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# S T A T E  O F  R H O D E  I S L A N D

**IN GENERAL ASSEMBLY**

**JANUARY SESSION, A.D. 2019**

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A N  A C T

RELATING TO FOOD AND DRUGS -- ENSURING ACCESS TO HIGH QUALITY CARE FOR THE TREATMENT OF SUBSTANCE USE DISORDERS

Introduced By: Senators Miller, Lynch Prata, McCaffrey, Goodwin, and Satchell

Date Introduced: March 21, 2019

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. The general assembly finds and declares that:

(1) The United States and Rhode Island continue to struggle with a nationwide epidemic stemming from opioid-related misuse, overdose and death as well as accidental injury and death from other drugs.

(2) According to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), more than two million people in the United States have a substance use disorder related to prescription opioid pain relievers and/or heroin.

(3) According to the U.S. Centers for Disease Control and Prevention (CDC), in 2016, 20,145 Americans died from illicit fentanyl, 15,446 died from heroin, 14,427 died from natural and semi-synthetic opioids, and 3,314 died from methadone-related overdose (for a total of 53,332); a staggering increase from 2015 (fentanyl deaths equaled 9,945; heroin deaths equaled 13,219; prescription deaths equaled 12,726; methadone deaths equaled 3,276; for a total of 39,166 deaths).

(4) Despite the millions with a substance use disorder, and the increasing death rate, nearly ninety percent (90%) of Americans who need treatment for addiction are not receiving it, according to SAMHSA data.

(5) Part of this epidemic can be addressed through enhanced efforts to increase treatment and prevention in Rhode Island, including increased access to Medication Assisted Treatment

(MAT), which has been proven to further recovery and help prevent relapse, overdose and death.

(6) MAT is the use of medications, commonly in combination with counseling and behavioral therapies, to provide a comprehensive approach to the treatment of substance use disorders. FDA-approved medications used to treat opioid addiction include methadone, buprenorphine (alone or in combination with naloxone) and extended-release injectable naltrexone. Types of behavioral therapies include individual therapy, group counseling, family behavior therapy, motivational incentives and other modalities.

(7) Research shows that when treating substance use disorders, a combination of medication and behavioral therapies along with mental health services is most successful.

(8) According to the Centers for Medicaid and CHIP Services, "there is strong evidence that use of MAT in managing substance use disorders provides substantial cost savings" to states. MAT services also have been shown to help reduce recidivism for those drug courts that offer MAT services.

(9) Many medical societies, including the American Medical Association, the American Society of Addiction Medicine (ASAM), the American Academy of Addiction Psychiatry, and other medical associations have long supported the use of MAT services due to their proven clinical benefits to patients and cost-effectiveness to society. A 2013 ASAM report, however, found considerable restrictions on coverage "by governments, Medicaid, and insurance companies on the use of methadone, buprenorphine, and naltrexone."

(10) Moreover, a Health Affairs analysis of SAMHSA data found that in 2016, only forty-one percent (41%) of treatment facilities in the United States offer one form of MAT; and only 319 (2.7%) offer all three forms of MAT. The analysis noted that, "eight states do not have any facilities that report offering all three forms of MAT, and 14 states do not have a facility offering all three forms of MAT that also accepts Medicaid."

(11) Despite the proven safety and efficacy of MAT services, more widespread use often is limited by a lack of understanding about its benefits, the stigma associated with having a substance use disorder as well as financial and administrative barriers. One study of six (6) large cities found that prior authorization for buprenorphine occurred forty-two percent (42%) of the time.

SECTION 2. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby amended by adding thereto the following chapter:

## CHAPTER 28.10

## ENSURING ACCESS TO HIGH QUALITY CARE FOR THE TREATMENT OF SUBSTANCE USE DISORDERS ACT

**21-28.10-1. Title.**

This chapter shall be known and may be cited as the "Ensuring Access to High Quality Care for the Treatment of Substance Use Disorders Act."

**21-28.10-2. Definitions.**

As used in this chapter, the following words and terms shall have the following meanings:

(1) "ASAM criteria" means the American Society of Addiction Medicine (ASAM) national set of criteria for providing outcome-oriented and results-based care in the treatment of addiction, a comprehensive set of guidelines for placement, continued stay and transfer/discharge of patients with addiction and co-occurring conditions.

(2) "Behavioral therapy" means an individual, family or group therapy designed to help patients engage in the treatment process, modify their attitudes and behaviors related to substance use, and increase healthy life skills.

(3) "Buprenorphine" means an opioid medication that acts as a partial agonist at opioid receptors it does not produce the euphoria and sedation caused by heroin or other opioids but reduces or eliminates withdrawal symptoms associated with opioid dependence and has a low risk of overdose.

(4) "Department of health" means the Rhode Island department of health, its employees, agents or assigns, that has jurisdiction over the provision of medical care, including substance use disorders.

(5) "Financial requirements" means deductibles, copayments, coinsurance, or out-of-pocket maximums.

(6) "Health care professional" means the person licensed under the professional licensing statutes of this state to provide care to individuals.

(7) "Health insurer" means any person or entity that issues, offers, delivers, or administers a health insurance plan.

(8) "Health insurance commissioner" means the Rhode Island health insurance commissioner its employees, agents or assigns, established pursuant to §§ 42-14-5 and 42-14.5-1, that has jurisdiction regulating a health insurer.

(9) "Health insurance plan" means an individual or group plan that provides, or pays the cost of health care items or services.

(10) "Mental Health Parity and Addiction Equity Act of 2008 (MEPAEA)" means The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 found at 42 U.S.C. 300gg-26 and its implementing and related regulations found at 45 CFR 146.136, 45

CFR 147.160, and 45 CFR 156.115.

(11) "Methadone" means a long-acting opioid agonist medication that can prevent withdrawal symptoms and reduce craving in opioid-addicted individuals.

(12) "Naloxone" means an opioid antagonist that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors. Naloxone has no potential for abuse, and it is not addictive.

(13) "Naltrexone" means an opioid antagonist. It blocks opioids from binding to their receptors and thereby prevents their euphoric and other effects. Naltrexone itself has no subjective effects following detoxification (that is, a person does not receive any particular drug effect), and it has no potential for abuse.

(14) "Nonquantitative treatment limitation" or "NQTL" means any limitation on the scope or duration of treatment that is not expressed numerically.

(15) "Pharmacy benefit management company" means a company that administers the prescription drug plan for commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program, state government employee plans, managed Medicaid plans, and others.

(16) "Pharmacologic therapy" means a prescribed course of treatment that may include methadone, buprenorphine, naltrexone or other FDA-approved or evidence-based medications for the treatment of substance use disorder.

(17) "Prior authorization" means the process by which the health insurer or the pharmacy benefit management company determines the medical necessity of otherwise covered health care services prior to the rendering of such health care services. Prior authorization also includes any health insurer's or utilization review entity's requirement that a subscriber or health care provider notify the health insurer or utilization review entity prior to providing a health care service.

(18) "Quantitative treatment limitation" means numerical limits on the scope or duration of treatment which include annual, episode, and lifetime day and visit limits.

(19) "Step therapy" or "fail first" means a protocol or program that establishes the specific sequence in which prescription drugs for a medical condition that are medically appropriate for a particular patient are authorized by a health insurers or prescription drug management company.

(20) "Suboxone" means the brand name of the combination of buprenorphine and naloxone.

(21) "Urgent health care service" means a health care service with respect to which the application of the time periods for making a non-expedited prior authorization, which, in the

opinion of a physician with knowledge of the subscriber's medical condition:

(i) Could seriously jeopardize the life or health of the subscriber or the ability of the subscriber to regain maximum function; or

(ii) Could subject the subscriber to severe pain that cannot be adequately managed without the care or treatment that is the subject of the utilization review.

For the purpose of this chapter urgent health care service shall include services provided for the treatment of substance use disorders.

**21-28.10-3. Requirements for provision and coverage of MAT services.**

(a) MAT services shall include, but not be limited to, pharmacologic and behavioral therapies. At a minimum, a formulary used by a health insurer or managed by a pharmacy benefit management company, or medical benefit coverage in the case of medications dispensed through an opioid treatment program, shall include all current and new formulations and medications approved by the U.S. Food and Drug Administration for the treatment of substance use disorder:

(1) Buprenorphine;

(2) Methadone;

(3) Naloxone;

(4) Extended-release injectable naltrexone; and

(5) Buprenorphine/naloxone combination.

(b) All MAT medications required for compliance under this chapter shall be placed on the lowest cost sharing tier of the formulary managed by the health insurer or the pharmacy benefit management company.

(c) MAT services provided for under this chapter shall not be subject to any of the following:

(1) Any annual or lifetime dollar limitations;

(2) Limitations to a pre-designated facility, specific number of visits, days of coverage, days in a waiting period, scope or duration of treatment, or other similar limits;

(3) Financial requirements and quantitative treatment limitations that do not comply with the Mental Health Parity and Addiction Equity Act of 2008 (MEPAEA), specifically 45 CFR 146.136(c)(3);

(4) Step therapy or other similar drug utilization strategies or policies, when they conflict or interfere with a prescribed or recommended course of treatment from a licensed health care professional; and

(5) Prior authorization for MAT services as specified in this chapter, as well as any behavioral, cognitive or mental health services prescribed in conjunction with or supplementary

to the MAT services for the purpose of treating a substance use disorder.

(d) The health care benefits and MAT services outlined in this chapter shall apply to all health insurance plans offered to consumers in Rhode Island.

(e) Any entity that holds itself out as a treatment program or that applies for licensure by this state to provide clinical treatment services for substance use disorders shall be required to:

(1) Use the ASAM criteria or other such nationally recognized, research validated criteria, for patient placement and review of ongoing need for treatment and meet or exceed the standards set forth in the ASAM or other criteria for the level of care being provided by such program; and

(2) Disclose the MAT services it provides, as well as which of its level of care have been certified by an independent, national or other organization that has competencies in the use of the applicable placement guidelines and level of care standards.

(f) The Rhode Island Medicaid program shall cover the MAT medications and services provided for under this chapter, and include those MAT medications in its preferred drug lists for the treatment of substance use disorder and prevention of overdose and death. At a minimum the preferred drug list shall include all current and new formulations and medications that are approved by the U.S. Food and Drug Administration for the treatment of substance use disorder.

(g) The Department of corrections and all other state entities responsible for the care of persons detained or incarcerated in jails or prisons shall be required to ensure all persons under their care be assessed for substance use disorders using standard diagnostic criteria by a licensed physician who actively treats patients with substance use disorders. The entity shall make available the MAT services covered under this chapter consistent with a treatment plan developed by the physician and shall not impose any limitations on the type of medication or other treatment prescribed or the dose or duration of MAT recommended by the physician.

(h) Drug courts or other diversion programs that provide for alternatives to jail or prison for persons with a substance use disorder shall be required to ensure all persons under their care be assessed for substance use disorders using standard diagnostic criteria by a licensed physician who actively treats patients with substance use disorders. The entity shall make available the MAT services covered under this chapter consistent with a treatment plan developed by the physician and shall not impose any limitations on the type of medication or other treatment prescribed or the dose or duration of MAT recommended by the physician.

(i) Requirements under this section shall not be subject to a covered person's prior success or failure of the service provided.

**21-28.10-4. Requirements for payer compliance.**

(a) All health insurers and other payers providing health coverage in Rhode Island shall be required to disclose which providers in its network provide MAT services, and what level of care is provided pursuant to ASAM criteria or other nationally recognized, research-validated substance use disorder-specific program standards recognized by the state's applicable licensure body. Such disclosure shall be made in a prominent location in the online and print provider directories.

(b) The health insurance commissioner shall require that provider networks meet maximum time/distance standards and minimum wait time standards for providers of MAT services.

(1) Such standards shall be established by the health insurance commissioner and reviewed biennially to ensure patient access to MAT services.

(2) Health insurers must include a description of how their provider networks meet the requirements under this chapter as part of their access plan and other required network adequacy documentation provided to the health insurance commissioner.

(c) A health insurance plan shall have a process to assure that an enrollee obtains a covered benefit for MAT and related treatment services at an in-network level of coverage or shall make other arrangements acceptable to the health insurance commissioner when:

(1) The health insurance plan has an otherwise sufficient network, but does not have an appropriate type of in-network provider available to provide the covered MAT services to the enrollee or it does not have an in-network provider available to provide the covered MAT services to the enrollee without unreasonable travel or delay; or

(2) The health insurance plan has an insufficient number or type of appropriate in-network providers available to provide the covered MAT services to the enrollee without unreasonable travel or delay.

(d) For purposes of an enrollee's financial responsibilities when the health insurance plan is deemed inadequate under the requirements of this section, the health insurance plan shall treat the health care services the enrollee receives from an out-of-network provider pursuant to this section as if the services were provided by an in-network provider including counting the enrollee's cost-sharing for such services toward the enrollee's deductible and maximum out-of-pocket limit applicable to services obtained from in- network providers under the health insurance plan.

(e) A health insurer shall render a determination to a request by an enrollee concerning a covered benefit for MAT services from an out-of-network provider and notify the enrollee and the enrollee's health care provider of that determination within twenty-four (24) hours from the

date and time on which the health insurer receives that request.

(f) A health insurer shall render a determination concerning urgent care services for MAT and related services, and notify the enrollee and the enrollees' health care provider of that determination within twenty-four (24) hours from the date and time on which the health insurer receives that request.

(g) The health insurance plan shall report bi-annually to the health insurance commissioner the frequency with which the process outlined in subsections (d), (e) and (f) of this section is used. All payers providing health coverage in Rhode Island shall submit an annual report to the health insurance commissioner on or before December 31 that contains the following information:

(1) A description of the process used to develop or select the medical necessity criteria for mental health and substance use disorder and the process used to develop or select the medical necessity criteria for medical and surgical benefits.

(2) Identification of all non-quantitative treatment limitations (NQTLs) that are applied to mental health and substance use disorder benefits.

(3) An analysis that demonstrates that for the medical necessity criteria and each NQTL as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the medical necessity criteria and each NQTL to mental health and substance use disorder benefits within each classification of benefits are comparable to, and applied no more stringently than the processes, strategies, evidentiary standards, or other factors used in applying the medical necessity criteria and each NQTL to medical and surgical benefits within the corresponding classification of benefits, at a minimum, the results of the analysis shall:

(i) Identify how the factors used to determine that NQTL will apply to a benefit including factors that were considered but rejected;

(ii) Identify and define the specific evidentiary standards used to define the factors and any other evidence relied upon in designing each NQTL;

(iii) Provide the comparative analyses, including the results of the analyses, performed to determine that the processes and strategies used to design each NQTL, as written, for mental health and substance use disorder benefits are comparable to, and are applied no more stringently than the processes and strategies used to design each QTL and NQTL as written, for medical and surgical benefits; and

(iv) Provide the comparative analyses, including the results of the analyses, performed to determine that the processes and strategies used to apply each NQTL in operation, for mental health and substance use disorder benefits are comparable to, and applied no more stringently

than, the processes or strategies used to apply each NQTL, in operation, for medical and surgical benefits.

(h) The health insurance commissioner shall publicly disclose the specific findings and conclusions reached by the payer.

(i) The health insurance commissioner shall be required to periodically perform parity compliance market conduct examinations of all health insurers that provide coverage for mental health and substance use disorder care in Rhode Island with a focus on determining compliance the requirements of this chapter.

(j) The department of health shall promote and make prominent on its website a mechanism to explain the requirements of this chapter and a feedback/complaint process for consumers and providers who have a bona fide complaint that a payer is not meeting the requirements of this chapter.

(k) The department of health shall promulgate guidelines or regulations as needed to implement and enforce the requirements of this chapter. Consultation with representatives of the mental health, medical, social work and other relevant organizations is strongly encouraged.

**21-28.10-5. Nullification and voidance.**

Any contract, written policy, or written procedure in violation of this chapter shall be deemed to be unenforceable and null and void.

**21-28.10-6. Severability.**

If any provision of this chapter or the application thereof to any person or circumstance shall be adjudged by any court of competent jurisdiction to be invalid, such invalidity shall not affect other provisions of applications of the chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are declared to be severable.

SECTION 3. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO FOOD AND DRUGS -- ENSURING ACCESS TO HIGH QUALITY CARE FOR THE TREATMENT OF SUBSTANCE USE DISORDERS

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This act would establish the Medication Assisted Treatment (MAT) program which uses medications, in combination with counseling and behavioral therapies, to create a comprehensive approach to the treatment of substance use disorders. This act would authorize the use of certain FDA-approved medications to treat opioid addiction including methadone, buprenorphine (alone or in combination with naloxone) and naltrexone in addition to behavioral therapies such as individual therapy, group counseling, and family behavior therapy.

This act would take effect upon passage.

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