



March 6, 2020

Bradley Gilbert, MD, MPP
 Director
 California Department of Health Care Services
 1500 Capitol Avenue
 Sacramento, CA 95814

RE: ODS Waiver Revision Proposal (CaAIM Behavioral Health Payment Reform Workgroup Comments)

Dear Director Gilbert:

We, the undersigned organizations, would like to express our concern related to recent statements and documents presented at a California Advancing and Innovating Medi-Cal (CaAIM) workgroup regarding medication assisted treatment (MAT). We understand that the California Department of Health Care Services (DHCS) is not requiring counties to provide all forms of FDA-approved MAT in the ODS waiver revision. The proposal discussed in the February 26, 2020 workgroup meeting states that counties may offer additional MAT, which under the current terms and conditions refers to injectable naltrexone.

We do not believe that this proposal is consistent with patient care or the concept of “no wrong door” for patients seeking substance use disorder (SUD) treatment services.

In the CaAIM proposal published on October 28, 2019, DHCS stated the following:

“DHCS aims to design a cohesive plan to address beneficiaries’ substance use disorder treatment needs across the continuum of care, ensure that all Medi-Cal beneficiaries receive coordinated services, and to promote long-term recovery. This requires developing new approaches to care delivery and system administration that will improve the beneficiary experience, increase efficiency, ensure cost-effectiveness, and achieve positive health outcomes.”

Under the current terms and conditions of the Drug Medi-Cal Organized Delivery System (DMC-ODS), counties are required to cover opioid treatment including methadone and buprenorphine programs. Currently, counties may elect to cover “additional medication assisted treatment” including the ordering, prescribing, administering, and monitoring of injectable naltrexone.

DHCS proposes keeping the “additional medication assisted treatment” services as an optional benefit but clarifies the coverage provisions to require that all SUD managed care providers demonstrate that they either directly offer, or have referral mechanisms to, medication assisted treatment. The goal is to have a county-wide multi-delivery system of coverage.

While it has been acknowledged that numerous organizations provided input stating all three FDA-approved medications should be included in parity and that there should not be an additional opt-in for medications outside of methadone and buprenorphine, DHCS reiterated its intent to only require two of the three FDA-approved medications for the treatment of opioid use disorder (OUD).

Since the current 1115 waiver was approved in 2015, the medical community and federal agencies have come to agreement that all three FDA-approved medications for the treatment of OUD are effective, underutilized, and should be available to patients in all settings of care. The FDA and the National Institute on Drug Abuse (NIDA) have also continued to distinguish the indications of oral naltrexone (the blockade of the effects of exogenously administered opioids)¹ and long acting injectable naltrexone (the prevention of relapse to opioid dependence following opioid detoxification)². Only extended-release injectable naltrexone is approved for treatment of people with OUD and on November 1, 2019, CMS SUPPORT Act Final Rule stated “the naltrexone drug product that is FDA approved for the treatment of opioid dependence is an extended-release, intramuscular injection. The naltrexone payment category refers only to this product.”³

FDA notes:

*All three of medications- methadone, buprenorphine, and long acting injectable naltrexone- have demonstrated to be safe and effective in combination with counseling and psychosocial support and that those seeking treatment for an OUD should be offered access to all three options as this allows providers to work with patients to select the medication best suited to the individual’s needs.*⁴

The Substance Abuse and Mental Health Services Administration’s (SAMHSA) *TIP 63: Medications for Opioid Use Disorder* publication states:

*Methadone, extended release injectable naltrexone (XR-NTX) and buprenorphine were each found to be more effective in reducing illicit opioid use than no medication in randomized clinical trials, which are the gold standard for establishing efficacy in clinical medicine.*⁵

*Improving access to treatment with OUD medications is crucial to closing the wide gap between treatment need and treatment availability, given the strong evidence of effectiveness for such treatments.*⁶

¹ <https://www.ncbi.nlm.nih.gov/books/NBK535266/>

² <https://www.ncbi.nlm.nih.gov/pubmed/29400929>

³ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24086.pdf> See page 237

⁴ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24086.pdf> See page 196

⁵ <https://www.cffutures.org/files/fdc/SAMHSA%20TIP%2063%20-%20Medication%20OUD%20-%202018.pdf>

⁶ See note 5, p. ES-3.

The National Academy of Sciences released its consensus study report *Medication Assisted Treatment Saves Lives* which came to the following conclusions:

FDA-approved medications to treat opioid use disorder- methadone, buprenorphine, and extended release naltrexone- are effective and save lives. The most appropriate medication varies by individual and may change over time. To stem the opioid crisis, it is critical for all FDA-approved options to be available for all people with opioid use disorder.

Available evidence suggests that medication-based treatment for opioid use disorder is highly effective across all subgroups of the population, including adolescents and older persons; pregnant women; individuals with co-occurring disorders (e.g., psychiatric, substance use disorders, infectious diseases); and all racial, sex and gender, and socioeconomic groups.

Medication-based treatment is effective across all treatment settings studied to date. Withholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment.

Confronting the major barriers to the use of medications to treat opioid use disorder is critical to addressing the opioid crisis.

The major barriers to the use of medications for opioid use disorder include the fragmented system of care for people with opioid use disorder and current financing and payment policies.⁷

The National Institute of Drug Abuse states:

Effective medications exist to treat opioid use disorder: methadone, buprenorphine, and naltrexone. These medications could help many people recover from opioid use disorder, but they remain highly underutilized.⁸

Likewise, the Surgeon General's Report, entitled *Facing Addiction in America*, also states:

Well-supported scientific evidence shows that medications can be effective in treating serious substance use disorders, but they are under-used. The U.S. Food and Drug Administration (FDA) has approved three medications to treat alcohol use disorders and three others to treat opioid use disorders. However, an insufficient number of existing treatment programs or practicing physicians offer these medications...Key components of care are medications, behavioral therapies, and recovery support services.⁹

On November 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis Final Report made specific recommendations¹⁰:

The Commission recommends HHS/CMS, the Indian Health Service (/HS), Tricare, the DEA, and the VA remove reimbursement and policy barriers to SUD treatment, including those, such as patient limits, that limit access to any forms of FDA-approved medication-

⁷ National Academy of Sciences "Medication Assisted Treatment Saves Lives" [nationalacademies.org/OUTreatment](https://www.nationalacademies.org/OUTreatment)

⁸ <https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview>

⁹ U.S. Department of Health and Human Services, Office of the Surgeon General. (Nov. 2016) *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*. Washington, DC: HHS, p.4-2, Available at: <https://addiction.surgeongeneral.gov/surgeon-generals-report.pdf>.

¹⁰ [President's Commission on Combating Drug Addiction and the Opioid Crisis](#), Office of National Drug Control Policy, Executive Office of the President. (Nov. 1, 2017). *Final Report*, p. 8.

*assisted treatment (MAT), counseling, inpatient/ residential treatment, and other treatment modalities, particularly fail-first protocols and frequent prior authorizations.*¹¹

*The Commission recommended several steps to increase the use of and access to all forms of SUD treatment, including MAT [medication assisted treatment] for SUDs [substance use disorders]*¹²

*Access to MAT (e.g., methadone, buprenorphine/naloxone, naltrexone). Choice of medication should be made by a qualified professional in consultation with patient, and based on clinical assessment.*¹³

Given the overwhelming evidence that all three FDA-approved medications for the treatment of OUD are supported by the medical community and federal agencies, we believe that California should rely on the clinical expertise of these entities and follow recommendations to open access to all FDA-approved medications.

We ask that you reconsider your proposal to have separate opt-ins for counties for the different medications and recommend that a single policy should cover all three FDA-approved medications at parity.

Thank you,

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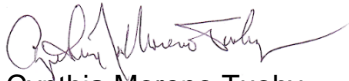

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¹¹ President's Commission on Combating Drug Addiction and the Opioid Crisis, Office of National Drug Control Policy, Executive Office of the President. (Nov. 1, 2017). *Final Report*, p. 8. Available at:

https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

¹² Id. At p. 60 [.pdf pagination]

¹³ Id. At p. 61 [.pdf pagination]



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