TITLE 440 DIVISION OF MENTAL HEALTH AND ADDICTION

Final Rule
LSA Document #14-343(F)

DIGEST

Amends 440 IAC 10-1 by adding definitions 440 IAC 10-1-10.5, 440 IAC 10-1-23.5, 440 IAC 10-1-24.5, 440 IAC 10-1-25.5, 440 IAC 10-1-25.7, 440 IAC 10-1-27.5, 440 IAC 10-1-39.5, and 440 IAC 10-1-54.5 for "buprenorphine", "guest dose", "Indiana scheduled prescription electronic collection and tracking" or "INSPECT", "informed consent", "initial assessment", "methadone", "phase treatment", and "state opioid treatment authority" or "SOTA", respectively. Adds 440 IAC 10-2-2 to designate the director of the Division of Mental Health and Addiction or his or her designee as the state opioid treatment authority. Amends 440 IAC 10-4-13 to clarify responsibilities of a program physician and a medical director and to allow a licensed clinical addiction counselor to work as a counselor for an opioid treatment program. Amends 440 IAC 10-4-16 to change the term physical evaluation to initial assessment and clarify the requirements for conducting an initial assessment. Amends 440 IAC 10-4-19 to list other medications as alternatives to methadone that may be used by opioid treatment programs to treat patients and to require the program physician to check the Indiana INSPECT program prior to administering any opioid treatment medications, to document the findings in the patient's record, and to explain to the patient the risks and benefits of treatment medication and relevant facts concerning the use of opioid treatment medications to ensure that the patient voluntarily chooses maintenance treatment. Amends 440 IAC 10-4-26 to require opioid treatment programs to submit exception requests to the division for all self-administered opioid treatment medication for more than seven days. Adds 440 IAC 10-4-42 to establish standards and protocols for patients who are receiving opioid treatment medications. Adds 440 IAC 10-4-43 to establish mandatory reporting requirements. Repeals 440 IAC 10-1-40 concerning "physical evaluation". Effective 30 days after filing with the Publisher.

440 IAC 10-1-10.5; 440 IAC 10-1-23.5; 440 IAC 10-1-24.5; 440 IAC 10-1-25.5; 440 IAC 10-1-25.7; 440 IAC 10-1-27.5; 440 IAC 10-1-39.5; 440 IAC 10-1-40; 440 IAC 10-1-54.5; 440 IAC 10-2-2; 440 IAC 10-4-13; 440 IAC 10-4-16; 440 IAC 10-4-19; 440 IAC 10-4-26; 440 IAC 10-4-42; 440 IAC 10-4-43

SECTION 1. 440 IAC 10-1-10.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-1-10.5 "Buprenorphine" defined

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18

Sec. 10.5. "Buprenorphine" means a synthetic opioid agonist –antagonist; the hydrochloride salt is used as an analgesic and as a substitute in the management of opioid addiction. It has been approved by the FDA for detoxification in maintenance treatment of opioid dependence.

(Division of Mental Health and Addiction; 440 IAC 10-1-10.5; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 2. 440 IAC 10-1-23.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-1-23.5 "Guest dose" defined

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18-4

Sec. 23.5. "Guest dose" means any dose provided on a temporary basis at a program other than the patient's home clinic.

(Division of Mental Health and Addiction; 440 IAC 10-1-23.5; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 3. 440 IAC 10-1-24.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-1-24.5 "Indiana scheduled prescription electronic collection and tracking" or "INSPECT"

defined

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18; IC 25-1-13-3

Sec. 24.5. "Indiana scheduled prescription electronic collection and tracking" or "INSPECT" has the same meaning as defined in IC 25-1-13-3.

(Division of Mental Health and Addiction; 440 IAC 10-1-24.5; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 4. 440 IAC 10-1-25.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-1-25.5 "Informed consent" defined

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18

Sec. 25.5. "Informed consent" means the following information shall be provided to the patient:
(1) A description of any reasonably foreseeable risks or discomforts to the patient.
(2) A description of any benefits to the patient that may reasonably be expected from treatment.
(3) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the patient.

(Division of Mental Health and Addiction; 440 IAC 10-1-25.5; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 5. 440 IAC 10-1-25.7 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-1-25.7 "Initial assessment" defined

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18

Sec. 25.7. "Initial assessment" means an evaluation carried out by a program physician to determine an applicant's eligibility for admission to an OTP.

(Division of Mental Health and Addiction; 440 IAC 10-1-25.7; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 6. 440 IAC 10-1-27.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-1-27.5 "Methadone" defined

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18

Sec. 27.5. "Methadone" means a synthetic opioid agonist that has been approved by the FDA for detoxification and maintenance treatment of opioid addiction.

(Division of Mental Health and Addiction; 440 IAC 10-1-27.5; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 7. 440 IAC 10-1-39.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-1-39.5 "Phase treatment" defined

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18

Sec. 39.5. "Phase treatment" means the patient's progress through treatment in a graduated sequence.

(Division of Mental Health and Addiction; 440 IAC 10-1-39.5; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 8. 440 IAC 10-1-54.5 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-1-54.5 "State opioid treatment authority" or "SOTA" defined

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18

Sec. 54.5. "SOTA" means state opioid treatment authority.

(Division of Mental Health and Addiction; 440 IAC 10-1-54.5; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 9. 440 IAC 10-2-2 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-2-2 Designation of state opioid treatment authority

Authority: IC 12-23-18-0.5; IC 12-23-18-5.5
Affected: IC 12-23-18-0.5

Sec. 2. The SOTA is the director of the division of mental health and addiction or his or her designee. The SOTA is responsible for governing opioid treatment facilities and programs in accordance with all applicable state and federal regulations. The SOTA shall also serve as a liaison with the appropriate federal agencies.

(Division of Mental Health and Addiction; 440 IAC 10-2-2; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 10. 440 IAC 10-4-13 IS AMENDED TO READ AS FOLLOWS:

440 IAC 10-4-13 OTP staff positions

Authority: 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, **which must include an assessment of risks or benefits of moving to other approved opioid treatment medications.**

(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~~ **program** physicians shall:

(A) be licensed in the state of Indiana; and

(B) work under the supervision of the medical director.

(2) ~~OTP~~ **Program** 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~~ **a program** 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 licensed clinical addiction counselor (IC 25-23.6-10.5).
~~(D)~~ **(E)** A psychologist (IC 25-33).
~~(E)~~ **(F)** A physician (IC 25-22.5-2).
~~(F)~~ **(G)** A physician assistant (IC 25-27.5), a nurse practitioner (IC 25-23-1), or a clinical nurse specialist (IC 25-23-1).
~~(G)~~ **(H)** 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; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 11. 440 IAC 10-4-16 IS AMENDED TO READ AS FOLLOWS:

440 IAC 10-4-16 Initial assessment

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18

Sec. 16. (a) ~~A physical evaluation~~ **An initial assessment** 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.
Only a program physician shall perform an initial assessment.

(b) The ~~physical evaluation~~ **initial assessment** 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.
(5) A physical examination.
~~(c)~~ **(6)** The risks and benefits of treatment medication **and appropriate alternative procedures or courses of treatment** shall be explained to the applicant. Documentation that this explanation was made shall be included in an admitted patient's record.

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

~~(f)~~ **(e)** 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).~~ **(d).**
(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)~~ **(f)** 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)~~ **(g)** 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),~~ **(e),** the OTP may refuse to admit the individual.

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

(Division of Mental Health and Addiction; 440 IAC 10-4-16; filed Dec 30, 2009, 2:00 p.m.: 20100127-IR-440080412FRA; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 12. 440 IAC 10-4-19 IS AMENDED TO READ AS FOLLOWS:

440 IAC 10-4-19 Initial opioid treatment medication

Authority: 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 may use any of the following medications as an alternative for methadone for opioid treatment:

(1) Buprenorphine.

(2) Buprenorphine combination products containing naloxone.

(3) Any other medication that has been approved by the federal Food and Drug Administration for use in the treatment of opioid addiction.

~~(b)~~ **(c)** 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)~~ **(d)** Before the patient may receive the initial dose of medication, the ~~OTP~~ **program physician** 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.

(4) The program physician checked INSPECT prior to initial medication administration to determine any potential contraindication of any schedule prescriptions. The program physician is in compliance with the requirements of this subsection when the program physician as follows:

(A) Documents any potential contraindications in the patient's record prior to determining which opioid treatment medications to administer.

(B) Documents that informed consent was provided to the patient in the patient's record prior to administering opioid treatment medications to the patient.

The program physician shall check INSPECT as frequently as clinically indicated.

~~(d)~~ **(e)** 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)~~ **(f)** 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)~~ **(g)** 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)~~ **(h)** 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)~~ **(i)** A patient's initial dose of opioid treatment medication shall be administered under the direction of a program physician.

~~(i)~~ **(j)** 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; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 13. 440 IAC 10-4-26 IS AMENDED TO READ AS FOLLOWS:

440 IAC 10-4-26 Self-administered medication

Authority: 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~~ **program** 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.~~ **SOTA.**

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

(k) An OTP shall submit exception requests to the ~~state authority~~ **SOTA** for all self-administered opioid treatment medication for more than ~~fourteen (14)~~ **seven (7)** 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; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 14. 440 IAC 10-4-42 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-4-42 Phase treatment

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 12-23-18

Sec. 42. (a) An OTP shall follow the maximum take home schedule as follows:
(1) For patient time in treatment starting day one (1) through day ninety (90), the patient shall be allowed no more than one (1) take home dose of medication per week.
(2) For patient time in treatment starting day ninety-one (91) through day one hundred eighty (180), the patient shall be allowed no more than two (2) take home doses of medication per week.
(3) For patient time in treatment starting day one hundred eighty-one (181) through day two hundred seventy (270), the patient shall be allowed no more than three (3) take home doses of medication per week.
(4) For patient time in treatment starting day two hundred seventy-one (271) through day three hundred sixty-five (365), the patient shall be allowed no more than six (6) take home doses of medication per week.
(5) For patient time in treatment after one (1) year, the patient shall be allowed no more than seven (7) take home doses of opioid treatment medications per week unless the OTP obtained prior authorization from the division.

(b) The OTP shall obtain prior authorization from the division before any patient is prescribed more than seven (7) take home doses of opioid treatment medications at one (1) time. The division may approve the authorization only under the following circumstances:
(1) The program physician has issued an order for the opioid treatment medication.
(2) The patient has not tested positive under a drug test for a drug for which the patient does not have a prescription for six (6) months.
(3) The OTP has determined that the benefit to the patient in receiving the take home opioid treatment medication outweighs the potential risk of diversion of the take home opioid treatment medication.

(Division of Mental Health and Addiction; 440 IAC 10-4-42; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 15. 440 IAC 10-4-43 IS ADDED TO READ AS FOLLOWS:

440 IAC 10-4-43 Legislative mandate reporting requirements

Authority: IC 12-23-1-6; IC 12-23-18
Affected: IC 5-14-6; IC 12-23-18-5.6

Sec. 43. (a) An OTP shall report the following to the division:
(1) The medications dispensed by the program.
(2) Total clinic enrollment.
(3) The medication delivery process, which includes whether the medication was in liquid, film, or another form.
(4) The total number of doses dispensed of each medication.
(5) The total dosage quantities dispensed for each medication.
(6) The number of patients receiving take home medications.
(7) The total number of days of medication dispensed, including take homes and from clinic, across all patients.
(8) Patient demographic information for each medication, including gender, age, and time in treatment.
(9) The dispenser's United States Drug Enforcement Agency registration number.

(b) An OTP shall provide the information required in subsection (a):
(1) for the twelve (12) month period starting July 1 and ending June 30 the following year;
(2) in electronic format by August 1.

(c) The division shall annually report the information collected under this section to the legislative council in an electronic format under IC 5-14-6 not later than October 1.

(Division of Mental Health and Addiction; 440 IAC 10-4-43; filed Feb 16, 2015, 1:02 p.m.: 20150318-IR-440140343FRA)

SECTION 16. 440 IAC 10-1-40 IS REPEALED.

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