TRANSFORMING THE ROLE OF OPIOID TREATMENT PROGRAMS

Opportunities, Considerations, and Choices in a Time of Crisis

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TAC TECHNICAL ASSISTANCE COLLABORATIVE

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Introduction: A Time of Crisis

The fight to combat the nationwide opioid overdose epidemic has been going on for nearly a decade at both the state and local levels. Millions of dollars in federal funding were channeled to such efforts through the U.S. Substance Abuse and Mental Health Services Agency's (SAMHSA) State Targeted Response grants, which evolved to become the State Opioid Response (SOR) grants. There appeared to be evidence of some success when overdose death rates decreased in 2018. However, that glimmer of hope was short-lived, as rates increased in 2019 and then skyrocketed during — and even after — the COVID pandemic.

In this context, it is imperative to use all effective strategies — and to eliminate gaps in access and services so that people suffering from substance use disorders (SUDs) have every possible opportunity to survive and thrive. Yet the evolving SUD care continuum is less effective than it could be, due to the fact that methadone, in spite of its well-established role as an effective addiction medication, remains in many ways separated from other resources. In this paper, we consider the complex historical reasons for this counterproductive division. We share the best thinking of experts on both the current and potential role of opioid treatment programs (OTPs) — the dispensers of methadone — as well as perspectives from other knowledgeable parties. We describe approaches taken by state agencies; point out opportunities for improvement available to treatment providers and to state and local governments; and highlight important decision points and policy considerations.

Because opioid treatment programs are the only agencies authorized to dispense methadone, the need is greater than ever for these providers to provide standardized, high-quality care that meets federal and state requirements.

The Changing Opioid Epidemic

According to the National Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics, nearly 91,799 Americans died of overdoses in 2020; the National Institute on Drug Abuse is reporting a drug overdose rate of 106,000 individuals in 2021. The national opioid overdose epidemic began in the mid-1990s with increasing rates of opioid prescribing, but has since evolved, with different drugs at different times identified as the primary substance involved in overdose deaths. Federal restrictions placed on opioid prescribing, the implementation of prescription drug monitoring programs, and increased education on the risks associated with opioid use for pain control all helped reduce deaths attributed to prescribed opioids. However, the reduction in the supply of prescription opioids led to an increase in deaths attributed to heroin.

Later, as deaths from heroin began to decline, the nation experienced another wave of the epidemic as deaths involving synthetic opioids like fentanyl and fentanyl analogs increased. By 2021, nearly 88% of opioid overdose deaths involved synthetic opioids.[1] Even more recently, a new trend is emerging: the use of illegally manufactured opioids in combination with psychostimulants such as cocaine and methamphetamine.

The Role of Methadone

There are three medications approved by the Food and Drug Administration (FDA) to treat opioid use disorder (OUD): methadone, buprenorphine, and naltrexone. Given the high potency of fentanyl relative to that of other opioids, demand is expected to increase for methadone — the most potent opioid replacement therapy. Because opioid treatment programs (OTPs) are the only agencies authorized by federal regulation to dispense methadone, the need is greater than ever for these providers to provide standardized, high-quality care that meets federal and state requirements.

Despite decades of evidence supporting the efficacy of methadone in the treatment of OUD,[2] several people interviewed for this paper shared their perception that states' efforts to increase access to medication for opioid use disorder (MOUD) are primarily focused on buprenorphine. In the early stages of the overdose epidemic fueled by prescription opioid use, this approach was necessary and appropriate to address the inaccessibility of buprenorphine. However, as deaths attributed to fentanyl continue to rise, it is imperative that these efforts expand to include access to methadone as an essential component of the treatment continuum. Years of rigid federal and state regulations, pervasive stigma related to the use of methadone to treat OUD, and isolation of OTPs from the rest of the treatment continuum have hindered access to this life-saving medication, while also limiting the capacity of OTPs to provide comprehensive care to the individuals they serve. Recognition by the federal government of the important role that methadone should play in addressing the opioid crisis has led to new consideration of regulatory barriers at the federal level. SAMHSA's proposed regulation changes related to OTPs seek to improve access to personcentered care and reduce long-established barriers. Other discussions occurring across the nation question the role that OTPs will play in the future of methadone treatment delivery, and whether the need for these structured programs may diminish. It is our opinion that OTPs are a necessary component of the SUD treatment system, and that they will remain so in the future. Further, we propose that OTPs can and should evolve to better meet the needs of the people who rely on them.

This paper draws on a review of relevant literature and recent developments, and on the results of interviews with national leaders, state policymakers, recovery community members, State Opioid Treatment Authorities, and OTPs recognized as innovators. First, we offer a brief history of methadone treatment and a description of recent developments. Next, we provide a summary of themes from interviews, followed by descriptions of innovative approaches taken by states and providers. Finally, we provide recommendations on re-envisioning an SUD treatment system that encompasses access to methadone treatment, along with a full array of recovery supports.

Acknowledgment

We extend our gratitude and respect to the many key informants who participated in our interviews. Their knowledge, candor, and dedication were not only indispensable in creating this paper, but are also inspiring to us as we join with so many others in the nationwide effort to end the opioid epidemic.

1. U.S. Centers for Disease Control & Prevention (last reviewed August 22, 2023). Drug overdose deaths remained high in 2021.
2. Fullerton, C.A., Meelee, K., Parks Thomas, C., Lyman, R., Montejano, L.,... & Delphin-Rittmon, M. (2014). Medication-assisted treatment with methadone: Assessing the evidence. *Psychiatric Services, 65* (2), 146–157.

Methadone Treatment in Context

A Brief History of Methadone Treatment[3]

From the mid-1930s until the mid-1960s, the entire federal drug treatment system consisted of two prison hospitals: Fort Worth and Lexington. At these facilities, the primary patients were federal prisoners transferred to the custody of the Public Health Service. Subject to available capacity of the hospitals, voluntary patients were also accepted for treatment. The programs and contributions of these two facilities are recognized as laying the groundwork for the treatment of addiction. In the 1950s, Synanon, a self-help therapeutic community, established the early pattern for programs that provided most community-based long-term residential treatment for individuals with SUDs — programs such as Daytop and Phoenix House. Throughout the 1950s and '60s there was also significant growth in the implementation of the "Minnesota Model," which took root in the establishment of the Hazeldon Foundation. Originally created for the treatment of alcoholism, the model expanded to address other drug addictions. This short-term residential model, with average stays of 28 days, promoted the understanding of alcoholism as a disease and developed a treatment approach that included blending professionals and trained nonprofessionals (usually individuals in recovery themselves), implementing the principles of Alcoholics Anonymous.

In the 1960s, Drs. Vincent Dole and Marie Nyswander, working in New York City, began to treat people with opioid addiction by experimenting with drug maintenance using methadone, which had already been shown to be safe and effective for detoxification. During this period, a Presidential Commission was established, chartered by President Kennedy, to examine issues and recommend new approaches to treatment. Legislation emerged from the Commission that 1) enabled a person to voluntarily seek federally funded treatment by self-commitment in a federal court, and 2) authorized federal government support for state and local programs through a grant-in-aid program. By the time of its implementation in the early 1970s, the treatment system consisted of federal facilities providing primary inpatient services and private contractors providing outpatient "aftercare" services in local communities.

"Opioid treatment programs were initially created as law enforcement programs for the war on drugs, and still operate against this legacy."
— Key Informant Interview

3. This overview is based on personal communication between Mady Chalk and Jerome Jaffe, M.D., who served as chief of President Nixon's drug programs in the Special Action Office of Drug Abuse Prevention.

The National Institutes of Mental Health was given responsibility for implementation of the legislation, and produced a standard contract governing all of its treatment agencies and specifying the frequency and purpose of patient contact — including counseling sessions, urine tests, psychological consultation, vocational training, and accepted treatment modalities (outpatient drug-free, therapeutic community, and methadone maintenance). The first methadone maintenance treatment programs were established In 1971; however, they were severely regulated. Patients received methadone under close supervision at federally approved (now accredited) clinics and were required to submit to regular urine tests.

On June 17, 1971, President Nixon established a Special Action Office for Drug Abuse Prevention as a component of the administration's War on Drugs; this office organized, directed, and evaluated the entire federal effort to provide drug treatment. Almost immediately, the Special Action Office initiated actions that changed the face of drug treatment in several ways: restricting the use of inpatient hospital treatment to detoxification and medical emergencies; using funds allocated to inpatient care for community outpatient treatment; severely restricting administrative costs paid by states as overhead; and producing treatment guidelines that standardized service expectations. A formula grant was established that gave states resources to develop outpatient programs at the local level, including both outpatient drug-free programs and methadone programs — and involved state governments in the management of the drug treatment system, which had previously been a federal system. The formula grants provided the foundation for federal block grants, which continue currently in the form of SAMHSA's Substance Abuse Prevention and Treatment Block Grant program.

The manufacture, labeling, and dispensing of methadone are subject to the general requirements of the FDA for establishing the standards of safety, effectiveness, and consistent quality that are applied to virtually all prescription drugs under the federal Food, Drug, and Cosmetic Act. Because methadone is a narcotic, it is also subject to the requirements applied to Schedule II controlled substances by the Drug Enforcement Administration (DEA) to prevent diversion and illicit use.

Additonal standards were established by the Department of Health and Human Services (HHS) in the oversight of how and under what circumstances methadone may be used to treat opioid addiction. Until 1993, the FDA implemented these regulations together with the National Institute on Drug Abuse (NIDA); since that time, SAMHSA has shared oversight responsibilities. These regulations served to create a closed system for the use of methadone to treat opioid addiction, and required OTP physicians to register with both the FDA and the DEA. OTPs were the only setting in which methadone could be used for this purpose.[4]

> *"Often, State Opioid Treatment Authorities want (need) more authority than they're given; are misunderstood and overlooked in state government; aren't housed with other SUD services (e.g., licensing); aren't housed with the Single State Agency; aren't consulted in policy and program development; work for state directors who don't understand their role; and experience notable turnover."*
>
> *— Key Informant Interview*

Methadone Today

Of the three FDA-approved medications to treat opioid use disorders, methadone is the least easily prescribed, despite the fact that according to the Office of the Assistant Secretary for Planning and Evaluation (ASPE), decades of research show that it effectively reduces opioid cravings, illicit opioid use, and risk of opioid overdose — and that it increases rates of treatment retention.[5] The triple layers of federal agency oversight identified in the historical

4. Institute of Medicine (1995). Federal regulation of methadone treatment. Washington, DC: The National Academies Press.
5. O'Brien, L., Schrader, K., Waddell, A., & Mulvaney-Day, N. (2020). Models for medication-assisted treatment for opioid use disorder, retention, and continuity of care. Cambridge, MA: IBM Watson Health.

section above continue today.[6] These restrictions specify who may provide methadone, who may receive methadone (e.g., a requirement that an individual be "addicted" for one year), how many doses can be provided to patients for unobserved use at home, and where a patient may receive methadone. As a result of this extensive regulation, entry barriers to the field and significant operating costs supress the supply of providers. These barriers were noted by some interviewees as prohibitive to expansion of methadone treatment beyond established OTPs to include more comprehensive treatment systems.

Oversight of each state's OTP system lies with the State Opioid Treatment Authority (SOTA), who exercises the responsibility and authority for governing the treatment of opioid addiction with a narcotic drug, (e.g., treatment with methadone in an opioid or narcotic treatment program), and oversees the regulations imposed by the federal and state governments on methadone treatment. The SOTA also serves as liaison between OTPs, the department overseeing other parts of the drug treatment system, the federal and state governments, and the organizations that provide services to individuals with OUDs.

In addition to the status of methadone as described above, the context in which the current treatment system for SUDs exists today has been deeply affected by a number of issues:

1. Opioid overdose death rates have skyrocketed, with the greatest increases seen among Black Americans and American Indians/Alaska Natives, while access to treatment has remained less than optimal.[7] Access to methadone, specifically, has continued to be restricted to OTPs, often requiring patients to travel long distances and wait in line. Access is further reduced by unaffordability (methadone is often not covered by insurance), stigma, lack of culturally responsive care, and discrimination. Public mistrust of methadone as a useful medical treatment has increased over the years, as much of the discussion of methadone treatment is focused on its use to reduce crime rather than on its therapeutic potential.[8]

2. Our nation's entire health care system, including its SUD treatment system, has been greatly affected by the COVID-19 public health emergency. All aspects of the system have seen its impact — states, counties, managed care plans, providers, and patients. Early in the pandemic, flexibilities were enacted related to telehealth, take-home medications, (particularly focused on methadone treatment programs), buprenorphine, information-sharing, and other areas.

3. Advances in technology and its use in health care settings during the restrictions of the COVID-19 pandemic — combined with concerns about maintaining access to SUD treatment services, including medications — have made telehealth an increasingly valued option to connect patients with treatment programs and clinicians. A number of e-health platforms, recovery support applications, and innovative devices are now being used in SUD treatment. Certain smartphone apps provide support tools for recovery, while other apps deliver contingency management services in SUD treatment to encourage patients to achieve their goals, including abstinence from drug and alcohol use. Still other apps offer 24/7 access to recovery coaches, support group communication, and provide SOS buttons. Finally, and perhaps especially important for OTPs and treatment with methadone, locked pill dispensers can now make medication doses available during a pre-programmed time period. Adding daily calls to assess stability and risk; using smartphones to observe individuals taking their medication; and saliva testing for opioids have been shown to be effective tools for individuals in rural, remote areas unable to attend treatment in OTPs.[9]

SAMHSA's experience with the flexibilities implemented during the height of the COVID-19 emergency, together with growing support for modernizing federal requirements, have led the agency to propose that the rules governing OTPs be updated — for the first time in 20 years — to support a patient-centered treatment approach. In its recently published Notice of Proposed Rulemaking, SAMHSA proposes to expand the definition of providers able to dispense and/or prescribe medications to include nurse practitioners and physician assistants; provide discretion to health care practitioner to complete a screening and full physical examination via telehealth for appropriate patients being admitted for treatment with either buprenorphine or methadone; add evidence-based delivery models to OTPs such as split dosing, telehealth, and harm reduction activities; update cri-

6. Personal communication between Mady Chalk and Jerome Jaffe, M.D., who served as chief of President Nixon's drug programs in the Special Action Office of Drug Abuse Prevention.
7. U.S. Centers for Disease Control & Prevention (2022, July 19). Overdose death rates increased significantly for Black, American Indian /Alaska Native people in 2020 [Press release].
8. Woo J, Bhalerao A, Bawor M, et al. (2017). "Don't judge a book by its cover: A qualitative study of methadone patients' experiences with stigma." *Substance abuse: research and treatment, 11,* https://doi.org/10.1177/1178221816685087
9. Steinkamp, J., Goldblatt, N., Borodovsk, J., LaVertu, A., Kronish, I., Marsch, L., & Schuman-Olivier, Z. (2019). Technological interventions for medication adherence in adult mental health and substance use disorders: A systematic review. *JMIR mental health, 6 (3)*, e12493.

teria for take-home doses of methadone; promote shared and evidence-based decision-making; allow early access to take-home doses of methadone for all patients to support their employment; and find ways to provide transportation for individuals who are unstable and need to receive face-to-face treatment in an OTP. SAMHSA also proposes to review the accreditation standards for OTPs and update admission criteria so that they no longer include a one-year requirement of an opioid addiction before an individual can be admitted. With regard to buprenorphine, Section 1262 of the Consolidated Appropriations Act, 2023 (also known as the Omnibus bill), removed the federal requirement for practitioners to obtain a waiver to prescribe this medication to treat OUD. These are important steps that will ultimately change the stucture, functioning, and financing of OTPs, and are part of the context that should be considered as states move forward.

Post-COVID Studies, Reports, and Events

In 2022, the National Academy of Sciences, with funding from the Office of National Drug Control Policy, conducted a two-day workshop on "Methadone Treatment for Opioid Use Disorder: Improving Access through Regulatory and Legal Change." The workshop was designed to examine the current federal regulations and legal landscape relevant to the provision of methadone for the treatment of OUDs, and to explore potential policy changes to address federal, state, and local barriers while also exploring opportunities for implementing office-based methadone treatment. Notably, the workshop began with the exploration of three individuals' personal journeys through methadone treatment, providing an early focus on person-centered issues with gaining access to and receiving methadone treatment. The two-day workshop can be summarized in the following six areas of agreement by all workshop participants:

- Flexibilities created under the COVID public health emergency, especially with regard to take-home methadone, should be made permanent.
- Current authorities of the federal government should be used to encourage states to assess coverage barriers to health insurance such as Medicaid and Medicare, including the revision of Medicare Advantage SUD risk adjustments.
- Existing rule-making authorities should be used to provide greater flexibility in prescribing, distributing, and dispensing methadone; counseling; urine drug screens; etc.
- Existing federal authorities should be used to incentivize state-level expansion of methadone access through mobile units and medication units; to eliminate state policies that are more restrictive than federal regulations; to tether incentives to block grants in order to integrate outpatient and methadone treatment for SUDs; and to aggressively innovate access to methadone treatment and other services for correctional facilities and skilled nursing facilities.
- Existing federal rule-making authorities should be used to allow more clinical discretion for:
    - Minimum/maximum daily doses;
    - The expansion of prescribers and settings, e.g., nurse practitioners and physician assistants, pharmacists, Federally Qualified Health Centers (FQHCs), mobile and non-mobile medication units, and harm reduction centers;
    - Take-home criteria, with a specific methodology for correctional facilities; and
    - Making permanent the SUPPORT Act requirement that Medicaid cover all three FDA-approved medications for OUD.

Finally, a George Washington Law School study, *Methadone's Regulatory Thicket* (L. Stanley and B. Dooling, 2022), and a subsequent report based on the study, *A Vast and Discretionary Regime: Federal Regulation of Methadone as a Treatment for Opioid Use Disorder*, examined the regulation of methadone and the impact of regulations on access to and use of methadone as a treatment for OUD. Together, the authors state, the regulatory requirements form "a thicket of particularized regulatory requirements that healthcare practitioners and patients must endure to provide or receive treatment."[10] They conclude that policies constraining access to methadone treatment should be examined to ensure that the restrictions adequately balance competing risks and are grounded in scientific evidence, given the continuing opioid crisis in the

10. Dooling, B., & Stanley, L. (2022). *A vast and discretionary regime: Federal regulation of methadone as a treatment for opioid use disorder*. Washington, D.C.: George Washington University Regulatory Studies Center.

United States. The study concludes that SAMHSA and the DEA have significant discretion to remove or significantly alter these regulatory barriers to methadone treatment. Ultimately, the study demonstrates that federal agencies have wide latitude to follow through on improving access to methadone treatment.[11]

11. Dooling, B., & Stanley, L. (forthcoming). Methadone's regulatory thicket. Annals of Health Law, 32 (1).

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Knowledge Holders Speak: Interview Findings and Themes

To inform this paper, we interviewed 28 individuals in 21 organizations with some relationship to the opioid treatment system. Interviewees included OTPs, SOTAs, researchers, SUD treatment providers, training and technical assistance providers, consumers, and policymakers at the federal, state, and county levels.

Provider and State-Level Interviews

Several interviewees recognized the importance of methadone treatment, acknowledging that the path to strengthening the SUD treatment system as a whole must include OTPs, who offer access to invaluable life-saving services. Some specifically noted the value of OTPs' access to prescribers when such access is limited in other areas of the SUD treatment system.

Challenges to Creating a Fully Unified System of OUD Care

In many states, methadone providers have been isolated from the rest of the continuum. OTP "silos" were often raised as a concern. Nationally, providers of methadone treatment are the most heavily regulated in the SUD system. The complexity of opening and maintaining OTPs compliant with the standards of multiple regulatory bodies limits the number of providers willing to offer this service, and places significant burdens on existing providers who might otherwise consider offering this critical service.

Stigma related to the use of methadone to treat OUD continues to be pervasive throughout the system. Interviews revealed continued stigma associated with the medication and its acceptance within the broader health care system, but also identified negative beliefs toward the OTP provider system itself. Historic inequity was another challenge noted by interviewees, as people of color (especially in urban centers) have responded to the racialized stigma associated with punitive and overregulated methadone delivery systems by avoiding this form of treatment.[12]

> *"Historically, there hasn't been good integration between opioid treatment providers and outpatient drug-free programs. This bifurcated system promotes stigma, which "flows" into people's recovery. Each type of provider offers options based on their beliefs and values, preventing consumers from making informed decisions about treatment and recovery. Treatment silos are hurting consumers."*
> — *Key Informant Interview*

12. Roberts, S. K. (2022). The politics of stigma and racialization in the early years of methadone maintenance regulation. *National Academies of Science, Engineering and Medicine Publication*.

As buprenorphine has rapidly become a more widespread option, disparities have been observed between predominantly white communities, where buprenorphine is prescribed more often, and BIPOC communities, where methadone clinics are clustered.[13]

Many key informants raised the need for the OTP system to evolve. Specifically, interviewees said that OTPs should coordinate care with other behavioral health care providers; offer counseling to patients that addresses more than just issues related to dosing; incorporate harm reduction strategies; and provide access to medication without layering on additional requirements and expectations. It is important to note that the provision of additional services by OTPs does not create a mandate for patients to receive them. SAMHSA's proposed revisions to OTP regulations, for example, require OTPs to adopt patient-centered practices and use shared decision-making approaches in order to identify services that a patient wants and needs. The regulatory structures that have dictated OTP service delivery for decades have stifled flexibilities in the system that could reduce barriers for vulnerable populations. One interviewee noted the challenge of access for homeless individuals in getting to a clinic every morning for limited dosing hours, when they may both lack transportation and have to carry all of their belongings with them.

Many of the OTP representatives we interviewed expressed a belief that methadone has been overlooked in response to the opioid crisis, with too much emphasis placed on increasing access to buprenorphine. In addition, OTP interviewees shared that in the efforts to expand buprenorphine, as a provider group they felt disadvantaged due to the requirement to apply federal methadone regulations to buprenorphine treatment. Federal guidance that relaxed such standards for buprenorphine treatment did not always translate to practice in OTP settings. Perhaps in result, a recently issued brief by the American Association for the Treatment of Opioid Dependence shows that nationally, OTPs only provide buprenorphine to roughly 7% of their patients.[14]

> *"Narcotics treatment providers offer invaluable, life-saving service."*
> *— Key Informant Interview*

Opportunities for Improvement

Many interviewees identified needs that may drive opportunity, such as the importance of increasing harm reduction efforts in OTPs (and specifically providing fentanyl test strips and naloxone kits). The need was frequently noted for increased access to culturally and linguistically appropriate OTP services and outreach to underserved communities. Another common call was for the diversification of services within the OTP setting to improve care coordination and connection to mental health, physical health, and recovery support services. New funding (opioid settlement funds and SOR) may allow for the creation of payment mechanisms to support value-based purchasing, which could incentivize outcome improvements and drive innovation.

National Key Informant Interviews

National key informants agreed that that utilization of methadone has not increased commensurate with the growth seen in buprenorphine prescribing. Limited access to methadone can be attributed to the use of "abstinence only" approaches by treatment programs; stigma related to the use of methadone; low reimbursement rates, which inhibit providers' interest in entering the market or expanding services; complicated and burdensome state and federal regulations; and inapplicability of the OTP business model and typical provider practices in rural areas. Some

13. Hansen, H. B., Siegel, C. E., Case, B. G., Bertollo, D. N., DiRocco, D., & Galanter, M. (2013). Variation in use of buprenorphine and methadone treatment by racial, ethnic, and income characteristics of residential social areas in New York City. *Journal of Behavioral Health Services & Research, 40* (3):367–77.
14. The National Association of State Alcohol and Drug Abuse Directors & the American Association for the Treatment of Opioid Dependence (AATOD) (2022). Technical brief: Census of opioid treatment programs. Washington, D.C.: National Association of State Alcohol and Drug Abuse Directors

of these same concerns drive the limited integration of OTPs within the SUD continuum and the behavioral health and health care environment overall.

Affecting both patients' interest in OTPs and OTPs' interest in more extensive services provision, stigma is front and center, in two forms: prejudice against receiving methadone treatment, and prejudice against receiving it within an OTP. Given the law enforcement aspect of many current federal regulations, OTPs may appear to have a profile more like that of a correctional facility than of a treatment facility. OTP policies and practices developed over the past 50 years have been, for the most part, neither very patient-centered nor intentionally sensitive to the patient experience of care. In particular, limited dosing hours, attendance requirements, lack of appointments or scheduled windows, long lines in parking lots, overreliance on urine drug screening, and counseling that is directed only toward medication adherence may discourage patients from choosing treatment at an OTP.

> *"Most states have focused on increased access to buprenorphine, at the expense of methadone."*
> *— Key Informant Interview*

National interviews yielded very few examples of states or OTPs with data-based quality improvement systems that provide analytics on access and quality or on the impact of OTPs on the overall population, or that incorporate information on the patients' experience of care. Informants identified the need for both methadone treatment and the OTP system to better meet patients' needs, while acknowledging that this would be difficult, given the regulatory framework that has governed their operations for 50 years as well as the effect of this framework on OTPs' treatment philosophies and clinical practices.

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Innovations by States and High-Performing Opioid Treatment Providers

Multiple factors are influencing the evolution of methadone treatment service delivery. The combined impact of COVID-19, new federal regulation flexibilities (now likely to become permanent), and the worsening overdose epidemic requires a new approach. A growing acceptance of harm reduction services for people who use drugs, and changing expectations on the part of treatment participants, further challenge existing structures. Finally, technological developments that expand care delivery strategies provide an opportunity to rethink traditional treatment models. The unique needs of individuals receiving methadone treatment for additional services to address co-occurring SUDs, mental illness, and physical health comorbidities require a comprehensive approach in a changing health care environment.

Change is necessary and inevitable. Some states and providers are leading the effort to increase access to high-quality treatment for OUD that includes methadone. It is important to note that this review of specific service-level innovations is limited to the providers interviewed for this report, and does not represent the totality of OTP innovations.

Eliminating Barriers to Access

A pillar of the HHS overdose prevention strategy is to ensure that whenever a person is ready, high-quality treatment is available to them without delay. Barriers to treatment admission — such as transportation challenges, organizational capacity limits, or ineffective admission procedures — result in lost opportunities and even in avoidable loss of life. The opioid overdose epidemic, combined with the COVID-19 pandemic, has served to hasten the development of low-barrier treatment options. These care delivery models seek to engage people who use drugs when they are ready by being flexible; available in convenient locations; centered on a harm reduction approach; and prepared to offer medications with minimal limitations.[15]

"Programs aren't effective when they are only in place for an hour on Monday morning — limited availability is harmful in terms of getting outcomes."
— Key Informant Interview

15. Aronowitz, S. V., Engel-Rebitzer, E., Dolan, A., Oyekanmi, K., Mandell, D., Miesel, Z.,... & Lowenstein, M. (2021). Telehealth for opioid use disorder treatment in low-barrier clinic settings: An exploration of clinician and staff perspectives. *Harm Reduction Journal 18*, 119.

Same-Day Admission and Extended Hours

Often, admission processes for methadone treatment are seen as provider-centric. Inflexibility in location, hours, and provider availability has presented barriers to meeting the needs of individuals with OUD, but has been a common feature of OTPs due to the countervailing need for operational efficiency. However, models have emerged over the last decade that suggest such limitations are not in fact necessary to support a cost-effective business model. Same-day admission that includes medication induction has become a common practice at OTPs in many states. This model generally involves select hours available daily to accommodate walk-ins. In 2017, Community Medical Services took same-day admission to a new level when it created the first OTP open 24/7 in Phoenix, Arizona; this opportunity was advanced by the SOTA, who believed that traditional dosing hours restricted access. By creating access outside of the traditional OTP early morning dosing hours, Community Medical Services facilitated a significant increase in new patients. It has since expanded 18- and 24-hour clinics to other states, and in Wisconsin admitted 500 new patients in the first six months after this change: more than half of all Wisconsin OTP admissions in 2019. Community Medical Services' 24/7 OTP has completed 20,000 unique intakes over five years. Another OTP, Behavioral Health Network (BHN) in Massachusetts, has expanded access in a "methadone desert" by offering same-day admissions in all sites, seven days a week. BHN had difficulty finding OTPs to which it could discharge clients after they were inducted on methadone in its detox and residential programs; to address this service gap, BHN opened accessible programs through partnerships with existing entities in the area.

> *"Community Medical Services took same-day admission to a new level when it became the first opioid treatment provider open 24/7 in Phoenix, AZ; by creating access outside of traditional early morning dosing hours, the agency saw a significant increase in new patients."*
> *— Key Informant Interview*

Interim Maintenance

Federal regulations allow for the use of interim maintenance when staffing or other capacity challenges limit availability within OTPs or when potential patients are not interested in more comprehensive services. SAMHSA requires OTPs to apply for permission to provide interim maintenance, and limits this service option to nonprofit organizations. Although proven to be safe and effective, this option of care continues to be underutilized.[16] As the harm reduction approach of meeting people where they are (literally and figuratively) is increasingly embraced, interim maintenance should be considered as a concrete option to provide people with life-saving medication without layering on additional requirements. A key principle of Missouri's Medication First approach, modeled on the Housing First concept, is that individualized psychosocial services are continually offered — but not required as a condition of pharmacotherapy. This cost-effective application of an interim treatment model has led to quicker access to methadone and demonstrated retention in treatment.

> *"In general, opioid treatment providers can't win...the ones that use a medication first approach are considered juice bars, but those that don't use a medication first approach are considered oppressive and restrictive."*
> *— Key Informant Interview*

Medication Units

A medication unit is a component of an OTP that is geographically separated from the OTP, but does not require an additional license. All required services can be provided by either the medication unit or the OTP, and many can now be delivered via telehealth. Medication units can be especially helpful for people living in rural areas with limited accessibility.[17] The State of Iowa partnered with its largest OTP and awarded State Opioid Response (SOR) funds to create four medication units: one at a hospital, another at a health center, and two at abstinence-based SUD outpatient programs,

16. McCarty, D., Chan, B., Bougatsos, C., Grusing, S., & Chou, R. (2021). Interim methadone – effective but underutilized: A scoping review. *Drug & Alcohol Dependence, 225*, 1 August 2021, 108766.
17. U.S. Substance Abuse and Mental Health Services Administration (n.d.). Certification of opioid treatment programs. Retrieved February 13, 2023.

with medical evaluations conducted through the medication units. According to our interviewee, the program has since expanded, Iowa has increased the number of patients receiving methadone by 40%, and new partners are interested in becoming host sites. The Iowa model has not only improved access, but has proven to be financially sustainable for both the medication units and their host sites, improving care coordination and decreasing stigma related to the use of methadone.

> *"Since the creation of opioid treatment provider medication units, Iowa has increased the number of patients receiving methadone by 40 percent."*
> *— Key Informant Interview*

Mobile Methadone Units

Using mobile units to provide methadone is one strategy to increase access to evidence-based treatment for underserved populations and improve treatment retention. These units may improve outreach to historically marginalized populations and provide incarcerated persons, people residing in rural communities, and those with transportation difficulties access to methadone treatment that would otherwise be out of reach. In 2021, the DEA released new rules that allow OTPs to operate mobile methadone vans without obtaining a separate DEA registration. Prior to the release of these rules, the DEA had not approved any new mobile methadone vans in over a decade. The John Brooks Recovery Center in New Jersey uses mobile units to provide medication-assisted treatment (MAT) to individuals in jails. Key informant interviewee Rose Evans, Senior Vice President of Behavioral Health Services at the Massachusetts-based Behavioral Health Network, sees mobile units as a better solution to reach individuals because transportation is a barrier in rural regions of the state; she also shared her opinion that mobile units are easier to manage than medication units. She reports that flexibilities from federal and state government have been critical in creating patient-centered programming to improve access and retention.

"No Wrong Door"

In order to improve access to MOUD, Massachusetts revised its regulations for all licensed SUD providers to mandate that they "ensure access directly or through a written agreement to medications for the treatment of addiction, including all FDA-approved medications for opioid use disorder." The revisions lower barriers for admission to all levels of care by "prohibiting providers from automatically denying treatment based upon the primary substance used by the patient, a mental health diagnosis, or any prescription medications required by the patient." Establishing agency priorities through policy, Massachusetts reduced discriminatory practice and stigma toward individuals receiving MOUD.

Patient-Centered Clinical Practices

Good clinical practice begins with the development of a clear philosophy of care, one that is patient-centered and measurement-based, with reliance on the therapeutic alliance at its core, and that builds recovery skills for individuals with OUD. The importance of patient-centered practices was highlighted in the National Academy of Sciences workshop described above. Staff members at high-performing OTPs focus on alliances between practitioners and patients that foster alignment on treatment expectations, clinical pathways, and duration of treatment. Most importantly, OTPs give hope to individuals with OUD that recovery is possible and that staff can help them build "recovery capital."

Years of prescriptive regulations with threats of legal consequences, financial penalties, and decertification yielded treatment programs with a deeply ingrained compliance focus. Rigid application of federal rules created a one-size-fits-all approach, which disregards the unique needs of individual service recipients. Movements to decriminalize SUDs and expand harm reduction have challenged the overregulated model of service delivery, which is framed as a barrier to care. While federal and state regulators may be open to regulation revision, it is important to be aware that a culture shift will still be necessary at the provider level. Direct engagement with OTPs to encourage change may be a wise investment on the part of states and counties.

Active Engagement and Retention Efforts

The historic model of waiting for patients to be "ready" and show up to OTPs seeking admission has had deadly consequences. Using SOR funding, many states have incorporated outreach strategies to meet individuals who are actively using in the community. Often these models of outreach employ peers to engage with individuals to provide overdose prevention education and harm reduction supplies, and to encourage connection to treatment. CODAC, a Rhode-Island-based SUD provider that offers methadone treatment, developed the first DEA-approved mobile unit after the rules were revised, partnering with harm reduction organizations to reach out to active opioid users in underserved areas. Potential patients may be engaged through medical screenings and if appropriate, offered one of three forms of MOUD along with harm reduction supplies.

We know that connecting individuals to treatment is not enough. Research shows that to receive the greatest benefit from MOUD, patients need to be retained in treatment.[18] Key informant interviewee Nick Stavros, CEO of Community Medical Services, reports that his organization measures quality through social determinants of health surveys (collected at every medical visit) and client retention rates. Community Medical Services conducted an internal review and found that 40 to 50 percent of its intakes are readmissions within a period from one to twelve months. The agency is focusing on this group, using texting and phone protocols for the first few days, which is a critical period. The agency's study results show that if a patient stays in treatment for the first three days, 85% will still be in treatment at thirty days. The agency's goal is 100% weekly engagement, either by text, by phone, or in-clinic. Community Medical Services has found that peer support and care management are very important to retention. To facilitate engagement between patients and their treatment teams, Community Medical Services recently created an app which is being rolled out across all of the agency's locations.

Engagement, connection, and support are the crucial initial activities in the effort to save lives. Early interactions through treatment initiation pave the way to successful partnerships. Greater attention to the patient's experience of care has been demonstrated to positively influence engagement and reduce no-show rates.[19] Initial conversations and the assessment process must be long enough to get treatment started, but not so long as to reduce retention.

Adopting patient-centered practices means that OTPs start with patient engagement followed by a thorough assessment and careful deliberation regarding an appropriate treatment pathway. Treatment focuses on the goals of improving function and quality of life, and optimizing patient independence, while reducing the risk of serious adverse incidents. In individualizing care, OTP practitioners ask patients about their expectations, what changes they'd like to make, and what they hope to accomplish. In this conversation with each patient, the practitioner also explains "what treatment will look like" in terms of clinical interventions, evidence-based practices (EBPs), and a patient-centered description of each EBP. The treatment plan is developed in collaboration with the patient, with consensus on the patient's priorities. Community Medical Services describes a practice of trauma-informed listening to patients (all employees go through Crisis Prevention Institute de-escalation training as part of onboarding). Instead of being limited by a preselected list of billable services, it has built a business model of identifying what is best for the client, and then seeing if that can be billed for.

Early counseling sessions are used to create a shared vision of the frequency, duration, and content of treatment. What can each patient expect during the first six months to a year? How long will they be in treatment? What's the roadmap and where are the road signs? Even though the answer to those questions varies among patients, staff at high-performing OTPs can describe the general trajectory of care and help the patient understand that progress and recovery status will be evaluated with them along the way. These checkpoints for a formal, joint evaluation of treatment are established in the very early days of treatment so that the patient has a clear picture of the clinical pathway. This should help them understand the process and potentially provide hope that this phase of treatment has a beginning, middle, and end. All of these practices serve to increase a patient's "health literacy" which has been shown to improve the quality of care.[20]

High-performing OTPs engage patients through a variety of methods, with telehealth and telephone counseling oc-

18. Timko C., Schultz, N. R., Cucciare, M. A., Vittorio, L., & Garrison-Diehn, C. (2016). Retention in medication-assisted treatment for opiate dependence: A systematic review. *Journal of Addictive Diseases*, *35* (1): 22–35.
19. See The CAHPS Ambulatory Care Improvement Guide: Section 2: Why Improve Patient Experience?, *Agency for Healthcare Research and Quality,* May 2017 for citations on good patient experience and improved clinical processes and outcomes.
20. The Wellness Network (2021, October 14). The value of health literacy for healthcare organizations. *Health News and Insights*, blog of The Wellness Network.

curring as often as clinic-based treatment, or even more frequently. These patient-centered, accessible practices minimize the burden of treatment and increase retention. Counseling sessions include an assessment of risk and protective factors that enables practitioner and patient to use a "treat to target" approach and choose adjustments to treatment that will improve the patient's recovery status. If risk factors are not decreasing and protective factors are not increasing, the clinical regimen is evaluated in order to make significant changes in the treatment plan.

Patient-Centered Medication Choice

There are three FDA-approved medications to treat OUD — however, many OTPs provide only one: methadone. A patient-centered approach engages the patient in decision-making on medication use. High-performing OTPs offer access to all forms of medication and provide education to patients on the risks and benefits of each. Each of the providers we interviewed reported that they offer all forms of MOUD. Many states have facilitated the incorporation of buprenorphine and injectable naltrexone into the medication choices offered by OTPs by eliminating regulatory disincentives and providing funding mechanisms for the cost of the medication.

In-Clinic Dosing and Take-Home Dosing

Until the recent introduction of flexibilities related to COVID-19, patients newly admitted to methadone treatment were required to attend the program in person daily in order to receive medication. Rigid regulations coupled with limited dosing hours at most clinics present a challenge to individuals in various stages of recovery to balance treatment compliance with everyday life. Daily dosing requirements serve as a deterrent to methadone treatment for many with OUD. For those who do access treatment, missed dosing days often lead to discharge and return to illicit opioid use. Los Angeles County specifically noted that people experiencing homelessness are one of the populations most underserved by OTPs. The process of getting to a clinic for daily dosing within specific hours can be challenging for most, but especially for individuals having to manage all their belongings while negotiating limited transportation options.

On December 13, 2022, SAMHSA proposed an update to federal rules that would make COVID-related medication flexibilities permanent.[21] Studies documented that increased take-homes produced positive treatment results and did not cause safety or public health harms.[22] While data is not available from a large number of states, the Massachusetts SOTA reported an increase in patients eligible for 28 days of take-home doses from 16 percent to between 60 and 70 percent with the COVID waivers; during the period covered by the waivers, Massachusetts experienced only 19 instances of medication diversion and no overdoses among 23,000 OTP patients. Despite the fact that these flexibilities never ceased, over time many OTPs returned to using more stringent criteria for take-home provision. Historically, many states chose to layer on additional requirements for take-homes and have not embraced all of the COVID flexibilities afforded by SAMHSA.[23] In recognition of the need to reduce treatment barriers, Massachusetts recently revised its regulations to align with federal standards.

High-performing OTPs consider take-home dosing to be the expectation, not the exception. As with other chronic conditions, facilitating the patient's self-management (including medications) is a key treatment component. Treatment mitigates the risk of relapse and overdose through specific interventions employed by staff. Every patient's treatment plan specifically addresses take-home dosing and records how clinical services increase the patient's ability to manage it. The patient-practitioner partnership acknowledges the motivational benefit of take-home dosing and its relationship to reducing treatment burden and building recovery capital. Key informant interviewee Rose Evans of the Behavioral Health Network believes that the flexibilities offered by SAMHSA and the Centers for Medicare and Medicaid Services (CMS) in response to COVID have fostered innovation. BHN incorporated a shared decision-making approach for the provision of take-homes that was tailored to the needs of the patient. Strategies to reduce risk of harm or diversion include increased risk education; the provision of Narcan to all patients; and outreach calls to remind patients to bring back bottles for bottle counts. BHN saw no increase in overdose deaths or diversion of medication.

21. U.S. Substance Abuse and Mental Health Services Administration (2022, December 13). SAMHSA proposes update to federal rules to expand access to opioid use disorder treatment and help close gap in care [Press release].
22. Hoffman, K. A., Foot, C., Levander, X. A., Terashima, J. P., McIlveen, J. W., ... & McCarty, D. (2022). Treatment retention, return to use, and recovery support following COVID-19 relaxation of methadone take-home dosing in two rural opioid treatment programs: A mixed methods analysis. *Journal of Substance Abuse Treatment* 2022;141:108801.
23. Caudell-Feagan, M., Huh, K., & Dube, S. (2022). Overview of opioid treatment program regulations by state: Restrictive rules put evidence-based medication treatment out of reach for many. Philadelphia, PA: The Pew Charitable Trusts.

Updating the Role of Testing/Analysis for Drug Use

SAMHSA rules require OTPs to "provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice." Most OTPs incorporate urine drug screens or oral swabs as the accepted methods of testing for illicit drug use. How the results of these tests are used to guide the treatment process is critically important.

It is common for individuals to use substances while in treatment. There is limited evidence that the use of drug testing in addiction treatment improves outcomes.[24] What drug testing can do is to provide information to the treatment program on patient progress toward established goals and guide treatment interventions. Unfortunately, in many cases, positive drug screens result in patients being discharged from treatment. Given what is known about the course of recovery, a positive drug screen result alone cannot justify adverse consequences, including administrative discharges.[25] It is an unfathomable thought in other chronic conditions to discontinue life-saving medication because a patient is demonstrating active symptoms of their disease.

High-performing OTPs consider positive drug screens and lack of connection to treatment as indications that the treatment plan may need to be modified, and that more rigorous attempts to engage may be indicated. In concert with the patient, providers may choose incorporating alternative EBPs, different modalities of treatment delivery (e.g., telehealth instead of face-to-face), changing staff, or changing services (e.g., peer support or case management versus traditional counseling).

Striving to Eliminate Administrative Discharges

Aside from positive toxicology screens, patients may face discharge from OTPs for other program rule infractions (e.g., loitering on premises, aggressive behavior, suspicion of medication diversion) which could contribute to high dropout rates. High-performing OTPs adopt the goal, to the greatest extent possible, of "no agency-initiated discharges," as described by Nick Stavros of Community Medical Services. To support the development of metrics to inform quality of care, states and counties may choose to apply baseline standards for administrative discharges across all OTP providers.

Measurement-Based Care

Measurement-based care (MBC) involves the use of repeated, validated measures to track symptoms and functional outcomes in clinical settings. MBC is commonly used in health care settings to monitor conditions such as high blood pressure and diabetes. Results of tests or screenings guide health care decisions and treatment planning. MBC has been shown to be improve outcomes in mental health and substance use treatment settings,[26] but most OTPs do not include regular use of validated and quantifiable symptom rating scales to guide treatment. Rhode Island used funding from the SAMHSA Promoting Integration of Primary and Behavioral Health Care and Medicaid Substance Use Disorder Provider Capacity-Building Initiative (PCBI) grants to implement MBC software at behavioral health sites across the state, including two OTPs (CODAC and Victa). In key informant interviews, Lisa Peterson of Victa reported that using MBC in the OTP setting is an important tool to improve patient outcomes. She noted that implementation challenges were related to competing initiatives and stated that successful integration of MBC in an OTP setting requires significant resources and attention to facilitate staff and patient buy-in. Another concern Peterson noted is the ability for MBC to be sustained once grant funding is discontinued. There is no current mechanism for reimbursement of MBC in Rhode Island. A report on MBC developed by the Meadows Mental Health Policy Institute noted that development of reimbursement mechanisms to facilitate the use of MBC is a critical component of successful expansion. The report notes that there are a limited number of specific billing codes for behavioral MBC tools, and therefore, a need for additional reimbursement mechanisms.[27]

In consideration of incorporating MBC into a value-based purchasing arrangement, it is important to note lessons learned from other OTP experiences. Specifically, in the midst of the opioid crisis, many OTPs face multiple competing initiatives to increase access and improve quality. "Innovation fatigue" can lead to staff burnout and ultimate failure of the proposed innovation. As noted by Peterson, significant time and resources should be devoted to staff

24. Olivares, E., & Olsen, Y. (n.d.) Drug testing management, [PowerPoint presentation slide deck].
25. Massachusetts Department of Public Health, Bureau of Substance Addiction Services (2013). Practice guidance: Drug screening as a treatment tool.
26. Goodman, J. D., McKay, J. R., & DePhillipps, D. (2013). Progress monitoring in mental health and addiction treatment: A means of improving care. *Professional Psychology: Research and Practice, 44* (4), 231–246.
27. Alter, C. L., Mathias, A., Zahniser, J., Shah, S., Schoenbaum, M., Harbin, H.T.,... & Sieger-Walls, J. (2021). Measurement-based care in the treatment of mental health and substance use disorders. Dallas, TX: Meadows Mental Health Policy Institute.

training and support to use MBC, and attention to ease of administration as it relates to patient flow is important in an OTP setting. Startup costs related to implementing MBC, including software, staff training, devices for patient use, and administration time, should be prioritized in funding considerations as well as payment mechanisms for sustainability.

Community-Centered Practices

In addition to tailoring treatment approaches to the needs of individuals, high-performing OTPs understand the unique needs of the communities in which they operate, and therefore also choose to tailor services to the needs of the community. All of the treatment programs interviewed in the development of this paper described some form of community-based program development. BHN considered the limited transportation options in rural settings, developing service delivery models in northwestern Massachusetts that included partnerships with other providers and the use of mobile methadone units. Community Medical Services developed a menu of clinic services based on a needs assessment of the community in which it operates. Based on these results, its program in Phoenix, Arizona includes an employment support specialist as well as incorporating transportation and housing supports to improve retention.

Innovative Practices and Technologies

Innovations in technology for use in health care settings were hastened by the advent of the COVID-19 pandemic. Public funding for a variety of applications and prescription digital therapeutics (PDTs) has increased dramatically, with Single State Agencies providing funding to make them available to OTPs; state departments of corrections purchasing them for prison inmates; MassHealth adding PDTs to its Non-Drug Product List; Oklahoma issuing a State Plan Amendment in order to create a value-based arrangement with a PDT provider; and CMS issuing a new Healthcare Common Procedure Coding System code for "Prescription Digital Behavioral Therapy."

Bringing Telehealth to OUD Care

In the health and behavioral health landscape, telehealth is increasingly valued for its ability to expand accessibility and reduce barriers to care. Telehealth has been proven effective for treating a variety of medical and behavioral conditions and can be a lifesaver for those with chronic conditions and disorders that are exacerbated by social isolation.[28, 29] Certainly, since the COVID-19 pandemic began, the field has seen the power of telehealth in connecting individuals with OUDs to critical treatment and recovery support. The need to limit face-to-face contact and minimize congregation in public settings challenged OTPs to rethink service delivery models and embrace advances in technology to meet the needs of their patients. Behavioral health treatment providers pivoted from providing only in-clinic treatment to offering group meetings with dial-in codes; daily calls for individual check-ins; video calls with doctors to discuss medication; and 24-hour lines with live response. CODAC received foundation funding to provide patients with smartphones to facilitate participation in telehealth services, and provided staff with training on the use of telehealth platforms. In conjunction with the waivers for take-home dosing offered by SAMHSA, telehealth allows OTP patients the ability to integrate treatment and support into their daily lives in a much more accessible manner. Yet despite evidence that telehealth improved retention and was more convenient for patients,[30] many providers returned to requiring in-person meetings once restrictions on public gatherings were lifted. High-performing OTPs continue to offer telehealth as an option.

Remote Patient Support

Methadone is most effective when taken daily, as directed. Concerns related to appropriate dosing behavior and medication diversion have driven in-person, observed methadone dosing requirements. However, as noted above, daily clinic attendance presents a significant barrier to tre-

28. Lin, L., Casteel, D., Shigekawa, E., Soulsby Weyrich, M., Roby, D. H., & McMenamin, S. (2019). Telemedicine-delivered treatment interventions for substance use disorders: A systematic review. *Journal of Substance Abuse Treatment*, *101*: 38–49.
29. Aronowitz, S. V., Engel-Rebitzer, E., Dolan, A., Oyekanmi, K., Mandell, D., Miesel, Z.,... & Lowenstein, M. (2021). Telehealth for opioid use disorder treatment in low-barrier clinic settings: An exploration of clinician and staff perspectives. *Harm Reduction Journal 18*, 119.
30. Jones, C. M., Shoff, C., Hodges, K., Blanco, C., Losby, J. L., Ling, S. M., & Compton, W. M. (2022). Receipt of telehealth services, receipt and retention of medications for opioid use disorder, and medically treated overdose among Medicare beneficiaries before and during the COVID-19 pandemic. *JAMA Psychiatry, 79* (10):981–992.

atment access for many individuals living with OUD. Missed doses resulting from unreliable transportation or other challenges create dosing instability, may lead to continued use or relapse, and can result in premature discharge. New technologies support safe, effective administration of methadone outside of the clinic setting and reduce the risk of diversion. During the first years of COVID, the use of smartphones to support remote observation of methadone ingestion was demonstrated to be an effective means to ensure patient safety.[31] Locked dispensers that make medication available only during pre-programmed time periods have been successfully incorporated in OTP settings. In one Vermont program, secure dosing with the addition of daily calls to assess drug use, cravings, and withdrawal potential, has demonstrated effectiveness in reducing the risk of nonadherence, even during interim treatment for patients on a waiting list for continued treatment.

Evidence-Based and Promising Practices

High-performing OTPs use EBPs that have shown success with OUD treatment: motivational interviewing, cognitive behavioral therapy, contingency management, and a community reinforcement approach. Commitment to the implementation of EBPs with fidelity requires a significant investment of time and resources on the part of states and providers. CODAC in Rhode Island made a commitment to the use of motivational interviewing in all of its OTPs, training all staff, supervising for fidelity, and expanding training efforts to other providers in the state. The development of digital therapeutics provides access to EBPs using technology as an adjunct to treatment. Contingency management has demonstrated effectiveness in addressing methamphetamine use in methadone-maintained patients.[32] Recent developments make the implementation of contingency management possible using digital technology. In addition, the recent approval of the California 1115 waiver including contingency management as a Medicaid benefit provides a path for states and providers to implement this EBP effectively without the concern of possibly violating federal anti-kickback statutes. Finally, in discussing best practices used by Community Medical Services, CEO Nick Stavros emphasized the importance of creating a culture of change in the agency's OTPs through patient engagement. Community Medical Services emphasized listening to patients and employees through weekly town hall meetings, providing them the opportunity to ask questions and provide feedback anonymously.

Using Data to Inform Practice

While TAC did not conduct an extensive review of OTPs' data-driven practices, a few encouraging examples were identified through interviews. Community Medical Services has developed a performance dashboard that allows staff and patients to gauge some qualitative features of the agency's services; for example, one of the measures sets a standard for how long patients have to wait to receive their in-clinic services. Community Medical Services also measures quality through its retention rates, and conducted a study of its readmission rates in relationship to retention. As noted above, an internal review showed that 40 to 50 percent of the agency's intakes were readmissions within a period of one to twelve months. This review further demonstated that 85% of patients who stayed in treatment for three days were still in treatment after thirty days. Based on these findings, Community Medical Services developed a clinical protocol that aims for 100% first-week engagement, either by text, phone or in-clinic visits; peer support and care management are emphasized for this group of patients.

> *"There is a long way to go to improve the quality of data collected and reported."*
> *— Key Informant Interview*

The state of Rhode Island makes information available to the public on the Prevent Overdose RI website. The information guides harm reduction efforts such as naloxone distribution and peer outreach. Rhode Island also used the state's data warehouse (the "ecosystem") to identify the individuals at greatest risk for overdose, and potential intervention opportunites based on their touch points within other systems.

31. Jones, C. M., Shoff, C., Hodges, K., Blanco, C., Losby, J. L., Ling, S. M., & Compton, W. M. (2022). Receipt of telehealth services, receipt and retention of medications for opioid use disorder, and medically treated overdose among Medicare beneficiaries before and during the COVID-19 pandemic. *JAMA Psychiatry, 79* (10):981–992.
32. Peirce, J. M., Petry, N. M., Stitzer, M. L., Blaine, J. D., Kellogg, S., Satterfield, F.,... & Kolodner, K. B. (2006). Effects of lower-cost incentives on stimulant abstinence in methadone maintenance treatment: A National Drug Abuse Treatment Clinical Trials Network study. *Archives of General Psychiatry, 63* (2): 201–208.

Risk and Recovery

Employing a cascade of care model,[33] we see that most OTPs have historically operated at the initiation and retention levels. Isolated from the full continuum of care, OTPs have not been engaged in community efforts focusing on prevention, or in active outreach to identify individuals in need of care. Rather, their focus has been to initiate medication, stabilize, and maintain. OTPs have also not fully engaged in systems that support active recovery through structural interventions (e.g., housing, employment programs) or partnered with recovery community centers and community-based peer support services. Expectations of the system are now changing to broaden the OTP continuum of care to include components of harm reduction and recovery support services.

Harm Reduction

The HHS overdose strategy states, "Individuals inherently deserve services that promote health, regardless of whether they use drugs. Evidence-based harm reduction strategies minimize negative consequences of drug use." As a component of the care continuum, separate and apart from treatment and recovery, harm reduction strategies are created for people who use drugs to improve health and well-being, even during active drug use.[34] These strategies include syringe service programs, naloxone and fentanyl test strip distribution, overdose prevention education, and safe consumption sites. Decades of research have documented that some harm reduction strategies provide significant individual and public health benefits including preventing deaths from overdose and preventing transmission of infectious diseases among people who use drugs and the larger community.[35]

Harm reduction in OTPs also means providing low-threshold options for accessing methadone. As mentioned in previous sections, OTPs practice harm reduction when they offer medication to individuals who are reluctant or unwilling to engage in additional services. They also practice harm reduction when they maintain individuals on methadone who continue to use illicit substances.

High-performing OTPs recognize that their patients are at high risk for overdose. Adopting a harm reduction approach that incorporates a nonjudgmental approach to patients' continued use of illicit substances, OTPs can choose to promote health and safety through overdose prevention education and distribution of supplies such as naloxone and fentanyl test strips. OTP providers interviewed for the purposes of this paper embrace the concept of harm reduction and routinely provide naloxone to their patients as part of an overdose prevention strategy. Several states have provided funding for naloxone distribution through OTPs, which is considered a best practice. In addition to state funding sources, OTPs in Rhode Island partnered with pharmacy delivery programs to access naloxone for their patients through their health insurance.

Recovery Support

In the not very distant past, combining the terms "methadone maintenance" and "recovery" was rare. It was common to hear individuals profess that people on methadone weren't really "in recovery." In the midst of today's opioid overdose epidemic, attitudes have shifted. Most people now embrace the fact that there are many paths to recovery and that some will involve medication. The combination of methadone treatment with recovery support services (RSS) is not necessarily new if RSS is defined as including transportation, employment, and housing supports. What is new is the engagement of peers with lived experience of SUDs to provide RSS for individuals receiving methadone.

The Office of National Drug Control Policy's (ONDCP) National Drug Control Strategy states that "RSS can be instrumental in engaging individuals with SUD and helping them navigate the early stages of recovery." ONDCP defines peer recovery support services (PRSS) as nonclinical and distinct from treatment. These services are provided to individuals with or in recovery from an SUD, commonly by individuals in recovery themselves. PRSS are anchored in peer specialists' experience, supplemented by training. Peer specialists work in diverse settings (including treatment settings) to engage, link, and otherwise serve both those in recovery and those with active SUDs.

High-performing OTPs understand the value of peers and PRSS in treatment delivery settings as well as in outreach efforts to individuals in need who are not engaged in treatment. Engaging peers as part of treatment and outreach

33. Yedinak, J. L., Goedel, W. C., Paull, K., Lebeau, R., Kriege, M. S., Thompson, C.,... & Marshall, B. (2019). Defining a recovery-oriented cascade of care for opioid use disorder: A community-driven, statewide cross- sectional assessment. *PLoS Medicine,* 16 (11): e1002963.

34. Marlatt, G. A. (1996). Harm reduction: Come as you are. *Addictive Behaviors, 21* (6): 779-788.

35. Puzhko, S., Eisenberg, M. J., Filion, K. B., Windle, S. B., Hébert-Losier, A., Gore, G.,... & Kudrina, I. (2022). Effectiveness of interventions for prevention of common infections among opioid users: A systematic review of systematic reviews. *Frontiers in Public Health*. 2022; 10:749033.

can be accomplished through a relationship with a recovery community center, or OTPs can hire peers as part of staff. If peer specialists are hired as part of the OTP staff, it is important to clarify their roles and the OTP's expectations of them as separate and apart from clinical staff. Many OTPs now employ peer recovery support specialists, including all OTPs interviewed for this paper. The John Brooks Recovery Center actually began as a recovery community center and later began to offer methadone maintenance treatment. Many states have either incorporated peer specialists into an inclusive payment bundle or authorize OTPs to bill Medicaid separately for peer-delivered services.

Organizational Models

As noted earlier, OTPs have traditionally operated apart from the broader health care system, behavioral health care system, and even the SUD continuum of care. This model can function effectively in communities where strong relationships exist among providers and where referral pathways are clear and connected. Unfortunately, this is not the case in most communities. In many instances, the stand-alone model has served to stigmatize methadone treatment and limit access to other necessary services. In order to meet the needs of patients, OTPs are beginning to expand services offered, co-locate in health care settings, and merge or create affiliations with other providers.

> *"Narcotics treatment providers need to reinvent themselves to be more comprehensive systems and diversify their business models, which would be (theoretically) more beneficial to patients."*
> *— Key Informant Interview*

There are some notable models in New York's Comprehensive Integrated Outpatient Programs, Pennsylvania's Centers of Excellence, and Rhode Island's and Vermont's OUD health homes. For example, New York has worked on the issue of OTP-outpatient (OTP/OP) integration for many years, beginning with the development of a set of combined standards of care for OTP/OP licensures. After several years during which there was almost no uptake by providers, the state issued an RFP through which it made startup awards for one of three modes. New York now has 15 integrated programs that focus on single point of access/intake, counseling, peer supports, telehealth, mental health, and medical services. There is also a growing number of OTPs dually licensed as FQHCs, e.g., Tarzana Treatment Centers in California and the SSTAR Family Healthcare Center in Massachusetts, as well as arrangements by which OTPs expand sites through colocation with community mental health centers and Certified Community Behavioral Health Centers (CCBHCs), e.g., Behavioral Health Network and SSTAR in Massachusetts. In evaluating this array of approaches, states and counties must make policy choices about whether the model is required, voluntary, or competitive.

Comprehensive programs that offer patient access to services beyond treatment of OUD in a no wrong door approach are setting a new standard of care and raising expectations for service delivery. Especially in areas where access to services may be limited, OTPs should be encouraged and incentivized to consider their potential role in meeting the needs of their patients. The high-performing OTPs interviewed all described such efforts as just "doing the right thing" to meet the needs of their patients. Each also emphasized the importance of partnership with state leaders to support program changes that may require additional licensing requirements, sustainable funding sources, and federal approvals.

Affiliations, Integrated Treatment, and Health Homes

There is clear consensus that many patients who receive treatment from OTPs have complex SUDs and serious co-occurring medical and mental health needs. Many observers believe that OTPs should not limit themselves to providing opioid substitution treatment, due to the significant patient needs and the opportunity presented by the long-term nature of methadone treatment. Also, given the relative isolation of OTPs from the rest of the SUD continuum, having OTPs diversify their services may help incorporate them into the SUD system of care. High-performing OTPs look for opportunities to expand their scope in order to meet patients' needs; this expansion can take various forms, both within SUD levels of care as well as across SUD, mental health, and primary care. Methods for accomplishing this expansion include contractually required affiliations, OTPs offering outpatient and intensive outpatient treatment, and integrated health home options. Health home programs created through the Affordable Care Act may be an even more attractive option for expanding comprehensive care, as the SUPPORT Act extended the 90%

enhanced federal match from 8 to 10 quarters for services focused on care coordination for beneficiaries with SUDs.

Expanded SUD Services

OTPs offer a specific outpatient SUD service using methadone or other FDA-approved medications to treat OUD. However, individuals receiving OTP services often present with other SUDs that require access to other levels of care. All the OTPs we interviewed provide access to some or all levels of care defined by the American Society of Addiction Medicine at one or more sites. Baymark offers withdrawal management in both inpatient and outpatient settings as well as outpatient and residential services. Tarzana Treatment Centers offers multiple treatment and recovery options, including recovery housing. The John Brooks Recovery Center offers the full continuum of SUD care from harm reduction to recovery housing. In addition to harm reduction, recovery support services provided by Community Medical Services include peer support, employment services, and a sober gym. Community Medical Services is also implementing a telepsychiatry service, offers hepatitis C and HIV testing, and is rolling out hepatitis C treatment at all locations. Adam Bucon, the New Jersey SOTA, reported that most New Jersey OTPs provide an intensive outpatient level of care. New York released an RFP for comprehensive integrated care that offers funds to OTPs to include an outpatient level of care for all SUDs and incentivizes providers of outpatient levels of care to become OTPs.

Integrated Mental and Physical Health Care

Rates of co-occurring psychiatric disorders are significant in patients maintained on methadone for treatment of OUD. Patients also present with multiple physical health comorbidities.[36] One study noted that 67 to 96 percent of OTP patients tested positive for Hepatitis C. OTPs provide an excellent setting for comprehensive care, staffed with medical professionals who have established relationships with patients, with opportunity for frequent observation. Combining psychiatric and medical care in a setting that offers MOUD may increase compliance for other conditions and improve outcomes. Another study found that offering co-located Hepatitis C treatment helped to improve treatment retention.[37] High-performing OTPs offer comprehensive services that meet the needs of their patients. Minimally, OTPs should serve as sites that can screen for these conditions and coordinate care for individuals in the community. All of the OTPs interviewed offer psychiatric services directly or through affiliation. Tarzana Treatment Centers provides mental health as well as primary and specialty care services. BHN is a community mental health center that expanded its services to include methadone treatment. The John Brooks Recovery Center offers primary care services, largely focused on prevention and treatment of Hepatitis C and HIV. To further improve integration of care, this agency has developed an affiliation with a larger health care system. Victa offers primary care that includes Hepatitis C screening and treatment. One of BHN's sites is integrated in a health care setting and in that location, BHN is seeing an influx of patients new to methadone treatment. BHN and Community Medical Services are both in the process of integrating treatment for Hepatitis C into their OTP sites.

> *"There are lots of licensing and funding barriers to integrated care."*
> *— National Informant*

Officials from New York State related the experience of a health plan in New York that initiated a pilot project to determine whether members who received both OTP and integrated primary care services had better outcomes than members who received OTP services alone. Metrics focused on these key outcomes:

- Comprehensive management of diabetes
- Controlling high blood pressure
- Follow-up after a hospital emergency department visit related to an SUD

Additionally, the plan reviewed the average total cost of care for each group. Prior to suspension of the project due to COVID-19, results appeared promising:

- Members in the primary care cohort had a 33% lower average total cost of care than members in the OTP-only cohort.
- Savings were driven by a lower average spend on all-cause inpatient admissions and emergency department visits.
- Members in the primary care cohort had better rates for seven out of ten chronic care measures compared to members in the OTP-only cohort.

36. U.S. Substance Abuse and Mental Health Services Administration (2023). Co-occurring disorders and other health conditions.

37. Severe, B., Tetrault, J. M., Madden, L., & Heimer, R. (2020). Co-located hepatitis C virus infection treatment within an opioid treatment program promotes opioid agonist treatment retention. *Drug and Alcohol Dependence, 213*.

Financing

In order to support patient-centered, recovery-oriented practices, OTPs need to be financed through mechanisms that are priced fairly, with clarity about what is covered in the rate and consistency between the rate amount and service expectations. Payment systems, either prospective or retrospective, should be understandable to the provider and should incentivize an array of services that are based on clinical practice and patients' treatment and recovery needs, with rewards for performance. Any payment mechanism must provide compensation for take-home dosing days and services delivered through telehealth. The role of value-based purchasing is discussed below.

Evolving Payment Models

Medicaid payment policies influence the structure of OUD treatment services for everyone with OUD treatment needs. A recent review of Medicaid rates for methadone treatment noted wide variation among states, with most substantially below Medicare reimbursement rates.[38] In addition to rates, the methods by which states reimburse OTPs vary from state to state. Some pay bundled fees that include all services provided, while others pay a bundled fee that includes only some of the required services and allow OTPs to bill for services outside of the bundle. In some states, the bundled fee includes only dosing, and all other services are billed separately. There are states that have established payment structures beyond dosing and required services, such as health home or case management payments. How the bundled rate is paid also varies; some states pay a daily rate, some weekly. In some states, the bundled rate can be paid only when the patient presents for dosing or another in-person service, leaving OTPs unable to bill for patients with take-homes. In other states, payment of the bundled fee requires only that the patient be active in treatment. In identifying a payment model for OTPs, states balance the need for accountability (what was paid for) with the need to incentivize EBPs and decrease administrative burden for providers. As the health care system moves away from fee-for-service approaches based on encounter data and focuses instead on outcomes, some states are beginning to consider applying a value-based purchasing approach in OTPs.

Focusing on Improving Practices

Payment drives practice. The study cited above found that in 2021, "states with higher rates of Medicaid enrollees treated for OUD, higher Medicaid enrollment and higher shares of Black enrollment had lower Medicaid-to-Medicare fee indexes for methadone bundles than lower-enrollment states, raising questions about how these fees are set and the need for close study of the need for reform."[39] As states are challenged to address inequities in health care, consideration of payment strategies that perpetuate such inequities is critical.

Lower rates decrease interest in Medicaid participation by willing providers and thus serve as a barrier to access for historically marginalized populations. Interviews with OTP providers highlighted that payment rates do influence decisions about location, meaning that forward-thinking, innovative programs are unlikely to site programs in states or counties with inadequate rates. Only one of the ten states in which Community Medical Services has sited new programs has a Medicaid-Medicare fee index lower than the national average. In recognition of the important role OTPs play in addressing the opioid crisis and of the need to support infrastructure, the State of Washington recently approved a 32% increase to the Medicaid managed care rates for methadone treatment. The legislation requires that the Health Care Authority direct Medicaid managed care organizations to adopt a value-based bundled payment methodology through contracts with OTPs.

Rates and payment methodologies influence the incorporation of EBPs. In order to facilitate the provision of low-barrier methadone access, Missouri found it necessary to adjust rates. The bundled rate for dosing was insufficient to support the infrastructure needed to provide the service, as the primary source of funding for the OTPs was billable services. Since billable services would likely not be provided to patients receiving low-barrier methadone treatment, the rates for dosing had to be raised. As states consider new federal flexibilities to expand access and improve retention, it will be critical to identify and eliminate payment methods that disincentivize take-home dosing. In some states (e.g., Rhode Island), payment is provided to OTPs as long as a patient is active in treatment, and is not dependent on their being present for dosing.

38. Clemans-Cope, L., Lynch, V., Payton, M., & Aarons, J. (2022). Medicaid professional fees for treatment of opioid use disorder varied widely across states and were substantially below fees paid by Medicare in 2021. *Substance Abuse Treatment, Prevention, & Policy 17*, Article 49.
39. Clemans-Cope, L., Lynch, V., Payton, M., & Aarons, J. (2022). Medicaid professional fees for treatment of opioid use disorder varied widely across states and were substantially below fees paid by Medicare in 2021. *Substance Abuse Treatment, Prevention, & Policy 17*, Article 49.

Re-envisioning SUD Treatment and Recovery Support

Leadership for Change

Leadership is critical is designing and guiding the transformation of any publicly funded system. As the stewards of SUD policy and practice, states and counties have the responsibility to periodically evaluate the quality and impact of their provider network and its services to ensure that patients receive high-quality, recovery-oriented treatment and support that produces positive outcomes, including reducing opioid overdoses and deaths. This is particularly true for OTPs that have been isolated from other SUD treatment providers and governed by federal and state regulations which are dramatically different than those for most clinical services. It is also critical that SOTAs be part of an integrated planning and policy development process so that decisions on OTP models, practices, and financing are made in the context of the SUD system as a whole, at both the state and county levels. Reconfiguring OTP services may affect other levels of care in the continuum, and vice versa; planning for OTPs in relationship to the full system may allow states and counties to create complementary arrangements between residential, outpatient, and opioid treatment programs.

"It all boils down to state leadership and what they consider the role of opioid treatment providers to be in their state."
— National Informant

As described earlier in this paper, the federally regulated OTP system has operated under essentially the same requirements for the past 50 years. With the recently announced proposed changes to SAMHSA's OTP rule, every state now has the opportunity to reset the OTP model and improve care quality and outcomes for beneficiaries with OUD. However, these federal flexibilities do not guarantee that OTPs will take advantage of them. As seen in many states, OTPs have quickly returned to "business as usual" with regard to take-home dosing, even though COVID-19 flexibilities have continued; strong state and county leadership is required in assuring that OTPs use a patient-centered lens in determining take-home dosing schedules with the individuals they serve. States would benefit from consensus on the role of OTPs within the continuum, their vision for OTPs' model of care, and ways in which this vision would become a reality. There does seem to be agreement among knowledge holders in this area that OTP practices should be infused with many of the patient-centered approaches that have grown in health care in the last decade.

In this paper, we have presented a number of approaches for improving the quality and scope of OTPs, some of which are available but perhaps not widely implemented, and others that have been put into play by states and forward-thinking providers. As states evaluate these opportunities, they can note the challenges and considerations that accompany each one to determine which

strategies are most feasible and would best advance their objectives for OTPs. As a first step, it is important that states conduct an examination of current regulations that exceed federal rules, especially as the newly proposed

SAMHSA requirements are finalized. Similarly, payment reform offers an opportunity to eliminate disincentives to take-home dosing and telehealth by ensuring that the rate methodology provides compensation for both. Additionally, the methodologies can offer incentives for OTPs to provide additional services that patients have identified as important for their recovery.

After reaching consensus on the highest-priority problems to solve, states can select the innovation opportunities most likely to address those priorities:

- Increase access (new OTPs, new locations, medication units
- Improve quality (clinical practices, EBPs, telehealth)
- Increase ease of access (same-day initiation, 24/7 availability, evening dosing schedules, scheduled appointments)
- Improve the patient experience of care (patient-centered approaches, shared decision-making, recovery support, harm reduction, satisfaction with care)
- Expand the scope of OTPs (SUDs, mental health, medical care)

As states evaluate these options, they can also consider diversification of the OTP system to include alternative provider types (e.g., FQHCs, CCBHCs, other SUD providers) by offering resources and assistance with removing regulatory barriers in order to encourage existing treatment providers to become OTPs. States could use federal funds (e.g., SOR) to seed innovations in OTP expansion, scope, and patient-centered practices. Effective change strategies could include disruptive innovation, use of regulatory/contractual levers, and financial incentives, particularly to shift philosophies, transform clinical practice, and create motivation for change.

Clinical Integration

States have taken varied approaches to expanding the scope of OTPs, either along the SUD continuum, across mental health and medical care, or outward to patients who are not receiving MOUD, as illustrated by the menu of options below. Any one of these models (or a combination) could qualitatively change the clinical characteristics and service mix of OTPs and improve outcomes for patients.

Expanded Array of SUD Treatment and Recovery Support (Voluntary)

- Improve the SUD options available to OTP patients by allowing OTPs to bill for addictions screening and psychiatric evaluation, outpatient treatment, intensive outpatient treatment, peer support, and case management/care coordination outside the "dosing bundle."

Create an Integrated OTP/OP Option with three models (Competitive):

- Develop new OTPs integrated with OP.
- Encourage existing co-located OTPs and OPs to integrate.
- Encourage existing OTPs to add OP and provide treatment to populations not receiving MOUD.

Expanded Scope of Services (Voluntary)

- Allow OTPs to offer medical services by opening up medical codes to them such as evaluation and management, toxicology, infectious disease screening, testing, and treatment.

Coordinated or Integrated OTP and Primary Care (Voluntary)

- OTPs partner with FQHCs/CHCs for medical services, or existing OTPs or SUD providers become FQHCs.

Create an OTP Center of Excellence Option (Competitive)

- Establish higher standards for Centers of Excellence than for "base OTPs."
- Standards would focus on strong patient-centered practices, recovery orientation, remote patient 'engagement' (aka "monitoring"), etc.
- Provide additional incentive funding, e.g., infrastructure bundle, bonus payments, higher OTP rate.

Create an OTP Health Home Option (Competitive)

- Establish higher standards for health homes than for "base OTPs."
- Standards would operationalize an OUD/SUD patient-centered medical home.
- Provide additional incentive funding, e.g., infrastructure bundle, bonus payments, higher OTP rate.

The Patient Experience of Care

In transforming the OTP system, not just the "what" (program model, clinical services) but the "how" is important. Regardless of service design or organizational model, the patient experience of care is paramount in a high-performing, high-standard system. Given the continuing opioid crisis, there is an urgency to adopt patient-centered care in methadone treatment since only about 60% of patients successfully remain in treatment for more than a year.[40] This percentage varies widely across OTPs.

Research has shown that patients receiving methadone who are more satisfied with their counselors and program had lower problem severity with drug use and legal involvements; these same patients who were more satisfied were more likely to remain in treatment for at least a year.[41] Retention in methadone treatment has also been shown to be dependent on a number of factors: employment, take-home "privileges"; positive relationship between patients and practitioners; family and social support; and positive attitudes toward methadone treatment itself.[42] "Trust" within the patient-provider relationship is a contributing factor in patient engagement. Just as in medical care, alignment of patients' perception of improvement with the clinical staff's perspective is critically important; without this, there is no partnership in the treatment plan and perceived quality of care.

While the patient experience of care may seem too intangible for the state and counties to address, ongoing conversations with and among providers may facilitate inclusion of patient-centered practices in OTPs. Additionally, encouraging the creation of patient advisory councils could lift up patients' voices through their direct feedback on OTPs' policies and practices. As payment mechanisms change and outcomes are incorporated, the inclusion of individuals with deep methadone treatment expertise in discussions will be critical; the patient's experience of care must specifically be represented.

Quality Improvement and Impact

High-quality care attracts and engages patients, meets their needs, employs evidence-based practices, and produces results. Payers and regulators must define quality in order to measure it — and given the potency of fentanyl, the hierarchy of quality goals for OUD treatment starts with saving lives, increasing engagement in treatment, and then retaining patients long enough for them to benefit. While these may seem like bare minimum expectations, focusing on the "bottom of the hierarchy" may be called for during these challenging times when overdose deaths continue to rise. The first step in the development of quality measures is to identify the most relevant data being reported by OTPs and how that data could be analyzed to improve quality and results. The data must then be distributed to regulators and OTPs so they can act on it.

> *"Consumers should be treated as people and 'people come first.'"*
> *— Key Informant Interview*

In order to encourage a laser focus on OUD treatment, especially at OTPs, states and counties could develop a small suite of quality measures, for example:

- Reducing overdose events (MODRN measure)
- Reducing overdose deaths (1115 SUD Demonstration Monitoring Measure)
- Reducing dropout rates and administrative discharges
- Increasing initiation and treatment engagement (NQF #0004) and continuity of pharmacotherapy/retention (NQF #3175)
- Increasing utilization of take-home dosing and telehealth

States and counties could require reporting of the measures and use the data to create provider profiles. The system would compare OTPs across the measures (de-identified) and provide feedback through published reports. Once the basic portfolio of measures has shown its utility in raising the quality bar, outcome measures could be added, especially those that are patient-reported. Over time, the state and counties could use this system to incentivize OTPs, build more sophisticated reimbursement systems, and begin to introduce value-based payment arrangements.

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40. Levine, A. R., Lundahl, L. H., Ledgerwood, D. M., Lisieski, M., Rhodes, G. L., & Greenwald, M. K. (2015). Gender-specific predictors of retention and opioid abstinence during methadone maintenance treatment. *Journal of Substance Abuse Treatment*, *54*:37–43.
41. Kelly, S., O'Grady, K. E., Brown, B. S., Gwin Mitchell, S., & Schwartz, R. P. (2010). The role of patient satisfaction in methadone treatment. *American Journal of Drug & Alcohol Abuse, 36* (3): 150-154.
42. O'Connor, A. M., Cousins, G., Durand, L., Barry, J., & Boland, F. (2020). Retention of patients in opioid substitution treatment: A systematic review. *PLoS One, 15* (5):e0232086.

Practice Transformation and Payment Reform

Designed to give providers more flexibility to coordinate and manage care for individuals, value-based payments (VBPs) or alternative payment models (APMs) incentivize the delivery of high-quality, cost-effective care — and, in the most sophisticated arrangements, person-focused, population-based payments. The simplest VBP systems pay providers for reporting timely and accurate data, provide case rate foundational payments for practice transformations, and sometimes offer rewards ("upside risk") and penalties ("downside risk") based on performance.

APMs are structured financially so that care is transformed and quality determines some portion of a provider's payment. Foundational bundles are developed based on clinical pathways, expected treatment protocols, and components of care that produce quality and outcomes. The payer must develop a rate that represents high-quality clinical practice. Providers must be able to track quality indicators and costs; standardize care against quality standards; and proactively manage care.

Currently, in state Medicaid programs, there are some examples of bundled SUD payment arrangements, but very few that reward performance or quality. Pennsylvania, Rhode Island, Vermont, and Virginia operate eight programs in which they pay select groups of providers case rates for a specific array of services, and three of these arrangements include "upside risk" for initiation and engagement, emergency department follow-up, or rapid induction; none include "downside risk." As states begin to consider value-based payments for OTPs, the most feasible models are likely to be represented by these examples, with components that incentivize the provision of additional services, improve quality, and enhance patient-centered care.

Conclusion

In this paper, we have provided a review of relevant literature and recent developments surrounding methadone treatment, and reported on key informant interviews with local and national leaders, SOTAs, and innovative opioid treatment providers. Based on themes from the interviews, we have identified both challenges and opportunities faced by states and OTPs as they struggle to turn the tide on the opioid crisis. We've also identified innovative approaches taken by states, providers, or a combination of the two. Finally, we provide considerations on re-envisioning an SUD system of care that encompasses recovery supports and methadone treatment.

Clearly, the origin and developmental history of methadone treatment have significantly shaped the system we see today; likewise, the federal regulatory framework, developed as much with a crime control objective as with a treatment focus, has resulted in a network of OTPs that typically rely on strict requirements for patients' compliance with program rules. Against this backdrop, SAMHSA has recently issued a Notice of Proposed Rulemaking for OTPs that eliminates many of the requirements that may have restricted OTPs from offering patient-centered, recovery-oriented treatment. All states must now review their OTP regulations in order to align them with the final regulations once these are published.

In spite of the many restrictions placed on the provision of methadone treatment through current regulations, many states and OTPs have managed to adopt innovative practices that have improved the quality and comprehensiveness of services, increased access, and emphasized patient-centered care. There is clear agreement that OTP practices must be infused with innovations seen in other parts of both SUD treatment and the broader health care system; the examples of innovation presented in this paper could serve as a menu from which states can choose programmatic directions to inform the evolution of OTP practices.

Finally, we have offered recommendations on how states could begin to explore new models for methadone treatment by identifying their objectives for OTPs, selecting the highest priorities, and identifying the innovation opportunities and organizational models most likely to address those priorities. In this process, the patient experience of care must be front and center, given the need to improve retention in treatment and, therefore, outcomes. Improving treatment impact is key to the development of a quality measurement system that starts with an inventory of required data, creates a suite of quality measures, and then profiles providers against the measures. With quality data in place, states could begin to look forward to a greater role for value-based providers that incentivize high-quality and patient-centered care.

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