

1 AN ACT relating to medication-assisted treatment.

2 *Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

3 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
4 READ AS FOLLOWS:

5 *Sections 1 to 11 of this Act shall be known as the Medication-Assisted Treatment*
6 *Program Licensing Act.*

7 ➔SECTION 2. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
8 READ AS FOLLOWS:

9 *As used in Sections 1 to 11 of this Act:*

10 *(1) "Addiction":*

11 *(a) Means a primary, chronic disease of brain reward, motivation, memory,*
12 *and related circuitry, in which dysfunction in these circuits leads to*
13 *characteristic biological, psychological, social, and spiritual manifestations,*
14 *which is reflected in an individual pathologically pursuing reward or relief*
15 *by substance use or both, and other behaviors;*

16 *(b) Is characterized by an inability to consistently abstain; impairment in*
17 *behavioral control; craving; diminished recognition of significant problems*
18 *with one's behaviors; interpersonal problems with one's behaviors and*
19 *interpersonal relationships; and a dysfunctional emotional response; and*

20 *(c) Includes definitions put forth by the American Society of Addiction*
21 *Medicine;*

22 *(2) "Biopsychosocial" means of, relating to, or concerned with biological,*
23 *psychological, and social aspects in contrast to the strictly biomedical aspects of*
24 *disease;*

25 *(3) "Center for Substance Abuse Treatment" means the center under the federal*
26 *Substance Abuse and Mental Health Services Administration that promotes*
27 *community-based substance use treatment and recovery services for individuals*

- 1 and families in the community and provides national leadership to improve
2 access, reduce barriers, and promote high quality, effective treatment, and
3 recovery services;
- 4 (4) "Commissioner" means the commissioner of the Department for Behavioral
5 Health, Developmental and Intellectual Disabilities;
- 6 (5) "Department" means the Department for Behavioral Health, Developmental and
7 Intellectual Disabilities in the Cabinet for Health and Family Services;
- 8 (6) "Medical director" means a physician licensed pursuant to KRS Chapter 311
9 who assumes responsibility for administering all medical services performed by a
10 medication-assisted treatment program, either by performing them directly or by
11 delegating specific responsibility to authorized program physicians and health
12 care professionals functioning under the medical director's direct supervision
13 and functioning with their respective scopes of practice;
- 14 (7) "Medication-assisted treatment" means the use of medications and drug screens,
15 in combination with counseling and behavioral therapies, to provide a holistic
16 approach to the treatment of substance use disorders;
- 17 (8) "Medication-assisted treatment program" or "program" means a publicly or
18 privately owned opioid treatment program or office-based medication-assisted
19 treatment program which prescribes medication-assisted treatment medications
20 and treats substance use disorders;
- 21 (9) "Medication-assisted treatment medication" means a medication that is approved
22 by the United States Food and Drug Administration under Section 505 of the
23 federal Food, Drug, and Cosmetic Act for use in the treatment of substance use
24 disorders that is an opioid agonist and is listed on the schedule of controlled
25 substances in KRS Chapter 218A;
- 26 (10) "Office based medication-assisted treatment" means a publicly or privately
27 owned medication-assisted treatment program in a clinic, facility, office, or

1 program that treats individuals with substance use disorders through the
2 prescription, administration, or dispensing of a medication-assisted treatment
3 medication in the form of a partial opioid agonist or other medication-assisted
4 treatment medication approved for use in an office-based medication-assisted
5 treatment setting;

6 (11) "Opioid agonist" means a substance that binds to and activates opiate receptors
7 resulting in analgesia and pain regulation, respiratory depression, and a wide
8 variety of behavioral changes. It does not include partial agonist medications
9 used as an alternative to opioid agonists in the treatment of opioid addiction;

10 (12) "Opioid treatment program" means a publicly or privately owned medication-
11 assisted treatment program in a clinic, facility, office, or program that treats
12 individuals with substance use disorders through on-site administration or
13 dispensing of a medication-assisted treatment medication in the form of an opioid
14 agonist or partial opioid agonist;

15 (13) "Owner" means any person, partnership, association, or limited liability
16 company listed as the owner of a medication-assisted treatment program on the
17 licensing forms required by Sections 1 to 11 of this Act. Only a physician having
18 a full and active license to practice medicine pursuant to KRS Chapter 311 may
19 have an ownership or investment interest in a medication-assisted treatment
20 program. Credit extended by a financial institution, as defined in KRS 136.500, to
21 a treatment program shall not be deemed an investment interest under this
22 section;

23 (14) "Partial opioid agonist" means a Federal Drug Administration-approved
24 medication that is used as an alternative to an opioid agonist for the treatment of
25 substance use disorders and that binds to and activates opiate receptors, but not
26 to the same degree as full agonists;

27 (15) "Physician" means an individual licensed to practice medicine or osteopathy

1 pursuant to KRS Chapter 311;

2 (16) "Prescriber" means a person who has prescriptive authority, as authorized by
3 state law and his or her professional scope of practice, to give direction, either
4 orally or in writing, for the preparation and administration of a medication to be
5 used in the treatment of substance use disorders;

6 (17) "Program sponsor" means the person named in the application for the licensure
7 of an opioid treatment program who is responsible for the administrative
8 operation of the opioid treatment program, and who assumes responsibility for all
9 of its employees, including any practitioners, agents, or other persons providing
10 medical, rehabilitative, or counseling services at the program;

11 (18) "Secretary" means the secretary of the Cabinet for Health and Family Services
12 or his or her designee;

13 (19) "Substance" means:

14 (a) Alcohol;

15 (b) A controlled substance; or

16 (c) Any chemical, gas, drug, or medication consumed which causes clinically
17 and functionally significant impairment, such as health problems,
18 disability, or failure to meet major responsibilities at work, school, or home;

19 (20) "Substance Abuse and Mental Health Services Administration" means the
20 agency under the United States Department of Health and Human Services
21 responsible for the accreditation and certification of medication-assisted
22 treatment programs and that provides leadership, resources, programs, policies,
23 information, data, contracts, and grants for the purpose of reducing the impact of
24 substance use and mental or behavioral illness;

25 (21) "Substance use disorder" means patterns of symptoms resulting from use of a
26 substance that the individual continues to take, despite experiencing problems as
27 a result; or as defined in the most recent edition of the American Psychiatric

1 Association's Diagnostic and Statistical Manual of Mental Disorders;
2 (22) "Variance" means written permission granted by the secretary to a medication-
3 assisted treatment program that a requirement of Sections 1 to 11 of this Act or
4 administrative regulations promulgated pursuant to Sections 1 to 11 of this Act
5 may be accomplished in a manner different from the manner set forth in Sections
6 1 to 11 of this Act or the associated administrative regulations; and

7 (23) "Waiver" means a formal, time-limited agreement between the designated
8 oversight agency and the medication-assisted treatment program that suspends a
9 rule, policy, or standard for a specific situation as long as the health and safety of
10 patients is better served in the situation by suspension of the rule, policy, or
11 standard than by enforcement.

12 ➔SECTION 3. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
13 READ AS FOLLOWS:

14 (1) No person, partnership, association, or limited liability company may operate an
15 opioid treatment program without first obtaining a license from the secretary in
16 accordance with the provisions of this section and the administrative regulations
17 lawfully promulgated pursuant to Sections 1 to 11 of this Act.

18 (2) A person, partnership, association, or limited liability company desiring a license
19 to operate an opioid treatment program in this state shall file with the department
20 an application in such form and with such information as the secretary shall
21 prescribe, accompanied by an application fee.

22 (3) (a) The commissioner or his or her designee shall inspect each facility and
23 review all documentation submitted with an application.

24 (b) The commissioner shall then provide a recommendation to the secretary
25 whether to approve or deny the application for a license.

26 (c) The secretary shall issue a license if the facility is in compliance with the
27 provisions of Sections 1 to 11 of this Act and with the administrative

1 regulations lawfully promulgated pursuant to Sections 1 to 11 of this Act.

2 (4) A license shall be issued in one (1) of three (3) categories:

3 (a) An initial one (1) year license shall be issued to an opioid treatment
4 program establishing a new program or service for which there is
5 insufficient consumer participation to demonstrate substantial compliance
6 with Sections 1 to 11 of this Act and with all administrative regulations
7 promulgated pursuant to Sections 1 to 11 of this Act;

8 (b) A provisional license shall be issued when an opioid treatment program
9 seeks a renewal license, or is an existing program as of the effective date of
10 this Act and is seeking an initial license, and the opioid treatment program
11 is not in substantial compliance with Sections 1 to 11 of this Act and with
12 all administrative regulations promulgated pursuant to Sections 1 to 11 of
13 this Act, but does not pose a significant risk to the rights, health, and safety
14 of a consumer. It shall expire not more than six (6) months from the date of
15 issuance, and may not be consecutively reissued; or

16 (c) A renewal license shall be issued when an opioid treatment program is in
17 substantial compliance with Sections 1 to 11 of this Act and with all
18 administrative regulations promulgated pursuant to Sections 1 to 11 of this
19 Act. A renewal license shall expire not more than one (1) year from the date
20 of issuance.

21 (5) (a) At least sixty (60) days prior to the license expiration date, an application
22 for renewal shall be submitted by the opioid treatment program to the
23 secretary on a form furnished by the secretary. A license shall be renewed if
24 the secretary determines that the applicant is in compliance with Sections 1
25 to 11 of this Act and with all administrative regulations promulgated
26 pursuant to Sections 1 to 11 of this Act.

27 (b) A license issued to one (1) program location pursuant to this section is not

1 transferable or assignable. Any change of ownership of a licensed
2 medication-assisted treatment program requires submission of a new
3 application. The medication-assisted treatment program shall notify the
4 secretary of any change of ownership within ten (10) days of the change
5 and shall submit a new application within the time frame prescribed by the
6 secretary.

7 (6) A person, partnership, association, or limited liability company that seeks to
8 obtain or renew a license for an opioid treatment program in this state shall
9 submit to the secretary the following documentation:

10 (a) Full operating name of the program as advertised;

11 (b) Legal name of the program as registered with the Office of the Secretary of
12 State;

13 (c) Physical address of the program;

14 (d) Preferred mailing address for the program;

15 (e) E-mail address to be used by the primary contact for the program;

16 (f) Federal Employer Identification Number assigned to the program;

17 (g) All business licenses issued to the program by this state, the Department of
18 Revenue, the Secretary of State, and all other applicable business entities;

19 (h) Documentation of each owner's medical license status;

20 (i) Brief description of all services provided by the program;

21 (j) Hours of operation;

22 (k) Legal name of the person registered as the owner of the program. If there is
23 more than one (1) legal owner, each owner shall be listed separately,
24 indicating the percentage of ownership;

25 (l) Medical director's full name, medical license number, Drug Enforcement
26 Administration registration number, and a list of all current certifications;

27 (m) For each employee of the program:

- 1 1. Employee's role and occupation within the program;
2 2. Full legal name;
3 3. Medical license, if applicable;
4 4. Drug Enforcement Administration registration number, if applicable;
5 5. Drug Enforcement Administration identification number to prescribe
6 buprenorphine, if applicable, and
7 6. Number of hours per week worked at the program;
8 (n) Name and location address of all programs owned or operated by the
9 applicant;
10 (o) Notarized signature of applicant;
11 (p) Check or money order for licensing fee and inspection fee;
12 (q) Verification of education and training for all physicians, counselors, and
13 social workers practicing at or used by referral by the program, including
14 but not limited to fellowships, additional education, accreditations, board
15 certifications, and other certifications; and
16 (r) Confirmation from each prescriber practicing at the program that they have
17 maintained a current account with the electronic system for monitoring
18 controlled substances established pursuant to KRS 218A.202 for the three
19 (3) months preceding the date of application.
20 (7) Upon satisfaction that an applicant has met all of the requirements of this
21 section, the secretary shall issue a license to operate an opioid treatment
22 program. An entity that obtains this license may possess, have custody or control
23 of, and dispense drugs indicated and approved by the United States Food and
24 Drug Administration for the treatment of substance use disorders.
25 (8) The opioid treatment program shall display the current license in a prominent
26 location where services are provided and in clear view of all patients.
27 (9) The secretary or his or her designee shall inspect on a periodic basis all opioid

1 treatment programs that are subject to Sections 1 to 11 of this Act and all
2 administrative regulations adopted pursuant to Sections 1 to 11 of this Act to
3 ensure continued compliance.

4 (10) (a) A license on the effective date of this Act shall remain in effect until such
5 time as new administrative regulations promulgated pursuant to Sections 1
6 to 11 of this Act become effective.

7 (b) Upon the effective date of the new administrative regulations, a licensee
8 shall file for a new license within six (6) months pursuant to the licensing
9 procedures and requirements of this section and the new administrative
10 regulations promulgated hereunder. The existing license shall remain
11 effective until receipt of the new license.

12 ➔SECTION 4. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
13 READ AS FOLLOWS:

14 (1) No person, partnership, association, or limited liability company may operate an
15 office-based medication-assisted treatment program without first obtaining a
16 license from the secretary in accordance with the provisions of this section and
17 the administrative regulations lawfully promulgated pursuant to Sections 1 to 11
18 of this Act.

19 (2) A person, partnership, association, or limited liability company desiring a license
20 to operate an office based medication-assisted treatment program in this state
21 shall file with the department an application in such form and with such
22 information as the secretary shall prescribe, accompanied by an application fee.

23 (3) (a) The commissioner or his or her designee shall inspect and review all
24 documentation submitted with an application.

25 (b) The commissioner shall then provide a recommendation to the secretary
26 whether to approve or deny the application for a license.

27 (c) The secretary shall issue a license if the facility is in compliance with the

1 provisions of Sections 1 to 11 of this Act and with the administrative
2 regulations lawfully promulgated pursuant to Sections 1 to 11 of this Act.

3 (4) A license shall be issued in one (1) of three (3) categories:

4 (a) An initial one (1) year license shall be issued to an office based medication-
5 assisted treatment program establishing a new program or service for which
6 there is insufficient consumer participation to demonstrate substantial
7 compliance with Sections 1 to 11 of this Act and with all administrative
8 regulations promulgated pursuant to Sections 1 to 11 of this Act;

9 (b) A provisional license shall be issued when an office-based medication-
10 assisted treatment program seeks a renewal license, or is an existing
11 program as of the effective date of this Act and is seeking an initial license,
12 and the office-based medication-assisted treatment program is not in
13 substantial compliance with Sections 1 to 11 of this Act and with all
14 administrative regulations promulgated pursuant to Sections 1 to 11 of this
15 Act, but does not pose a significant risk to the rights, health, and safety of a
16 consumer. It shall expire not more than six (6) months from the date of
17 issuance, and may not be consecutively reissued; or

18 (c) A renewal license shall be issued when an office-based medication-assisted
19 treatment program is in substantial compliance with Sections 1 to 11 of this
20 Act and with all administrative regulations promulgated pursuant to
21 Sections 1 to 11 of this Act. A renewal license shall expire not more than
22 one (1) year from the date of issuance.

23 (5) (a) At least sixty (60) days prior to the license expiration date, an application
24 for renewal shall be submitted by the office-based medication-assisted
25 treatment program to the secretary on a form furnished by the secretary. A
26 license shall be renewed if the secretary determines that the applicant is in
27 compliance with Sections 1 to 11 of this Act and with all administrative

- 1 regulations promulgated pursuant to Sections 1 to 11 of this Act.
- 2 (b) A license issued to one (1) program location pursuant to this section is not
3 transferable or assignable. Any change of ownership of a licensed
4 medication-assisted treatment program requires submission of a new
5 application. The medication-assisted treatment program shall notify the
6 secretary of any change of ownership within ten (10) days of the change
7 and shall submit a new application within the time frame prescribed by the
8 secretary.
- 9 (6) A person, partnership, association, or limited liability company that seeks to
10 obtain or renew a license for an office-based medication-assisted treatment
11 program in this state shall submit to the secretary the following documentation:
- 12 (a) Full operating name of the program as advertised;
- 13 (b) Legal name of the program as registered with the Office of the Secretary of
14 State;
- 15 (c) Physical address of the program;
- 16 (d) Preferred mailing address for the program;
- 17 (e) E-mail address to be used by the primary contact for the program;
- 18 (f) Federal Employer Identification Number assigned to the program;
- 19 (g) All business licenses issued to the program by this state, the Department of
20 Revenue, the Secretary of State, and all other applicable business entities;
- 21 (h) Documentation of each owner's medical license status;
- 22 (i) Brief description of all services provided by the program;
- 23 (j) Hours of operation;
- 24 (k) Legal name of the person registered as the owner of the program. If there is
25 more than one (1) legal owner, each owner shall be listed separately,
26 indicating the percentage of ownership;
- 27 (l) Medical director's full name, medical license number, Drug Enforcement

1 Administration registration number, and a list of all current certifications;

2 (m) For each employee of the program:

3 1. Employee's role and occupation within the program;

4 2. Full legal name;

5 3. Medical license, if applicable;

6 4. Drug Enforcement Administration registration number, if applicable;

7 5. Drug Enforcement Administration identification number to prescribe
8 buprenorphine, if applicable, and

9 6. Number of hours per week worked at the program;

10 (n) Name and location address of all programs owned or operated by the
11 applicant;

12 (o) Notarized signature of applicant;

13 (p) Check or money order for licensing fee and inspection fee;

14 (q) Verification of education and training for all physicians, counselors, and
15 social workers practicing at or used by referral by the program, including
16 but not limited to fellowships, additional education, accreditations, board
17 certifications, and other certifications; and

18 (r) Confirmation from each prescriber practicing at the program that they have
19 maintained a current account with the electronic system for monitoring
20 controlled substances established pursuant to KRS 218A.202 for the three
21 (3) months preceding the date of application.

22 (7) Upon satisfaction that an applicant has met all of the requirements of this
23 section, the secretary shall issue a license to operate an office-based medication-
24 assisted treatment program. An entity that obtains this license may possess, have
25 custody or control of, and dispense drugs indicated and approved by the United
26 States Food and Drug Administration for the treatment of substance use
27 disorders.

1 (8) The office-based medication-assisted treatment program shall display the current
2 license in a prominent location where services are provided and in clear view of
3 all patients.

4 (9) The secretary or his or her designee shall inspect on a periodic basis all office
5 based medication-assisted treatment programs that are subject to Sections 1 to 11
6 of this Act and all administrative regulations adopted pursuant to Sections 1 to 11
7 of this Act to ensure continued compliance.

8 (10) (a) A person, partnership, association, or limited liability company operating a
9 medication-assisted treatment program shall be permitted to continue
10 operation until the new administrative regulations promulgated pursuant to
11 Sections 1 to 11 of this Act become effective.

12 (b) Upon the effective date of the new administrative regulations, a person,
13 partnership, association, or limited liability company shall file for a new
14 license within six (6) months pursuant to the licensing procedures and
15 requirements of this section and the new administrative regulations
16 promulgated hereunder. The existing procedures shall remain effective
17 until receipt of the new license.

18 ➔SECTION 5. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
19 READ AS FOLLOWS:

20 (1) A medication-assisted treatment program shall be licensed and registered in this
21 state with the Secretary of State, the Department of Revenue, and all other
22 applicable business or licensing entities.

23 (2) A program sponsor of a medication-assisted treatment program shall be a
24 licensed physician pursuant to KRS Chapter 311 and in good standing with the
25 Kentucky Board of Medical Licensure.

26 (3) A medication-assisted treatment program shall designate a medical director. If
27 the medication-assisted treatment program is accredited by a Substance Abuse

1 and Mental Health Services Administration-approved accrediting body that meets
2 nationally accepted standards for providing medication-assisted treatment,
3 including the Commission on Accreditation of Rehabilitation Facilities or the
4 Joint Commission, then the program may designate a medical director to oversee
5 all facilities associated with the accredited medication-assisted treatment
6 program. The medical director shall be responsible for the operation of the
7 medication-assisted treatment program, and may delegate the day-to-day
8 operation of the medication-assisted treatment program as provided in the
9 administrative regulations promulgated pursuant to Sections 1 to 11 of this Act.
10 Within ten (10) days after termination of a medical director, the medication-
11 assisted treatment program shall notify the commissioner of the identity of
12 another medical director for that program. Failure to have a medical director
13 practicing at the program may be the basis for a suspension or revocation of the
14 program license. The medical director shall:

15 (a) Have a full, active, and unencumbered license to practice medicine or
16 osteopathy from the Kentucky Board of Medical Licensure, and be in good
17 standing and not under any probationary restrictions;

18 (b) Meet both of the following requirements:

19 1. If the physician prescribes a partial opioid agonist, he or she shall
20 complete the requirements for the federal Drug Addiction Treatment
21 Act of 2000; and

22 2. Complete other programs and continuing education requirements as
23 further described in the administrative regulations promulgated
24 pursuant to Sections 1 to 11 of this Act;

25 (c) Practice at the licensed medication-assisted treatment program a sufficient
26 number of hours, based upon the type of medication-assisted license issued
27 pursuant to Sections 1 to 11 of this Act, to ensure regulatory compliance

- 1 and carry out those duties specifically assigned to the medical director as
2 further described in the administrative regulations promulgated pursuant to
3 Sections 1 to 11 of this Act;
- 4 (d) Be responsible for monitoring and ensuring compliance with all
5 requirements related to the licensing and operation of the medication-
6 assisted treatment program;
- 7 (e) Supervise, control, and direct the activities of each individual working or
8 operating at the medication-assisted treatment program, including any
9 employee, volunteer, or individual under contract, who provides
10 medication-assisted treatment at the program or is associated with the
11 provision of that treatment; and
- 12 (f) Complete other requirements prescribed by the secretary by administrative
13 regulation.
- 14 (4) Each medication-assisted treatment program shall designate counseling staff,
15 either employees or those used on a referral-basis by the program, who meet the
16 requirements of Sections 1 to 11 of this Act and the administrative regulations
17 promulgated pursuant to Sections 1 to 11 of this Act. The individual members of
18 the counseling staff shall be:
- 19 (a) A physician licensed to practice medicine or osteopathy pursuant to KRS
20 Chapter 311 who is certified by the American Board of Psychiatry and
21 Neurology, Inc.;
- 22 (b) A certified alcohol and drug counselor, licensed clinical alcohol and drug
23 counselor, or licensed clinical alcohol and drug counselor associate
24 certified or licensed pursuant to KRS Chapter 309;
- 25 (c) A counselor, marriage and family therapist, or social worker licensed or
26 certified pursuant to KRS Chapter 335 with a master's level education with
27 a specialty or specific training in treatment for substance use disorders;

- 1 (d) A psychologist licensed or certified pursuant to KRS Chapter 319 with a
2 master's level education with a specialty or specific training in treatment for
3 substance use disorders;
- 4 (e) An individual with a bachelor's degree in social work or another relevant
5 human services field operating under the direct supervision of a licensed
6 clinical alcohol and drug counselor, so long as the individual applies for
7 certification as an alcohol and drug counselor within three (3) years of the
8 date of employment; or
- 9 (f) An individual with a graduate degree in social work or another relevant
10 human services field actively working toward licensure or certification and
11 operating under supervision of a licensed or certified professional or a
12 licensed clinical alcohol and drug counselor.
- 13 (5) A medication-assisted treatment program shall be eligible for, and not prohibited
14 from, enrollment with the Medicaid program or any health benefit plan. Prior to
15 directly billing a patient for any medication-assisted treatment, a medication-
16 assisted treatment program shall receive either a rejection of prior authorization,
17 rejection of a submitted claim, or a written denial from a patient's insurer or
18 Medicaid denying coverage for such treatment, except that the secretary may
19 grant a variance from this requirement pursuant to Section 6 of this Act. The
20 program shall also document whether a patient has no insurance. At the option
21 of the medication-assisted treatment program, treatment may commence prior to
22 billing.
- 23 (6) A medication-assisted treatment program shall apply for and receive approval as
24 required from the United States Drug Enforcement Administration, Center for
25 Substance Abuse Treatment, or an organization designated by the Substance
26 Abuse and Mental Health and Mental Health Administration.
- 27 (7) All persons employed by a medication-assisted treatment program shall comply

1 with the requirements for the operation of a medication-assisted treatment
2 program established within Sections 1 to 11 of this Act or by any administrative
3 regulation adopted pursuant to Sections 1 to 11 of this Act.

4 (8) All employees of an opioid treatment program shall furnish fingerprints for a
5 state and federal criminal records check by the Kentucky State Police and the
6 Federal Bureau of Investigation. The fingerprints shall be accompanied by a
7 signed authorization for the release of information and retention of the
8 fingerprints by the Kentucky State Police and the Federal Bureau of
9 Investigation.

10 (9) A medication-assisted treatment program shall not be owned by, nor shall it
11 employ or associate with, any physician or prescriber:

12 (a) Whose Drug Enforcement Administration number is not currently full,
13 active, and unencumbered;

14 (b) Whose application for a license to prescribe, dispense, or administer a
15 controlled substance has been denied by and is not full, active, and
16 unencumbered in any jurisdiction; or

17 (c) Whose license is anything other than a full, active, and unencumbered
18 license to practice by the Kentucky Board of Medical Licensure, and, who is
19 in good standing and not under any probationary restrictions.

20 (10) A person may not dispense any medication-assisted treatment medication,
21 including a controlled substance as defined by KRS 218A.010, on the premises of
22 a licensed medication-assisted treatment program, unless he or she is a physician
23 or pharmacist licensed in this state and employed by the medication-assisted
24 treatment program unless the medication-assisted treatment program is a
25 federally-certified narcotic treatment program. Prior to dispensing or prescribing
26 medication-assisted treatment medications, the treating physician shall access the
27 electronic system for monitoring controlled substances established pursuant to

1 KRS 218A.202 to ensure the patient is not seeking medication-assisted treatment
2 medications that are controlled substances from multiple sources, to assess
3 potential adverse drug interactions, or both. Prior to dispensing or prescribing
4 medication-assisted treatment medications, the treating physician shall also
5 ensure that the medication-assisted treatment medication utilized is related to an
6 appropriate diagnosis of a substance use disorder and approved for such usage.
7 The physician shall also review the electronic system no less than quarterly and
8 at each patient's physical examination pursuant to KRS 218A.202(8).

9 (11) A medication-assisted treatment program responsible for medication
10 administration shall comply with:

11 (a) The Kentucky Board of Pharmacy administrative regulations;

12 (b) The Kentucky Board of Nursing administrative regulations;

13 (c) All applicable federal laws and regulations relating to controlled
14 substances; and

15 (d) Any requirements as specified in the administrative regulations
16 promulgated pursuant to Sections 1 to 11 of this Act.

17 (12) Each medication-assisted treatment program location shall be licensed
18 separately, regardless of whether the program is operated under the same
19 business name or management as another program.

20 (13) A medication-assisted treatment program shall develop and implement patient
21 protocols, treatment plans, or treatment strategies and profiles, which shall
22 include but not be limited by the following guidelines:

23 (a) When a physician diagnoses an individual as having a substance use
24 disorder, the physician may treat the substance use disorder by managing it
25 with medication in doses not exceeding those approved by the United States
26 Food and Drug Administration as indicated for the treatment of substance
27 use disorders and not greater than those amounts described in the

1 administrative regulations promulgated pursuant to Sections 1 to 11 of this
2 Act. The treating physician and treating staff member's diagnoses and
3 treatment decisions shall be made according to accepted and prevailing
4 standards of medical care;

5 (b) A medication-assisted treatment program shall maintain a record of all of
6 the following:

- 7 1. Medical history and physical examination of the individual;
- 8 2. The diagnosis of substance use disorder of the individual;
- 9 3. The plan of treatment proposed, the patient's response to the
10 treatment, and any modification to the plan of treatment;
- 11 4. The dates on which any medications were prescribed, dispensed, or
12 administered, the name and address of the individual for whom the
13 medications were prescribed, dispensed, or administered, and the
14 amounts and dosage forms for any medications prescribed, dispensed,
15 or administered;
- 16 5. A copy of the report made by the physician or staff member to whom
17 referral for evaluation was made, if applicable; and
- 18 6. A copy of the coordination of care agreement, which is to be signed by
19 the patient, treating physician, and treating staff member. If a change
20 of treating physician or treating staff member takes place, a new
21 agreement shall be signed. The coordination of care agreement shall
22 be updated or reviewed at least annually. If the coordination of care
23 agreement is reviewed, but not updated, this review shall be
24 documented in the patient's record. The coordination of care
25 agreement shall be provided in a form prescribed and made available
26 by the secretary;

27 (c) A medication-assisted treatment program shall report information, data,

1 statistics, and other information as directed in Sections 1 to 11 of this Act
2 and the administrative regulations promulgated pursuant to Sections 1 to 11
3 of this Act to required agencies and other authorities;

4 (d) A physician, physician assistant, or advanced practice registered nurse shall
5 perform a physical examination of a patient on the same day that the
6 prescriber initially prescribes, dispenses, or administers a medication-
7 assisted treatment medication to a patient and at intervals as required in the
8 administrative regulations promulgated pursuant to Sections 1 to 11 of this
9 Act;

10 (e) A physician, physician assistant, or advanced practice registered nurse shall
11 not see or treat more than six (6) patients per hour;

12 (f) A psychiatrist, alcohol and drug abuse counselor, psychologist, counselor,
13 or social worker shall perform a biopsychosocial assessment, including but
14 not limited to a mental status examination of a patient on the same day or
15 nor more than seven (7) days prior to the day that the physician initially
16 prescribes, dispenses, or administers a medication-assisted treatment
17 medication to a patient and at intervals as required in the administrative
18 regulations promulgated pursuant to Sections 1 to 11 of this Act;

19 (g) A prescriber authorized to prescribe a medication-assisted treatment
20 medication who practices at a medication-assisted treatment program is
21 responsible for maintaining the control and security of his or her
22 prescription blanks and any other method used for prescribing a
23 medication-assisted treatment medication. The prescriber shall comply with
24 all state and federal requirements for tamper-resistant prescription paper.
25 In addition to any other requirements imposed by law or administrative
26 regulation, the prescriber shall notify the secretary and appropriate law
27 enforcement agencies in writing within twenty-four (24) hours following

1 any theft or loss of a prescription blank or breach of any other method of
2 prescribing a medication-assisted treatment medication; and

3 (h) A medication-assisted treatment program shall have a drug testing program
4 to ensure a patient is in compliance with the treatment strategy.

5 (14) A medication-assisted treatment program shall only prescribe, dispense, or
6 administer liquid methadone to patients pursuant to the restrictions and
7 requirement of the administrative regulations promulgated pursuant to Sections
8 1 to 11 of this Act.

9 (15) A medication-assisted treatment program shall immediately notify the secretary,
10 or his or her designee, in writing of any changes to its operations that affect the
11 medication-assisted treatment program's continued compliance with licensure
12 requirements.

13 (16) If a physician treats a patient with more than sixteen (16) milligrams per day of
14 buprenorphine, then clear medical notes shall be placed in the patient's medical
15 file indicating the clinical reason or reasons for the higher level of dosage.

16 (17) If a physician is not the patient's obstetrical or gynecological provider, the
17 physician shall consult with the patient's obstetrical or gynecological provider to
18 the extent possible to determine whether the prescription is appropriate for the
19 patient.

20 (18) A practitioner providing medication-assisted treatment may perform certain
21 aspects of telehealth if permitted under his or her scope of practice.

22 (19) The physician shall follow the recommended manufacturer's tapering schedule
23 for the medication-assisted treatment medication. If the schedule is not followed,
24 the physician shall document that in the patient's medical record and the clinical
25 reason why the schedule was not followed. The secretary may investigate a
26 medication-assisted treatment program if a high percentage of its patients are not
27 following the recommended tapering schedule.

1 ➔SECTION 6. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
2 READ AS FOLLOWS:

3 (1) A medication-assisted treatment program shall not be located, operated,
4 managed, or owned at the same location where a pain management facility, as
5 licensed and defined in KRS 218A.175, is located.

6 (2) A medication-assisted treatment program shall not have procedures for offering a
7 bounty, monetary, equipment, or merchandise reward, or free services for
8 individuals in exchange for recruitment of new patients into the facility.

9 (3) A medication-assisted treatment program shall not be located within one-half
10 (1/2) mile of a public or private licensed child-care center or public or private
11 elementary or secondary school. Existing medication-assisted treatment
12 programs, including both opioid treatment programs and office-based
13 medication-assisted treatment programs, that are located within one-half (1/2)
14 mile of a public or private licensed child-care center or public or private
15 elementary or secondary school, shall be granted a variance, if the facility
16 demonstrates adequate patient population controls and that it may otherwise meet
17 the requirements of Sections 1 to 11 of this Act and the administrative regulations
18 promulgated pursuant to Sections 1 to 11 of this Act.

19 (4) (a) The secretary may grant a waiver or a variance from any licensure
20 standard, or portion thereof, for the period during which the license is in
21 effect.

22 (b) A request for a waiver or variance of licensure standards shall be in writing
23 to the secretary and shall include:

24 1. The specific section of Sections 1 to 11 of this Act or administrative
25 regulations promulgated pursuant to Sections 1 to 11 of this Act for
26 which a waiver or variance is sought;

27 2. The rationale for requesting the waiver or variance;

1 3. Documentation by the medication-assisted treatment program's
2 medical director to the secretary that describes how the program will
3 maintain the quality of services and patient safety if the waiver or
4 variance is granted; and

5 4. The consequences of not receiving approval of the requested waiver or
6 variance.

7 (c) The secretary shall issue a written statement to the medication-assisted
8 treatment program granting or denying a request for a waiver or variance
9 of program licensure standards.

10 (d) The medication-assisted treatment program shall maintain a file copy of all
11 requests for waivers or variances and the approval or denial of the requests
12 for the period during which the license is in effect.

13 (e) The department shall inspect each medication-assisted treatment program
14 prior to a waiver or variance being granted, including a review of patient
15 records, to ensure and verify that any waiver or variance request meets the
16 spirit and purpose of Sections 1 to 11 of this Act and the administrative
17 regulations promulgated pursuant to Sections 1 to 11 this Act. The
18 department may verify, by unannounced inspection, that the medication-
19 assisted treatment program is in compliance with any waiver or variance
20 granted by the secretary for the duration of such waiver or variance.

21 ➔SECTION 7. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
22 READ AS FOLLOWS:

23 (1) The department shall inspect each opioid treatment program annually, including
24 a review of the patient records, to ensure that the program complies with Sections
25 1` to 11 of this Act and the applicable administrative regulations. A pharmacist,
26 employed or contracted by the secretary, licensed in this state, and a law
27 enforcement officer may be present at each inspection.

- 1 (2) The department shall perform unannounced complaint and verification
2 inspections at office based medication-assisted treatment programs, including a
3 review of the patient records, to ensure that the program complies with Sections 1
4 to 11 of this Act and the applicable administrative regulations. A pharmacist,
5 employed or contracted by the secretary, licensed in this state and a law
6 enforcement officer may be present at each inspection.
- 7 (3) During an onsite inspection, the inspectors shall make a reasonable attempt to
8 discuss each violation with the medical director or other owners of the
9 medication-assisted treatment program before issuing a formal written
10 notification.
- 11 (4) Any action taken to correct a violation shall be documented in writing by the
12 medical director or other owners of the medication-assisted treatment program
13 and may be verified by follow-up visits by the department.
- 14 (5) Notwithstanding the existence or pursuit of any other remedy, the secretary may,
15 in the manner provided by law, maintain an action in the name of the state for an
16 inspection warrant against any person, partnership, association, or limited
17 liability company to allow any inspection or seizure of records in order to
18 complete any inspection allowed by Sections 1 to 11 of this Act or the
19 administrative regulations promulgated pursuant to Sections 1 to 11 of this Act,
20 or to meet any other purpose of Sections 1 to 11 of this Act or the administrative
21 regulations promulgated pursuant to Sections 1 to 11 of this Act.
- 22 (6) When possible, inspections for annual licensure by the medication-assisted
23 treatment programs will be done consecutively or concurrently. However, this
24 provision does not limit the ability to conduct unannounced inspections pursuant
25 to a complaint.

26 ➔SECTION 8. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
27 READ AS FOLLOWS:

- 1 (1) The secretary may, by order, impose a ban on the admission of patients or reduce
2 patient capacity of a medication-assisted treatment program, or any combination
3 thereof, when he or she finds upon inspection of the medication-assisted
4 treatment program that the licensee is not providing adequate care under the
5 medication-assisted treatment program's existing patient quota, and that a
6 reduction in quota or imposition of a ban on admissions, or any combination
7 thereof, would place the licensee in a position to render adequate care. Any notice
8 to a licensee of reduction in quota or ban on new admissions shall include the
9 terms of the order, the reasons therefor, and the date set for compliance.
- 10 (2) The secretary shall deny, suspend, or revoke a license issued pursuant to Sections
11 1 to 11 of this Act if the provisions of Sections 1 to 11 of this Act or of the
12 administrative regulations promulgated pursuant to Sections 1 to 11 of this Act
13 are violated. The secretary may revoke a program's license and prohibit all
14 physicians and licensed disciplines associated with that medication-assisted
15 treatment program from practicing at the program location based upon an
16 annual, periodic, complaint, verification, or other inspection and evaluation.
- 17 (3) Before any license is denied, suspended, or revoked, written notice shall be given
18 to the licensee, stating the grounds for the denial, suspension, or revocation.
- 19 (4) An applicant or licensee has ten (10) working days after receipt of the secretary's
20 order denying, suspending, or revoking a license to request a formal hearing
21 contesting the denial, suspension, or revocation of a license under this section. If
22 a formal hearing is requested, the applicant or licensee and the secretary shall
23 proceed in accordance with the provisions of KRS Chapter 13B.
- 24 (5) If a license is denied or revoked, a new application for a license shall be
25 considered by the secretary if, when, and after the conditions upon which the
26 denial or revocation was based have been corrected and evidence of this fact has
27 been furnished. A new license shall then be granted after proper inspection, if

1 applicable, has been made and all provisions of Sections 1 to 11 of this Act and
2 the administrative regulations promulgated pursuant to Sections 1 to 11 of this
3 Act have been satisfied.

4 (6) Any applicant or licensee who is dissatisfied with the decision of the secretary as
5 a result of the hearing provided in this section may, within thirty (30) days after
6 receiving notice of the decision, petition the Circuit Court of Franklin County,
7 for judicial review of the decision.

8 (7) The court may affirm, modify, or reverse the decision of the secretary and either
9 the applicant or licensee or the secretary may appeal from the court's decision to
10 the Court of Appeals.

11 (8) If the license of a medication-assisted treatment program is denied, suspended, or
12 revoked, the medical director of the program, any owner of the program, or
13 owner or lessor of the medication-assisted treatment program property shall cease
14 to operate the clinic, facility, office, or program as a medication-assisted
15 treatment program as of the effective date of the denial, suspension, or
16 revocation. The owner or lessor of the medication-assisted treatment program
17 property is responsible for removing all signs and symbols identifying the
18 premises as a medication-assisted treatment program within thirty (30) days. Any
19 administrative appeal of such denial, suspension, or revocation shall not stay the
20 denial, suspension, or revocation.

21 (9) Upon the effective date of the denial, suspension, or revocation, the medical
22 director of the medication-assisted treatment program shall advise the secretary
23 and the Kentucky Board of Pharmacy of the disposition of all medications located
24 on the premises. The disposition is subject to the supervision and approval of the
25 secretary. Medications that are purchased or held by a medication-assisted
26 treatment program that is not licensed may be deemed adulterated.

27 (10) If the license of a medication-assisted treatment program is suspended or

1 revoked, any person named in the licensing documents of the program, including
2 persons owning or operating the medication-assisted treatment program, may
3 not, as an individual or as part of a group, apply to operate another medication-
4 assisted treatment program for up to five (5) years after the date of suspension or
5 revocation. The secretary may grant a variance pursuant to Section 6 of this Act
6 to the prohibition of this subsection.

7 (11) The period of suspension for the license of a medication-assisted treatment
8 program shall be prescribed by the secretary, but shall not exceed one (1) year.

9 ➔SECTION 9. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
10 READ AS FOLLOWS:

11 (1) A person, partnership, association, or limited liability company which establishes,
12 conducts, manages, or operates a medication-assisted treatment program without
13 first obtaining a license, or who violates any provision of Sections 1 to 11 of this
14 Act or any administrative regulation promulgated pursuant to Sections 1 to 11 of
15 this Act, shall be assessed a civil penalty by the secretary in accordance with this
16 subsection. Each day of continuing violation after conviction shall be considered
17 a separate violation:

18 (a) If a medication-assisted treatment program or an owner or medical director
19 is found to be in violation of any provision of Sections 1 to 11 of this Act,
20 unless otherwise noted in this subsection, the secretary may limit, suspend,
21 or revoke the program's license;

22 (b) If a program's medical director knowingly and intentionally misrepresents
23 actions taken to correct a violation, the secretary may, in addition to any
24 other penalty available by law, impose a civil penalty not to exceed ten
25 thousand dollars (\$10,000) and, in the case of an owner-operator
26 medication-assisted treatment program, limit or revoke a medication-
27 assisted treatment program's license;

1 (c) If an owner or medical director of a medication-assisted treatment program
2 concurrently operates an unlicensed medication-assisted treatment
3 program, the secretary may, in addition to any other penalty available by
4 law, impose a civil penalty upon the owner or medical director, or both, not
5 to exceed five thousand dollars (\$5,000) per day;

6 (d) If an owner of a medication-assisted treatment program that requires a
7 license under Sections 1 to 11 of this Act fails to apply for a new license for
8 the program upon a change of ownership and operates the program under
9 new ownership, the secretary may, in addition to any other penalty available
10 by law, impose a civil penalty upon the owner, not to exceed five thousand
11 dollars (\$5,000); or

12 (e) If a physician:

13 1. Operates, owns, or manages an unlicensed medication-assisted
14 treatment program that is required to be licensed pursuant to Sections
15 1 to 11 of this Act;

16 2. Knowingly prescribes or dispenses or causes to be prescribed or
17 dispensed a medication-assisted treatment medication through
18 misrepresentation or fraud;

19 3. Procures, or attempts to procure, a license for a medication-assisted
20 treatment program for any other person by making or causing to be
21 made any false representation;

22 the secretary may assess a civil penalty of not more than twenty thousand
23 dollars (\$20,000). The penalty may be in addition to or in lieu of any other
24 action that may be taken by the secretary or any other board, court, or
25 entity.

26 (2) Notwithstanding the existence or pursuit of any other remedy, the secretary may,
27 in the manner provided by law, maintain an action in the name of the state for an

1 injunction against any person, partnership, association, or limited liability
2 company to restrain or prevent the establishment, conduct, management, or
3 operation of any medication-assisted treatment program or violation of any
4 provision of Sections 1 to 11 of this Act or any administrative regulation
5 promulgated thereunder without first obtaining a license in the manner herein
6 provided.

7 (3) In determining whether a penalty is to be imposed and in fixing the amount of
8 the penalty, the secretary shall consider the following factors:

9 (a) The gravity of the violation, including the probability that death or serious
10 physical or emotional harm to a patient has resulted, or could have resulted,
11 from the medication-assisted treatment program's actions or the actions of
12 the medical director or any practicing physician, the severity of the action or
13 potential harm, and the extent to which the provisions of the applicable laws
14 or administrative regulations were violated;

15 (b) What actions, if any, the owner or medical director took to correct the
16 violations;

17 (c) Whether there were any previous violations at the medication-assisted
18 treatment program; and

19 (d) The financial benefits that the medication-assisted treatment program
20 derived from committing or continuing to commit the violation.

21 (4) Upon finding that a physician has violated the provisions of Sections 1 to 11 of
22 this Act or administrative regulations adopted pursuant to Sections 1 to 11 of this
23 Act, the secretary shall provide notice of the violation to the applicable licensing
24 board.

25 ➔SECTION 10. A NEW SECTION OF KRS CHAPTER 218A IS CREATED
26 TO READ AS FOLLOWS:

27 An advertisement made by or on behalf of a medication-assisted treatment program

1 through public media, such as a telephone directory, medical directory, newspaper,
2 periodical, outdoor advertising, radio, television, or through written or recorded
3 communication, concerning the treatment of substance use disorders, as defined in
4 Section 2 of this Act, shall include the name of, at a minimum, the medical director
5 responsible for the content of the advertisement.

6 ➔SECTION 11. A NEW SECTION OF KRS CHAPTER 218A IS CREATED
7 TO READ AS FOLLOWS:

8 The secretary shall promulgate administrative regulations in accordance with the
9 provisions of KRS Chapter 13A for the licensure of medication-assisted treatment
10 programs to ensure adequate care, treatment, health, safety, welfare, and comfort of
11 patients at these facilities and in these programs. The administrative regulations shall
12 include, at a minimum:

13 (1) The process to be followed by an applicant seeking a license;

14 (2) The qualifications and supervision of licensed and unlicensed personnel at a
15 medication-assisted treatment program and training requirements for facility
16 health care practitioners who are not regulated by another board;

17 (3) The provision and coordination of patient care, including the development of a
18 written plan of care and patient contract;

19 (4) The management, operation, staffing, and equipment of a medication-assisted
20 treatment program;

21 (5) The clinical, medical, patient, and business records kept by a medication-assisted
22 treatment program;

23 (6) The procedures for inspections, review of utilization, and quality of patient care;

24 (7) The standards and procedures for the general operation of a medication-assisted
25 treatment program, including facility operations, physical operations, infection
26 control requirements, health and safety requirements, and quality assurance;

27 (8) Identification of drugs that may be used to treat substance use disorders that

- 1 identify a facility as a medication-assisted treatment program;
- 2 (9) Any other criteria that identify a facility as a medication-assisted treatment
- 3 program;
- 4 (10) The standards and procedures to be followed by an owner in providing
- 5 supervision, direction, and control of individuals employed by or associated with
- 6 a medication-assisted treatment program;
- 7 (11) Data collection and reporting requirements;
- 8 (12) Criteria and requirements related to specific medication-assisted treatment
- 9 medications; and
- 10 (13) Other standards or requirements as the secretary determines are appropriate.