NARRATIVE MEDICINE

The X-Waiver and the Culture of Addiction Medicine

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Earlier this year, the Substance Abuse and Mental Health Services Association (SAMHSA) released its findings from the 2021 National Survey on Drug Use and Health (NSDUH). The NSDUH provides an annual estimate of the burden of substance use disorders in the United States, and the 2021 report unsurprisingly described a tremendous unmet need for the treatment of opioid use disorder (OUD).

Of the 5.6 million individuals with OUD in 2021, only 887,000 — approximately 15% — received medication treatment.[1] Owing to this treatment gap, the Centers for Disease Control and Prevention (CDC) separately reported that more than 80,000 unintentional opioid overdose deaths occurred in 2021.[2] Recent legislation heralds optimism, but a culture change in our profession is also required to close this treatment gap.

The Mainstreaming Addiction Treatment (MAT) Act was passed by Congress and signed by President Joe Biden at the end of 2022. The law eliminated one regulatory barrier to prescribing buprenorphine, a mainstay treatment for OUD. Buprenorphine, often and accurately characterized as "lifesaving" because of its association with a substantial reduction in mortality when treating OUD,[3-5] is no longer restricted by the regulatory confines of the Drug Addiction Treatment Act of 2000 (DATA 2000). Though justly lauded as a mechanism to offer an effective treatment for OUD in primary care settings, DATA 2000 contained many pernicious elements that shaped the culture of addiction medicine these past two decades.

This erstwhile federal law placed a government-approved training and registration burden upon health care providers who wished to prescribe buprenorphine within their practice settings. DATA 2000 also set arbitrary caps on the number of patients a provider can treat and included the ominous specter of routine audits by the Drug Enforcement Agency (DEA).

The tracking mechanism utilized by the DEA was an additional notation on a registrant's license that always began with the letter X, commonly referred to as the "X-number" or "X-waiver." The "waiver" referred to an exemption from potential criminal prosecution as long as one adhered to the tenets of DATA 2000; prescribing buprenorphine to treat OUD was otherwise considered a violation of the Controlled Substance Act.

Placement of the X-number on each prescription for buprenorphine served as a powerful subconscious reminder to prescribers that they were towing a fraught line. In the face of constant oversight from law enforcement, addiction treatment providers tended to focus less on health promotion and became unwitting agents of social control.[6] The most persistent example of this phenomenon is our profession's preoccupation with urine drug testing to monitor biopsychosocial illnesses.

SAMHSA published a Treatment Improvement Protocol, *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*[7] (TIP-40), in 2004. Though buprenorphine only treats opioid use disorder, TIP-40 recommended frequent urine testing for a wide range of illicit non-opioid drugs when providing buprenorphine treatment. Absent from TIP-40 is how providers should use the results of such testing to guide buprenorphine treatment.

Within this information vacuum, I once presumed that I should threaten to withdraw buprenorphine treatment if a patient used a non-opioid illicit drug like cannabis or cocaine. This approach cultivated evasive behavior and an adversarial relationship but never helped a single patient.

Multiple publications[8-10] have since validated that frequent reflexive urine drug testing does not improve patient outcomes and rarely influences medication management decisions. Yet, the multi-panel urine drug test remains a sacred cow in our profession, and its utilization is also commonplace in law enforcement and community correctional control.

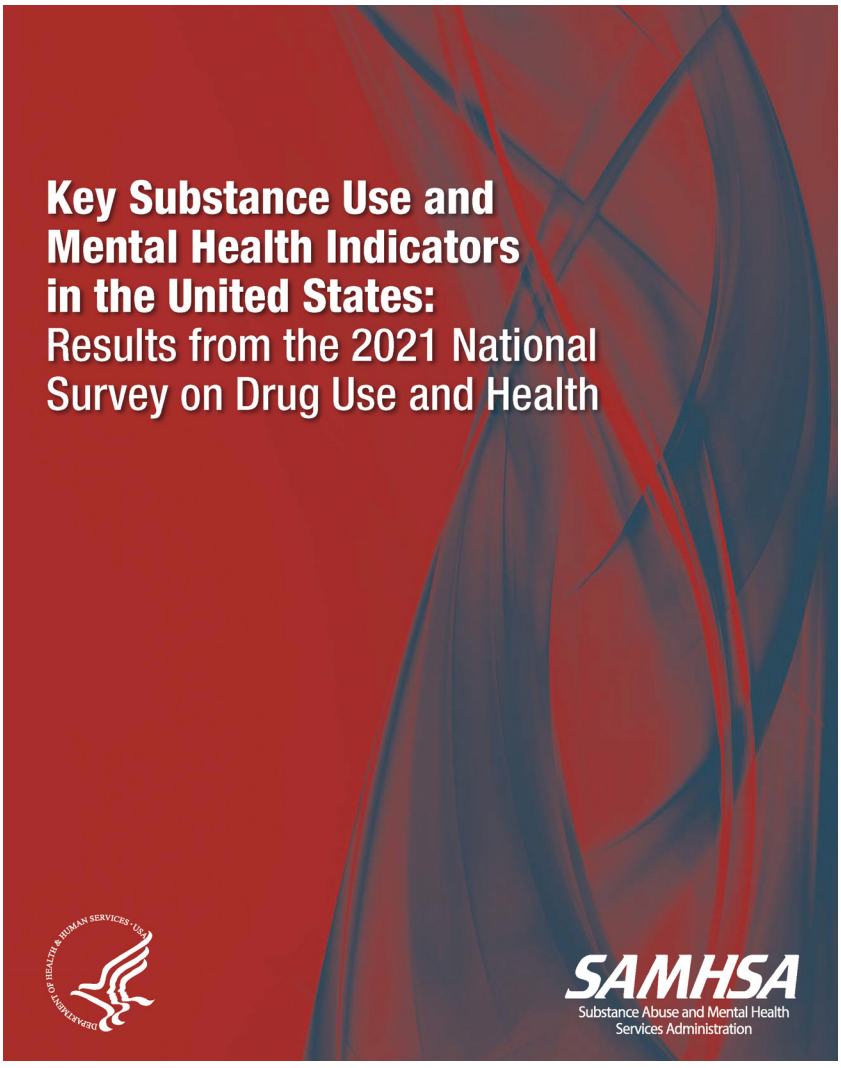
Parallels between addiction treatment and correctional control are well described,[11] and I have wit-

nessed them firsthand while working in correctional medicine, residential addiction treatment, and primary care throughout my career. I've observed urine drug test results used as a rationale for placing an individual in jail for violating terms of probation. Similarly, I've observed urine drug test results be the sole basis for dismissing patients from lifesaving buprenorphine treatment for violating the terms of a medication agreement.

Asking an individual to surrender all possessions and disrobe into a thin paper gown to "squat and cough" in front of a staff member is something I've known to occur both upon intake into jail and residential addiction treatment. Video cameras in bathrooms strategically placed to provide a viewpoint of genitalia during urination are indecent and violate obscenity laws in almost any context. Yet they were a part of some opioid treatment programs (OTPs) and are still commonplace, described to me as the "least intrusive way" to adhere to state regulations by good people who work in these institutions.

Health care settings that implement quasi-strip searches, use a body fluid analysis as the sole measure of success in treating a psychosocial disease, and utilize video cameras in bathrooms should raise alarms by anyone appraising the status quo in addiction treatment. I am further alarmed by the laissez-faire acceptance among many colleagues that these mechanisms have a place in treating addiction. A cynical approach to patient care is the legacy of the X-waiver and the OTP model for delivering methadone and buprenorphine treatment.

Theories abound as to why nearly half of all health care providers who attained an X-waiver to prescribe buprenorphine never issued a single prescription[12] and many others prescribed well below their capacity.[13] Perhaps a confused and cynical approach to patient care is chiefly responsible for our labor shortage in addiction medicine. The standardized buprenorphine waiver training I delivered many times over the years contained a slide that described random, observed urine collection as "ideal," although the same slide paradoxically also recommended urine collection be done in a way that is "convenient" for the patient.



Such mixed messaging is a by-product of the incompatibility between intrusive government regulation and patient-centered care. Undoubtedly, many attendees left this training confused and surmised that people requesting help for addiction could not be trusted. Overly complicated treatment algorithms and mistrust of patients may be reasons primary care providers do not provide buprenorphine treatment.[14]

Congress may have eliminated the X-waiver in 2022, but it is incumbent upon readers of this journal to eliminate the disrespectful approach to patient care that is its legacy. Take the opportunity afforded by the MAT Act to reappraise how

you deliver addiction treatment in your practice and whether your approach aligns with the values that inspired you to enter the health care profession.

Consider eliminating reflexive urine testing as the centerpiece of office-based buprenorphine treatment.[15] Recognize that observed urine collection is potentially traumatizing[15,16] and unlikely to improve outcomes or influence medication management decisions.[8-10] Align intake processes in residential treatment settings with what occurs in local hospitals, not in our jails.

Our profession will thrive when addiction treatment resembles the rest of mainstream medical care. Increased patient engagement and retention will follow.

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