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50 Years of Policy-Driving Legislation and the Growing Role of MAT in Combatting the Opioid Crisis

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Over the last 50 years, the use of medication-assisted treatment (MAT) for opioid use disorder (OUD) has evolved from a controversial therapy on the outskirts of accepted medical practice and drug abuse prevention strategy to what a report issued by the Surgeon General in 2018 called "the gold standard for treating opioid addiction" (in combination with psychosocial therapy and community-based recovery support).[1]

The last five decades have ushered in tremendous advances in policy promoting MAT: from recognition and standardization of the practice, to expansion of patient access (to drugs and treatment settings), to enhanced reimbursement designed to attract additional willing providers. Federal policy has consistently endorsed the efficacy of this treatment model through its efforts to promote access in the face of rising opioid-related drug overdose deaths.

However, despite federal policy promoting MAT, access to, and utilization of, MAT to date has not kept pace with the rapid worsening of the opioid crisis. Between 2009 and 2019, the number of substance use disorder treatment facilities offering MAT increased just 18 percent, according to annual data prepared by the Substance Abuse and Mental Health Services Administration (SAMHSA).[2] Meanwhile, drug overdose deaths involving opioids increased nearly 130 percent between 2009 and 2018, fueled by an increase in overdose deaths involving synthetic opioids (other than methadone) of 964 percent during the same time period, according to the Centers for Disease Control (CDC).[3]

While opioid-related drug overdose deaths declined by 2 percent from 2017 to 2018 (the first year-over-year decline in decades), according to the CDC,[4] 128 people still die every day from an opioid overdose.[5]

The Milestones

October 27, 2020, marked the 50th anniversary of Congress's first foray into legislation governing MAT, and the last half-century has been punctuated by five milestone acts that have profoundly impacted the standard of care for OUD, addiction treatment policy, and the lives of millions of Americans.

In the midst of an opioid epidemic that rages on, claiming nearly 50,000 American lives in 2018,[6] this article pauses to examine the five laws that have, in two generations, propelled MAT to prominence, if not preeminence, in the fight against opioid addiction:

- Comprehensive Drug Abuse Prevention and Control Act of 1970 (October 27, 1970)
- Narcotic Addict Treatment Act of 1974 (May 14, 1974)
- Drug Addiction Treatment Act of 2000 (October 17, 2000)
- Comprehensive Addiction and Recovery Act of 2016 (July 22, 2016)
- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (October 24, 2018)

MAT Prior to Congressional Action

Opioid addiction first emerged around the time of the Civil War, following widespread use of opioids to treat pain and stress.[7] As the number of addicted Americans rose, reaching approximately 300,000 by 1900, some providers in locations with high concentrations of opioid-addicted residents began prescribing or dispensing morphine, and even heroin and cocaine, in decreasing doses for the specific purpose of detoxification treatment or, in some cases, maintaining, but controlling, the opioid addiction. This practice was common until 1919, when the Supreme Court upheld the federal government's interpretation that the Harrison Narcotic Act of 1914, which allowed physicians and dentists to dispense or distribute opioids "to a patient . . . in the course of [the physician's] professional practice only," prohibited the prescribing or dispensing of opioids for the purpose of treating opioid addiction.

Between 1919 and the mid-1950's, MAT effectively disappeared from legitimate OUD treatment. After decades of increasing addiction rates and failing treatment efforts centered largely around institutionalization, the medical community including the American Medical Association and the New York Academy of Medicine, followed by policymakers, began to advocate for research of controlled dispensation of opioids for treatment of addiction. A promising study in New York City in the mid-1960's identified methadone, a narcotic that had been approved through Food and Drug Administration (FDA) new drug procedures for specific (non-MAT) indications, as the most promising medication for maintenance treatment of OUD.

Responding to Industry Pressure and Requesting Evaluation of MAT: Comprehensive Drug Abuse Prevention and Control Act of 1970 (October 27, 1970)

As interest in MAT swelled, Congress took the initial legislative step in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (CDAPCA) of directing the secretary of Health, Education, and Welfare (predecessor to HHS), "after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts," to "determine the appropriate methods of professional practice in the medical treatment of narcotic addiction." (Pub. L. 91-513, Title I, Section 4)

Notably, CDAPCA also included the brand new Controlled Substances Act, which required all manufacturers, distributors and practitioners wishing to prescribe, dispense or administer controlled substances, including methadone, for any purpose to register with the Bureau of Narcotics and Dangerous Drugs (BNDD, which was an agency within the Department of Justice and predecessor to the Drug Enforcement Administration (DEA)).

Rulemaking subsequent to the passage of CDAPCA by FDA (an agency within Health, Education and Welfare) and BNDD established the initial framework for regulation of methadone as an OUD maintenance treatment. Parallel final rules by FDA and BNDD in 1971 allowed the investigational use of methadone as a treatment for narcotic addiction, but required treating providers to receive approval from both FDA and BNDD. Additional rulemaking in 1972 moved methadone out of traditional investigational new drug status and established a unique system of oversight for programs offering MAT through maintenance dispensing of methadone.

Recognizing MAT as Maintenance Treatment and Requiring Registration: Narcotic Addict Treatment Act of 1974 (May 14, 1974)

Through the Narcotic Addict Treatment Act of 1974 (NATA), Congress recognized methadone as a maintenance treatment for OUD for the first time and established a requirement that practitioners wishing to dispense methadone for detoxification treatment or maintenance treatment obtain a special annual registration from DEA, in addition to the standard registration to prescribe, dispense or administer controlled substances. (Pub. L. 93-281)

NATA, which established these new MAT requirements in an amendment to the Controlled Substances Act, provided that in order to be eligible for this DEA registration, the practitioner had to first obtain approval from

FDA. This Congressional directive deepened the collaborative oversight of FDA and DEA established in CDAPCA and the subsequent regulations. Under this shared authoritative structure:

- FDA established standards of qualification for engaging in MAT and determined whether applicants for DEA registration were qualified.
- FDA (in consultation with DEA) established standards regarding quantities of narcotic drugs that could be provided to individuals for unsupervised use and determined whether applicants were likely to comply with those standards.
- DEA determined if the applicant was likely to comply with DEA standards regarding handling and recordkeeping of narcotics.
- DEA issued the registration annually.

For the next 25 years, FDA regulated providers engaging in MAT. In some instances, FDA collaborated with SAMHSA, a new agency created by the 1992 Alcohol, Drug Abuse and Mental Health Administration Reorganization Act "to support and administer programs relating to substance abuse and mental health prevention and treatment services." (Pub. L. 102-321, Title I)

In 1999, a cascade of studies by various government agencies regarding the regulation of MAT services culminated in an HHS notice of proposed rulemaking suggesting that the existing FDA regulations governing MAT be repealed and authority for the regulation of MAT be transferred from FDA to SAMHSA. Approximately 18 months later, HHS finalized its proposal and created 42 C.F.R. Part 8 establishing new standards for the certification of opioid treatment programs (OTPs) under SAMHSA's purview. These federal regulations remain the primary regulatory authority for OTPs today.

Allowing Office-Based Opioid Treatment: Drug Addiction Treatment Act of 2000 (October 17, 2000)

While HHS navigated stakeholder concerns and inter-agency politics to shift governance of OTPs from FDA to SAMHSA, Congress took another giant step in MAT policy by passing the Drug Addiction Treatment Act of 2000 (DATA) to amend the Controlled Substances Act and allow physicians to prescribe and dispense certain opioids for MAT without meeting HHS (initially FDA, now SAMHSA) requirements for, or registering with the DEA as, an OTP. (Pub. L. 106-310, Sec. 3502)

Under this new waiver, colloquially (and still) known as a DATA waiver, physicians approved by HHS (initially FDA, now SAMHSA) can dispense or prescribe FDA-approved Schedule III, IV, or V medications (currently, only buprenorphine and buprenorphine/naloxone) for opioid addiction detoxification or maintenance treatment to a certain number of patients (initially 30, expanded by a 2006 amendment to the Controlled Substances Act to be 30 in the first year and 100 thereafter (Pub. L. 109-469, Sec. 1102)).

In order to be eligible for a DATA waiver, DATA requires physicians to demonstrate expertise in addiction treatment through board certification, training by a qualifying organization, or satisfaction of other specialized criteria. If HHS (initially FDA, now SAMHSA) approves the physician's request to obtain a DATA waiver, the secretary notifies DEA of such approval, and DEA includes notation of the DATA waiver in the physician's existing controlled substances registration.

Note that beginning in 2003, regulations governing OTPs also allow dispensing (but not prescribing) of buprenorphine and buprenorphine/naloxone, in addition to methadone.

Expanding the Reach of the DATA Waiver: Comprehensive Addiction and Recovery Act of 2016 (July 22, 2016)

The primary impact of the Comprehensive Addiction and Recovery Act of 2016 (CARA) on MAT was expanding the provider population eligible to receive DATA waivers from only physicians to include also nurse practitioners and physician assistants (in accordance with state law regarding prescribing authorities for those practitioners). (Pub. L. 114-198, Sec. 303)

This expansion appears to have significantly impacted patient access to buprenorphine after nurse practitioners and physician assistants began receiving DATA waivers in February 2017, especially for Medicaid beneficiaries.[8] According to one study, the number of nurse practitioners prescribing buprenorphine increased by nearly 80 percent during a period beginning four months after nurse practitioners and physicians assistants began prescribing buprenorphine (approximately July 2017) and ending in June 2018. The number of physician assistants prescribing buprenorphine during this time period increased nearly 50 percent. Contrast those increases with a 4.5 percent increase in the number of physician buprenorphine prescribers during the same time period.

Additionally, between the third quarter of 2017 and the second quarter of 2018, the number of patients receiving buprenorphine prescriptions from a nurse practitioner rose 182 percent, and from a physician assistant 242 percent (compared with a 2 percent increase in the number of patients receiving buprenorphine prescriptions from physicians during this time period). The number of patients with at least one buprenorphine prescription fill paid for by Medicaid increased 12 percent between July 2017 and June 2018, more than twice the increase for patients with other payor types.

New Federal Reimbursement and Further DATA Wavier Expansion: Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (October 24, 2018)

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) primarily advanced MAT by increasing reimbursement opportunities for providers and further expanding the reach of the DATA waiver. (Pub. L. 115-171, Secs. 1106, 2005, and 3201)

The SUPPORT Act allowed OTPs to enroll as Medicare Part B providers for the first time, making bundled payments available for OUD treatment services beginning January 1, 2020. The "bundle" includes medications approved by FDA for MAT (which are methadone, buprenorphine and naltrexone), and their dispensing and administration, as applicable; substance use counseling; individual and group therapy; toxicology testing; and other appropriate items as determined by the secretary of HHS. This coverage expansion is significant, as Medicare historically had not covered methadone.

Additionally, the legislation required all state Medicaid programs to cover medications approved by FDA for MAT. Although most state Medicaid programs already covered buprenorphine and naltrexone, fewer covered methadone, meaning the legislation significantly expands access to MAT, especially methadone treatment at OTPs, for Medicaid beneficiaries. This Medicaid coverage requirement is currently only slated to last through September 30, 2025.

Finally, the SUPPORT Act increases the impact of the DATA waiver in two significant ways:

- The law makes clinical nurse specialists, certified registered nurse anesthetists, and clinical nurse midwives available eligible for DATA waivers. Currently, this eligibility is temporary, expiring October 1, 2023. However, the expanded eligibility for nurse practitioners and physician assistants granted in CARA was also initially temporary, and the SUPPORT Act eliminated the sunset date for those

practitioners' eligibility.

- The law also allows practitioners with additional credentialing or who practice in certain qualified settings to go straight to the 100-patient limit for their DATA waivers, without having to first spend a year limited to 30 patients. Regulations in 2016 had added a third-tier patient limit of 275, for which providers are eligible after spending one year at the 100-patient limit. The SUPPORT Act's acceleration of eligibility for the 100-patient limit means some providers will be able to treat caseloads of 275 patients after one year, instead of two years.

A Look at the Next 50 Years

Despite the significant policy strides discussed above, the Office of Inspector General (OIG) has indicated concern that patients suffering from OUD may experience difficulty accessing MAT, resulting in under-utilization of an intervention that offers what OIG characterized as "well-documented effectiveness." In the June 2020 update to its Work Plan, which identifies audits and evaluations that are underway and proposed by OIG's Audit Services and Office of Evaluation and Inspection, OIG added two separate items specifically related to potential under-utilization of MAT.

Based on the trajectory of policy over the last 50 years, the continuation of what the Office of the Surgeon General has called "a public health crisis that is ravaging our country,"[9] and federal officials' repeated, bipartisan insistence on the federal government's commitment to stemming the tide of the opioid epidemic, it appears likely that future policy will continue to promote access to MAT by decreasing financial, administrative and social barriers for both patients and providers.

While the last 50 years have seen milestone after milestone in MAT-promoting legislation, the next 50 years are likely to hold even more dramatic growth for this critical segment of the behavioral health community.

If you have specific questions about this article and how it affects your health care organization, please contact Michaela Poizner or a member of the Firm's Behavioral Health and Substance Use Disorders Group.

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[3] "Drug Overdose Deaths in the United States, 1999-2018," HHS, CDC, National Center for Health Statistics (NCHS), January 2020, *available at* https://www.cdc.gov/nchs/products/databriefs/db356.htm.

[4] "Understanding the Epidemic," CDC, Opioid Overdose, *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html#:~:text=Nearly%2070%25%20of%20the%2067%2C367,death%20rates%20decreased%20by%2013.5%25.

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[6] "Drug Overdose Deaths in the United States, 1999-2018," HHS, CDC, NCHS, January 2020, *available at* https://www.cdc.gov/nchs/products/databriefs/db356.htm.

[7] Historical Information in this Section From: "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs: A Treatment Improvement Protocol, TIP 43," Chapter 2, "History of Medication-Assisted Treatment for Opioid Addiction" HHS, SAMHSA, Center for Substance Abuse Treatment, 2005, *available at* https://www.ncbi.nlm.nih.gov/books/NBK64157/.

[8] Data in this Section From: Karin E. Johnson, Rekha Varghese, Bo Feng, Mike Liu, Ali Sanford, Paul Dowell, and John Wedeles, "The Effects of the Comprehensive Addiction and Recovery Act of 2016 on Nurse Practitioner and Physician Assistant Buprenorphine Prescribing in Medicaid," *Health Affairs Blog*, November 6, 2019, *available at* https://www.healthaffairs.org/do/10.1377/hblog20191105.242580/full/.

[9] "Surgeon General Priority: Opioids and Addiction," HHS, Office of the Surgeon General, Opioids and Addiction, *available at* https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/index.html.