it was dispensed."

(h) The OTP shall have written policies addressing the responsibilities of patients who are granted privileges for the self-administration of opioid treatment medication, including the following:

(1) Methods of assuring a patient's appropriate use and storage of medication in the home.

(2) The return of self-administered medication bottles, including a policy and procedure that:

(A) requires bottles to be returned:

(i) immediately upon request; and

(ii) with labels intact; and

(B) addresses the consequences of a failure to return bottles as requested.

(i) Regardless of a patient's time in treatment, the medical director may deny or rescind, if clinically appropriate, a patient's privileges to receive opioid treatment medication for self-administration.

(j) Exceptions for self-administered medication may be requested, consistent with the federal requirements in 42 CFR Part 8, and submitted to the following:

(1) The state authority.

(2) The federal Center for Substance Abuse Treatment, Division of Pharmacologic Therapy.

(k) An OTP shall submit exception requests to the state authority for all self-administered opioid treatment medication for more than fourteen (14) days.

(l) Any OTP request under subsection (j) or (k) for an exception to the federal regulations for self-administered medications shall, at a minimum, include the following:

(1) The dates and results of the patient's drug tests within the past three (3) months.

(2) The patient's progress toward treatment plan goals.

(3) Documentation, as appropriate, of a private physician's recommendation that the patient is unable to travel to the OTP due to a medical condition.

(4) Documentation of employment travel hardship, as appropriate.

(5) Documentation of other travel hardship, as appropriate.

(6) For a temporary exception request due to travel, documentation that interim services are not available at the location to which the patient is temporarily traveling.

*(Division of Mental Health and Addiction; [440 IAC 10-4-26](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-27](#) Reduction or discontinuation of medication**

**Sec. 27. (a) An OTP shall do the following:**

**(1) Comply with the requirements in this section with regard to the reduction or discontinuation of treatment medication.**

**(2) Perform routine evaluations to determine the readiness of a patient to reduce or discontinue treatment medication, with the goal of achieving complete abstinence, if clinically appropriate for the patient in the reasonable judgment of an OTP program physician. An OTP is responsible for ongoing relapse prevention treatment for patients who reduce or discontinue medication, either directly or through a referral to an allied clinician or treatment program.**

**(b) A medication reduction shall involve the administration of opioid treatment medication in decreasing amounts to an individual for the following reasons:**

**(1) To alleviate adverse physiological or psychological effects incidental to withdrawal from the continuous or sustained use of opioids.**

**(2) To withdraw the individual from opioid treatment medication if clinically appropriate for the patient in the reasonable judgment of an OTP program physician.**

**(c) A reduction or discontinuation of opioid treatment medication shall meet the following requirements:**

**(1) Be initiated when requested by the patient unless clinically contraindicated.**

**(2) Be carried out in a manner that minimizes the psychological and physical effects of the reduction or discontinuation.**

**(d) A reduction or a discontinuation of a patient's opioid treatment medication may be initiated by an OTP at any of the following times:**

**(1) When clinically appropriate for the patient.**

**(2) If the patient demonstrates noncompliance with therapeutic interventions.**

**(3) If the patient violates program rules.**

**(e) The tapering of opioid treatment medication shall be completed in a manner appropriate to the following:**

**(1) The patient's level of medication.**

**(2) The circumstances justifying the action.**

**(f) An OTP may immediately discontinue a patient's opioid treatment medication if either of the following exists:**

**(1) A safety concern.**

**(2) A concern that opioid treatment medication has been diverted.**

**(g) If a patient's opioid treatment medication has been immediately discontinued under subsection (f), the OTP shall offer the patient a referral to another service.**

**(h) An OTP may facilitate a transfer to another program or a referral to a medical facility in place of the discontinuation of opioid treatment medication under subsection (f).**

*(Division of Mental Health and Addiction; [440 IAC 10-4-27](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-28](#) Medication in extenuating circumstances**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 28. (a)** Based on reasonable clinical judgment, the medical director may grant opioid treatment medication to a patient for extenuating circumstances that prevent the patient's attendance at the OTP for a period not exceeding forty-eight (48) hours related to the following:

- (1) The patient's medical condition.
- (2) The patient's criminal justice requirements.
- (3) The patient's family or employment circumstances.
- (4) Other circumstances of the patient.

**(b)** The bases for the medical director's action shall be the following:

- (1) The patient's conformance with the criteria listed in section 26(e) of this rule.
- (2) The nature and extent of the circumstances preventing the patient's attendance at the OTP.

**(c)** The action, circumstances, and outcome shall be documented in the patient's record.

**(d)** The OTP shall do the following:

- (1) Inform the division in writing within twenty-four (24) hours if the OTP administers any opioid treatment medication under this section.
- (2) Submit an exception request to the state authority if extenuating circumstances prevent the patient's attendance at the OTP for a period greater than forty-eight (48) hours.

*(Division of Mental Health and Addiction; [440 IAC 10-4-28](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-29](#) Interim services**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#)

**Sec. 29. (a)** An OTP shall have written policies and procedures concerning guest dosing pertaining to both:

- (1) the OTP's patients; and
- (2) a patient receiving interim services at the OTP.

**(b)** A patient who has not met the criteria in section 26(e) of this rule to qualify for self-administration privileges shall first be evaluated for the availability of interim services at an OTP in close proximity to a location where the patient will be present.

**(c)** An OTP shall make arrangements for interim services on behalf of the patient.

**(d)** An OTP whose enrolled patient is receiving interim services at another OTP shall document the interim services to be received in the patient's record.

**(e)** If an OTP provides interim services to a patient enrolled at another OTP, the OTP providing those services shall record information concerning the services in a log maintained for that purpose.

*(Division of Mental Health and Addiction; [440 IAC 10-4-29](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-30](#) Patient transfer**

**Authority:** [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

**Affected:** [IC 12-23-18](#)

**Sec. 30. (a)** An OTP shall have written policies and procedures concerning a patient's transfer from one (1) OTP to another.

(b) For all transferring patients, the transferring OTP shall do the following:

(1) With written authorization from the patient:

(A) contact the receiving OTP to inform the receiving OTP of the transfer; and

(B) provide all relevant patient records, including necessary treatment information, to the receiving OTP.

(2) Provide the reason for the transfer.

(c) If a patient's transfer is within the state of Indiana, the OTP shall take appropriate action in the central registry to assure that the patient:

(1) has been removed from the census of the transferring OTP; and

(2) can be entered in the receiving OTP's census.

(d) A transferring patient is required to meet the admission criteria of the OTP to which the patient is transferring, that is, the receiving OTP.

(e) A receiving OTP shall evaluate a transferring patient upon admission to assure that the patient is placed in the appropriate level of treatment.

(f) If the patient fails or refuses to provide the necessary consent for the transfer of relevant patient records to the receiving OTP, the receiving OTP shall not be required to admit the patient.

*(Division of Mental Health and Addiction; [440 IAC 10-4-30](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-31](#) Outcome measures**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 31. (a) Among the goals established for all patients are the following outcome measures:**

(1) An elimination of the following:

(A) The use of prescription opioids.

(B) The illegal use of nonprescription opioids.

(C) The illegal use of drugs other than opioids.

(D) Criminal behavior.

(E) Risky behavior related to the spread of infectious disease.

(F) Alcohol abuse.

(2) An improvement in the following:

(A) Education or vocational training.

(B) Employment.

(C) Family relationships.

(b) An OTP shall evaluate the above outcome measures for each patient at the following times at a minimum:

(1) Upon the patient's admission to the OTP.

(2) By December 31 of each year.

*(Division of Mental Health and Addiction; [440 IAC 10-4-31](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### **[440 IAC 10-4-32](#) Quality assurance**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-5.7](#)

**Sec. 32. An OTP shall do the following:**

- (1) Participate in and meet the requirements of all quality assurance efforts required by the division.
- (2) Prepare and maintain current quality assurance and quality control plans that include the following:
  - (A) An annual review of program policies and procedures.
  - (B) At least an annual review and evaluation of patient outcomes, including, but not limited to, a review of random samples of the following:
    - (i) The records of patients, including pregnant patients, currently in treatment.
    - (ii) The records of patients who voluntarily withdrew from treatment, including the following:
      - (AA) Patients who completed medically supervised dosage reduction.
      - (BB) Patients who left treatment against medical advice.
  - (C) The records of patients who have undergone a medically supervised dosage reduction as a result of involuntary discharge from the program.
- (3) Use the results of the reviews and evaluations for the following purposes:
  - (A) To modify the OTP's provision of services as appropriate.
  - (B) To increase the efficacy of the OTP's services.

(Division of Mental Health and Addiction; [440 IAC 10-4-32](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

**[440 IAC 10-4-33](#) Central registry**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-5.6](#); [IC 12-23-18-5.7](#)

**Sec. 33. (a) The division shall establish and maintain an electronic central registry to collect the following:**

- (1) Information concerning each patient served by Indiana OTPs.
- (2) Information specific to each OTP.

**(b) An OTP shall do the following:**

- (1) Provide information required by the division concerning patients receiving treatment.
- (2) Report patient specific information to the central registry in a form such that an individual patient may not be personally identified.
- (3) Enter de-identified patient specific information into the central registry maintained by the division at the following times:
  - (A) Immediately upon admission of a patient.
  - (B) Within twenty-four (24) hours of:
    - (i) a patient's discharge; or
    - (ii) the transfer of a patient to another OTP.
  - (C) Not less frequently than annually for patients remaining in treatment.
  - (D) At other intervals required by the division.
- (4) Enter information into the central registry regarding an evaluation of each patient's progress in treatment via recovery indicators at the following times:
  - (A) By December 31 of each year.
  - (B) Within thirty (30) days of a patient's discharge.
- (5) Enter additional specific information into the central registry as required by the division.

**(c) The information in the central registry is confidential.**

(Division of Mental Health and Addiction; [440 IAC 10-4-33](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

**[440 IAC 10-4-34](#) Submission of data to the central registry**

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-5.6](#); [IC 12-23-18-5.7](#)



**Sec. 34. (a)** An OTP shall report and maintain information in the central registry, or by other means designated by the division, to assure that the division collects all information required by [IC 12-23-18-5.7](#), including the following:

- (1) The number of OTPs in Indiana.
- (2) The number of patients receiving opioid treatment in Indiana.
- (3) The length of time each patient received opioid treatment.
- (4) The average length of time all patients received opioid treatment.
- (5) The cost of each patient's opioid treatment.
- (6) The average cost of opioid treatment.
- (7) The number of patients who are:
  - (A) determined to be no longer in need of services; and
  - (B) no longer receiving opioid treatment.
- (8) The number of individuals, by geographic area, who are on a waiting list to receive opioid treatment.
- (9) The patient information reported to the central registry.
- (10) The number of patients who tested positive under a test for a controlled substance or illegal drug not allowed under section 22 of this rule.
- (11) The number of patients in subdivision (10) who were discharged from the OTP.
- (12) Any other information the division determines to be relevant to assure the quality of an OTP.

**(b)** An OTP shall enter in the central registry all data in subsection (a) for:

- (1) all patients treated during the calendar year; and
- (2) the period ending on December 31 of each calendar year by January 15 of the following year.

*(Division of Mental Health and Addiction; [440 IAC 10-4-34](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))*

#### [440 IAC 10-4-35](#) Incident reporting

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 35. (a)** An OTP shall notify the division in the manner designated by the division within twenty-four (24) hours after an OTP is notified of the occurrence of any of the following events:

- (1) A serious patient injury with the potential loss of functioning or the marked deterioration of a patient's condition occurring under unanticipated or unexpected circumstances.
- (2) A chemical poisoning occurring within the OTP resulting in harm or injury to a patient.
- (3) An unexplained loss or theft of a controlled substance.
- (4) The death of either of the following:
  - (A) An enrolled patient.
  - (B) An individual residing with an enrolled patient if the death is related to the ingestion of opioid treatment medication.
- (5) A disruption, exceeding four (4) hours, in the continued safe operation of the OTP or in the provision of patient care, caused by any of the following:
  - (A) Internal or external disasters.
  - (B) Strikes by health care workers.
  - (C) Unscheduled revocation of vital services.
- (6) Any fire or explosion.

**(b)** An OTP shall send a written report to the division within ten (10) business days of the occurrence of any of the events listed in subsection (a).

**(c)** A death report shall including the following information:

- (1) A deceased patient's:
  - (A) opioid treatment medication; and
  - (B) dosage of opioid treatment medication at the time of death.
- (2) The date and the results of a deceased patient's last drug test.
- (3) The number of days per week a deceased patient was attending the OTP at the time of death.

- (4) Whether any take-home bottles were:
  - (A) returned to the OTP after the patient's death; or
  - (B) unaccounted for after the patient's death.
- (5) The nature and extent of the outreach provided to a deceased patient's family.
- (6) Whether a coroner's inquest is expected concerning the patient's death.
- (7) When available, the coroner's report shall be forwarded to the division.

(Division of Mental Health and Addiction; [440 IAC 10-4-35](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

#### [440 IAC 10-4-36](#) Community education and outreach

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 36. (a)** The OTP shall develop and implement a plan for a community education program designed to provide information to, but not limited to, the following sectors of the community where the OTP is located:

- (1) Law enforcement.
- (2) Local coordinating councils.
- (3) The medical community, including the following:
  - (A) Obstetricians.
  - (B) Pediatricians.
  - (C) Hospitals.
- (4) Health departments.
- (5) Mental health and addiction service providers.
- (6) Courts.
- (7) Government agencies.
- (8) Schools.

**(b)** The community education program plan shall meet the following requirements:

- (1) Contain educational objectives.
- (2) Be reviewed, signed, and dated annually.

(Division of Mental Health and Addiction; [440 IAC 10-4-36](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

#### [440 IAC 10-4-37](#) Program monitoring

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

**Sec. 37.** The division shall conduct the following program monitoring:

- (1) An annual on-site inspection of each OTP to assess compliance with the program requirements of this article.
- (2) Monitoring of each OTP's diversion control plan under section 2 of this rule.
- (3) Other monitoring activities as needed to:
  - (A) investigate complaints; and
  - (B) assure compliance with:
    - (i) this rule;
    - (ii) other applicable state rules; and
    - (iii) federal regulations.

(Division of Mental Health and Addiction; [440 IAC 10-4-37](#); filed Dec 30, 2009, 2:00 p.m.: [20100127-IR-440080412FRA](#))

#### [440 IAC 10-4-38](#) Program fees

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18-3](#); [IC 12-23-18-4](#)

Sec. 38. (a) Each OTP shall annually, as set forth herein, submit fees to the division to be deposited in the OTP fund administered by the division, hereinafter referred to as "the fund".

(b) Money in the fund shall be used to pay all expenses of administering the following:

(1) The requirements of [IC 12-23-18](#).

(2) The OTP fund.

Money in the fund does not revert to the state general fund.

(c) An OTP shall pay an annual fee for each patient treated by the OTP during each calendar year; provided, however, that an OTP shall not be required to pay the fee for an individual being treated temporarily under guest dosing arrangements with another OTP.

(d) The following methodology shall be used to calculate the fee for each patient for the calendar year:

(1) The division's expenses from the preceding calendar year to pay the cost of implementing and administering [IC 12-23-18](#) shall be divided by the number of patients treated by all OTPs during the preceding calendar year as reported by each OTP to the central registry.

(2) The resulting number represents the fee per patient for the present calendar year; provided, however, the fee shall not exceed seventy-five dollars (\$75) for each OTP patient who was treated by the OTP during the preceding calendar year.

(e) The division shall calculate the per patient fee by February 15 of each year based on the division's expenses for the preceding calendar year to pay the cost of the implementation and administration of [IC 12-23-18](#).

(f) On or before February 15 of each year, the division shall give each OTP written notice of the fee per patient due by May 15 of that year.

(g) By May 15 of each year, each OTP shall submit to the division the fee determined by the division in subsection (f).

*(Division of Mental Health and Addiction; [440 IAC 10-4-38](#); filed Dec 30, 2009, 2:00 p.m.: 20100127-IR-440080412FRA)*

#### [440 IAC 10-4-39](#) Conditional status for specific approval of opioid treatment program

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 39. The division shall do the following:

(1) Issue to an OTP a notice of conditional status of the specific approval granted under this rule upon the division's investigation and determination of any of the following conditions:

(A) A substantive change in the OTP's accreditation status other than revocation of the accreditation.

(B) A failure to do the following:

(i) Renew accreditation within ninety (90) days following the expiration of an OTP's current accreditation.

(ii) Comply with the provisions of section 2 of this rule concerning the requirements for a diversion control plan.

(iii) Comply with this article.

(C) Any conduct or practice in the operation of an OTP that is found to be detrimental to the health or welfare of the patients or the staff of the OTP.

(D) The physical health or safety of the patients or the staff of the OTP is compromised by a physical or sanitary condition of a physical facility of the OTP.

- (E) The violation of, or failure to comply with, a federal or state statute, rule, or regulation, including [IC 12-23-18](#), 42 CFR Part 8, or this rule, in the course of the operation of an OTP.
- (2) Determine the time period of an OTP's conditional status; provided, however, that the time period may not exceed twelve (12) months from the effective date of conditional status.
- (3) Give the OTP written notice of the following:
  - (A) The requirements that the OTP has not met.
  - (B) The intermediate steps required by the division that the OTP shall take in order to meet the requirements in clause (A).
  - (C) The time period granted by the division for the OTP to meet the requirements in clause (A).
- (4) Terminate the specific approval of the OTP for a failure to meet the division's requirements in subdivision (3).

(Division of Mental Health and Addiction; [440 IAC 10-4-39](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### [440 IAC 10-4-40](#) Termination of specific approval of opioid treatment program

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 12-23-18](#)

Sec. 40. (a) The division shall terminate the specific approval of an OTP if any of the following occurs:

- (1) The OTP that has a conditional status fails to meet the division's requirements within the allotted time period.
- (2) The accreditation of the OTP is revoked.
- (3) The OTP's federal Drug Enforcement Agency registration is terminated.
- (4) The OTP's controlled substances registration certificate issued by the Indiana board of pharmacy is terminated.
- (5) The OTP's facility certification is terminated.

(b) If the division terminates an opioid treatment program's specific approval, the division shall give written notice to the following:

- (1) The Indiana family and social services administration.
- (2) The Indiana department of administration.

(Division of Mental Health and Addiction; [440 IAC 10-4-40](#); filed Dec 30, 2009, 2:00 p.m.:  
[20100127-IR-440080412FRA](#))

#### [440 IAC 10-4-41](#) Penalties and appeals

Authority: [IC 12-8-8-4](#); [IC 12-23-1-6](#); [IC 12-23-18](#)

Affected: [IC 4-21.5](#); [IC 12-23-18-5.8](#)

Sec. 41. (a) The division director may take any of the following actions based on any grounds described in subsection (b):

- (1) Issue a letter of correction to the OTP.
- (2) Reinspect the OTP.
- (3) Issue a notice of conditional status of the OTP's specific approval.
- (4) Deny the renewal of or revoke the OTP's specific approval.
- (5) Impose a civil penalty in an amount not exceeding ten thousand dollars (\$10,000).

(b) The division director may take action under subsection (a) based on any of the following grounds:

- (1) Violating, or failing to comply with, either of the following:
  - (A) [IC 12-23-18](#).
  - (B) This rule.
- (2) Permitting, aiding, or abetting the commission of any illegal act in an OTP facility.
- (3) Conduct or a practice found by the director to be detrimental to the welfare of an OTP patient.

(c) **IC 4-21.5**, the administrative orders and procedures act, applies to an action under this rule.

(Division of Mental Health and Addiction; [440 IAC 10-4-41](#); filed Dec 30, 2009, 2:00 p.m.:  
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Notice of Intent: [20080528-IR-440080412NIA](#)

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Documents Incorporated by Reference: 21 U.S.C. 355; 21 CFR 1301.71 through 21 CFR 1301.76; 42 CFR Part 2; 42 CFR Part 8

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