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Jay Higham
Chief Executive Officer

April 12, 2024

The Honorable Edward J. Markey
United States Senator
255 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Braun
United States Senator
404 Russell Senate Office Building
Washington, DC 20510

The Honorable Maggie Hassan
United States Senator
324 Hart Senate Office Building
Washington, DC 20510

The Honorable Elizabeth Warren
United States Senator
309 Hart Senate Building
Washington, DC 20510

The Honorable Donald Norcross
Member of House of Representatives
2427 Rayburn House Office Building
Washington, DC 20515

The Honorable Don Bacon
Member of House of Representatives
2014 Raburn House Office Building
Washington, DC 202515

Dear Senators Markey, Braun, Hassan, and Warren, and Representatives Norcross and Bacon:

Thank you for the opportunity to respond to your March 12th letter regarding the ongoing opioid use disorder (OUD) epidemic and *The Modernization of Opioid Treatment Access Act* ("MOTAA"). We at BHG share your desire to eliminate OUD and believe that with personalized, evidenced-based medical and behavioral therapies, real recovery is possible. Furthermore, as long-time providers on the forefront of treating patients suffering from OUD, BHG shares your commitment to identifying and promoting policy and best practices that will improve access to lifesaving treatment.

The fight against the opioid epidemic is personal; all of us have been impacted by addiction or know someone who has. With that understanding, we are laser-focused on addressing OUD as a chronic disease of the brain that requires evidence-based treatment and management. We believe that recovery requires integrated care, not just a prescription. That is why we are providing critical access to patient-centered treatment with 114 programs across 21states and DC, helping over 42,000 people move into recovery every single day.

The number of opioid-related deaths in this country has skyrocketed. We have been doing our part to counter this ongoing crisis by investing in the necessary resources to improve clinical care and access with best-in-class physicians and support staff across our entire geographic footprint. As a result, we're proud that we have increased the number of individuals we treat by more than 100% over the last five years. However, this is not the time for victory laps; our collective work is more important than ever. It's why we must tackle OUD head on, and, most importantly, together.

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In the pages that follow, we provide details of how BHG endeavors to combat OUD, the evidence-based research and data that underpins our clinical approach and opposition to a methadone-only construct, and how access can be further expanded to patient-centered Medications for Opioid Use Disorder (MOUD) care.

We welcome the chance to engage in meaningful dialogue on these matters and are optimistic that we can find solutions that meet our shared objective of expanding access and ensuring high quality care for those who want and need it.

BHG supports the modernization of SAMHSA's updated Federal regulations.

We should start by acknowledging the fact that the Biden Administration has already demonstrated strong leadership and taken game-changing steps in improving access to MOUD. It cannot be stated clearly enough: We emphatically support and applaud the totality of SAMHSA's modernization of the Opioid Treatment Program (OTP) regulations, including making COVID-era take-home flexibilities permanent.

Before we turn to discussion of the take-home flexibilities, it is important to note that the modernized regulations do much to increase access to OTPs. They allow Advanced Practice Providers (such as Nurse Practitioners and Physician Assistants) to operate at the top of their license and admit people into treatment and manage their medication. They remove non-evidence-based barriers like the requirement that patients have one year of documented OUD before admission to care. They allow for greater use of teleservices during the admissions process, which is particularly important given the shortage of providers who choose to do this work. Finally, the regulations allow for full-service dosing units, which can serve as satellites to a patient treatment center and allow for much smaller populations to be served in a viable manner.

We agree that during the pandemic, the standard for dispensing take-home doses changed from the "eight-point criteria"[1] to an individual, benefit vs. risk assessment for the patient. This was a positive development, and we educated our providers and developed tools to help support a decision-making process that might result in prescribing take-homes. As we did during the pandemic, and now with the Final Rule, we routinely raise this change with our clinicians, and encourage our physicians to think of the least restrictive treatment approach that will safely and effectively help our patients meet their goals.

We do not, however, direct medical decision-making. It is essential that physicians preserve their independence such that their primary focus is the patient's well-being and care. Our patients

[1] 42 CFR Part 8 (i)(2)i-viii

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have complex medical, psychiatric, and concomitant SUD histories.[2,3,4, 5] Other medical conditions, psychiatric conditions, medications, and on-going use of other substances all factor into the risk associated with the provision of take-home doses.

Recovery requires an integrated approach.

SAMHSA's revised OTP Regulation, while enormously impactful, is not the reason we feel so strongly that moving to "medication-only" treatment is problematic. Our concerns are more fundamental, and our support of integrated care delivery is aligned with SAMHSA's views on what constitutes "recovery."

As per SAMHSA,[6] recovery is a holistic construct that entails a restoration, or attainment, of harmony, meaning, and functionality to a person's life. It is predicated on, but not defined by, abstinence from harmful substances. Our goal is to support and guide people, so motivated, to recovery. For patients with OUD, MOUD is a critical piece of this task, but it is not the only piece.

Medications do not teach people how to identify and avoid internal and external triggers or high-risk situations. They do not help a person develop a coping plan or problem-solving skills. They do not teach new ways to relate to negative emotions, or to refuse drugs when offered. They do not help people repair broken relationships, identify a new peer group, find meaningful employment, or identify diverting recreational activities. The medications absolutely help create the space for this learning and discovery to happen, but they do not bring these things into being. Psychosocial interventions, like counseling and case management, do. OUD patients need support services beyond medication.

Outside of OUD and Alcohol Use Disorder (AUD), there are no effective FDA-approved medications to offer patients with other SUDs. For these conditions, psychosocial interventions are the mainstay of treatment. Psychosocial treatments are routinely used to serve these populations as they work to recover, and we believe that OUD patients deserve no less.

To conflate the mere provision of MOUD with fully supporting the recovery process is to fundamentally over-privilege the role of medication in a person's treatment. While the magnitude and impact of MOUD for those in addiction treatment are extraordinary, they don't support the full weight of SAMHSA's multidimensional definition of *recovery*.

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[2] O'Grady MA, Neighbors CJ, Randrianarivony R, Shapiro-Luft D, Tempchin J, Perez-Cubillan Y, Collymore DC, Martin K, Heyward N, Wu M, Beacham A, Greenfeld B. "Identifying the physical and mental healthcare needs of opioid treatment program clients." *Substance Use & Misuse*. 57(7):1164-1169 (2022)
[3] Han B, Polydorou S, Ferris R, Blaum CS, Ross S, McNeely J. "Demographic trends of adults in New York City Opioid Treatment Programs- an aging population." *Substance Use & Misuse*. 50(13):1660-1667 (2015)
[4] Barry DT, Cutter CJ, Beitel M, Kerns RD, Liong C, Schottenfeld RS. "Psychiatric disorders among patients seeking treatment for co-occurring chronic pain and opioid use disorder." *Journal of Clinical Psychiatry*. 77(10):1413-1419 (2016)
[5] Santo T, Campbell G, Gisev N, Martina-Burke D, Wilson J, Colledge-Frisby S, Clark B, Tran LT, Degenhardt L. "Prevalence of mental disorders among people with opioid use disorder: A systematic review and meta-analysis." *Drug and Alcohol Dependence*. 238 (2022) https://doi.org/10.1016/j.drugalcdep.2022.109551
[6] SAMHSA's Working Definition of Recovery. (2012) https://store.samhsa.gov/sites/default/files/pep12-recdef.pdf

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These medications do not prevent people from using other substances, and 42% of OTP patients have another SUD in addition to OUD.[7] It is not surprising that counseling, and specifically Cognitive Behavioral Therapy (CBT) has been shown to improve outcomes in MOUD.[8,9,10,11]

Every step the government takes to de-emphasize the importance of psychosocial interventions in supporting recovery undermines the treatment of non-opioid SUDs and increases the chance MOUD patients will be denied real recovery and be told they must settle for mere abstinence. Not forcing patients into counseling is acceptable; not forcing treatment providers to have counseling readily available is terrible. Patients will hear the message that they need to be satisfied just to survive but won't be helped to thrive. This could propel the persistent and pernicious attitude that people on MOUD aren't *really* in recovery at all. Not all patients want recovery or counseling services, and no one should be mandated into services against their will as a precondition to receiving treatment. At a time when "fragmented care" is shorthand for a problem with the health care status quo, we should not turn away from a model built on a premise of full integration of necessary services.

As we consider how to improve the provision of MOUD services, it is worth paying attention to the valuable lessons learned with buprenorphine. Although the DATA 2000 waiver (i.e., the X-waiver) was not identified in the research as an impediment to the provision of buprenorphine

[7] Rosic T, Naji L, Bawor M, Dennis BB, Plater C, Marsh DC, Thabane L, Samaan Z. "The impact of comorbid psychiatric disorders on methadone maintenance treatment in opioid use disorder: A prospective cohort study." *Neuropsychiatric Disease and Treatment*. 13:1399-1408 (2017)

[8] Moore BA, Fiellin DA, Cutter CJ, Buono FD, Barry DT, Fiellin LE, O'Connor PG, Schottenfeld RS. "Cognitive Behavioral Therapy Improves Treatment Outcomes for Prescription Opioid Users in Primary-Care Based Buprenorphine Treatment." *Journal of Substance Abuse Treatment*. 71:54-57. (2017) doi: 10.1016/j.jsat.2016.08.016

[9] Weiss RD, Griffin ML, Potter JS, Dodd DR, Dreifuss JA, Connery HS, Carroll KM. "Who benefits from additional drug counseling among prescription opioid dependent patients receiving buprenorphine-naloxone and standard medical management?" *Drug and Alcohol Dependence*. 140:118-122 (2014) https://doi.org/10.1016%2Fj.drugalcdep.2014.04.005

[10] Dalton K, Bishop L, Darcy S. "Investigating interventions that lead to the highest treatment retention for emerging adults with substance use disorder: A systemic review. *Addictive Behaviors*. 122 (2021) https://doi.org/10.1016/j.addbeh.2021.107005

[11] Dugosh dfdK, Abraham A, Seymour B, McLoyd K, Chalk M, Festinger D. "A systemic review on the use of psychosocial interventions in conjunction with medications for the treatment of opioid addiction." *Journal of Addiction Medicine*. 10(2): 93-103 (2016) DOI: 10.1097/ADM.0000000000000193

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services,[12,13,14,15] the waiver requirement was first weakened[16] and later removed.[17] Leaders of organizations, including the American College of Physicians,[18] the American Society of Addiction Medicine,[19] and the Office of National Drug Control Policy[20] hailed this move as an important step in improving access to care. However, improved treatment utilization with buprenorphine has not materialized. Neither the weakening[21] nor the removal[22] of the waiver improved the number of Americans receiving buprenorphine for OUD.

Federal Regulation is not a barrier to OUD treatment and methadone.

BHG is unaware of peer-reviewed evidence that supports the assertion that 42 CFR Part 8 is a barrier, let alone the primary barrier, to people with OUD accessing methadone. In fact, evidence suggests that would-be "regulatory barriers" are a distraction, especially when measured against treatment for other substance use disorders as discussed below.

SAMHSA estimates that roughly only 18% of the 6.1 million Americans with OUD receive one of the three FDA-approved medications.[23] Our clinical mission is tied to improving this dismal statistic, especially when 80,000 people a year are dying of opioid overdose.[24]

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[12] Hutchinson E, Catlin M, Andrilla HA, Baldwin LM, Rosenblatt RA. "Barriers to primary care physicians prescribing buprenorphine." *Annals of Family Medicine*. 12(2):128-133 (2014)

[13] Louie DL, Assefa MT, McGovern MP. "Attitudes of primary care physicians toward prescribing buprenorphine: a narrative review. *BMC Family Practice*. 20(157) (2019)

[14] DeFlavio JR, Rolin SA, Nordstrom BR, Kazal LA. "Analysis of barriers to adoption of buprenorphine maintenance therapy by family physicians." *Rural and Remote Health*. 15(1):93-103 (2015)

[15] Andraka-Christou B, Capone MJ. "A qualitative study comparing physician-reported barriers to treating addiction using buprenorphine and extended-release naltrexone in US office-based practices. *International Journal of Drug Policy*. 54:9-17 (2018)

[16] https://www.samhsa.gov/newsroom/press-announcements/202104270930

[17] https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act#:~:text=Section%201262%20of%20the%20Consolidated,opioid%20use%20disorder%20(OUD).

[18] Frost, M. "Big barrier to buprenorphine removed." *IM Matters*. March (2023) https://immattersacp.org/archives/2023/03/big-barrier-to-buprenorphine-removed.html

[19] https://www.asam.org/docs/default-source/advocacy/letters-and-comments/21-02-24-x-waiver-press-release_final1f9b3a9472bc604ca5b7ff000030b21a.pdf

[20] https://www.whitehouse.gov/ondcp/briefing-room/2022/12/30/dr-gupta-applauds-removal-of-x-waiver-in-omnibus-urges-healthcare-providers-to-treat-addiction/

[21] Jones CM, Olsen Y, Ali MM et al. "Characteristics and prescribing patterns of clinicians waivered to prescribe buprenorphine for opioid use disorder before and after release of new practice guidelines." *JAMA Health Forum*. 4(7):e231982 (2023) doi:10.1001/jamahealthforum.2023.1982

[22] Chua K, Nguyen TD, Zhang J, Conti RM, Lagisetty P, Bohnert AS. Trends in buprenorphine initiation and retention in the United States, 2016-2022. *JAMA.* 329(16):1402–1404. (2023) doi:10.1001/jama.2023.1207

[23] Substance Abuse and Mental Health Services Administration. (2023). *Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health* (HHS Publication No. PEP23-07-01-006, NSDUH Series H-58). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. p. 53

[24] Centers for Disease Control

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Instead, reasons for low treatment take-up for those with SUD are more fundamental and personal. In 2022,[25] of the 39.7 million adults who met criteria for a SUD, only 0.8% sought care. According to SAMHSA, of those that did not seek treatment, 94.7% did not think they needed it. The 4.5% who thought they needed treatment but didn't seek it out listed several reasons, including: feeling they should have been able to control their use on their own; not being ready to start treatment or to even cut down on their use; not knowing where to get treatment; worrying about paying for treatment; and worrying about the social consequences of treatment. Although this data is not OUD-specific, it highlights the role played by personal motivation and economic accessibility in the utilization of SUD treatment.

Proximity to treatment does not equal access to treatment, rather ability to pay is key for sustained recovery.

Identifying what patient "access" means is particularly important for addiction treatment, and it is common to conflate challenges of geographic access with that of a patient's ability to pay. Research shows that 87.2% of the US population lives within the federal definition of reasonable access to an OTP, and 99% of the US population lived within reasonable access to a buprenorphine provider, even before the X-waiver was eliminated.[26]

Participants in the National Survey of Drug Use and Health[5] found that economic access plays a vital role in accessing MOUD, and retention in MOUD is significantly better when a third-party payor, rather than the patient, is paying for care.[27] Notwithstanding the value of commercial coverage, the burden of OUD is disproportionately borne by the Medicaid and uninsured population.[14] The Kaiser Family Foundation has estimated that 72% of the low-income OUD population either has Medicaid or is uninsured,[28] and Medicaid expansion significantly increases

[25] Substance Abuse and Mental Health Services Administration. (2023). *Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health* (HHS Publication No. PEP23-07-01-006, NSDUH Series H-58). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. pp. 54-55

[26] Research & Planning Consultant, LP report, March 11, 2024

[27] Williams AR, Rowe C, Minarik L, Gray Z, Murphy SM, Pincus HA. "Use of in-network insurance benefits is critical for improving retention in telehealth-based buprenorphine treatment." *Health Affairs Scholar*. 2(3) (2024) https://doi.org/10.1093/haschl/qxae009

[28] The Opioid Epidemic and Medicaid's Role in Facilitating Access, Kaiser Family Foundation Issue Brief, April 2018.

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the rate of MOUD service utilization.[29,30,31] This is relevant as the benefits of medication are only available to a patient who *takes* the medication, and overall retention in MOUD is low.[32]

Despite the stated benefit of Medicaid expansion and state waivers that provide access for those needing treatment, it's irrelevant if there isn't a provider that accepts Medicaid. Unfortunately, based on research we commissioned, *nearly two-thirds of addiction boarded doctors do not accept Medicaid*. Specifically, in n a review of providers who are (1) Board Certified in Addiction Medicine or Addiction Psychiatry, (2) practice outside of an area that already has reasonable access to methadone, and (3) accept Medicaid, *only 85 physicians in the country* meet these criteria.[33]

While relying solely on addiction medicine physicians to improve access to rural areas carries significant risk without meaningful improved access, we do believe there are other more effective solutions to achieve our otherwise mutually agreed upon policy objectives. We would welcome discussion and collaboration on how best to execute on any or all of the following ideas:

- Establish dosing units in partnership with Federally Qualified Health Centers (FQHCs) in rural areas – research we commissioned shows that establishing a dosing unit partnership with rural FQHCs would enable approximately 19.5 million adults living in rural areas to gain reasonable access (as defined by federal guidelines of reasonable access to behavioral health);[34]
- Target loan forgiveness for addiction professionals working in rural areas;
- Create a rural reimbursement add-on to enable smaller OTPs with less scale to operate in rural areas; and
- Set aside federal funds to support mobile and satellite dosing units in rural areas that cannot be sustained with traditional reimbursement programs.

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[29] Sugarman OK, Li W, Saloner B. "Medications for opioid use disorder increased among Louisiana Medicaid enrollees during policy reforms, 2018-21." *Health Affairs*. January 2024. https://doi.org/10.1377/hlthaff.2023.00715

[30] Harris SJ, Landis RK, Li W, Stein BD, Saloner B. "Utilization of medications for opioid use disorder among West Virginia Medicaid enrollees following Medicaid coverage of methadone." *Substance Use & Addiction Journal*. 45(1) (2023) https://doi.org/10.1177/29767342231208516

[31] Wen H, Hockenberry JM, Borders TF, Druss BG. "Impact of Medicaid expansion on Medicaid-covered utilization of buprenorphine for opioid use disorder treatment. *Medical Care*. 55(4):336-341. (2017) DOI: 10.1097/MLR.0000000000000703

[32] Krawczyk N, Williams AR, Saloner B, Cerda M. "Who stays in medication treatment for opioid use disorder?" A national study of outpatient specialty treatment settings." *Journal of Substance Abuse Treatment*. 151 (2021) https://doi.org/10.1016/j.jsat.2021.108329

[33] Research & Planning Consultants, LP report, July 17, 2023. Included as a separate file in April 12, 2024 transmittal to staff.

[34] *Ibid.*

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Incorporating private capital has enabled us to increase access to life-saving treatment.

Your letter references concerns related to private equity investments in health care and addiction treatment. We believe that OTPs generally, and BHG specifically, have an excellent track record that belies this criticism.

Over the last 10 years, under guidance and support from our investors, we've grown from 53 locations serving 17,000 patients in 12 states, to 116 locations serving over 42,000 patients in 21 states and DC. Many of those locations were acquired from sole proprietors; others were newly opened in an area where people did not have reasonable access to OTP services. Most of the acquired treatment centers were in terrible condition with underpaid staff, substandard facilities, and only focused on cash payments from patients at the point of service. In every case, with the support of our investor group, we made significant follow-on investments in people, systems, compliance, and expanded access by relocating and upgrading facilities and going in network with every payor group – Medicaid, Medicare, Commercial, VA, and grant funding. We continue to serve patients who do not have or qualify for coverage with low-cost services based on their ability to pay. As a recent example, many of our patients have lost their Medicaid coverage due to the ongoing Medicaid redetermination process. While we lament the loss of Medicaid coverage for these patients, in every case, we have been able transfer the patient to a low-cost program to help them remain in treatment. The following sections provide further information about specific aspects of what BHG has been able to do with the support of our investors.

Investment allows for operational efficiency and more focus on patients, lower administrative burden.

Typically, the sole leadership of an OTP is provided by a Program Director and a part-time Medical Director. There are counselors, whose academic preparation, credentials, experience, and licensure requirements vary widely from state to state. There are dosing nurses, and often an administrative support employee as well. When a clinic's census is large enough, other medical providers and clinical supervisors might be added. The policies and procedures, clinical practices, and culture are the product of the experience, training, and best judgment of the on-site leadership. The obligation of the various forms of regulatory compliance (e.g. from SAMHSA, the State Opioid Treatment Authority, state-specific OTP regulations, state-specific licensure requirements, DEA requirements) falls solely on that team as well. In addition, outreach, clinical training, third-party payor contracts (and compliance with the same), IT, and human resource functions fall within the team's duties. The medical record may be on paper, or "flat" PDF documents stored in a computer. Stand-alone clinic leadership can be burdened and siloed away from other OTPs, meaning wide variations in outcomes are possible. Operating at scale, however, much more is possible. The quotidian work can be shared, allowing for on-site staff to focus on the needs of the patients. Clinical and operational leadership can help programs adopt best practices, policies, and procedures, as well as a uniform culture.

Investment enables us to create a best-in-class team which means we can provide best-in-class treatment.

Because of the scale made possible by private investment, we created a clinical leadership team and structure that would have otherwise been impossible. Our clinical team includes:

- **Dr. Benjamin Nordstrom, MD, PhD (Chief Medical Officer)**, a board-certified Addiction Psychiatrist who was previously on the faculties of the University of Pennsylvania and Dartmouth medical schools. Dr. Nordstrom worked for years with the State of Vermont's Hub and Spoke Model for MOUD and co-led the Learning Collaboratives with that program. He has worked with the National Association of Drug Court Professionals to co-write their white paper on MOUD, was selected to help create the American Society of Addiction Medicine (ASAM) guidelines on the use of MOUD and was recently invited by SAMHSA to act as advisor as the Agency revamped the guidelines mentioned above.
- **Dr. Kamala Greene-Genece, PhD (Chief Clinical Officer),** a clinical psychologist who has previously overseen MOUD at Montefiore Medical Center in the Bronx and is the past Chief Clinical Officer of Phoenix House New York.
- **Samson Teklemariam, LPC, CPTM (Vice President of Clinical Services)**, previously the Director of Training with NAADAC. Previously, he was the Director of Training at Phoenix House Foundation.
- **National Clinical Directors** who oversee and support the clinical supervisors and clinical operations at our programs, including Christine Martin, LMFT, LAC-S, CS who, with Dr. Nordstrom, was invited by SAMHSA to offer clinical support and expertise as the Agency revised their OTP guidelines.

This leadership team has set a national, clinical culture that is strengths-based and motivational in nature. A few principles include:

- We are medication agnostic and do not take a position on the primacy of methadone, buprenorphine, or depo naltrexone, in an OTP or an Office-Based Opioid Treatment model.
- We believe the decision of the framework and medication to be used are best left to the shared decision between the patient and their provider.
- We do not tolerate punitive or carceral mindsets or behavior and believe that we must adapt our treatment offerings to the patient, rather than expect the patient to adapt to our treatment.
- We insist on individualized treatment decisions and plans of care.
- We do not believe that participation in counseling is a pre-requisite for program admission and note that we must always stay within state-specific regulations on this matter.

Investment helped us create defined clinical pathways and improve the traditional MOUD clinical model.

As a result of real-time data and the work of the clinical leadership team, we have been able to develop specific pathways for patients that most align with their own goals, including:

The Standard Programming Pathway for those patients who are seeking recovery. This pathway involves the provision of a form of Cognitive Behavioral Therapy (CBT) which was validated in the OTP context. We have created an on-demand Continuing Education Unit-bearing training in CBT for all our counselors.

The Harm Reduction Pathway for patients who are not looking for recovery, but only want to survive this crisis by reducing or eliminating their use of opioids (but who still want to use other illicit drugs). In this pathway, the focus is on getting patients to an effective dose of medication to reduce the chance of fatal overdose, connecting them to services they need, and meeting state-defined minimal counseling requirements by using another Evidence Basted Treatment called Motivational Interviewing to build motivation to change.

To ensure the totality of providers have the benefit of the clinical team's learnings, there is a monthly company-wide "Provider's Rounds" where Medical Directors and program providers from all over the company can join to learn about topics of interest and share best practices. Topics that have been covered include methadone induction in the age of high-potency synthetics, micro-dosing inductions onto buprenorphine, non-fentanyl high-potency synthetic drugs, kratom, and tianeptine. For counselors, we have robust, in-house clinical training covering topics such as clinical documentation, treatment planning, and leading group sessions.

Investment allowed us to upgrade our data and technology infrastructure to support patient care and outcomes.

We routinely interrogate our clinical data, made possible by having a state-of-the-art data warehouse and analytic tools, pulling information from a single unified Electronic Medical Record. We compare outcomes, and take lessons learned from high-performing sites to improve the results at lower-performing sites. One example is a project where we track the methadone dose of every admitted patient to ensure they are, as swiftly as can be done safely, getting to an effective dose of medication.

Investment helped us create more jobs in the communities we serve.

OTPs are highly regulated. These regulations vary by state, and in most cases, we are required to maintain a minimum staffing ratio. As a result, we pay close attention to maintaining required staffing levels, state compliance, and support patient care at the treatment centers. Over the last two years we've added 250 additional employees to support the operations. In addition, we've built a home office support infrastructure of over 150 people in clinical, IT, HR and other departments to make sure we are positioned to support the operations. The only job these teammates have is to support delivery of high-quality patient care.

Examples of outcomes include:

- Reduced turnover rates among staff by approximately 36% during our partnership with our investors. This matters because high turnover challenges outcomes and quality of care and is incredibly important for patients. Retention of highly skilled clinicians translates into better care. While we believe we have industry leading staff retention, we

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view turnover as still too high and would encourage Congress to take additional action on workforce development for behavioral health.

- Added comprehensive benefits including 401(k) with company match and tuition reimbursement.
- An HR infrastructure that provides ongoing training and development for teammates, as well as a recruiting and onboarding function to support treatment center operations.
- A compensation program that ensures total compensation is in line with similar roles in each market. Physicians are paid a fixed hourly rate and are not given an incentive to admit patients or to over utilize services.

Investment has helped us engage patients to drive better outcomes.

As noted above, BHG's clinical model is designed to help patients access and stay in treatment until they have achieved their goals. We closely monitor patient engagement with clinicians and providers and track patient progress in treatment. We have designed this program to maximize clinical outcomes. Our mantra is good clinical service will produce good business outcomes.

To ensure that providers and clinicians are not thinking about treatment needs from a financial point of view, we have always had a fixed bundled pricing model for patients. We charge the same low-cost weekly rate for patients who do not have insurance regardless of the number of daily visits, counseling interactions, provider visits, and lab testing required. Patients who are new in treatment and highly unstable that need aggressive intervention are charged the same low-cost bundle rate. Virtually all our payor contracts are also structured in this way with a weekly or monthly bundle. We were emphatic in advising CMS to adopt this approach when *The SUPPORT Act* was passed. Our philosophy is that providers should not think about how much they are billing when making clinical decisions, and patients should not have to worry about the cost of care when they come to treatment. Our entire structure is designed to support access and quality. The only examples of traditional fee for service (FFS) billing at BHG are in states that maintain a FFS requirement. While many states have voluntarily adopted the G codes, others have not. We encourage Congress to take action, or work with the Administration, to require all state Medicaid programs adopt the CMS G code bundles for OTP services.

As a final note, in my experience working in both for-profit and not-for-profit health care settings, the overwhelming instinct of providers is to provide high-quality services. The tax status or source of capital does not typically impact the instinct to provide high quality care. However, it is true that the US health care system does rely on access to capital to achieve that objective. Capital typically flows to health care sectors where there is an opportunity to achieve good outcomes for all stakeholders. Behavioral health generally, and certainly OUD treatment, is a sector that is attracting capital because it has been severely underfunded historically and because there is a dire need. Without outside capital, we would not be able to achieve parity with traditional health care in the US. We're proud of the impact we are having and look forward to continued impact in the future.

We believe well-intentioned people operating in good faith can find common ground for addressing big problems. BHG respects your intention to advance sound policy to address the

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OUD epidemic and looks forward to working collaboratively to find ways to address the crisis of rising "deaths of despair" (drug overdose deaths, alcohol-related deaths, and suicides) that has inversely mirrored the falling fortunes of non-college educated Americans.[35] Reversing these trends is key to our national public health and to living up to the promise of the American Dream. I am confident that we have much to learn from each other, and this dialogue can help achieve what we all want: more help for the vulnerable that need it most.

Respectfully,

DocuSigned by:

C54F0E48B8B841D...

Jay Higham
Chief Executive Officer

[35] Case A, Deaton A. *Deaths of Despair and the Future of Capitalism.* Princeton University Press. 2020

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Written answers in response to your March 12, 2024 inquiry:

1. Please provide a comprehensive overview of any private equity investment in your OTP, including the date of the investment, the geographic location(s) of the investment, the name(s) of the private equity firm(s) involved, and a summary of the non-confidential terms and conditions of the investment. Please also provide any term sheet.

   The Vistria Group, December of 2018

2. If there is any private equity investment in your OTP, what specific objectives or goals were outlined in the agreement between the OTP and the private equity firm(s)? How have these objectives been tracked and measured over time?

   As noted above, BHG has been able to scale our services including: bringing in additional clinical support staff, increasing access, improving patient experience, and upgrading operations and infrastructure. This has allowed us to improve clinical outcomes and most importantly save lives.

3. What is the total amount of capital that the private equity firm(s) invested in your OTP, if any? How has this investment been allocated within the OTP, and what key areas or projects have received funding as a result of the private equity investment?

   As noted in the letter above, funds have been invested to upgrade all aspects of the operations – medical and clinical service, human capital, facilities, information technology and regulatory compliance.

4. Please provide an overview of the financial performance and profitability of the OTP before and after any private equity investment. Please include relevant financial metrics and any changes in revenue, expenses, or profit margins.

   By scaling our financial performance, we have been able to scale access to care and the patient experience. As articulated above, this has led to better outcomes and has saved lives.

5. Has your OTP made any modifications to the criteria or guidelines for prescribing or dispensing methadone since any private equity investment? If so, please identify them.

   BHG has worked to respond to the fentanyl crisis by educating providers and clinical staff alike on how methadone (and buprenorphine) doses likely have to be higher than when treating heroin use.[36],[37] We have undertaken a large initiative focused on getting patients to a minimally therapeutic dose as quickly as can be done safely. Further, we trained providers and staff alike on the importance of using the least restrictive treatment

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[36] Volkow ND. "The epidemic of fentanyl misue and overdoses: challenges and strategies." *World Psychiatry*. 20(2): pp. 196-196. (2021)

[37] Bisaga, A. "What should clinicians do as fentanyl replaces heroin?" *Addiction*. 114 pp. 782-783. 2019

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environment necessary and to include take home doses (where appropriate) and counseling frequency necessary to treat patients safely and effectively.

6. Since any private equity investment, has there been any involvement by the PE firm(s) in any decisions regarding clinical practices? If so, please describe that involvement.

   Our investors share the same long-term policy objectives to support patients as well as treat and ultimately end OUD. They routinely encourage us to upgrade clinical practices and provide additional professional guidance including the creation of a clinical advisory board that includes some of the leading medical professionals in the country.

7. Since any private equity investment, have there been any updates or enhancements to the training programs provided to OTP staff involved in methadone prescribing and dispensing? If so, please describe them.

   Yes, as noted in the letter, we have materially upgraded our medical protocols and programs, which are ongoing, in addition to recruitment and retention of highly skilled clinicians such as a Chief Medical Officer. Further, we have added a counseling training effort, helmed by Mr. Teklemariam, that offers continuing education unit bearing trainings for counseling staff. This includes trainings on providing CBT.

8. Has any private equity investment influenced patient education and counseling regarding methadone usage, potential side effects, and associated risks? If so, how?

   Yes, as noted, our investors continue to support our efforts to expand access and appropriate care to create the best patient outcomes, and most importantly, save lives.

9. Please provide data on patient outcomes specifically related to methadone treatment, both pre- and post- any private equity investment, including data on key performance indicators related to patient success rates, relapse rates, and overall satisfaction. Have there been any notable improvements or challenges in patient outcomes linked to methadone treatment since the involvement of private equity?

   Some of the KPI’s we track include:

   - Patient satisfaction – Net Promotor Score (NPI) = 66
   - Admission on demand – 80% of patients admitted within 48 hours of first contact.
   - Brief addiction monitor[38] – Average risk and use scores reduced by 38% and 53% respectively within 3 months of admission.
   - Medication stabilization – improved time to minimum therapeutic dose.
   - Percent of patients utilizing third party funding – improved from 0% to 75%.

[38] Brief Addiction Monitor is a 17-item, multidimensional, progress monitoring instrument validated by the Veteran’s Administration for patients in treatment for a substance use disorder. Our data includes over 225,000 patient scores showing continual improvement for up to five years following admission.

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10. How has any private equity investment affected the OTP's compliance with state and federal regulations governing the use of methadone in opioid treatment programs? Are there any specific challenges or successes related to regulatory compliance that can be attributed to the private equity investment?

    Our investors actively insist that we operate in strict compliance with relevant federal and state regulations and guidelines. Our investors supported building a modern health care compliance infrastructure and the investments they supported in information technology have enabled us to ensure high quality clinical care and regulatory compliance. In further service of our commitment to responsible governance, compliance and quality, we stood up a board level quality and compliance committee to help ensure rich communication between the company and board of directors around all compliance related matters.

BayMark HEALTH SERVICES

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April 12, 2024

The Honorable Edward Markey
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The Honorable Mike Braun
404 Russell Senate Office Building
Washington, DC 20510

The Honorable Maggie Hassan
324 Hart Senate Office Building
Washington, DC 20510

The Honorable Elizabeth Warren
309 Hart Senate Office Building
Washington, DC 20510

The Honorable Donald Norcross
2427 Rayburn House Office Building
Washington, DC 20515

The Honorable Don Bacon
2104 Rayburn House Office Building
Washington, DC 20515

Dear Senator Markey, Senator Hassan, Senator Braun, Senator Warren, Representative Norcross and Representative Bacon,

Thank you for the opportunity to respond to your letter dated March 12, 2024, regarding BayMark Health Services (BayMark) and our Opioid Treatment Programs (OTPs). These programs provide methadone, buprenorphine and naltrexone along with patient centered, evidence-based multidisciplinary services to help patients succeed in stabilizing and managing their substance use disorders (SUD). We share your concern about, and attention to, our nation's opioid overdose epidemic. We also support your commitment to finding productive solutions to mitigate the tragic consequences of Opioid Use Disorder (OUD) impacting individuals, families and entire communities across the United States of America.

BAYMARK HEALTH SERVICES

BayMark is an opioid treatment provider and a provider of other SUD services that has been delivering high-quality, evidence-based medication-assisted treatment (MAT) for more than 46 years. Further, BayMark has been fully engaged in modernizing and innovating treatment in the OUD field. Our multidisciplinary team of physicians, pharmacists, nurses, counselors, case managers, medical assistants, peers and support staff have dedicated their careers to caring for others and especially some of the most disenfranchised populations across our country.

In the U.S., BayMark operates 118 OTPs in 29 states as well as an additional 21 programs in conjunction with correctional systems in 13 states. We also manage 71 office based opioid treatment programs (OBOTs) in 20 states. BayMark also has an established presence inside of hospitals where it operates withdrawal management services in partnership with 33 acute care hospitals in 15 states.

Specifically, as it pertains to your constituents:

- In Massachusetts BayMark has 269 employees serving 6,895 patients on any given day in 18 programs.
- In New Hampshire BayMark has 264 employees serving 1,596 patients on any given day in 8 programs.
- In Indiana BayMark has 57 employees serving 1,124 patients on any given day in 8 programs.
- In Nebraska BayMark has 35 employees serving 716 patients on any given day in 4 programs.

In short, BayMark provides services to those most in need within a wide variety of settings that allow it to meet its patients where they are best able to receive services.

BAYMARK'S POSITIVE IMPACT VIA INVESTMENT IN RESEARCH AND DEVELOPMENT

For nearly two decades, BayMark has been a leader in investing in research and development to improve patient outcomes and contribute to the body of literature guiding safe and effective methadone maintenance treatment and policy.

We recognize that participating in rigorous research is among the best tools we have to advance our understanding of services and public policies that have the greatest opportunity to help people reduce and eliminate their drug use, decrease criminal activity and maintain or return to pro-social behavior such as work, school and taking care of family and living a life in recovery. Each of these benefits accrues to the individual, the family, the community and society generally. Some examples of our commitment to research and development include:

- For more than 18 years, we have participated in studies conducted by the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN). One of our earliest projects was the Starting Treatment with Agonist Replacement Therapy (START) project which evaluated hepatic safety among MAT patients.[1] We continue to support the work of the NIDA CTN. We are also currently involved in non-CTN research, including a recent trial examining the efficacy of a U.S. Food and Drug Administration (FDA)approved prescription digital therapeutic for use in MAT. This MAT Study is led by RTI International.
- We are currently in the second year of a 5-year National Instituted of Health (NIH) Research project (R01) examining practice changes (e.g., take-homes and telehealth) forced by the COVID pandemic.
- We have also entered into a second NIH research grant alongside UCLA and Beacon Health to compare existing and new treatment initiatives and their impact on patient retention in treatment.
- Our internal clinical research efforts have recently produced an outcomes Whitepaper, [2] leveraging data from over 30,000 patients in recent treatment. The data strongly validate previous literature reporting significant improvements in multiple domains among patients

[1] Buprenorphine/Naloxone and Methadone Effects on Laboratory Indices of Liver Health: a Randomized Trial

[2] 2023 Nationwide Opioid Use Disorder Treatment Outcomes Report (BayMark Whitepaper)

receiving methadone and buprenorphine in both our OTP and Office-Based Opioid Treatment (OBOT) settings. A few highlights include:

- Illicit drug use decreases by 65% over the first three months in treatment and decreases by an additional 23% throughout the course of treatment;
- 32% reduction in substance use-related problems over the first two years in treatment;
- 33% and 38% improvements in comprehensive mental and physical health assessment scores over the first two years in treatment, respectively;
- 67% reduction in legal problems over the first two years in treatment;
- 30% improvement in family/social relationships over the first two years in treatment;
- 16% improvement in employment-related challenges over the first two years in treatment.

Perhaps most exciting for many of us in the OUD field is that we have developed and implemented a pilot study to evaluate a novel accelerated dosing protocol for patients using fentanyl. As you know, fentanyl is extremely potent and a leading contributor to overdose deaths. The good news is that our clinician team's novel protocols, combining accelerated dosing with robust counseling and psychosocial services, is proving highly effective in reducing fentanyl use and in increasing patient retention in OTP treatment. Our ongoing study methods to improve outcomes for patients using fentanyl have increased retention by 7% and have reduced illicit fentanyl use by 43% over the first three months of a patients' treatment in our OTP program.

We care about our patients' outcomes and their experiences. We have feedback from our patient satisfaction data which demonstrate that, of the 14,000 patients that completed surveys (a 30% response rate), the average rating was 4.6 out of 5 with an overall satisfaction score of 91.2%.

We can collect, analyze and report on these data in part because of the resources our capital has provided for us to access the data and for building a more sophisticated health care provider. Our understanding is that most of the smaller single site OTPs and a vast majority of the addiction medicine private practices do not have sufficient resources to do this important research. Nor can they afford a dedicated work force to support these research efforts.

PROGRAM, NOT A PILL CAMPAIGN

We agree with your letter that methadone maintenance treatment is the gold standard for treating opioid use disorder. However, all of the evidence for the safety and efficacy emanates from methadone treatment delivered in the context of the highly structured, licensed and accredited OTPs – with physicians, nurses and counselors working together to provide whole-person care - that has produced decades of evidence of safety and efficacy. To date, there have been no U.S. clinical trials that have evaluated the safety or efficacy of using methadone outside of the resource-rich, multidisciplinary OTP setting. In fact, since being approved by the Food and Drug Administration (FDA) for its efficacy in treating opiate addiction in 1972, there has been decades of research that show "Overall, there is a high level of evidence for the effectiveness of [Methadone maintenance treatment] (MMT) in improving treatment retention and decreasing illicit methadone or other opioid use."[3]

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[3] Medication-Assisted Treatment With methadone: Assessing the Evidence. Catherine Anne Fullerton, M.D., M.P.H., Meelee Kim, M.A., Cindy Parks Thomas, Ph.D., D. Russell Lyman, Ph.D., Leslie B. Montejano, M.A., C.C.R.P., Richard H.

The evidence is clear that the combination of medication and psychosocial services is critical to retention in treatment. If patients don't stay in treatment, they don't reduce or eliminate drug use. That is why methadone without wraparound interdisciplinary services is not as effective and, we believe based on the available research, will certainly be more dangerous for both patients and communities. Indeed, there are five separate federal agency reports that each independently concluded that private practice physician prescribing of methadone without the array of support services provided at OTPs leads to increases in diversion, overdose and death.[4,5,6,7,8]

UNHELPFUL STEREOTYPES, BIASES AND STIGMAS AROUND OTPS AND OUD TREATMENT

We take pride in the accomplishments of BayMark in providing high quality OUD treatment over many years. We are particularly proud that we have continued to serve communities and help families in the face of stigma and prejudice that could have easily impeded our important work.

As you know well, methadone clinics have been called several derogatory, judgmental and insulting names over the years such as "juice bars" and "pill mills". More recently, OTP clinics have even been referred to by the sinister name "clinic cartels". These epithets and the stigma they project are harmful to those seeking treatment. In our experience, these prejudiced comments contribute to the challenges those suffering from OUD have in selecting and reaching out for the treatment they need.

Part of the reason for names like "pill mills" and "juice bars" was because in the latter part of the 1900's, many bad actors were not providing counseling, case management and other wrap around services, which led to poor patient outcomes. We at BayMark have always understood that methadone was not the cure, but a means to reduce both the cravings and withdrawal symptoms to stabilize the patients sufficiently for them to receive the benefit of counseling, case management and other services they would need to turn their life around. Research backs this up and shows that 2-5 years in treatment is related to stronger outcomes than if someone leaves treatment earlier.[9]

That is why we joined the "*Program, not a pill*" campaign. We are driven by the science; our 46 years of experience and proven research that taking methadone is only a piece of a comprehensive treatment plan for OUD.

Dougherty, Ph.D., Allen S. Daniels, Ed.D., Sushmita Shoma Ghose, Ph.D., and Miriam E. Delphin-Rittmon, Ph.D. Published Online:15 Oct 2014.

[4] SAMHSA's Center for Substance Abuse Treatment. *methadone-Associated Mortality: Report of a National Assessment*. 2003

[5] U.S. Department of Justice, National Drug Intelligence Center. *methadone Diversion, Abuse, anmethadone Diversion, Abuse, and Misuse: Deaths Increasing at Alarming Rated Misuse: Deaths Increasing at Alarming Rate*. 2007

[6] SAMHSA's Center for Substance Abuse Treatment. *methadone Mortality – A Reassessment: Summary Report of the Meeting.* 2007

[7] Government Accountability Office. *methadone Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them*. 2009.

[8] SAMHSA's Center for Substance Abuse Treatment. *methadone Mortality – A 2010 Reassessment.* 2010

[9] https://www.endsud.org/mat-act-preventing-overdoses

We appreciate that methadone treatment is finally getting the recognition it deserves. Until recently, the stigma and the negative connotation of methadone treatment have been quite unfair to patients in need of treatment. We know that our efforts to professionalize treatment, decrease wait times, improve the grounds and buildings which house our clinics, and ensure coverage for patients in Medicare, Medicaid or covered in the commercial market have improved patient access and patient outcomes. We believe no one wants to go back to those times when patient care and quality was substandard. Methadone treatment should move forward with researched approaches that can add to the quality results currently demonstrated.

SHARED COMMITMENT TO BETTER ACCESSIBILITY OF HIGH-QUALITY CARE

We share your commitment to better access of high-quality care. However, the flexibility for "take-homes" that you mention in your letter was based solely on OTP physicians and multidisciplinary staff working in a coordinated manner to assess and make judgements during the COVID pandemic on precisely which patients could best manage such flexibilities without compromising their successful treatment.

We also disagree with your assertion in your letter that, "few people in need of methadone treatment receive it due to restrictions on access under federal law." On the contrary, the Substance Abuse and Mental Health Services Administration (SAMHSA)'s National Survey on Drug Use and Health clearly reports that most people don't get treatment because they don't perceive a need for treatment. According to the 2021 SAMHSA report, *"Among the 40.7 million people aged 12 or older in 2021 with an illicit drug or alcohol use disorder in the past year who did not receive treatment at a specialty facility, 96.8 percent (or 39.5 million people) felt they did not need treatment, 2.1 percent (or 837,000 people) felt that they needed treatment but did not make an effort to get treatment, and 1.1 percent (or 447,000 people) felt that they needed treatment and made an effort to get treatment."*[10] And perhaps most importantly, access to MAT in OTPs is very good across the country. In fact, Research and Planning Consultants found that 87% of the U.S. adult population lives within 30 miles or a 40-minute drive (Affordable Care Act reasonable access standard) of an OTP. So, the need for increased geographic access exists only in some of the most rural and geographically challenging parts of the U.S.

We point this out, in part, to highlight that access means many things- geographic availability, immediacy of availability when an individual decides they want to seek treatment, and adequate insurance coverage or funding so that people in need can afford to enter and stay in treatment.
Our priority is to find solutions to decrease overdose deaths, improve treatment access, both geographic and economic while continually advancing quality. That is why we strongly supported the modernization of federal regulations by SAMHSA.

Several years ago, as calls for modernization grew louder, SAMHSA heeded the call and worked diligently to modernize OTP regulations. As you correctly highlight, the year-long regulatory process convened by the experts at SAMHSA and including input from stakeholders across the country was finalized in January 2024. These new rules promise significant improvements in patient access and flexibility to methadone maintenance treatment. Revised federal rules continuing to allow more

[10] Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health

immediate take home methadone medication upon entry to treatment, telehealth admissions for methadone treatment and full-service mobile units create a powerful opportunity to safely expand access to methadone while ensuring that services are patient centered without compromising patient and public safety through new, untested models. In short, the new SAMHSA regulations have addressed each of the concerns about access that you have expressed in your letter while explicitly stating that methadone should not be prescribed for opioid use disorder outside of the patient centered MAT model provided by licensed OTPs.[11]

We would also correct the prevalent misconception that patients have to come into the clinic for treatment every day. Prior to 2020 when the temporary take-home flexibilities were created, only approximately 60% of patients were coming to the clinic on any one day as many had take-home provisions. The problem was by regulation, it took 90 days of successful treatment to be given the first take-home and it might take a year or longer for a patient to earn six take-home medications per week, only coming to the clinic four times per month. And exceptions could be granted but only by states and by SAMHSA. However, since the COVID Pandemic in 2020 when SAMHSA granted temporary flexibilities to OTPs, there are less barriers for providers to grant take-homes to patients such that now, approximately 41% of BayMark's nearly 40,000 OTP patients come into the clinic just once-per-week or less (15% once per week, 17% twice per month and 9% once per month). Continuing to propagate this myth despite evidence to the contrary increases stigma and discourages new patients from accessing treatment.

ALTERNATIVE POLICY SOLUTIONS

In your letter you reference the passage of the Mainstreaming Addiction Treatment Act (MAT Act) in 2022 and the success of the recently codified SAMHSA COVID prescribing flexibilities that promise significant improvements in patient flexibility, geographic access and more.

These are both relatively new policy developments. We support conducting studies on the outcomes of these substantial advances before considering the recently introduced "Modernizing Opioid Treatment Access Act" (MOTAA) - proposed legislation to expand the prescribing of methadone outside of the patient centered evidenced based multidisciplinary treatment program found in the licensed and accredited OTP setting.

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[11] SAMHSA believes that evidence underlying the initiation of buprenorphine using telehealth also is applicable to the treatment of OUD with methadone, and warrants expanding access to methadone therapy by applying some of the buprenorphine in-person examination flexibilities to treatment with methadone in OTPs. However, SAMHSA also acknowledges that there are differences between these two medications. Accordingly, this final rule allows for the use of audio-visual telehealth for any new patient who will be treated by the OTP with methadone if a program physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform. SAMHSA is not extending this change to the use of audio-only telehealth platforms in assessing new patients who will be treated by the OTP with methadone because methadone, in comparison to buprenorphine, holds a higher risk profile for sedation in patients presenting with mild somnolence which may be easier to identify through an audio-visual telehealth platform. The final rule is not applicable to, and does not authorize, the prescription of methadone pursuant to a telehealth visit. Instead, this change applies to the ordering of methadone by appropriately licensed OTP practitioners and dispensed to the individual patient by the OTP under existing OTP procedures. SAMHSA/HHS Final Rule **Medications for the Treatment of Opioid Use Disorder** Published February 2, 2024

We would be happy to work to compile needed data to assist with these reports. We know that time is of the essence in terms of finding a solution to the staggering number of overdose deaths daily. Yet, in our opinion, it is a step backward to replace the gold standard of treatment – patient centered evidenced based multidisciplinary treatment program found in the licensed and accredited OTP setting - with an untested and, as of yet, unstudied approach that could lead to diversion, deaths, and create a blemish on methadone treatment which would be shameful, given how long it has taken for methadone in the OTP setting to earn the "gold standard" label.

We take issue with the assumption that passage of MOTAA is the logical next step as a successor bill to the MAT Act passed in 2022. The MAT Act eliminated the X-waiver for buprenorphine which took many years to socialize and pass after years of utilizing the X waiver. On the other hand, MOTAA would legalize a practice that has not yet been used, i.e., the prescribing of methadone by physicians outside of an OTP setting. Not even the recently codified SAMHSA prescribing flexibilities during COVID went that far. Methadone and buprenorphine are very different drugs, as SAMHSA has also concluded. [12]

We also do not yet have enough studies or data from the implementation of the MAT Act to see if this flexibility for buprenorphine is working. Before we jump from eliminating the X waiver for buprenorphine to removing methadone treatment from OTPs – a very large leap in our opinion – we need to study both the impact of the MAT Act and the recently codified SAMHSA flexibilities. This is the next logical policy step.

In our view, more data is needed before such wide-ranging flexibilities should be permitted. What we can say is the data to date show that the widespread adoption of buprenorphine prescribing, and the elimination of the X waiver has not resulted in the promised 30,000 less opioid related deaths. [13] Further, as of April 1,2024, Thomas Prevoznik , deputy assistant administrator for the Drug Enforcement Administration (DEA) lamented at Politico's Illicit Drug Summit that the expected increase in buprenorphine scripts from the elimination of the X-waiver in the MAT Act has not come to pass. [14]

We share your goal in addressing the lack of access to MAT in rural and otherwise underserved areas where "over half of all census tracts do not have an OTP" and "huge areas of the country where the nearest OTP is more than 2 hours away by car" as you point out in your letter. We also believe that greater and safer access to care can be achieved working with OTPs to open more clinics in these markets. The historical challenges to opening a clinic in a rural market could likely be resolved by putting forward policies that make it easier to open an OTP in geographically challenging areas, much like has been accomplished with Critical Access Hospitals (CAHs) and Rural Health Clinics (RHCs). We believe this would lead to a better clinical solution, particularly given how few board-certified addictionologists actually live and reside in the markets where access to care is lacking.

You also may want to consider federal grant funding to co-locate OTPs with Federally Qualified Health

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[12] *See* Footnote 11

[13] https://statnews.com/2023/02/14/x-waiver-buprenorphine-prescribing-gone-spread-the-word/

[14] https://subscriber.politicopro.com/article/2024/04/dea-official-expected-increase-in-buprenorphine-scripts-hasnt-come-to-pass-00150027

Centers (FQHCs) or RHCs that are already serving the same populations that are experiencing challenges with access to OTPs. Co-locating OTPs with these other committed health providers through government grants and regulatory flexibility would likely help solve the access issue without burdening already overworked clinicians in geographically challenging areas with the responsibility to manage MAT for an addicted individual without the needed continuum of resources and support provided by OTPs. This would also address the challenge OTPs have in finding a community that wants to host an OTP.

CONCLUSION

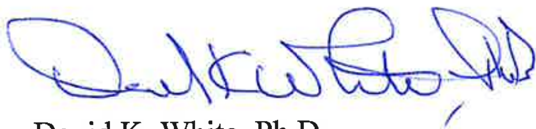
We are passionate about the gains and strides we have made to improve the lives of individuals, families and communities suffering from the devastating impacts of OUD. Our goal at BayMark is to work within the parameters of existing regulations, data and science to improve and advocate for accessible evidenced based care for those struggling with OUD.

We do not want to go backwards to the days when good evidence-based treatments were unavailable. We want to move forward with evidence-based practices that have demonstrated efficacy while also continuing to improve our offerings based on what the science and data support. If we move too quickly, it could lead to unnecessary deaths and unnecessary diversions.

Your letter suggested that the source of our capital could somehow corrupt our commitment to patient care. That suggestion is baseless. In order for a health care provider to succeed in the marketplace, the provider needs to provide great patient care and maintain high clinical standards. Our goal is to be successful in the marketplace for our patients, our staff and the communities we serve. We ultimately share a common commitment and look forward to helping Congress put forth policies that will help those suffering from OUD gain better access to appropriate treatment and care.

Thank you again for the opportunity to engage with you on this critical issue of best practices for treating OUD. We know that together we can work to find a path forward that will improve access and enhance outcomes based on the science and data.

Sincerely,



David K. White, Ph.D.
CEO, BayMark Health

April 12, 2024

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The Honorable Mike Braun
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The Honorable Maggie Hassan
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The Honorable Elizabeth Warren
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The Honorable Donald Norcross
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The Honorable Don Bacon
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Washington, DC 20515

Dear Senators Markey, Braun, Hassan, and Warren and Representatives Norcross and Bacon:

I write in response to your letter dated March 12, 2024 on the Modernizing Opioid Treatment Access Act (MOTAA). I want to start by thanking the members of Congress who authored the March 12th letter, as I think discussion on the current opioid epidemic in this country is critical, even when such discussion involves disagreements on how best to address the epidemic. As you know, Crossroads is a member of the Opioid Treatment Program (OTP) industry group, Advocates for Opioid Addiction Treatment (AOAT), for which I submitted a letter to Congress voicing our industry's clinical concerns with MOTAA, attached as Addendum 1 to this letter.

As I explained in that letter, I recognize that MOTAA is another commendable attempt by Congress to further expand access to OUD treatment in this country. To be clear, I fully support the goal of MOTAA, **which is to reduce barriers to treatment and thus, improve *access* to care**. This too, has been my sole mission since starting Crossroads in 2005. My desire to modify MOTAA in its current proposed state comes from my 20 years of experience in the area of addiction medicine and seeing attempts in the past to reduce certain barriers result in additional lives lost because of inadequate structures to support a very complicated area of medicine.

I would also like to take this opportunity to share the life-saving work that Crossroads has been doing in this country since I opened my first OTP in Greenville, South Carolina in 2005, and share the important role that institutional capital has played in my company's ability to both expand **access** to treatment for opioid use disorder (OUD) and increase the **quality** of OUD care.

Expansion of Access:
Crossroads is a physician-founded and physician-led OUD treatment provider. When I started Crossroads in 2005, I had one OTP in Greenville, South Carolina, with no access to third-party reimbursement or other resources to expand access to treatment beyond a limited geographic region. Assuring *access* for those impacted by OUD is one of the most critical requirements for fighting this devastating disease. Access can be improved in two very important ways: (1) providing physical access to locations that are convenient to a patient population that struggles with transportation, housing insecurity, and childcare and (2) ensuring access is not limited to those with the socio-economic means to afford treatment. As a physician, it was one of the worst feelings imaginable knowing what was needed for the people that were suffering, but not having the resources to expand life-saving care offered by OTPs. It took me 10 years to grow to 9 OTP locations with no institutional capital, and those 9 locations were still geographically limited and without the resources to navigate the complicated process of obtaining third-party insurance contracts. While I had the ability to treat 3,000 patients per month, it felt completely inadequate in the face of an opioid epidemic that was killing hundreds of thousands each year.

In the ten years since gaining access to institutional capital in 2014, I have been able to expand to over 100 locations across 9 states, serving over 25,000 patients each month. We treat some of the hardest hit communities in Georgia, Kentucky, New Jersey, North Carolina, Pennsylvania, South Carolina, Tennessee, Texas, and Virginia. Institutional capital has also allowed me to hire more than 700 employees, including investment in significant corporate resources that enable third-party insurance contracts with Medicare, Medicaid and commercial health plans. This investment has allowed Crossroads to greatly expand access to and improve affordability for patients who are not otherwise able to seek OUD treatment.

Quality:
Crossroads has always modeled its clinical care around the "gold standard" of care for OUD, known as medication-assisted treatment by the U.S. Department of Health and Human Services and U.S. Surgeon General.[1] All clinical decisions continue to be made by myself along with our industry leading Crossroads Medical Operations Team, that includes both medical directors at each OTP in addition to regional and national medical directors. Institutional capital has allowed for continued investment in employing outstanding, passionate providers to serve as the clinical leaders of our organization. Crossroads employs over 500 treatment team members across our 100+ locations that deliver the life-saving treatment to our 25,000+ patients each

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[1] *See* https://addiction.surgeongeneral.gov/sites/default/files/Spotlight-on-Opioids_09192018.pdf at p. 2 (in which the Assistant Secretary for Mental Health and Substance Use refers to MAT, along with psychosocial therapies and community-based recovery supports as being the "gold standard for treating opioid addiction").

month. Our OTPs are all licensed by the Substance Abuse and Mental Health Services Administration (SAMHSA) and maintain the highest level of accreditation from the Commission on Accreditation of Rehabilitation Facilities (CARF) (3-year accreditations), without any history of any suspended, revoked, or denied licenses or registrations. Additionally, we have built out a 40+ member Legal and Compliance Department to ensure our commitment to quality of care and compliance.

In closing, I think it is worth noting that 2024 has already been a historic year with respect to Congressional action taken to address the opioid epidemic, with the passing of the recent SAMHSA 42 CFR Part 8 regulations that represent the most substantial and modernization of OTP treatment standards in over 20 years. The revised Part 8 regulations will greatly expand access to care and improve the patient's experience with OUD treatment. The new Part 8 regulations will allow for increased access to OTP services with the broad expansion of telehealth permissions for both telehealth inductions for methadone patients and buprenorphine patients, and with the expansion of the type of practitioners who are permitted to conduct the intake process at OTPs. The new Part 8 regulations also increased flexibilities for take-home medication privileges and eliminated archaic requirements of a mandatory 1 year of proven addiction to opiates for admission to an OTP. These changes will allow for an easier admissions process and will allow even new patients to be eligible for treatment at home following proper education on safe transport and storage of medications.

While I fully support the goal of MOTAA, and any action that would reduce barriers to treatment and thus, improve access to care, I don't support it in its current form. My opposition to MOTAA is not based on profit motive, since Crossroads would realize increased profits if MOTAA were law, but on patient-safety concerns that would arise if methadone, a Schedule II narcotic, could be prescribed for unsupervised pharmacy pickup. I think some important modifications to MOTAA could protect against this risk and I welcome an opportunity to discuss those modifications in order to ensure MOTAA is a large success for our great country's efforts to fight this most unacceptable opioid epidemic.

Sincerely,

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Rupert McCormac, M.D., Founder and CEO

Addendum 1

Letter Dated December 5, 2023

(See attached)

December 5, 2023

Senator Bob Casey
393 Russell Senate Office Building
Washington, DC 20510

Dear Senator Casey,

Thank you for all you have done in Congress to combat the opioid epidemic. As founder and CEO of Crossroads Treatment Centers, the leading provider of office-based opioid addiction treatment in Pennsylvania, I respectfully ask that you oppose S. 644, the *Modernizing Opioid Treatment Access Act (MOTAA)* when it comes before the HELP Committee next week. I also request that you ask HELP Committee Chairman Bernie Sanders to postpone consideration of S. 644 until the Committee can examine the negative impacts this legislation will have on patients and communities across America. Crossroads has 52 (soon to be 53 with a new location under construction in Pottsville) office-based opioid treatment (OBOT) locations in the state – all of which hold a distinguished Center of Excellence designation. Overall, we treat over 15,000 patients in Pennsylvania and employ hundreds of Pennsylvanians. To be clear, we do not operate a single opioid treatment program (OTP) in the Keystone State.

My company and its addiction treatment practices would likely benefit financially if MOTAA were to become law, as many of our locations would be able to write prescriptions for methadone to new patients. So why do I oppose MOTAA? I oppose this legislation because it is dangerous to allow methadone, a Schedule II narcotic, to be prescribed for unsupervised pharmacy pickup. MOTAA would allow 70, 150, or even 300 methadone pills to be picked up on the first day a patient sees a doctor, depending upon how the policy is implemented. Keep in mind, just a few pills taken early on in treatment could be lethal. Evidence has repeatedly shown that when pharmacies dispense methadone, misuse, diversion, overdose, and deaths increased exponentially. Simply stated, the risks MOTAA would pose to communities across the country are far greater than any perceived benefit of providing access to methadone to the one-in-ten Americans who do not currently have access to an OTP.

Policymakers must put patients and communities ahead of provider profits, as I am doing with my opposition to S. 644. The group that is tirelessly pushing MOTAA argued for years that buprenorphine was a wonder drug that would end the opioid use disorder (OUD) crisis and Congress listened, completely deregulating the prescribing of this Schedule III drug. However, few physicians and clinicians have taken advantage of their new ability to prescribe buprenorphine to an unlimited number of patients. As a result, the group went back to the drawing board - this time urging Congress to pass MOTAA, arguing that methadone is the silver bullet that will end the addiction crisis – perhaps because it would bring new patients and more money into their members' offices. This irresponsible effort ignores that fact that a patient generally cannot overdose from misusing buprenorphine, but can easily die from misusing methadone.

Senator, I again ask that you tell Chairman Sanders and Ranking Member Cassidy to keep MOTAA out of the SUPPORT Act bill. If MOTAA is considered as an amendment during committee markup of the SUPPORT Act reauthorization, I urge you reject it. If this legislation is included in the base bill, I respectfully ask that you offer an amendment to strike the provision. Thank you for your attention to this matter.

Sincerely,

Rupert J. McCormac, IV M.D.
CEO
Crossroads Treatment Centers

April 12, 2024

Senator Ed Markey
255 Dirksen
Washington, DC 20510

Senator Mike Braun
404 Russell
Washington, DC 20510

Senator Maggie Hassan
324 Hart
Washington, DC 20510

Senator Elizabeth Warren
309 Hart
Washington, DC 20510

Representative Donald Norcross
2427 Rayburn
Washington, DC 20515

Representative Don Bacon
2104 Rayburn
Washington, DC 20515

Dear Sens. Markey, Braun, Hassan, Warren and Reps. Norcross and Bacon,

Thank you for your interest in addressing the opioid addiction epidemic. While we may disagree about policies contained in the *Modernizing Opioid Treatment Access Act* (MOTAA), we share the goal of expanding access to safe and affordable treatment for opioid use disorder (OUD). It is my sincere hope that we can work together to find meaningful solutions to address this crisis.

New Season is a leading provider of high-quality, specialized OUD treatment services. The company was established 38 years ago by Dr. Randall Greene, a psychiatrist specializing in addiction medicine who still serves on our Board of Advisors. What began as a single clinic in Orlando, Florida grew to 19 treatment facilities in its first 10 years. Today, New Season operates 87 opioid addiction treatment centers in 20 states, including Indiana, and New Hampshire. Our care teams provide life-saving treatment to 31,500 patients each day, using the latest science to create a comprehensive plan for patients that includes medication, counseling, medical services, and support services.

Our responses to the questions posed in your March 12 letter are in the attached appendix. Though we have addressed each of your questions, I want to take this opportunity to address some of the statements in your letter:

- We deeply care about our patients and want to see them successfully complete their recovery journey. We place the well-being and safety of our patients above all else. That is why, unlike many provider types or businesses, OTPs remained open and fully operational during the COVID-19 public health emergency despite not being eligible for Provider Relief Fund money. That is why, unlike the vast majority of board-certified addiction physicians, we accept Medicaid patients. And that is why we oppose MOTAA. We've learned from our clinical experience that the uncontrolled use of methadone will lead to adverse outcomes including, but not limited to, more overdoses, increased recidivism, and death. There are better solutions to achieve the results you desire, and we remain available to discuss those solutions with you.

- Medication-assisted treatment (MAT) is more than just the administration of medication. The medication helps to stabilize the patient by mitigating withdrawal symptoms and cravings. The actual treatment begins once the patient is stabilized. Specifically, MAT consists of a comprehensive range of medical and rehabilitative services designed to alleviate the adverse medical, psychological and physical effects caused by OUD. This includes the counseling and psychosocial supports that assist the patient address the issues that may cause opioid addiction. Treating OUD using medication alone is <u>not</u> the gold standard of care. As the National Institutes of Health points out, "methadone maintenance coupled with relevant social, medical and psychological services has the highest probability of being the most effective of all treatments for opioid addiction."[1] The medication must be coupled with treatment and services. Simply prescribing medication is insufficient and will not lead to recovery.

- Methadone is, for good reason, the most heavily-regulated of the three medications approved for the treatment of OUD. Methadone is classified as a Schedule II narcotic under the Controlled Substances Act (21 U.S.C. §§ 801 -904), and is the only Scheduled II medication approved to treat OUD. By definition, Schedule II narcotics are drugs that have a high potential for abuse, with use potentially leading to severe psychological or physical dependence. If misused, methadone can be lethal, which explains why OTPs are one of the most heavily regulated healthcare providers in the United States. With this in mind, careful consideration should be given to eliminating a regulatory structure that was carefully constructed over 50 years with patient safety in mind.

- Methadone has not always been considered a "safe" medication. In the early 2000s, it was not uncommon for pain physicians to prescribe methadone to patients for pick up in pharmacies. Not coincidentally, diversion, overdose, and death spiked, resulting in five different federal reports[2] examining the origin of these adverse events.

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[1] "Confronting an Epidemic: The Case for Eliminating Barriers to Medication-Assisted Treatment of Heroin and Opioid Addiction," Legal Action Center, March 2015.

Each report found that methadone dispensed in pharmacies (and not in OTPs) was causing these troubling trends. Not surprisingly, physicians largely stopped prescribing methadone for pain, resulting in the decline of diversion, overdose, and death rates related to methadone prescriptions for pain.

Due to the existence of stringent federal and state laws and robust regulatory oversight, methadone, when administered to patients within the structure of an OTP, is safe and effective. Our staff carefully titrates each patient in accordance with federal guidelines and well-developed treatment protocols. Typically, it takes two to three weeks, with daily evaluations by medical professionals, until a patient achieves an optimal therapeutic-level dose of methadone. This is due to the fact that the medication must slowly build in the patients' body so as to avoid any adverse reactions. The concept of starting patients on low doses, which are rarely effective in achieving relief from withdrawal symptoms, is seeded in the knowledge that therapeutic doses are achieved over time in the vast majority of patients. And while we would agree that there are instances when medication take-home requirements can be relaxed, our physicians would never provide a new patient with more than a few days' supply. OTPs are also the only MAT provider-type required to employ anti-diversion measures and administer toxicology screens. Over 95% of the methadone we dispense is in liquid form, which is much more difficult to misuse and divert than tablets.

OTPs have treatment teams in place to ensure that methadone, as part of a holistic treatment regimen, is used in accordance with longstanding medical protocols safely. Physicians, nurses, physician's assistants, pharmacy technicians, counselors, and caseworkers all work together to implement a care plan uniquely tailored to a patient's needs, then ensure that the plan is followed. Physicians in private practice simply do not have the time or resources to assemble, manage and support such a team, which is one of the primary reasons physicians cite for not prescribing buprenorphine, a Schedule III narcotic and, by definition, a much safer drug.[3] One should not assume that because methadone is safe in the highly-regulated OTP setting that it would be equally safe in another setting, particularly when that setting lacks the resources that OTPs are legally required to have in place.

- Independent research shows that SAMHSA's policy to relax methadone take-home medication regulations during the COVID-19 public health emergency resulted in increased methadone-related overdoses, even under the OTP construct. All

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[2] https://atforum.com/documents/CSAT-MAM_Final_rept.pdf; https://www.justice.gov/archive/ndic/pubs25/25930/index.htm; https://www.atforum.com/pdf/Methadone_Draft_Report_101807_Brief-w-attch.pdf; https://www.gao.gov/assets/gao-09-341.pdf; https://cdn.vox-cdn.com/uploads/chorus_asset/file/19541909/Methadone_Mortality_A_2010_Reassessment.0.pdf

[3] https://www.samhsa.gov/sites/default/files/proceedings_of_2014_buprenorphine_summit_030915_508.pdf

assertions claiming otherwise are simply wrong. In fact, one study found that methadone-related overdoses were 48% higher in 2020 than 2019.[4] Another study found a "steep increase starting in April 2020" of methadone-involved overdose deaths, with the highest death rates found in "Hispanic and non-Hispanic black individuals."[5]

Keep in mind, OTPs, including those operated by New Season, did not apply these take-home flexibilities uniformly. Our physicians quickly realized that some patients, namely those who were stable in treatment, benefitted from the relaxed take-home medication rules. In contrast, patients who were new to treatment or not yet stable in treatment were more likely to be adversely impacted.

- 87% of the U.S. population lives within a 30-mile or 40-minute radius of an OTP, the time and distance standard for behavioral health network adequacy under the *Affordable Care Act*. Some states lack a sufficient number of OTP clinics due to state and local laws and regulations that effectively restrict the establishment of OTPs.

  MOTAA would do very little to expand geographic access to methadone, as physicians who are board certified in addiction medicine overwhelmingly practice in the same communities that are already served by an OTP. Not surprisingly, these physicians find it difficult to build a practice in a rural community. Due, in part, to federal and state regulations (most notably staffing ratios that effectively restrict the number of patients an OTP can treat at any given time), OTPs generally need at least 150 patients to be financially viable. As we know from our experience as a national operation, it can be extremely difficult to find 150 patients in need of MAT services in a rural community.

- Geographic access is just one piece of the puzzle. OTPs need adequate coverage and reimbursement for the services they provide. Unfortunately, the track record for federal health programs paying for MAT with methadone is poor. For years, our clinics were drastically underfunded and short on revenue. Medicaid wasn't required to cover MAT with methadone until October 1, 2020. Similarly, Medicare did not begin covering MAT with methadone until January 1, 2020. Following Medicare's lead, commercial health insurers are just starting to pay for MAT services.

  In response to these deficiencies, private investment stepped in to fill the void and provide OTPs with the financial resources to expand access to treatment via new clinics while improving care quality through investment in existing facilities and staff.

[4] https://www.sciencedirect.com/science/article/pii/S0379073823000294?via%3Dihub
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9674402/

It is worth noting that my colleagues and I formally endorsed the *Extending Access to Addiction Treatment Act (S. 3136)*, which Sen. Hassan introduced to extend coverage for MAT in Medicaid.

- Our payor mix at New Season is 40% Medicaid, 10% Medicare, 20% private insurance, 30% uninsured and self-pay. 85% of our patients are low-income. Our Medicaid reimbursements can be as low as $9.00, while Medicare pays us an average of $260 for a week's worth of treatment (i.e., about $37 per day). OTPs do not provide high-profit, highly-reimbursed services. Our industry is not positioned to negotiate with Medicaid and Medicare for higher reimbursements, which comprise half of our patients. We take what they give us.

- My colleagues and I have met with most of your staffs to discuss solutions designed to expand MAT services to underserved geographic regions. Allowing OTPs to work with community health centers, rural hospitals, and rural clinics to form a "hub and spoke" care delivery model would harness the experience and expertise of the OTPs with the geographic reach of rural providers. Under this model, rural providers would serve as a satellite facility for OTPs and utilize technologies (such as telehealth) to treat patients in rural communities with existing facility staff. Partnering with CHCs alone would bring convenient access to MAT with methadone to 95% of the population. I would welcome the opportunity to work with you to make this vision a reality.

I firmly believe that the new regulatory reforms recently implemented by SAMHSA effective April 2, 2024, will address many of the issues MOTAA seeks to resolve. By expanding the scope of MAT services that can be provided on mobile units and through telehealth, coupled with relaxed take-home medication rules, patients will not need to travel to OTPs as often to receive care. The new mobile unit and telehealth rules will also bring OTP services to areas that do not have brick and mortar facilities. As a result of these positive regulatory changes, New Season has already purchased a new mobile unit, thereby allowing New Season to serve a footprint of an additional 75 miles.

Other policies that Congress could adopt to expand access to MAT with methadone include expanding health insurance coverage in states that have not expanded Medicaid eligibility, providing rural add-on and/or low-volume payments to attract OTPs to rural communities, removing health insurers' ability to use prior authorization and utilization management tools to restrict access to MAT with methadone, and investing in clinical workforce training. I stand ready to work with you and your staff to advance these policies.

In closing, I believe that our interests in expanding access to treatment for OUD are aligned. It is my hope that we can work together to ensure that those in need of MAT

for OUD have access to safe and affordable treatment. I stand ready to work with you and your staff to achieve our shared goals.

Sincerely,

Jim Shaheen
Chief Executive Officer
New Season

APPENDIX

Role of Private Equity

I respectfully disagree with the inference that Private Equity has negatively impacted the OTP landscape. In fact, New Season's ownership group committed significant funds that allowed us to build an experienced and robust compliance department that audits every aspect of our operations to ensure our clinics meet all applicable federal and state laws and regulations, as well as Independent Accreditation standards (CARF). Also, New Season, over the last 28 years, has reinvested profits to build over 65 de novo OTP clinics, thereby enabling us to treat an additional 25,000 patients today.

I can unequivocally state that New Season's ownership group has never inserted itself in clinical practices or medical decision making. Each of our clinics has an independent physician serving as the Medical Director responsible for the care provided in that clinic. We also have a Chief Medical Officer who supports all of our Medical Directors. Finally, New Season has an independent compliance department that ensures our clinical practices follow all federal and state laws and regulations, accrediting body standards, and best practice guidelines.

OTPs are subject to robust and comprehensive regulatory structure. OTPs must receive a certification from an independent, SAMHSA-approved accrediting body and be certified by SAMHSA. OTPs are also subject to requirements from the Department of Justice and Drug Enforcement Administration via the Controlled Substances Act. Regulatory requirements include staffing ratios, frequency around the provision of behavioral health services, random toxicology screens, anti-diversion programs, and medication inventory tracking management programs. OTPs must follow these rules and regulations regardless of ownership structure or tax status.

Patient Outcomes

At New Season, we are very proud of our patient outcomes. Our patients enter treatment in crisis. Our comprehensive care and team-based approach, which involves far more than just dispensing methadone, has proven to significantly increase employment rates, decrease incidences of crime and illicit opioid use, and materially improve our patients' quality of life. Below is a quick snapshot of our patients' outcomes with time in treatment:

Employment - Increasing the workforce and economy within your community.
Crime - Decreasing misconduct and lawlessness in your neighborhood.

	Intake	6-months into treatment	1-Year into treatment	3-Years into treatment
Employment rate	59.2%	75%	77.1%	83.1%
Crime rate	16.7%	4.9%	4.4%	2.2%

The goal of OTP's is full recovery, including the ability to live a self-directed life. This treatment approach has been shown to reduce non-prescribed opioid use.

	Intake	6-months into treatment	1-Year into treatment	3-Years into treatment
Non-Prescribed Opioid Use	87%	37%	30%	13%

A standardized test measuring the severity of addiction across 3 dimensions: Physical/Emotional/loss of control. BARC-10 (Brief Assessment of Recover Capital) is administered at intervals to our patients. The higher the score the higher the chance of long-term recovery (a score of 47 or higher is the goal).

	Intake	90-Days into treatment	6- Months into treatment	1-Year into treatment
BARC-10 Score	35	48	49	52

WESTERN PACIFIC MED CORP
ESTABLISHED 1979

April 11, 2024

The Honorable Edward Markey
255 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Braun
404 Russell Senate Office Building
Washington, DC 20510

The Honorable Maggie Hassan
324 Hart Senate Office Building
Washington, DC 20510

The Honorable Elizabeth Warren
309 Hart Senate Office Building
Washington, DC 20510

The Honorable Donald Norcross
2427 Rayburn House Office Building
Washington, DC 20515

The Honorable Don Bacon
2104 Rayburn House Office Building
Washington, DC 20515

Senators Markey, Braun, Hassan and Warren and Representatives Bacon and Norcross:

I write to you today in response to your inquiry sent March 12, 2024, relating to our corporate structure, and probing its impact on patient care. While I welcome the opportunity to answer your questions, they are wholly unrelated to patient care and protecting crucial access to comprehensive treatment programs. As it appears from your inquiry that you and your staff have not been provided with sufficient information to understand the critical role served by Opioid Treatment Programs (OTPs), I also offer further information with regard to how OTPs, and specifically Western Pacific, are a lifeline for patients and a safe way to provide access to a full Medication-Assisted Treatment (MAT) program, including both the use of methadone as well as counseling and behavioral therapies.

Western Pacific has been providing narcotic treatment services continuously since 1979, and currently operates facilities in Los Angeles, Orange and Ventura counties, in California. As OTPs, we are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), are accredited, licensed by the California Department of Health Care Services, and hold registrations with the Drug Enforcement Administration (DEA). Our mission is to provide evidence-based narcotic treatment services to any eligible person seeking them. These services are provided in a cost effective, high quality, humane, culturally sensitive, and non-discriminatory manner. With our forty-five-year history of providing services and helping to change the lives of patients, I am troubled by the statements included in your letter that accuse profits over our patients' well-being.

4544 Fernando Road, Suite 202, Glendale, CA 91204

Phone (818) 956-3737 Fax (818) 543-6767 www.westpacmed.com

I sponsor eighteen OTPs, of which seven are not for profit, and eleven are for profit. Western Pacific is not related to private equity in any way, and never has been. This is readily available information. Our reimbursement rates are based on our costs as determined by our government regulators, not profit.

With that said, I'd like to take this opportunity to outline why I have concerns with the Modernizing Opioid Treatment Access Act (MOTAA) (H.R. 1359/S.644). As an initial point, your letter fails to acknowledge the historical success that OTPs have had for individuals with opioid substance use disorder and their families. OTPs hold the highest success rate in all forms of treatment, with comprehensive MAT services combining medication with counseling and behavioral therapies. Western Pacific's MAT program addresses all aspects of recovery, recognizing that relieving withdrawal symptoms is just the beginning. Importantly, comprehensive MAT has been shown to be effective in reducing drug use, improving social functioning, and reducing the risk of overdose and other negative health outcomes associated with substance use disorders.

OTPs also provide critical resources to non-substance use disorder lifesaving healthcare management for opioid dependent patients. These healthcare needs may not normally be discovered or addressed without oversight of OTP case management.

As you note, there are a number of federal regulations establishing requirements for entities that provide MAT using methadone, which have ensured safe and monitored prescribing and administration. I remain concerned that allowing physicians outside of this highly regulated setting to prescribe methadone for opioid use disorder could lead to abuse, misuse, and diversion. Each of these resulting negative consequences would have catastrophic impacts on not only this patient population, but the general public, as well. While fentanyl has certainly accelerated the opioid epidemic, it is not responsible for the onset. This is widely acknowledged to result from opioid prescribing practices, with limited oversite.

You note that when waivers were allowed during the COVID-19 pandemic, resulting in more take home doses as opposed to in-person dosing at an OTP, an increase in "methadone-involved overdoses never materialized". This is inaccurate based on what I have experienced and does not fully acknowledge other negative impacts of the policy. Our primary focus during the COVID-19 pandemic was to provide lifesaving treatment, without interruption, which we did accomplish. However, waivers and exceptions provided to OTPs to help with management of the pandemic, were not always successful and, in my experience, the take-home flexibility provided did, in fact, result in abuse, misuse, diversion, and increased risk to public safety.

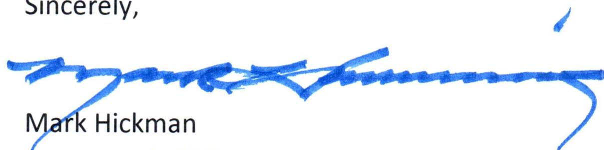
I recognize the concern and have a common interest of providing greater access to MAT services for those who are not close to an OTP, but believe a comprehensive program is necessary over allowing access to methadone alone.

I am not simply voicing my concerns over this legislation to limit treatment to on-site locations, but rather emphasizing the long-term, evidence-based benefits that a comprehensive program can offer patients that gives them the tools to manage their addiction throughout their lives. At Western Pacific, our patients are central to our mission and are the focus of the care we deliver and our advocacy on this issue.

With so many special interests at play here, patients and evidence-based, comprehensive care, must remain the focus of the Congress. Hasty solutions should not be sought that could result in significant harm or risk to the public, including those suffering from substance use disorders.

Please feel free to contact me with any further questions.

Sincerely,



Mark Hickman
President & CEO

mark@westpacmed.com