Emergency Rule Filing Form

Emergency rules are effective from date of filing, unless otherwise stated in the rule, for a period of up to 180 days.

Agency/Board/Commission: Tennessee Department of Finance and Administration
Division: Division of TennCare
Contact Person: George Woods
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310 Great Circle Road
Nashville, TN 37243
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Revision Type (check all that apply):
X Amendments
X New
__ Repeal

Statement of Necessity:
The U.S. Department of Health and Human Services first declared opioid abuse a Public Health Emergency on October 26, 2017, when drug overdose deaths became the leading cause of injury death in the United States. This national Public Health Emergency determination remains in effect, having been extended every ninety (90) days as required by law, with the most recent extension dated January 7, 2021.

Also in 2017, the Tennessee General Assembly, the Attorney General, and members of the Executive Branch stated that prescription opioid use in Tennessee was a crisis and an epidemic. In response, the Division of TennCare adopted emergency rules to limit coverage of opioid medications. Those emergency rules were promulgated as permanent rules and remain in effect. As a result of those rules, the Division of TennCare, working with other state agencies, has facilitated the reduction of the negative effects of opioid use in Tennessee.

Even though inroads into reducing opioid use have been made, Tennessee must continue to address the impacts of this public health emergency in our state, including the impact on infant and maternal health. Substance use disorder (SUD) was a contributing factor in thirty-three percent (33%) and thirty-four percent (34%) of pregnancy-associated deaths during 2017 and 2018, respectively. In addition, the rate of infants born with Neonatal Abstinence Syndrome (NAS) has plateaued, with 668 cases reported through the forty-seventh (47th) week of 2020 (November 28), and sixty-three and two-tenths percent (63.2%) of those cases involved at least one (1) opioid prescribed to the mother by a health care provider. During this time, the highest rates of NAS have been reported in the Northeast and East Regions, Knox and Sullivan counties.

With efforts to limit over-utilization of prescription opioids, Tennessee saw a fifteen percent (15%) decrease in prescription opioid overdose deaths in 2017-2018. However, overdose deaths from nonprescription opioids increased eighteen percent (18%) between 2018 and 2019, equaling one-thousand-eight-hundred-eighteen (1,818) deaths, with twenty-eight percent (28%) of those deaths occurring in persons aged eighteen through twenty-four (18-24).

Tennessee is now battling another public health emergency in the COVID-19 pandemic, which is also negatively impacting the opioid crisis. With the onset of the COVID-19 pandemic, some effects of the ongoing opioid crisis
have increased. Based upon preliminary data from county health departments in Tennessee, nonprescription opioid deaths are on the increase in 2020. The isolation resulting from the COVID-19 pandemic appears to be impacting persons with SUD and their use of opioid drugs and COVID-19 patients with SUD have elevated rates of hospitalization and death.

Finally, in 2018, the federal SUPPORT Act required that states cover Medication-Assisted Treatment (MAT) as part of their Medicaid programs. Further, on December 30, 2020, the Centers for Medicare and Medicaid Services (CMS) also required that states specifically add MAT to their state plans retroactive to October 1, 2020. While TennCare has covered MAT for opioid use disorder (OUD) for many years, due to the effects of the current public health crisis on the opioid epidemic, TennCare determined the need for a dedicated comprehensive MAT program for its members.

Taking all the above into consideration, the Division of TennCare submitted to CMS a request for a State Plan Amendment (SPA) permitting TennCare to implement a Buprenorphine Enhanced Supportive Medication-Assisted Recovery and Treatment program to be known as BESMART. The BESMART program will be administered by TennCare Managed Care Organizations (MCOs) to increase access to comprehensive MAT for members through a group of high-quality, vetted Medicaid providers that provide comprehensive treatment and recovery related supports for individuals with OUD. The BESMART benefit is a coordinated set of services consisting of psychosocial assessment and development of a treatment plan, individual or group counseling, peer recovery services, care coordination, and opioid-agonist therapy. The opioid-agonist therapy used will be buprenorphine products that have been FDA approved for OUD treatment. CMS approved the BESMART SPA for an effective date of January 1, 2021.

T.C.A. § 4-5-208 permits an agency to adopt an emergency rule when the agency finds an immediate danger to the public health, safety or welfare exists, and the nature of this danger is such that the use of any other form of rulemaking authorized by Title 4, Chapter 5 would not adequately protect the public.

Based upon the above information, I have made the finding that the emergency adoption of these rule amendments is required in order to achieve immediate implementation.

For a copy of these emergency rules contact George Woods at the Bureau of TennCare by mail at 310 Great Circle Road, Nashville, Tennessee 37243 or by telephone at (615) 507-6446.

Stephen Smith
Director, Division of TennCare

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that ALL new rule and repealed rule numbers are listed in the chart below. Please enter only ONE Rule Number/Rule Title per row.)

<table>
<thead>
<tr>
<th>Chapter Number</th>
<th>Chapter Title</th>
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<tbody>
<tr>
<td>1200-13-13</td>
<td>TennCare Medicaid</td>
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<table>
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<tr>
<th>Rule Number</th>
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<td>1200-13-13-.01</td>
<td>Definitions</td>
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<tr>
<td>1200-13-13-.15</td>
<td>BESMART</td>
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Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Chapter 1200-13-13 TennCare Medicaid Table of Contents is amended by adding a new rule number and title "1200-13-13-.15 BESMART" at the end of the Table.
Rule 1200-13-13-.01 Definitions is amended by inserting in alphabetical order the following new paragraph, with all paragraphs numbered appropriately so that the new paragraph shall read as follows:

(#) Buprenorphine Enhanced Supportive Medication-Assisted Recovery and Treatment ("BESMART"). A treatment model comprised of comprehensive treatment and recovery related supports for adult (21 and older) enrollees with opioid use disorder (OUD) ("participants").


Chapter 1200-13-13 is amended by inserting a new Rule .15 BESMART which shall read as follows:

1200-13-13-.15 BESMART. This rule supersedes any other rules related to the use of buprenorphine products for treatment of opioid use disorder (OUD) in office based opioid treatment (OBOT) or an opioid treatment program (OTP) by a treating provider participating in an MCO's network of BESMART providers.

1. BESMART treatment is a component of covered outpatient substance abuse benefits and consists of a set of coordinated medically necessary covered services which includes:

   (a) Psychosocial assessment and development of a treatment plan;

   (b) Individual or group counseling;

   (c) Peer recovery services;

   (d) Care coordination;

   (e) Opioid-agonist therapy consisting of buprenorphine products that have been FDA approved for OUD treatment and may be prescribed in excess of the limits described in rules .04 and .10, when determined to be medically necessary by a treating provider in an MCO's network of BESMART providers and under the participant's plan of care.

   1. Except as otherwise provided for in this rule, participants may receive up to sixteen (16) mg of buprenorphine containing products daily; however, providers shall initiate and lead a discussion regarding a participant's readiness to taper down or off treatment at any time upon a participant's request, but no later than one (1) year after initiating treatment and every six (6) months thereafter.

   2. Under the best practices for treatment of OUD, the BESMART provider shall utilize the lowest effective dose of Medication-Assisted Treatment (MAT).

   3. The following adult populations shall be eligible to receive a maximum daily dosage of twenty-four (24) mg of buprenorphine, not to exceed one (1) year in duration:

      (i) Pregnant participants confirmed by provider attestation.

      (ii) Postpartum participants for a period of twelve (12) months from delivery date as shown by medical records or insurance claim.

      (iii) Recent intravenous (IV) drug users confirmed by prescriber attestation and a positive urine drug screen.

      (iv) Current users receiving greater than fifty (50) mg of methadone for OUD treatment transitioning to buprenorphine agonist therapy demonstrated by paid claims data from the participant's health insurer, provider attestation, or medical records.

      (v) Current users of sixteen (16) mg to twenty-four (24) mg per day of buprenorphine demonstrated by paid claims data from the participant's previous health insurer.

      (vi) For one (1) year from the effective date of this rule, a member who does not qualify under the criteria of this part but receives greater than sixteen (16) mg per day of
buprenorphine as demonstrated by the controlled substance monitoring database shall be eligible to receive a maximum daily dose of twenty-four (24) mg.

(2) BESMART treatment requires physician office visits at least weekly for participants in the induction and stabilization phase of treatment; at least every two (2) to four (4) weeks for participants in the maintenance phase of treatment; and at least every two (2) months for participants who have been in the maintenance phase of treatment for one (1) year or longer.

(3) To be reimbursed for a BESMART covered service, treating providers must demonstrate an ability to provide all BESMART services in a coordinated, person-centric way, including the ability to facilitate access to all related treatment modalities and provider types, and must participate in at least one (1) MCO's network of BESMART providers.

(4) Prescriptions of buprenorphine containing products to TennCare enrollees by nurse practitioners and physician assistants for the treatment of OUD will not be reimbursed unless the nurse practitioner or physician assistant participates in at least one (1) MCO's network of BESMART providers.

I certify that this is an accurate and complete copy of an emergency rule(s), lawfully promulgated and adopted.

Date: March 23, 2021

Signature: 

Name of Officer: Stephen Smith
   Director, Division of TennCare
Title of Officer: Tennessee Department of Finance and Administration

Agency/Board/Commission: Division of TennCare
Rule Chapter Number(s): 1200-13-13

All emergency rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
   Attorney General and Reporter
   5/24/2021

Department of State Use Only

Filed with the Department of State on: 4/15/2021
Effective for: 180 *days
Effective through: 10/12/2021

* Emergency rule(s) may be effective for up to 180 days from the date of filing.

Tre Hargett
   Secretary of State

RECEIVED

Secretary of State
Division of Publications
Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (http://publications.tnsosfiles.com/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly.)

These rules are not anticipated to have an impact on local governments.
Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

These rules are being adopted to implement a CMS approved TennCare State Plan Amendment for a Buprenorphine Enhanced Supportive Medication-Assisted Recovery and Treatment (BESMART) program to combat the opioid epidemic and public health emergency.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The Rules are lawfully adopted by the Bureau of TennCare under T.C.A. §§ 4-5-208, 71-5-105, 71-5-107 and 71-5-109.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The persons and entities most directly affected by these Rules are TennCare enrollees, providers and the managed care contractors. The governmental entities most directly affected by these Rules are the Division of TennCare, Tennessee Department of Finance and Administration.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

These Rules were approved by the Tennessee Attorney General. No additional opinion was given or requested.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The adoption of these Rules is projected to have a minimal impact on state expenditures as the BESMART program does not offer new services, rather a comprehensive method of service delivery.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Donna K. Tidwell
Deputy General Counsel

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Donna K. Tidwell
Deputy General Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

310 Great Circle Road
Nashville, TN 37243
(615) 477-8970
donna.tidwell@tn.gov
(I) Any additional information relevant to the rule proposed for continuation that the committee requests.
“1200-13-13-.01 Definitions

(#) Buprenorphine Enhanced Supportive Medication-Assisted Recovery and Treatment ("BESMART"). A treatment model comprised of comprehensive treatment and recovery related supports for adult (21 and older) enrollees with opioid use disorder (OUD) ("participants").

1200-13-13-.15 BESMART.

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1. Except as otherwise provided for in this rule, participants may receive up to sixteen (16) mg of buprenorphine containing products daily; however, providers shall initiate and lead a discussion regarding a participant’s readiness to taper down or off treatment at any time upon a participant’s request, but no later than one (1) year after initiating treatment and every six (6) months thereafter.

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