

1 AN ACT relating to medication-assisted treatment program licensing.

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

3 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 222 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 222 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 program" means a publicly or  
27 privately owned medication-assisted treatment program in a clinic, facility, office,

1 or 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. This ownership or investment requirement shall not be enforced against  
23 any medication-assisted treatment program existing and operating on January 1,  
24 2019, unless there is an administrative sanction or criminal conviction relating to  
25 controlled substances imposed on the program, any person employed by the  
26 program, or any person working for the program as an independent contractor  
27 for an act or omission done within the scope of the program's licensure or the

1 person's employment;

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

6 (15) "Physician" means an individual licensed to practice medicine or osteopathy  
7 pursuant to KRS Chapter 311;

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

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

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

19 (19) "Substance" means:

20 (a) Alcohol;

21 (b) A controlled substance; or

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

25 (20) "Substance Abuse and Mental Health Services Administration" means the  
26 agency under the United States Department of Health and Human Services  
27 responsible for the accreditation and certification of medication-assisted

1 treatment programs and that provides leadership, resources, programs, policies,  
2 information, data, contracts, and grants for the purpose of reducing the impact of  
3 substance use and mental or behavioral illness;

4 (21) "Substance use disorder" means patterns of symptoms resulting from use of a  
5 substance that the individual continues to take, despite experiencing problems as  
6 a result; or as defined in the most recent edition of the American Psychiatric  
7 Association's Diagnostic and Statistical Manual of Mental Disorders;

8 (22) "Variance" means written permission granted by the secretary to a medication-  
9 assisted treatment program to allow a requirement of Sections 1 to 11 of this Act  
10 or administrative regulations promulgated pursuant to Sections 1 to 11 of this Act  
11 to be accomplished in a manner different from the manner set forth in Sections 1  
12 to 11 of this Act or the associated administrative regulations; and

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

18 ➔SECTION 3. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
19 READ AS FOLLOWS:

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

24 (2) A person, partnership, association, or limited liability company desiring a license  
25 to operate an opioid treatment program in this state shall file with the department  
26 an application in a form and including information that the secretary prescribes,  
27 accompanied by an application fee.

- 1 (3) (a) The commissioner or his or her designee shall inspect each facility and  
2 review all documentation submitted with an application.
- 3 (b) The commissioner shall then provide a recommendation to the secretary  
4 whether to approve or deny the application for a license.
- 5 (c) The secretary shall issue a license if the facility is in compliance with  
6 Sections 1 to 11 of this Act and with the administrative regulations lawfully  
7 promulgated pursuant to Sections 1 to 11 of this Act.
- 8 (4) A license shall be issued in one (1) of three (3) categories:
- 9 (a) An initial one (1) year license shall be issued to an opioid treatment  
10 program establishing a new program or service for which there is  
11 insufficient consumer participation to demonstrate substantial compliance  
12 with Sections 1 to 11 of this Act and with all administrative regulations  
13 promulgated pursuant to Sections 1 to 11 of this Act;
- 14 (b) A provisional license shall be issued when an opioid treatment program  
15 seeks a renewal license, or is an existing program as of the effective date of  
16 this Act and is seeking an initial license, and the opioid treatment program  
17 is not in substantial compliance with Sections 1 to 11 of this Act and with  
18 all administrative regulations promulgated pursuant to Sections 1 to 11 of  
19 this Act, but does not pose a significant risk to the rights, health, and safety  
20 of a consumer. It shall expire not more than six (6) months from the date of  
21 issuance, and may not be consecutively reissued; or
- 22 (c) A renewal license shall be issued when an opioid treatment program is in  
23 substantial compliance with Sections 1 to 11 of this Act and with all  
24 administrative regulations promulgated pursuant to Sections 1 to 11 of this  
25 Act. A renewal license shall expire not more than one (1) year from the date  
26 of issuance.
- 27 (5) (a) At least sixty (60) days prior to the license expiration date, an application

1 for renewal shall be submitted by the opioid treatment program to the  
2 secretary on a form furnished by the secretary. A license shall be renewed if  
3 the secretary determines that the applicant is in compliance with Sections 1  
4 to 11 of this Act and with all administrative regulations promulgated  
5 pursuant to Sections 1 to 11 of this Act.

6 (b) A license issued to one (1) program location pursuant to this section is not  
7 transferable or assignable. Any change of ownership of a licensed  
8 medication-assisted treatment program requires submission of a new  
9 application. The medication-assisted treatment program shall notify the  
10 secretary of any change of ownership within ten (10) days of the change  
11 and shall submit a new application within the time frame prescribed by the  
12 secretary.

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

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

17 (b) Legal name of the program as registered with the Office of the Secretary of  
18 State;

19 (c) Physical address of the program;

20 (d) Preferred mailing address for the program;

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

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

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

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

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

27 (j) Hours of operation;

- 1        (k) Legal name of the person registered as the owner of the program. If there is  
2                more than one (1) legal owner, each owner shall be listed separately,  
3                indicating the percentage of ownership;
- 4        (l) Medical director's full name, medical license number, Drug Enforcement  
5                Administration registration number, and a list of all current certifications;
- 6        (m) For each employee of the program:
- 7                1. Employee's role and occupation within the program;  
8                2. Full legal name;  
9                3. Medical license, if applicable;  
10                4. Drug Enforcement Administration registration number, if applicable;  
11                5. Drug Enforcement Administration identification number to prescribe  
12                buprenorphine, if applicable, and  
13                6. Number of hours per week worked at the program;
- 14        (n) Name and location address of all programs owned or operated by the  
15                applicant;
- 16        (o) Notarized signature of applicant;
- 17        (p) Check or money order for licensing fee and inspection fee;
- 18        (q) Verification of education and training for all physicians, counselors, and  
19                social workers practicing at or used by referral by the program, including  
20                but not limited to fellowships, additional education, accreditations, board  
21                certifications, and other certifications; and
- 22        (r) Confirmation from each prescriber practicing at the program that he or she  
23                has maintained a current account with the electronic system for monitoring  
24                controlled substances established pursuant to KRS 218A.202 for the three  
25                (3) months preceding the date of application.
- 26        (7) Upon satisfaction that an applicant has met all of the requirements of this  
27                section, the secretary shall issue a license to operate an opioid treatment



1 program. An entity that obtains this license may possess, have custody or control  
2 of, and dispense drugs indicated and approved by the United States Food and  
3 Drug Administration for the treatment of substance use disorders.

4 (8) The opioid treatment program shall display the current license in a prominent  
5 location where services are provided and in clear view of all patients.

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

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

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

18 ➔SECTION 4. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
19 READ AS FOLLOWS:

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

24 (2) A person, partnership, association, or limited liability company desiring a license  
25 to operate an office based medication-assisted treatment program in this state  
26 shall file with the department an application in a form and including information  
27 that the secretary prescribes, accompanied by an application fee.

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

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

5 (c) The secretary shall issue a license if the facility is in compliance with  
6 Sections 1 to 11 of this Act and with the administrative regulations lawfully  
7 promulgated pursuant to Sections 1 to 11 of this Act.

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

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

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

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

- 1 (5) (a) At least sixty (60) days prior to the license expiration date, an application  
2 for renewal shall be submitted by the office-based medication-assisted  
3 treatment program to the secretary on a form furnished by the secretary. A  
4 license shall be renewed if the secretary determines that the applicant is in  
5 compliance with Sections 1 to 11 of this Act and with all administrative  
6 regulations promulgated pursuant to Sections 1 to 11 of this Act.
- 7 (b) A license issued to one (1) program location pursuant to this section is not  
8 transferable or assignable. Any change of ownership of a licensed  
9 medication-assisted treatment program requires submission of a new  
10 application. The medication-assisted treatment program shall notify the  
11 secretary of any change of ownership within ten (10) days of the change  
12 and shall submit a new application within the time frame prescribed by the  
13 secretary.
- 14 (6) A person, partnership, association, or limited liability company that seeks to  
15 obtain or renew a license for an office-based medication-assisted treatment  
16 program in this state shall submit to the secretary the following documentation:
- 17 (a) Full operating name of the program as advertised;  
18 (b) Legal name of the program as registered with the Office of the Secretary of  
19 State;  
20 (c) Physical address of the program;  
21 (d) Preferred mailing address for the program;  
22 (e) E-mail address to be used by the primary contact for the program;  
23 (f) Federal Employer Identification Number assigned to the program;  
24 (g) All business licenses issued to the program by this state, the Department of  
25 Revenue, the Secretary of State, and all other applicable business entities;  
26 (h) Documentation of each owner's medical license status;  
27 (i) Brief description of all services provided by the program;

- 1        (j) Hours of operation;
- 2        (k) Legal name of the person registered as the owner of the program. If there is
- 3                more than one (1) legal owner, each owner shall be listed separately,
- 4                indicating the percentage of ownership;
- 5        (l) Medical director's full name, medical license number, Drug Enforcement
- 6                Administration registration number, and a list of all current certifications;
- 7        (m) For each employee of the program:
- 8                1. Employee's role and occupation within the program;
- 9                2. Full legal name;
- 10                3. Medical license, if applicable;
- 11                4. Drug Enforcement Administration registration number, if applicable;
- 12                5. Drug Enforcement Administration identification number to prescribe
- 13                        buprenorphine, if applicable, and
- 14                6. Number of hours per week worked at the program;
- 15        (n) Name and location address of all programs owned or operated by the
- 16                applicant;
- 17        (o) Notarized signature of applicant;
- 18        (p) Check or money order for licensing fee and inspection fee;
- 19        (q) Verification of education and training for all physicians, counselors, and
- 20                social workers practicing at or used by referral by the program, including
- 21                but not limited to fellowships, additional education, accreditations, board
- 22                certifications, and other certifications; and
- 23        (r) Confirmation from each prescriber practicing at the program that that he or
- 24                she has maintained a current account with the electronic system for
- 25                monitoring controlled substances established pursuant to KRS 218A.202 for
- 26                the three (3) months preceding the date of application.
- 27        (7) Upon satisfaction that an applicant has met all of the requirements of this

1 section, the secretary shall issue a license to operate an office-based medication-  
2 assisted treatment program. An entity that obtains this license may possess, have  
3 custody or control of, and dispense drugs indicated and approved by the United  
4 States Food and Drug Administration for the treatment of substance use  
5 disorders.

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

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

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

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

23 ➔SECTION 5. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
24 READ AS FOLLOWS:

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

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

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

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

23 (b) Meet both of the following requirements:

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

27 2. Complete other programs and continuing education requirements as

1                   further described in the administrative regulations promulgated  
2                   pursuant to Sections 1 to 11 of this Act;

3           (c) Practice at the licensed medication-assisted treatment program a sufficient  
4           number of hours, based upon the type of medication-assisted license issued  
5           pursuant to Sections 1 to 11 of this Act, to ensure regulatory compliance  
6           and carry out those duties specifically assigned to the medical director as  
7           further described in the administrative regulations promulgated pursuant to  
8           Sections 1 to 11 of this Act;

9           (d) Be responsible for monitoring and ensuring compliance with all  
10           requirements related to the licensing and operation of the medication-  
11           assisted treatment program;

12           (e) Supervise, control, and direct the activities of each individual working or  
13           operating at the medication-assisted treatment program, including any  
14           employee, volunteer, or individual under contract, who provides  
15           medication-assisted treatment at the program or is associated with the  
16           provision of that treatment; and

17           (f) Complete other requirements prescribed by the secretary by administrative  
18           regulation.

19   (4) Each medication-assisted treatment program shall designate counseling staff,  
20   either employees or those used on a referral-basis by the program, who meet the  
21   requirements of Sections 1 to 11 of this Act and the administrative regulations  
22   promulgated pursuant to Sections 1 to 11 of this Act. The individual members of  
23   the counseling staff shall be:

24           (a) A physician licensed to practice medicine or osteopathy pursuant to KRS  
25           Chapter 311 who is certified by the American Board of Psychiatry and  
26           Neurology, Inc.;

27           (b) A certified alcohol and drug counselor, licensed clinical alcohol and drug

- 1           counselor, or licensed clinical alcohol and drug counselor associate  
2           certified or licensed pursuant to KRS Chapter 309;
- 3           (c) A counselor, marriage and family therapist, or social worker licensed or  
4           certified pursuant to KRS Chapter 335 with a master's level education with  
5           a specialty or specific training in treatment for substance use disorders;
- 6           (d) A psychologist licensed or certified pursuant to KRS Chapter 319 with a  
7           master's level education with a specialty or specific training in treatment for  
8           substance use disorders;
- 9           (e) An individual with a bachelor's degree in social work or another relevant  
10           human services field operating under the direct supervision of a licensed  
11           clinical alcohol and drug counselor, so long as the individual applies for  
12           certification as an alcohol and drug counselor within three (3) years of the  
13           date of employment; or
- 14           (f) An individual with a graduate degree in social work or another relevant  
15           human services field actively working toward licensure or certification and  
16           operating under supervision of a licensed or certified professional or a  
17           licensed clinical alcohol and drug counselor.
- 18           (5) A medication-assisted treatment program shall be eligible for, and not prohibited  
19           from, enrollment with the Medicaid program or any health benefit plan. Prior to  
20           directly billing a patient for any medication-assisted treatment, a medication-  
21           assisted treatment program shall receive either a rejection of prior authorization,  
22           rejection of a submitted claim, or a written denial from a patient's insurer or  
23           Medicaid denying coverage for the treatment, except that the secretary may grant  
24           a variance from this requirement pursuant to Section 6 of this Act. The program  
25           shall also document whether a patient has no insurance. At the option of the  
26           medication-assisted treatment program, treatment may commence prior to billing.
- 27           (6) A medication-assisted treatment program shall apply for and receive approval as



1 required from the United States Drug Enforcement Administration, Center for  
2 Substance Abuse Treatment, or an organization designated by the Substance  
3 Abuse and Mental Health and Mental Health Administration.

4 (7) All persons employed by a medication-assisted treatment program shall comply  
5 with the requirements for the operation of a medication-assisted treatment  
6 program established within Sections 1 to 11 of this Act or by any administrative  
7 regulation adopted pursuant to Sections 1 to 11 of this Act.

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

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

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

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

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

24 (10) A person may not dispense any medication-assisted treatment medication,  
25 including a controlled substance as defined by KRS 218A.010, on the premises of  
26 a licensed medication-assisted treatment program, unless he or she is a physician  
27 or pharmacist licensed in this state and employed by the medication-assisted

1 treatment program unless the medication-assisted treatment program is a  
2 federally-certified narcotic treatment program. Prior to dispensing or prescribing  
3 medication-assisted treatment medications, the treating physician shall access the  
4 electronic system for monitoring controlled substances established pursuant to  
5 KRS 218A.202 to ensure the patient is not seeking medication-assisted treatment  
6 medications that are controlled substances from multiple sources, to assess  
7 potential adverse drug interactions, or both. Prior to dispensing or prescribing  
8 medication-assisted treatment medications, the treating physician shall also  
9 ensure that the medication-assisted treatment medication utilized is related to an  
10 appropriate diagnosis of a substance use disorder and approved for that usage.  
11 The physician shall also review the electronic system no less than quarterly and  
12 at each patient's physical examination pursuant to KRS 218A.172.

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

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

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

17 (c) All applicable federal laws and regulations relating to controlled  
18 substances; and

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

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

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

27 (a) When a physician diagnoses an individual as having a substance use

1 disorder, the physician may treat the substance use disorder by managing it  
2 with medication in doses not exceeding those approved by the United States  
3 Food and Drug Administration as indicated for the treatment of substance  
4 use disorders and not greater than those amounts described in the  
5 administrative regulations promulgated pursuant to Sections 1 to 11 of this  
6 Act. The treating physician and treating staff member's diagnoses and  
7 treatment decisions shall be made according to accepted and prevailing  
8 standards of medical care;

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

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

1                   documented in the patient's record. The coordination of care  
2                   agreement shall be provided in a form prescribed and made available  
3                   by the secretary;

4           (c) A medication-assisted treatment program shall report information, data,  
5           statistics, and other information as directed in Sections 1 to 11 of this Act  
6           and the administrative regulations promulgated pursuant to Sections 1 to 11  
7           of this Act to required agencies and other authorities;

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

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

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

23           (g) A prescriber authorized to prescribe a medication-assisted treatment  
24           medication who practices at a medication-assisted treatment program is  
25           responsible for maintaining the control and security of his or her  
26           prescription blanks and any other method used for prescribing a  
27           medication-assisted treatment medication. The prescriber shall comply with

1 all state and federal requirements for tamper-resistant prescription paper.  
2 In addition to any other requirements imposed by law or administrative  
3 regulation, the prescriber shall notify the secretary and appropriate law  
4 enforcement agencies in writing within twenty-four (24) hours following  
5 any theft or loss of a prescription blank or breach of any other method of  
6 prescribing a medication-assisted treatment medication; and

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

9 (14) A medication-assisted treatment program shall only prescribe, dispense, or  
10 administer liquid methadone to patients pursuant to the restrictions and  
11 requirement of the administrative regulations promulgated pursuant to Sections  
12 1 to 11 of this Act.

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

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

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

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

26 (19) The physician shall follow the recommended manufacturer's tapering schedule  
27 for the medication-assisted treatment medication. If the schedule is not followed,

1 the physician shall document that in the patient's medical record and the clinical  
2 reason why the schedule was not followed. The secretary may investigate a  
3 medication-assisted treatment program if a high percentage of its patients are not  
4 following the recommended tapering schedule.

5 ➔SECTION 6. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
6 READ AS FOLLOWS:

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

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

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

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

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

- 1           1. The specific section of Sections 1 to 11 of this Act or administrative  
2           regulations promulgated pursuant to Sections 1 to 11 of this Act for  
3           which a waiver or variance is sought;  
4           2. The rationale for requesting the waiver or variance;  
5           3. Documentation by the medication-assisted treatment program's  
6           medical director to the secretary that describes how the program will  
7           maintain the quality of services and patient safety if the waiver or  
8           variance is granted; and  
9           4. The consequences of not receiving approval of the requested waiver or  
10           variance.
- 11           (c) The secretary shall issue a written statement to the medication-assisted  
12           treatment program granting or denying a request for a waiver or variance  
13           of program licensure standards.
- 14           (d) The medication-assisted treatment program shall maintain a file copy of all  
15           requests for waivers or variances and the approval or denial of the requests  
16           for the period during which the license is in effect.
- 17           (e) The department shall inspect each medication-assisted treatment program  
18           prior to a waiver or variance being granted, including a review of patient  
19           records, to ensure and verify that any waiver or variance request meets the  
20           spirit and purpose of Sections 1 to 11 of this Act and the administrative  
21           regulations promulgated pursuant to Sections 1 to 11 this Act. The  
22           department may verify, by unannounced inspection, that the medication-  
23           assisted treatment program is in compliance with any waiver or variance  
24           granted by the secretary for the duration of the waiver or variance.

25           ➔SECTION 7. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
26 READ AS FOLLOWS:

- 27           (1) The department shall inspect each opioid treatment program annually, including

- 1 a review of the patient records, to ensure that the program complies with Sections  
2 1 to 11 of this Act and the applicable administrative regulations. A pharmacist,  
3 employed or contracted by the secretary, licensed in this state, and a law  
4 enforcement officer may be present at each inspection.
- 5 (2) The department shall perform unannounced complaint and verification  
6 inspections at office based medication-assisted treatment programs, including a  
7 review of the patient records, to ensure that the program complies with Sections 1  
8 to 11 of this Act and the applicable administrative regulations. A pharmacist,  
9 employed or contracted by the secretary, licensed in this state and a law  
10 enforcement officer may be present at each inspection.
- 11 (3) During an onsite inspection, the inspectors shall make a reasonable attempt to  
12 discuss each violation with the medical director or other owners of the  
13 medication-assisted treatment program before issuing a formal written  
14 notification.
- 15 (4) Any action taken to correct a violation shall be documented in writing by the  
16 medical director or other owners of the medication-assisted treatment program  
17 and may be verified by follow-up visits by the department.
- 18 (5) Notwithstanding the existence or pursuit of any other remedy, the secretary may,  
19 in the manner provided by law, maintain an action in the name of the state for an  
20 inspection warrant against any person, partnership, association, or limited  
21 liability company to allow any inspection or seizure of records in order to  
22 complete any inspection allowed by Sections 1 to 11 of this Act or the  
23 administrative regulations promulgated pursuant to Sections 1 to 11 of this Act,  
24 or to meet any other purpose of Sections 1 to 11 of this Act or the administrative  
25 regulations promulgated pursuant to Sections 1 to 11 of this Act.
- 26 (6) When possible, inspections for annual licensure by the medication-assisted  
27 treatment programs will be done consecutively or concurrently. However, this



1 provision does not limit the ability to conduct unannounced inspections pursuant  
2 to a complaint.

3 ➔SECTION 8. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
4 READ AS FOLLOWS:

5 (1) The secretary may, by order, impose a ban on the admission of patients or reduce  
6 patient capacity of a medication-assisted treatment program, or any combination  
7 thereof, when he or she finds upon inspection of the medication-assisted  
8 treatment program that the licensee is not providing adequate care under the  
9 medication-assisted treatment program's existing patient quota, and that a  
10 reduction in quota or imposition of a ban on admissions, or any combination  
11 thereof, would place the licensee in a position to render adequate care. Any notice  
12 to a licensee of reduction in quota or ban on new admissions shall include the  
13 terms of the order, the reasons therefor, and the date set for compliance.

14 (2) The secretary shall deny, suspend, or revoke a license issued pursuant to Sections  
15 1 to 11 of this Act if the provisions of Sections 1 to 11 of this Act or of the  
16 administrative regulations promulgated pursuant to Sections 1 to 11 of this Act  
17 are violated. The secretary may revoke a program's license and prohibit all  
18 physicians and licensed disciplines associated with that medication-assisted  
19 treatment program from practicing at the program location based upon an  
20 annual, periodic, complaint, verification, or other inspection and evaluation.

21 (3) Before any license is denied, suspended, or revoked, written notice shall be given  
22 to the licensee, stating the grounds for the denial, suspension, or revocation.

23 (4) An applicant or licensee has ten (10) working days after receipt of the secretary's  
24 order denying, suspending, or revoking a license to request a formal hearing  
25 contesting the denial, suspension, or revocation of a license under this section. If  
26 a formal hearing is requested, the applicant or licensee and the secretary shall  
27 proceed in accordance with the provisions of KRS Chapter 13B.

- 1 (5) If a license is denied or revoked, a new application for a license shall be  
2 considered by the secretary if, when, and after the conditions upon which the  
3 denial or revocation was based have been corrected and evidence of this fact has  
4 been furnished. A new license shall then be granted after proper inspection, if  
5 applicable, has been made and all provisions of Sections 1 to 11 of this Act and  
6 the administrative regulations promulgated pursuant to Sections 1 to 11 of this  
7 Act have been satisfied.
- 8 (6) Any applicant or licensee who is dissatisfied with the decision of the secretary as  
9 a result of the hearing provided in this section may, within thirty (30) days after  
10 receiving notice of the decision, petition the Circuit Court of Franklin County,  
11 for judicial review of the decision.
- 12 (7) The court may affirm, modify, or reverse the decision of the secretary and either  
13 the applicant or licensee or the secretary may appeal from the court's decision to  
14 the Court of Appeals.
- 15 (8) If the license of a medication-assisted treatment program is denied, suspended, or  
16 revoked, the medical director of the program, any owner of the program, or  
17 owner or lessor of the medication-assisted treatment program property shall cease  
18 to operate the clinic, facility, office, or program as a medication-assisted  
19 treatment program as of the effective date of the denial, suspension, or  
20 revocation. The owner or lessor of the medication-assisted treatment program  
21 property is responsible for removing all signs and symbols identifying the  
22 premises as a medication-assisted treatment program within thirty (30) days. Any  
23 administrative appeal of the denial, suspension, or revocation shall not stay the  
24 denial, suspension, or revocation.
- 25 (9) Upon the effective date of the denial, suspension, or revocation, the medical  
26 director of the medication-assisted treatment program shall advise the secretary  
27 and the Kentucky Board of Pharmacy of the disposition of all medications located

1 on the premises. The disposition is subject to the supervision and approval of the  
2 secretary. Medications that are purchased or held by a medication-assisted  
3 treatment program that is not licensed may be deemed adulterated.

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

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

13 ➔SECTION 9. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
14 READ AS FOLLOWS:

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

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

26 (b) If a program's medical director knowingly and intentionally misrepresents  
27 actions taken to correct a violation, the secretary may, in addition to any

1 other penalty available by law, impose a civil penalty not to exceed ten  
2 thousand dollars (\$10,000) and, in the case of an owner-operator  
3 medication-assisted treatment program, limit or revoke a medication-  
4 assisted treatment program's license;

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

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

16 (e) If a physician:

17 1. Operates, owns, or manages an unlicensed medication-assisted  
18 treatment program that is required to be licensed pursuant to Sections  
19 1 to 11 of this Act;

20 2. Knowingly prescribes or dispenses or causes to be prescribed or  
21 dispensed a medication-assisted treatment medication through  
22 misrepresentation or fraud; or

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

26 the secretary may assess a civil penalty of not more than twenty thousand  
27 dollars (\$20,000). The penalty may be in addition to or in lieu of any other

1 action that may be taken by the secretary or any other board, court, or  
2 entity.

3 (2) Notwithstanding the existence or pursuit of any other remedy, the secretary may,  
4 in the manner provided by law, maintain an action in the name of the state for an  
5 injunction against any person, partnership, association, or limited liability  
6 company to restrain or prevent the establishment, conduct, management, or  
7 operation of any medication-assisted treatment program or violation of any  
8 provision of Sections 1 to 11 of this Act or any administrative regulation  
9 promulgated thereunder without first obtaining a license in the manner herein  
10 provided.

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

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

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

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

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

25 (4) Upon finding that a physician has violated the provisions of Sections 1 to 11 of  
26 this Act or administrative regulations adopted pursuant to Sections 1 to 11 of this  
27 Act, the secretary shall provide notice of the violation to the applicable licensing

1        board.

2        ➔SECTION 10. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
3 READ AS FOLLOWS:

4        An advertisement made by or on behalf of a medication-assisted treatment program  
5        through public media, such as a telephone directory, medical directory, newspaper,  
6        periodical, outdoor advertising, radio, television, or through written or recorded  
7        communication, concerning the treatment of substance use disorders, as defined in  
8        Section 2 of this Act, shall include the name of, at a minimum, the medical director  
9        responsible for the content of the advertisement.

10       ➔SECTION 11. A NEW SECTION OF KRS CHAPTER 222 IS CREATED TO  
11 READ AS FOLLOWS:

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

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

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

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

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

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

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

- 1 (7) The standards and procedures for the general operation of a medication-assisted  
2 treatment program, including facility operations, physical operations, infection  
3 control requirements, health and safety requirements, and quality assurance;
- 4 (8) Identification of drugs that may be used to treat substance use disorders that  
5 identify a facility as a medication-assisted treatment program;
- 6 (9) Any other criteria that identify a facility as a medication-assisted treatment  
7 program;
- 8 (10) The standards and procedures to be followed by an owner in providing  
9 supervision, direction, and control of individuals employed by or associated with  
10 a medication-assisted treatment program;
- 11 (11) Data collection and reporting requirements;
- 12 (12) Criteria and requirements related to specific medication-assisted treatment  
13 medications; and
- 14 (13) Other standards or requirements as the secretary determines are appropriate.