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How Public Service Values were diminished by the Drug Addiction Treatment Act of 2000

Introduction: The United States continues to face an ever-growing epidemic of drug-related overdose deaths, most of which are among people with opioid use disorder (OUD). According to the Centers for Disease Control and Prevention (CDC), "…there were an estimated 100,306 drug overdose deaths in the United States during the 12-month period ending in April 2021, an increase of 28.5% from the 78,056 deaths during the same period the year before" (CDC, 2021). This statistic serves as a stark and immediate call to action for the public sector to implement policies aimed at preventing overdose deaths from occurring. While research indicates that multiple strategies must be employed to prevent overdose deaths effectively, a critical intervention is increasing access to medications for opioid use disorder (MOUD) (Medicaid Outcomes Distributed Research et al., 2021). A primary factor that previously limited access to MOUD was the regulations associated with administering and prescribing buprenorphine, a medication used to treat OUD (D'Onofrio, Melnick, & Hawk, 2021).

This paper describes how the regulations previously imposed by the Drug Addiction Treatment Act (DATA 2000) limited access to lifesaving MOUD (LaRochelle & Hodder, 2021). While multiple revisions to the DATA 2000 legislation had been enacted to increase access to MOUD further, these revisions failed to achieve their goal (Marino et al., 2019). Demonstrating how the DATA 2000 limited access to MOUD, the opposite of what the law intended, serves as an excellent example of how public policies can have the opposite effect compared to their original intent (Louie, Assefa, & McGovern, 2019). This analysis of the DATA 2000 provides clear evidence of why public administrators must prioritize the ongoing analysis of enacted policies to ensure they deliver on their intended purpose. In an additional review of the Public Service Values (PSV) outlined by (R. B. Denhardt & Denhardt, 2000) (Molina & McKeown, 2012) (Wang, van Witteloostuijn, & Heine, 2020), it is clear that the DATA 2000 legislation diminishes the PSVs of responsiveness, effectiveness, and impartiality.

Overview of MOUD and DATA 2000 Legislation: Buprenorphine, also known as Suboxone, "is a mixed agonist-antagonist with high affinity at both μ and κ opiate receptors" (Lewis, 1985) used in the treatment of OUD. Buprenorphine is the gold standard treatment for individuals with OUD (West, O'Neal, & Graham, 2000) (Hochheimer & Unick, 2022). While buprenorphine is used in treating OUD, it is classified similarly to other more addictive and dangerous opioids by the Controlled Substances Act (CSA) of 1970 (Act, 1970). The classifications included in the CSA are known as schedules. Based on this scheduling structure, buprenorphine is subject to many of the same regulations as heroin and other illicit opioids. The legislatively imposed regulation established by the CSA created barriers for practitioners who aimed to treat patients suffering from OUD with MOUD outside of a licensed SUD treatment facility (Fiellin, 2007).

In an attempt to increase patient access to buprenorphine/MOUD, the Drug Addiction Treatment Act of 2000 (DATA 2000), Title XXXV, Section 3502 of the Children's Health Act (Congress, 2000), was enacted to revise the scheduling parameters of the CSA. Practitioners who choose to have the ability to treat patients with MOUD under the DATA 2000 were required to obtain a waiver issued by the Drug Enforcement Administration (DEA). The waiver, known as the "X Waiver" due to the "X" that is added to the practitioner's DEA registration number, required a practitioner to complete addiction education and subjected the practitioner to specialized auditing by the DEA (Fiellin, 2007). The DATA 2000 also limited the number of patients each provider could treat at any given time (Treatment, 2004). The DATA 2000 aimed to prevent diversion through strict regulation while expanding the types of providers that could administer MOUD. The intended increase in access to MOUD was to be accomplished by allowing general practitioners to dispense MOUD, which prior to the DATA 2000, was limited to only licensed substance use disorder treatment facilities under the CSA (Ward, Hall, & Mattick, 1999).

While the DATA 2000 legislation did allow MOUD to be administered in primary care settings, the complex and highly regulated policies limited the number of practitioners willing to obtain the X Waiver (Woodruff et al., 2019). By imposing separate and distinct regulations only on MOUD, the policies set forth by the DATA 2000 helped to foster many stigmatizing conditions specific to SUD. The pervasive stigma combined with the strict regulations unique to

MOUD caused most practitioners to be hesitant to obtain the DATA 2000 waiver, thereby limiting access to MOUD (Witte, Jaiswal, Mumba, & Mugoya, 2021). This paper will describe how the shortcomings of the DATA 2000 legislation can be attributed to three PSVs being diminished. The three diminished PSVs are responsiveness, effectiveness, and impartiality. If the DATA 2000 legislation had followed the PSV framework offered by (R. B. Denhardt & Denhardt, 2000), it would have more effectively accomplished its intended goals.

The following table summarizes each legislative action chronologically to provide further evidence of how the DATA 2000 and subsequent revisions have diminished the PSVs of responsiveness, effectiveness, and impartiality by failing to keep pace with the needs of the public effectively and impartially.

Summary of Legislation Impacting MOUD			
Title of Legislation	Description/Impact of the Legislation	Year Enacted	Source
Controlled Substances Act (CSA)	Created the framework to classify drugs into different categories based on the substance's medical use, the potential for abuse, and safety or dependence liability.	1970	(Gilbert Jr, 2010) (Act, 1970)
Drug Addiction Treatment Act (DATA 2000)	Revised the scheduling parameters of the CSA to permit practitioners who meet specific qualifications to treat opioid addiction with MOUD. This expanded the types of practitioners that could dispense MOUD after obtaining a waiver issued by the Drug Enforcement Administration (DEA) and set limits to the number of patients each practitioner could treat.	2000	(Congress, 2000) (Record, 2000) (Woodruff et al., 2019)
Comprehensive Addiction Recovery Act (CARA)	Expanded the categories of practitioners who may dispense MOUD and increased the number of patients a practitioner can treat.	2016	(Whitehouse, 2016)
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act)	Revised the definition of a qualifying practitioner and the time a practitioner must practice before being able to dispense MOUD. It also allows a pharmacy to deliver prescribed controlled substances to a practitioner's registered location for the purpose of maintenance or detoxification treatment to be administered.	2018	(Congress, 2018)
"X Waiver" Elimination through Executive Order	In the final days of the Trump Administration, it was announced that the "X Waiver" established in the DATA 2000 would be eliminated through executive order. Unfortunately, the incoming Biden Administration determined these changes could not be implemented through executive order and instead required legislative revision.	BLOCKED in 2021	(Dan Diamond, 2021)

Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder	Revision eliminates a practitioner's required education before obtaining an "X Waiver ."Practitioners must only submit a notice of intent to the Substance Abuse and Mental Health Services Administration (SAMHSA) to receive a restricted "X Waiver."	2021	(Coderre, 2021) (D'Onofrio et al., 2021)
Mainstreaming Addiction Treatment Act (MAT)	Removed the requirement that a practitioner apply for a separate waiver through the DEA to dispense MOUD. Conduct a national campaign to educate practitioners and encourage them to integrate MOUD into their practices.	12/29/22	(Varisco, Wanat, Hill, & Thornton, 2023)

Democratic: Lack of Responsiveness – Evolution of the DATA 2000 compared to the Opioid Epidemic: The public sector must be action-oriented based on its essential duty to respond quickly and effectively to emerging needs. Programs such as the Buprenorphine Field Initiation of ReScue Treatment by Emergency Medical Services (Bup FIRST EMS) (Carroll et al., 2021) and the RWJBarnabas Health Peer Recovery Program (PRP) (Liebling, Perez, Litterer, & Greene, 2021) are examples of how the public sector quickly and effectively responded to the increase in overdose deaths in New Jersey. Unfortunately, prior to the signing of the MAT Act on December 29, 2022, policies specific to MOUD imposed by the DATA 2000 legislation were not as responsive. As defined by (Molina & McKeown, 2012), the PSV of responsiveness is "the effort to provide helpful, expeditious service to the public." While the DATA 2000 legislation intended to increase access to MOUD by eliminating barriers created by the CSA of 1970, it fell short of establishing policies that accomplished this goal. While the trending increase in overdose-related deaths was first identified in 2000 (Milam, Furr-Holden, Wang, & Simon, 2021), it was not until October 26, 2017, that the U.S. Surgeon General declared the opioid epidemic as a national public health emergency (Leshner & Dzau, 2019). This substantial delay in recognizing the severity of the opioid epidemic further demonstrates the lack of responsiveness by the federal government. In an article by (Woodruff et al., 2019), the authors explain,

> *"The last 20 years have seen millions suffer from untreated OUD and hundreds of thousands of preventable deaths. This regulation [DATA 2000] has not kept pace with the grim reality…DATA [2000] limited the expansion of treatment in communities across the country and placed regulatory burdens on the medical providers who would have otherwise been able to treat people with OUD" (Woodruff et al., 2019).*

Based on the evidence presented in this section, it is clear that the DATA 2000 and subsequent legislative revisions before the MAT Act failed to respond to the needs of individuals with SUD by not addressing regulatory barriers placed on MOUD.

PSV Professional: Limited Effectiveness – Lack of Diversion and Limited Access MOUD: The PSV of effectiveness is defined as "to act in a manner that best achieves the desired result" (Molina & McKeown, 2012). While the DATA 2000 legislation aimed to expand access to MOUD, it failed to achieve that goal effectively. Between 2000 and 2014, deaths from drug overdoses involving opioids increased by 200% (Rudd, Aleshire, Zibbell, & Gladden, 2016). Research supports that "despite the high prevalence of comorbid SUD, just 26% of persons with OUD received 'any' alcohol/drug use treatment, and 19% used opioid-specific treatment [MOUD]"(Wu, Zhu, & Swartz, 2016). In the study by (Woodruff et al., 2019), the authors state that an estimated 2.2 million people with OUD are left untreated. When DATA 2000 was passed, legislators were not facing the same crisis as today. While this can be understood, the necessary revisions to the DATA 2000 did not keep pace with the exponential growth and lethality of the overdose crisis (Woodruff et al., 2019). Research cited in this paper makes clear that the DATA 2000 legislation failed to effectively respond to the opioid epidemic, thereby diminishing the PSV of effectiveness (Bowen & Irish, 2019).

People: Impartiality – Stigma and health inequity fostered by DATA 2000: Substance use disorder (SUD) has been recognized by the American Medical Association (AMA) as a chronic disease since 1987 (White, Boyle, & Loveland, 2002). Unfortunately, SUD continues to be considered a "bad choice" or a "moral failing" by many (Greiner & Dixon, 2021). The stigma and false perception of shame associated with SUD have created tremendous barriers for people suffering from the disease of addiction (Faugier & Sargeant, 2016). By imposing strict regulations only on MOUD based on unsubstantiated fears of diversion, the DATA 2000 has helped to foster the stigma associated with SUD. The PSV of impartiality is "to act without prejudice or bias toward particular individuals or groups" (Molina & McKeown, 2012). The DATA 2000 created health inequity for individuals with SUD compared to other chronic diseases. By enacting legislation disproportionately affecting people with SUD, the DATA 2000 failed to demonstrate impartiality and served as a biased and prejudiced policy. As stated by (Woodruff et al., 2019)

> *"The historical view that treating people with substance use disorders is not part of standard medical care is perpetuated by the carving out of regulations and processes for medications to treat addiction. To adequately expand access to evidence-based treatment for OUD, it is paramount that addiction treatment be seen as part of medical care for all patients. Removing the X-waiver requirement and allowing buprenorphine to be treated like other Schedule III drugs is one way to address this."* (Woodruff et al., 2019)

Over the past 21 years, more than one million people have died from a drug-related overdose, resulting in a documented decline in U.S. life expectancy (Harper, Riddell, & King, 2021). When the DATA 2000 was in effect, MOUD could have saved many of the people who died if the public sector had been more equitable and responsive. By not eliminating the policies set forth by the DATA 2000 sooner, the public sector failed to provide equitable access to the care people with SUD deserve.

The DATA 2000 established policies that fostered a prejudiced and biased approach to care for people with SUD. (Witte et al., 2021) states "…that patients receiving agonist medication [MOUD] for an OUD may be the target of public stigma" (Witte et al., 2021). In order to ensure people with OUD have equitable access to equitable care, the DATA 2000 should have been eliminated sooner.

Conclusion: It is clear that the DATA 2000 legislation diminished key PSVs by failing to respond effectively and impartially. The Mainstreaming Addiction Treatment (MAT) Act of 2021 (Varisco et al., 2023) has finally removed the overregulating policies imposed by the DATA 2000. Repealing the DATA 2000 legislation through enacting the MAT Act has started the process of equitably reducing barriers to care and the stigma associated with SUD/OUD. Research suggests that "…multifaceted interventions are required to change macro-environmental attitudes and knowledge towards OUD and treatment (e.g., misperceptions, stigma) in order to develop a more supportive culture and infrastructure" (Wu et al., 2016). As (J. V. Denhardt & Denhardt, 2015) point out, public service must be action-oriented with strong consideration of all PSVs. Legislation must never limit a practitioner's ability to provide lifesaving treatment nor foster inequitable care for any disease or condition. While eliminating the X Waiver is transformative, much work remains in order to increase access to MOUD truly. This includes comprehensive provider education, evidence-based efforts to eliminate stigma,

increasing access to harm reduction, and addressing the many disparities associated with access to care. Public administrators must continue efforts to address the opioid epidemic in order to ensure that health justice is achieved.

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