Development and Implementation of Tennessee Nonresidential Buprenorphine Treatment Guidelines

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Abstract

Objective: *To describe the recent legislation in Tennessee and subsequent development and implementation of state-wide buprenorphine treatment guidelines.*

Practice Innovation: *In 2016, Tennessee began licensing office-based opioid treatment (OBOT) clinics. Due to initial licensing criteria, not all providers were required to be licensed with the Department of Mental Health and Substance Abuse Services (TDMHSAS). The gap in licensing made it difficult to ensure an appropriate standard of care was being met by all addiction treatment providers. Therefore, the state developed legislation that allowed for the creation of best practice guidelines to encompass all providers of buprenorphine in the state of Tennessee, not just the licensed OBOT clinics. The guidelines define what the standard of care should entail while treating this vulnerable addiction population.*

Results: *Tennessee legislation granted the formation of a committee to create the Tennessee Nonresidential Buprenorphine Treatment Guidelines. The committee was comprised of physicians, pharmacists, lawyers, law enforcement, and state officials. The finalized guidelines were published and effective January 1, 2018, and adopted as policy by the boards of medical examiners, osteopathic examination, and pharmacy shortly thereafter. The guidelines are now enforceable by the boards and give them the ability to discipline physicians who practice outside the standard of care.*

Conclusion: *Tennessee legislation provides a model for other states to take action in combating this opioid crisis by not only increasing access to addiction treatment, but increasing access to quality care.*

Key Words: Buprenorphine; Opioid; Guidelines; Treatment

In 2016, the CDC estimated 2.1 million people had an opioid use disorder. There were more than 42,000 opioid overdose deaths in the United States[1,2], 1,186 of those overdose deaths were in Tennessee alone[3]. Being in the midst of an opioid pandemic, many states are taking action to help combat this opioid crisis including stricter penalties for overprescribing, over-dispensing of opioids, and increasing prevention strategies. Tennessee is attempting to increase access to addiction treatment, by not only increasing access to care but access to quality care.

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), medication-assisted treatment (MAT) is the use of FDA-approved medications, in combination with counseling and other behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. Medication is one tool that can be used as adjunct to counseling or other behavioral therapies. MAT services can be provided in opioid treatment programs (OTPs), which are more commonly known as "methadone clinics", office-based opioid treatment (OBOT) clinics, and in inpatient settings. The medications used in these facilities are methadone, naltrexone, or buprenorphine. To be eligible to prescribe buprenorphine for the treatment of opioid use disorder (OUD), a prescriber must apply and receive their DATA 2000 waiver, or better known as their "X" DEA number. Buprenorphine exerts a mixed agonist-antagonist action on the CNS opiate receptors[4]. Advantages of using buprenorphine include increased safety in cases of overdose, when compared to methadone, and can be filled at a pharmacy. The MAT approach has been shown to improve patient survival, increase retention in treatment, decrease illicit opiate use and other criminal activity, and increase patients' ability to gain and maintain employment[5]. The ultimate goal of MAT is to improve the patients' quality of life and help them to enter full recovery[5].

In 2016, Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) began licensing office-based opioid treatment (OBOT) clinics to better regulate the standard of care which buprenorphine clinics provided. However, due to the licensing requirements, not all DATA 2000 waived physicians were required to apply for a licensure. As a

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DOI: https://doi.org/10.24926/iip.v9i3.1317

state, Tennessee began to see an influx of clinics providing only prescription services without counseling or behavioral therapy services, to patients with an opioid use disorder while staying below the licensing criteria. This made it difficult to regulate these clinics and ensure patients were receiving appropriate care. As a result, the state then set forth to establish the "adequate care" standard for buprenorphine treatment of opioid use disorder with the development of legislation that would allow for the creation of best practice guidelines to encompass all providers of buprenorphine in the state of Tennessee, not just the licensed OBOT clinics.

As of March 2018, only four states, including Tennessee, have buprenorphine treatment guidelines that are endorsed by their state legislature[6,7,8]. Other states have buprenorphine treatment guidelines created by institutions within the state, but do not have support from state legislature. These latter states include the Baltimore Buprenorphine Initiative developed by the Baltimore City Health Department, Baltimore Substance Abuse Systems, and HealthCare Access Maryland[9]. Of importance, most states do have guidelines for the treatment of opioid use disorder, which includes sections addressing the use of buprenorphine. However, these documents do not address buprenorphine treatment alone in great detail, typically only devoting a few paragraphs to the matter or referring providers to the SAMHSA guidelines. The SAMHSA guidelines are thorough; however, they do not address some important issues relevant to practice, such as guidance on interdisciplinary patient care. For example, the role of the pharmacist in the treatment of opioid use disorders is not clearly established in these guidelines. Additionally, further guidance was needed on how to initiate pharmacist-led discussions with patients, how to collaborate with providers, and how to determine what constitutes a high quality clinic and provider. For this reason, the Tennessee Nonresidential Buprenorphine Treatment Guidelines aim to address many aspects of treatment including assessment, diagnosis, maintenance, tapering, relapse indicators, pharmacist involvement, and provides an extensive list of resources for providers who treat substance use disorders. The guidelines were created by an expert panel of physicians who specialize in treating substance use disorders, law enforcement, pharmacists, lawyers, and state officials. The guidelines were grounded in evidence from SAMHSA[10], the American Society of Addiction Medicine (ASAM)[11], and the American Board of Preventative Medicine.

Tennessee Senate Bill 0709[12]

There are two core elements of the Tennessee legislation:

1. Development of Nonresidential Treatment Guidelines for the Use of Buprenorphine

The Department of Mental Health and Substance Abuse Services, in collaboration with the Department of Health will develop recommended nonresidential treatment guidelines. The guidelines developed will be used by practitioners, prescribing buprenorphine-containing products, in Tennessee as a guide for caring for patients with opioid use disorder in a nonresidential, outpatient setting.

2. Publishing and Updating Requirements of the Guidelines

Beginning in 2019, the guidelines will be reviewed and updated by September 30 of each year. The guidelines are posted on both the TN Department of Mental Health and Substance Abuse Services and the Department of Health's websites. When the guidelines are updated each year, the finished product must be provided to the chairs of the Health Committee of the House of Representatives and the Health and Welfare Committee of the Senate.

The Legislative Process

The bill itself encountered no opposition as it made its way through the legislature, after questions and concerns were clarified through committee hearings. It passed unanimously in both the House and Senate, was signed by the Governor on April 7, 2017, and became Public Chapter 112 on April 19, 2017. The guidelines were developed and took effect on January 1, 2018.

The Tennessee legislature raised questions throughout the hearings. First, representatives asked for clarification on the difference between the OBOT rules that passed the year prior and the need for best practice guidelines. The Department of Mental Health and Substance Abuse Services explained the need for the guidelines based on issues with gaps in licensure and inadequate care being provided by some clinicians in the community. The growing need for access to good, quality substance use disorder care further provided evidence of the necessity for the development of best practice guidelines.

Another question surrounded the genesis of the legislation. Some expressed concern for overregulation of the profession of medicine. Explanation was given expressing the treatment-focused approach by the Department of Mental Health and Substance Abuse Services is and how development of these guidelines would establish a minimum standard of care that was not previously being met.

The legislature requested a copy of the guidelines and any revisions of the guidelines developed be provided to the chairs of the Health Committee of the House of Representatives and the Health and Welfare Committee of the Senate. The guidelines and revisions must be posted to the websites of the Department of Mental Health and Substance Abuse Services and the Department of Health.

The final question asked for clarification whether the bill would create a committee that would in turn create the guidelines. The Department of Mental Health and Substance Abuse Services, in conjunction with the Department of Health, invited appropriate addiction physicians, alcohol and substance use

DOI: https://doi.org/10.24926/iip.v9i3.1317

counselors, law enforcement, pharmacists, and other government entities to form a committee to develop the nonresidential buprenorphine treatment best practice guidelines.

Guideline Development

The commissioners of Mental Health and Substance Abuse Services and Health convened a group of expert providers and stakeholders in substance abuse treatment. The committee consisted of representatives from residential inpatient treatment settings, law enforcement, healthcare providers specialized in treating opioid use disorders, pharmacists, lawyers, state officials, and patient advocates. The committee convened was rather large, and opted to create a smaller, working group to do the bulk of the work in the development of the guidelines. The working group met on several occasions, for several hours at a time, to work through the formation of the guidelines. Once a final draft was prepared, the guidelines were brought back to the larger group for wordsmithing and finalization. The finished product was then presented to the commissioners of mental health and health for final approval and publication.

After their publication, the Tennessee Nonresidential Buprenorphine Treatment Guidelines were presented to the board of medical examiners, osteopathic examination, and pharmacy, respectively; each board adopted the guidelines as policy and provided a link to the guidelines on their respective websites. This adoption allows the boards to take action against licensees who practice outside the guidelines without proper documentation. The guidelines were not presented to the board of nursing due to their inability to prescribe or dispense buprenorphine in the state of Tennessee. https://www.tn.gov/content/dam/tn/mentalhealth/documents/2018_Buprenorphine_Treatment_Guidelines.PDF

Conclusion

Public Chapter 112 grants the Department of Mental Health and Substance Abuse Services and the Department of Health the authority to create guidelines for the use of buprenorphine for opioid use disorder in a nonresidential setting[12]. As such, it provides a potential model for other states to pursue in the years ahead. The entire process took approximately a year and a half from the beginning development of the legislation in November 2016 to the final completion and publication of the guidelines in January 2018. The guideline committee worked for approximately six months to progress from a working draft to the final document. Though we encountered no opposition overall in this endeavor, the legislature did have some questions regarding regulations and the genesis of the legislation. By soliciting comment and bringing key stakeholders to the table early on in the process, we developed a collaborative approach to addressing and resolving any technical or philosophical issues that may have been potential barriers. Our department also leveraged existing relationships with advocates within the substance use disorder treatment community to garner support for the legislation, facilitating its passage. Other jurisdictions looking to implement similar legislation may also benefit from utilizing community resources, such as medical provider association and continuing education events, to provide education to healthcare providers. It is essential to work collectively and collaboratively with multiple state departments, community partners, the general public and healthcare providers to ensure all potential barriers are identified and discussed.

The guidelines were adopted as policy by the boards of Medical Examiners, Osteopathic Examination, and Pharmacy to allow for enforcement. It was self-evident that opioid deaths were a problem in Tennessee; therefore it was our aim not to prove there was a problem, but rather to provide an interdisciplinary approach as part of the solution. Our hope with this legislation, and subsequent guideline development and adoption, is that the standard of care in outpatient, nonresidential substance use disorder treatment will be elevated and allow for the residents of Tennessee to received quality substance use disorder care. By addressing the opioid crisis from an access to care standpoint, we hope to make a positive impact by decreasing the number of overdose deaths in our state. Moving forward, the guidelines will be updated yearly, giving the Department and the community the opportunity to evaluate its relevance and applicability in improving patient care. The guidelines will continue to be an ever evolving, living document with the aim to improve patient care and substance use disorder treatment.

Funding Support: None
Conflicts of Interest: None

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DOI: https://doi.org/10.24926/iip.v9i3.1317