

**Treatment to Reduce the Burden of Disease and
Deaths from Opioid Use Disorder**

**J. Clark Kelso, Receiver
October 11, 2018**

After many months of study and deliberation, I have decided to direct my staff to plan for the implementation of a comprehensive substance use disorder treatment program, including the use of Medication Assisted Treatment (MAT), to reduce the substantial number of patients within CDCR who have substance and/or opioid use disorders (OUD). A high level paper authored by Dr. Renee Kanan, *Substance-Use Disorder Treatment for Patients in the California Department of Corrections and Rehabilitation – An Evidence-Based Clinical Approach* (reproduced below in Appendix A), describes the need for a radically different and expanded approach to substance use disorder treatment within CDCR. This new approach is also supported by a report drafted by the three court experts in the *Plata* litigation (reproduced below in Appendix B).

Detailed planning will occur over the next four to six months with the expectation of presenting the initial plan to the Administration and Legislature in time for possible inclusion in the 2019-2020 budget.

The *Analysis of 2016 Inmate Death Reviews in the California Correctional Healthcare System* (Oct. 8, 2017) (authored by Dr. Kent Imai, MD), documents a reduction during the Receivership in the rate of deaths from many of the serious chronic conditions that afflict patients within the prisons and are amenable to medical treatment. For example, there have been reductions in the death rates related to cardiovascular disease (p. 29), preventable cancers (p. 30), coccidioidomycosis related deaths (p. 33), and perhaps from chronic Hepatitis C (p. 19), although it is too early to tell definitively whether the recent reductions in Hep C related deaths actually represents a sustainable trend.

Notwithstanding these efforts and improvements, the death rate from drug overdoses – most of which relate to abuse of opioids – has actually *increased* over the last decade, and the death rate from drug overdoses in California’s prisons is *three times higher* than in all U.S. state prisons (p. 31-32). Dr. Imai’s report explains as follows:

“It should be recognized that this problem mirrors what is known to be happening in American society. The so-called opioid epidemic has resulted in similar increases in opioid use, abuse, addiction, and death by overdose. The Center for Disease Control (CDC) reported in January 2016, that drug overdose death rates had more than doubled from 2000 to 2014, from 6.2 to 14.7/100,000. The CCHCS has experienced a similar rise

in drug overdose death rates over the past eleven years, with rates ranging from a low of 5.3/100,000 in 2007 to a high of 22.5/100,000 in 2016. The national concern triggered by this problem has produced a campaign to educate the public about the dangers of addiction and overdose which accompany narcotic prescriptions for chronic non-cancer pain, and to educate prescribing physicians about safer opioid prescribing practices and encouraging the use of buprenorphine and naloxone to make opioid narcotic use less prone to death by overdose.” (p. 32).

Early on in the Receivership – and long before the issue had received national attention – CCHCS recognized that its patients were being prescribed opioids for pain relief in circumstances where other treatment options not involving opioids had become available. In 2009, CCHCS issued new guidelines for pain management to reduce the reliance upon opioids and to try to ensure that prescribed drugs were not being diverted to barter or sell to other inmates. However, CCHCS did not take further actions to identify patients with opioid abuse disorder – i.e., a chronic addiction to opioids – or to offer treatment to patients with this condition. As noted by Dr. Imai, the rate of overdose deaths from opioid abuse has increased since that time.

In 2016, at the urging of Senator Jim Beall, CDCR’s mental health program began a small, three-year pilot project to create, develop and implement a Medication Assisted Treatment (MAT) program at one or more institutions. As explained in the *Medication Assisted Treatment for Substance Use Disorders 2nd Report to the Legislature* (March 2018), “MAT is the use of medications, in combination with counseling and behavioral therapies, to provide a ‘whole-patient’ approach to the treatment of substance use disorders [citation omitted]. Research shows that a combination of medication and psychosocial treatment improves outcomes over psychosocial treatment alone [citations omitted]” (p. 1). According to this report, one hundred eighty-nine inmates were referred to the MAT program, and sixty were ultimately placed on medications (mostly naltrexone). Preliminary results include a reduction in the rate of rules violations given to MAT participants after receiving medication, a decrease in the need for participants to receive higher levels of medical and mental health care after receiving medications, and no reports of positive toxicology screens for alcohol or opioids for inmates who have started medication.

In October 2017, the Court Experts submitted a report to the Receiver which reviewed the death rates within CDCR, noting the high death rate from overdoses compared with other prison systems, and the national literature and current treatment practices for substance use disorder. The Court Experts recommended, among other things, implementation of a systemwide MAT program for patients with substance use disorder. A slightly edited and updated version of that report appears in Appendix B.

In January 2018, the American Correctional Association and the American Society of Addiction Medicine issued a *Joint Public Correctional Policy on the Treatment of Opioid Use Disorders*

for Justice Involved Individuals. This policy statement urges that “[p]harmacotherapy, behavioral health treatment, and support service should be considered for all individuals with OUD that are involved in the justice system,” and it contains specific recommendations for screening/prevention, treatment, reentry and community supervision considerations, and education.

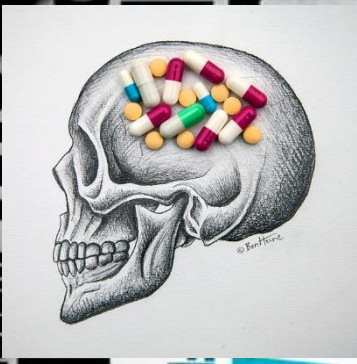
Finally, in August 2018, Dr. Renee Kanan authored a high level paper, *Substance-Use Disorder Treatment for Patients in the California Department of Corrections and Rehabilitation – An Evidence-Based Clinical Approach* (reproduced below in Appendix A), which describes the need for a radically different and expanded approach to substance use disorder treatment within CDCR.

Based on all of the above, it is clear that CDCR and CCHCS should begin planning for an expanded drug treatment program that focuses upon:

- (1) reducing opioid overdose deaths within CDCR;
- (2) improving continuity of treatment for inmates coming into and leaving CDCR; and,
- (3) developing a system wide SUDT program, based in the chronic disease management and complete care programs, including MAT, with an ultimate goal of providing treatment for all patients in CDCR with chronic OUD who wish to participate in the program.

Appendix A.

Substance-Use Disorder Treatment for Patients in the California Department of Corrections and Rehabilitation



Substance-Use Disorder Treatment for Patients in the California Department of Corrections and Rehabilitation

An Evidence-Based Clinical Approach

California Correctional Health Care Services
Medical Services Division
Renee Kanan, MD, MPH, Deputy Director



BACKGROUND

General Information about Substance Use Disorder and its Treatment

Substance-use disorders (SUD) affect people from all strata of society, with nearly 10 percent of the United States (U.S.) population estimated to have a SUD.^{1,2} SUD is a primary driver of the current opioid epidemic which has claimed record numbers of overdose related deaths each year totaling over 72,000 drug overdose deaths in 2017.³

Beside fatal and non-fatal overdoses, SUD is associated with lost work productivity, motor vehicle and gun-related accidents, child abuse and neglect, crime, permanent disability and premature death. SUD not only impacts afflicted individuals but takes a heavy toll on families and communities, and burdens health care, child welfare and criminal justice systems.⁴

In the last decade, advances in genetics, molecular biology, behavioral neuro-pharmacology, and brain imaging offer insights into understanding SUD as a chronic brain disorder. Similar to other chronic diseases, such as hypertension and diabetes, SUD results from a combination of biological, genetic, and environmental factors. However, rather than affecting the circulatory or endocrine system, SUD affects areas of the brain involved in reward, motivation, and memory, and leads to characteristic changes in mood, affect and behaviors.^{5,6}

The underlying brain disorder associated with substance-use is dopamine dysregulation, which causes the afflicted individuals to irrationally pursue reward and/or relief through continued substance use.^{7,8} SUD is characterized by predictable behavioral manifestations including impaired control of drug use, social impairment involving interactions and relationships with others, persistent drug use despite risk of life threatening harms and a dysfunctional emotional response. Similar to other chronic diseases, SUD involves cycles of relapse and remission. Without treatment or engagement in recovery activities, SUD is progressive and can be fatal.⁹

However, like other chronic diseases, SUD can be treated, usually involving long-term medical and/or behavior modification treatments, and treatment efficacy is similar to treatments for other chronic diseases. Specifically, research studies show that compared to placebo, treatment with medications is two times more effective with response rates ranging between approximately 20-60%.¹⁰ And, Medication Assisted Treatment (MAT) is associated with increased retention in treatment programs, reductions in illicit opiate-use, decreased craving, and improved social functioning.^{11,12,13,14,15} MAT decreases transmission of infectious diseases such as hepatitis C by reducing risky injection drug use.¹⁶ There is also evidence from large trials and quantitative reviews that support efficacy of behavioral therapy for SUD.¹⁷ Providing access to both behavior and medication therapies for SUD, while individuals are incarcerated, and then linking them to community resources upon release, has been shown to reduce recidivism and overdose risk and increase function such as maintaining employment.^{18,19,20}

There are three U.S. Food and Drug Administration-approved medications used to treat opiate addiction: Buprenorphine, Methadone (most commonly used agents), and Naltrexone (less commonly prescribed for treatment of opiate addiction). The regulatory structure that governs treatment of opiate addiction with methadone in the U.S. differs significantly from that governing treatment with buprenorphine (or naltrexone) in office-based practice.

This difference in the regulatory management of methadone and buprenorphine significantly affects the cost of treatment, the characteristics of the patient population that uses each of the medications, and the ability to substitute treatment with methadone for treatment with buprenorphine for some patients.

Use of methadone to treat opiate addiction may be provided only in a clinic certified under the auspices of the Substance Abuse and Mental Health Services Administration. Other federal agencies (such as the Drug Enforcement Administration (DEA) and State Methadone Authorities) also regulate clinics that provide opiate addiction treatment with methadone. Patients must attend these clinics daily for at least the first 90 days of treatment. Then, patients who have complied with treatment may be permitted to have up to two days of take-home drugs. After successfully completing a year of continuous treatment and maintaining stable health, a patient may be given up to a two-week supply of take-home medication. Methadone clinics can also administer buprenorphine under the same conditions.

In contrast to methadone, buprenorphine can be prescribed in an office-based setting by qualified physicians. Under these circumstances, buprenorphine is regulated more like other prescription opiate medications. Under federal regulations, physicians who prescribe buprenorphine must have a DEA number, and they must complete appropriate training, and possess a buprenorphine waiver from the Center for Substance Abuse Treatment (CSAT). Individual physicians who have CSAT waivers may treat a maximum of 30 patients in the first year and increase to a maximum of 100 patients with buprenorphine at any time if at least one year has elapsed since the physician submitted their initial request for a buprenorphine waiver. Physicians who have prescribed buprenorphine to 100 patients for at least one year can then apply to increase their patient limits to 275 under new federal regulations.

Because there are differences in regulations governing the use of buprenorphine and methadone, and other influences on availability of methadone clinics (few rural areas have the potential patient population necessary to support a methadone clinic), and the manner in which these two agents are dispensed, methadone and buprenorphine are not perfect substitutes for one another. Patient preference is another significant factor in the choice of medications for treatment of opiate addiction. Patients who are successfully treated with buprenorphine may refuse treatment with methadone and vice versa. Patients who are reluctant or unable to travel daily to a methadone clinic may choose buprenorphine treatment. Comparison of cost effectiveness of buprenorphine versus methadone must be done with the caveat that the two medications aren't interchangeable; they differ clinically; and may not be universally available.

Naltrexone, best studied as a treatment for alcohol-use disorder, has also shown modest benefit in treating opioid-use disorder (OUD) but does not have the track record that methadone and buprenorphine have in the treatment of OUD. However naltrexone has benefits over methadone and buprenorphine in that it is not a restricted medication. The main concerns regarding its use are hepatic toxicity.

Different formulations have evolved for each medication which has particular implication to an incarcerated population. For example, the long-acting injectable form of Naltrexone can be given once each month and results in better compliance than the oral formulation. Buprenorphine also comes in various formulations: sublingual formulation in both tablets and films; the tablets contain either a combination of buprenorphine and naloxone or just buprenorphine. Generally naloxone is included in this product to discourage the injection misuse of the medication, thus the combination product is recommended in the treatment of OUD except in pregnant patients (where exposure should be limited to naloxone), or in patients with a confirmed allergy to naloxone. Buccal film and implant formulations are also available. Implants are placed in the medial arm and replaced at six month intervals. The FDA recently approved a once-monthly injectable formulation of buprenorphine for the treatment of OUD.

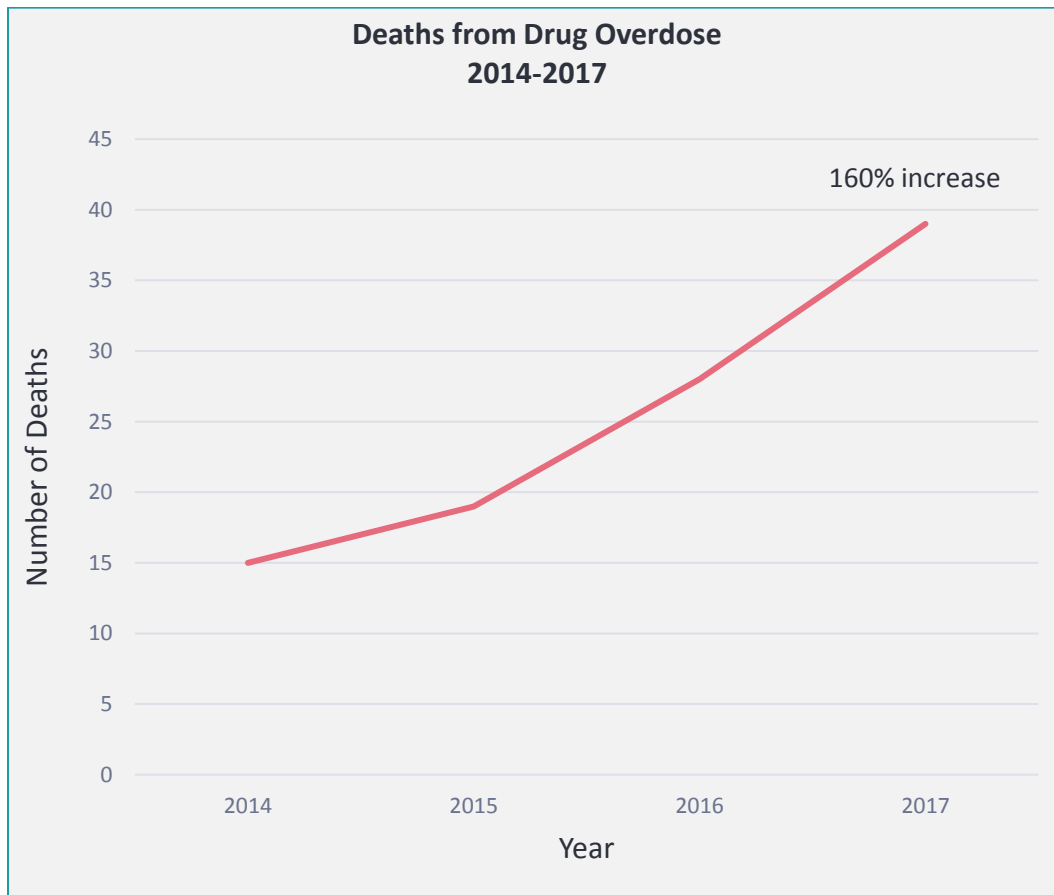
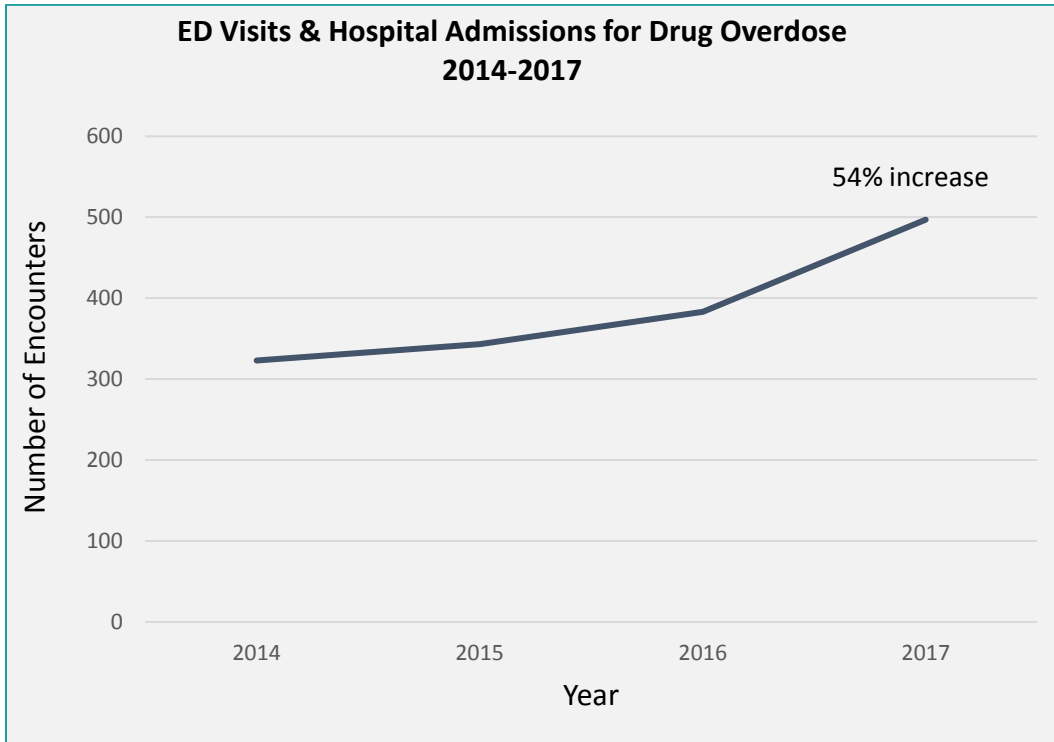
Methadone is only available as oral formulations, either liquid or solid (tablet or disk) for the treatment of OUD. Injectable methadone is available but not approved for treatment of OUD and is used only for patients unable to take oral medication such as hospitalized patients. All state Medicaid programs cover at least one MAT medication, and most cover all three.²¹

Substance-use Disorder and its Treatment in CDCR

Although currently there are not official validated data regarding the prevalence of SUD or specific subtypes of SUD (i.e. opioid, alcohol, methamphetamine, etc.) in CDCR, it has been estimated that the prevalence of SUD among the CDCR population is approximately 80 percent or 100,000 patients and it is estimated that at least 26 percent of these individuals with SUD, or about 26,000 patients, have an opiate use disorder.

Similar to trends in the U.S. and California, the number of fatal and non-fatal drug overdoses in CDCR related mostly to opiates has significantly increased. Between 2014 and 2017, CDCR experienced a 54% increase in Emergency Department transports and hospitalizations related to drug overdoses and a 160% increase in overdose deaths (see the graphs below).

Substance-Use Disorder Treatment



Within CDCR, the Division of Rehabilitative Programs (DRP) offers behavioral therapies at all 35 institutions through several different independent contractors with a budget of \$149,000,000 in fiscal year 2016-17.²² Although most of the behavioral therapy services delivered by the contractors are based on models that have been shown to be efficacious in specific groups of patients if implemented as intended, the actual fidelity and effectiveness of these treatments within CDCR is unknown. In addition, the current SUD treatment model used by DRP is not based on the chronic care model. Instead treatment duration is only five months and current available treatment capacity is less than 12,000 individuals per year.²³

Other limitations of the current SUD treatment model include - 1) Eligibility for treatment is not based on the patient's clinical need or risk for harm; 2) MAT is not available to the vast majority of patients who could benefit; and 3) Continuum of services and levels of care are not currently available in CDCR that are available in other healthcare delivery systems such as the Veteran's Health Administration and Kaiser, which include but is not limited to, withdrawal management, and inpatient, residential, intensive outpatient and aftercare programs. Because of the reasons noted above, the current SUD treatment model is likely not as cost-effective as other treatment models, and may be putting some patients at heightened risk for harm including death during incarceration and when they return to their communities because of reduced opioid tolerance.

PROPOSAL TO ESTABLISH A CLINICALLY ORIENTED SUBSTANCE-USE DISORDER TREATMENT PROGRAM

In light of the paradigm shift in understanding SUD as a chronic illness, CCHCS/CDCR is proposing establishment of a comprehensive and integrated Substance Use Disorder Treatment Program that can be conceptualized as three "Phases" staggered in implementation - 1) Transitioning the prescribing of MAT from addiction specialists to primary care providers and delivering ongoing evidence-based behavior therapy facilitated by social workers to individual patients and groups, which supplements current behavioral therapies offered through the DRP *at the three MAT test sites*; 2) Expanding MAT, which is prescribed by primary care providers to appropriate patients with opiate use disorder and behavior therapy facilitated by *nursing* staff and social workers *at all 35 institutions*; and, 3) Creating a continuum of care model within Healthcare Services that begins at entry with systematic screening and assessment, diagnosis, triage, referrals, and treatments and services delivered at the appropriate level of care along with discharge planning and linkages to community resources upon release, which is coordinated with other programs.

The remainder of the proposal focuses on Phase 1, which can be implemented without a Budget Change Proposal (BCP) and Phase 2, which will require a BCP. Details for Phase 3 are forthcoming after further discussions with stakeholders and decision makers across multiple program areas.

PHASE 1: MEDICATION ASSISTED TREATMENT AND BEHAVIORAL THERAPY WITHIN THE COMPLETE CARE MODEL AT THREE TEST SITES

Phase 1 of the SUD Treatment Program, which can begin without new funding involves identifying patients undergoing treatment for HCV at the three test sites (California Institute for Women and California Institute for Men, followed by the Substance Abuse Treatment Facility in November) who also may be appropriate for MAT. Patients identified as good candidates for MAT will be prescribed naltrexone or buprenorphine by an addiction medicine physician who is an internist or family medicine physician rather than a psychiatrist. Once a patient on MAT is stabilized, the addiction physician will *transition prescribing of MAT to the primary care provider* who is already assigned the patient as part of their panel. After the initial wave of patients who were started on MAT by an addiction specialist are completed, it is expected that primary care providers will be confident and competent to initiate MAT on their own for most patients without involving an addiction specialist. Patients identified with a SUD also will be referred for *behavior therapy provided* through DRP and/or by trained *social workers* in health care services who are civil service employees. As part of preparing for release, patients will be connected to community resources to continue MAT and behavior therapy as well as other clinical and social services.

PHASE 2: STATEWIDE EXPANSION OF MEDICATION ASSISTED TREATMENT AND BEHAVIORAL THERAPY WITHIN THE COMPLETE CARE MODEL

Phase 2 involves statewide expansion of MAT prescribed by primary care providers for patients with OUD, which will require a Budget Change Proposal with estimated *annual ongoing medication cost between approximately \$190M and \$252M for primarily injectable versions of buprenorphine or naltrexone* prescribed to approximately 13,000 patients with OUD each year.

Estimates for the number of patients who will receive MAT were derived using U.S. Department of Justice estimates of opiate-use among state prisoners which indicate 26 percent of state prisoners actively use opioids ($0.26 \times 126,000$ inmates in CDCR = 32,760 patients who have an OUD). Of the 32,760 patients with an OUD, it is estimated that 40% are appropriate for and agree to receive MAT known as “uptake” ($0.40 \times 32,760 = 13,104$ patients on MAT).

The BCP will also include funding for nursing and social worker positions at all 35 institutions (estimated at 183 positions if the SATF model is used), diagnostic testing, equipment, American Society of Addiction Medicine (ASAM) assessment training, and Self-Management and Recovery Training (SMART) psychosocial intervention training and curriculum.

SUMMARY AND RECOMMENDATION

SUD is a complex chronic health condition involving dopamine dysregulation in the brain that controls reward and motivation and can lead to uncontrollable cravings, continued substance use and other aberrant behaviors, which contributes to permanent disability, premature death, and other adverse consequences for afflicted individuals, and for families and communities. In recent years, OUD is the primary SUD associated with alarming increases in fatal and non-fatal overdose nationally and in California and CDCR.

There are effective treatments for OUD that involve long-term combination therapy with medications and behavior interventions best delivered in an integrated healthcare setting using interdisciplinary teams who take care of their patients through the continuum of care.

Given that SUD is a chronic illness and there are effective clinical treatments, it is recommended that the SUD treatment program and patients with SUD be managed by Health Care Services and integrated within the Complete Care Model including leveraging primary care teams who are mainly civil service staff and making MAT and behavior therapy available system-wide to those patients who require treatment, which continues after they are released.

This organizational structure will provide greater opportunity to ensure fidelity, effectiveness and efficiency in the delivery of clinical treatments, which in turn allows better cost control, and promotes positive outcomes including decreases in relapse, fatal and non-fatal overdoses, aberrant behaviors within the prison setting and recidivism. Although it's recommended that the SUD treatment program be managed within Health Care Services, the entire organization will need be involved with SUD treatment in order for it to be successful.

¹ Florence CS, Zhou C, Luo F, Xu L. (2013). The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, *Med Care*. 2016;54(10):901-906. doi:10.1097/MLR.0000000000000625. <https://www.ncbi.nlm.nih.gov/pubmed/27623005>

² SAMHSA (2014). National Survey on Drug Use and Health <https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>

³ CDC/NCHS, (2017). National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA: US Department of Health and Human Services, CDC. <https://wonder.cdc.gov>.

⁴ U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) https://www.samhsa.gov/sites/default/files/partnersforrecovery/docs/Briefing_Substance_Use_Treatment.pdf

⁵ ASAM Definition of Addiction <https://www.asam.org/resources/definition-of-addiction>

⁶ Chandler RK, Fletcher (2009). Treating drug abuse and addiction in the criminal justice system: improving public health and safety; 301(2):183-90. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2681083/>

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¹⁰ Connery, H.S. (2015). Medication-assisted treatment of opioid use disorder: review of the evidence and future directions. *Harvard Rev Psychiatry*, 23(2), 63-75. Doi: 10.1097/HRP.0000000000000075. <https://pdfs.semanticscholar.org/959c/e3caf1fe3bed9da973bc8a1530a9ead497b1.pdf>

¹¹ Bart, G. (2012). Maintenance Medication for Opiate Addiction: The Foundation of Recovery. *Journal of Addictive Diseases*, 31(3), 207-225. Doi: 10.1080/10550887.2012.694598. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3411273/>

¹² RP Mattick et al. *Cochrane Database of Systematic Reviews* (2014). <https://www.ncbi.nlm.nih.gov/pubmed/24500948>

¹³ Krupitsky, E., Nunes, E.V., Ling, W., Illeperuma, A., Gastfriend, D.R., Silverman, B.L. (2011). Injectable extended-release naltrexone for opioid dependence: a double-blind, placebo-controlled, multicenter randomized trial. *Lancet*, 377(9776), 1506-1513. Doi: 10.1016/S0140-6736 (11) 60358-9. <https://www.ncbi.nlm.nih.gov/pubmed/21529928/>

¹⁴ Robert P. Schwartz et al., "Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009," *American Journal of Public Health* 103, no. 5 (2013): 917–22, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670653>. *Currently, there are no randomized double-blind controlled trials comparing all three medications (methadone, buprenorphine and extended release injectable naltrexone). However, 24-week retention rates were 84 percent for methadone, 59 percent for buprenorphine, and 21 percent for naltrexone.

¹⁵ Sandra D. Comer et al., "Injectable, Sustained-Release Naltrexone for the Treatment of Opioid Dependence: A Randomized, Placebo-Controlled Trial," *JAMA Psychiatry* 63, no. 2 (2006): 210–8, <http://archpsyc.jamanetwork.com/article.aspx?articleid=209312>

¹⁶ Judith I. Tsui et al., (2014). Association of Opioid Agonist Therapy With Lower Incidence of Hepatitis C Virus Infection in Young Adult Injection Drug Users, *JAMA Internal Medicine* 174, no. 12 1974–81, <http://archinte.jamanetwork.com/article.aspx?articleid=1918926>

¹⁷ Dutra L, Stathopoulou G, Basden SL, Leyro TM, Powers MB, Otto MW *Am J Psychiatry*. (2008). A meta-analytic review of psychosocial interventions for substance use disorders. Feb; 165(2):179-87. <https://www.ncbi.nlm.nih.gov/pubmed/18198270/>

¹⁸ Richard P. Mattick et al., (2009). Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence, *Cochrane Database of Systematic Reviews* 3: CD002209, <http://www.ncbi.nlm.nih.gov/pubmed/19588333>;

¹⁹ Robert P. Schwartz et al., (2013). Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009," *American Journal of Public Health* 103, no. 5: 917–22, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670653>.

²⁰ Christopher M. Jones et al., (2015). National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment, *American Journal of Public Health* 105, no. 8: e55–63, <https://www.ncbi.nlm.nih.gov/pubmed/26066931>.

²¹ Medicaid Coverage of Medication Assisted Treatment (MAT): A 50-state overview. (2017). MAT Medication-Assisted Treatment. Retrieved from <http://www.ncsl.org>.

²² Pew Results First Clearinghouse

²³ 22

Appendix B.

Report on Drug Treatment in CDCR

Report on Drug Treatment in CDCR

Mike Puisis DO, Joe Goldenson MD, Madie LaMarre MN, FNP-BC; August 10, 2018

The CCHCS Analysis of 2016 Inmate Death Reviews notes that while there has been a reduction in preventable deaths from cardiovascular disease, non-liver cancers, and cocci, “there has been a continued rise in the incidence of drug overdose deaths.¹ Over the past decade, deaths related to drug use (which includes deaths from end-stage liver disease, hepatocellular carcinoma, overdose deaths and endocarditis) have been the number 1 or 2 causes of death in the CDCR.

The CDCR death rate from overdose per 100,000 in 2015 was slightly lower than the US civilian drug overdose death rate in the USA (14.7 vs. 16.3 per 100,000).² However, the death rate from all drug overdoses in CDCR in 2015 (14.7 / 100,000) was 32% higher than the civilian overdose death rate in California (11.3 / 100,000). With respect to state correctional systems, from 2001-2014, the California state prison system had 32% of all overdose deaths in state and federal prison systems in the country.³ Yet, in 2014, California had only approximately 8.7% of state and federal prison inmates⁴. Bureau of Justice Statistics⁵ describe that the average overdose death rate from 2001-2014 in state prisons nationwide is 3 per 100,000. CDCR describes⁶ that the average overdose death rate in California prisons from 2006 to 2016 was 12.1 per 100,000, four times as large as the average overdose death rate for state prisoners nationwide over a similar time period.⁷ Incarceration therefore exposes California state prisoners to a higher risk of death from overdose than either California civilians or United States state prison inmates nationwide.

The latest CCHCS Death Review Analysis in 2016 states that liver disease in the 3rd leading cause of death and drug overdose is the 5th leading cause of death. Combined these 2 causes of death are the 2nd leading cause of death and are mostly caused by injection drug use. Additional deaths from endocarditis and infections due to injection drug use would further increase the mortality from injection drug use. From a public health perspective, these causes of death are potentially preventable. Given the increased risk of death of California state prisoners a response to this excess mortality from potentially preventable causes is required.

¹ Kent Imai, Analysis of 2015 Inmate Death Reviews in the California Correctional Healthcare System, p. 31 (Oct. 8, 2017).

² Hedegaard, H; Warner M; Minino A; Drug Overdose Deaths in the United States, 1999-2015: NCHS Data Brief No. 273 (Feb. 2017) for US data; Kent Imai, Analysis of 2015 Inmate Death Reviews in the California Correctional Healthcare System, Table 16 (Sept. 20, 2016) for CDCR data.

³ Margaret Noonan, Mortality in State Prisons, 2001-2014 – Statistical Tables, Table 13 (US Department of Justice, Dec. 2016), NCJ 250150 as found at <https://www.bjs.gov/content/pub/pdf/msp0114st.pdf>.

⁴ E. Ann Carson and Elizabeth Anderson; Prisoners in 2015: US Department of Justice Bureau of Justice Statistics; December 2016, NCJ 250229

⁵ Mortality in State Prisons, 2001-2014 – Statistical Tables, Margaret Noonan BJS statistician; US Department of Justice; December 2016, NCJ 250150 as found at <https://www.bjs.gov/content/pub/pdf/msp0114st.pdf>

⁶ Kent Imai, Analysis of 2016 Inmate Death Reviews in the California Correctional Healthcare System, Table 17 (Oct. 8, 2017).

⁷ Please note that the comparison is for 2001-2014 for BJS data and from 2006-2016 for CDCR rates. This is because this is the only data available. We believe the data is comparable enough to make this point.

The current standard of care⁸ in the community for opiate addiction treatment includes:

- Access to naloxone for the addicted person to prevent overdose.
- Access to medication substitution therapy with methadone, buprenorphine, and naltrexone as medication-assisted therapies. Best results are obtained with medication therapy and behavioral therapy combined.
- In-patient and out-patient treatment for addiction.
- Needle exchange programs to reduce potential for transmission of infectious diseases (hepatitis A, B, and C and HIV) during injecting drug use.

The efforts by CCHCS and CDCR do not meet these community standards.

In 2008, concerned about the large number of opiates being prescribed by CCHCS providers, CCHCS issued a Care Guide for Pain Management which was intended, among other things, to ensure that opiate prescriptions were based upon actual patient need to manage pain and to reduce the number of opiates that were being diverted through barter or sale to other inmates. Implementation of this care guide has resulted in a significant reduction in the number of opiate prescriptions issued by CCHCS providers. While it is appropriate to prescribe opiates based only on medical necessity, the reduction in opiate prescriptions has clearly not stopped illicit drug use or overdose deaths. Reducing opiate prescriptions without treating drug addiction is, in effect, an abstinence-based therapeutic approach which promotes further illicit drug use.

Aside from attempts to reduce unnecessary opiate prescriptions, there are two other CCHCS efforts to combat the opioid epidemic. The first of two efforts is the expanded use of naloxone in the event of overdose. Specifically, in addition to registered nurses, licensed vocational nurses (LVNs) and psychiatric technicians (PTs) can now administer naloxone for suspected overdose victims. Since LVNs and PTs are often first medical responders, this has the potential to reduce overdose mortality. However, providing naloxone directly to injecting opioid users is the community standard in California and has been shown to reduce opioid overdose deaths.⁹ Since prevention of opioid overdose death is time dependent, it is recognized as important to allow opioid users to have access to naloxone in addition to implementing first provider use. Use of intranasal naloxone delivery devices eliminates the need for needles. California regulations allow pharmacists to dispense naloxone to anyone without a prescription amounting to over-the-counter medication.¹⁰ This gives addicts direct access to life saving medication for personal use from a pharmacy without a prescription. Custody staff should also have access to naloxone for use in the event of a suspected overdose. Police officers in many jurisdictions use naloxone to

⁸ Based on what is available to a Medicaid population.

⁹ Sarz Maxwell, Dan Bigg, Karen Stanczykiewicz, Suzanne Carlberg-Racich; Prescribing Naloxone to Actively Injecting Heroin Users: A Program to Reduce Heroin Overdose Deaths; *Journal of Addictive Diseases*, Vol. 25(3) 2006.

¹⁰ Lisa Girion, Antidote for opioid overdoses now available without a prescription. *LA Times* online April 17, 2015.

prevent overdose deaths. Inmates in CDCR should have the same access to naloxone as civilians in California.

The second effort by CCHCS includes a small pilot program at a single facility (CIM) to establish a medication assisted treatment (MAT) program. This small pilot is limited to inmates with a history of overdose and with an expectation of being released in two years. This program also uses only naltrexone and does not include methadone and buprenorphine, the more commonly used and more effective medications. Restriction to those who have a history of overdose also significantly reduces the numbers of persons involved in this program. These efforts could be significantly expanded.

With respect to MAT programs, methadone, buprenorphine, and naltrexone are 3 types of available medications used to treat opiate addiction in California communities. Opioid disorders have been likened to chronic illnesses and long term monitoring is indicated.¹¹ Yet treatment of addiction is not part of the chronic care program in CDCR. Use of maintenance methadone or buprenorphine and use of naltrexone for detoxified persons should be used for appropriate individuals. Use of medications should be combined with psychosocial treatment.

Naltrexone is an opioid antagonist unlike methadone and buprenorphine which are opioid agonists.¹² Naltrexone is the only drug offered in CDCR and it is offered only in a pilot program for persons about to be discharged to the community. Naltrexone is thought to be beneficial for persons who are already de-toxified to prevent relapse, in persons who are highly motivated to stop using drugs and have relapse risk, and in persons with short or less severe addiction and who must demonstrate abstinence.¹³ Although the use of naltrexone in this pilot program is appropriate, it is only a pilot study.

There is more experience in the use of methadone and buprenorphine in treatment of opiate disorder. Retention in methadone and buprenorphine treatment was associated with a significant reduction in overall mortality and in fatal overdoses.¹⁴ Methadone with counseling while incarcerated has been shown to result in less illicit drug use and reduce recidivism after release from prison.¹⁵ The lack of availability of methadone and buprenorphine within CDCR, despite ongoing widespread drug use, contrasts with the standard of care provided to the civilian population. Medicaid in all 50 states reimburses for methadone and buprenorphine use.

¹¹ Treatment of Opioid-Use Disorders, Mark Schuckit; New England Journal of Medicine July 28, 2016;375:357-368

¹² These opioid agonists are opioid like drugs that are regulated as narcotics by the FDA. Opioid agonists are not regulated and can be prescribed as any other prescription medication by any provider.

¹³ Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide: Substance Abuse and Mental Health Services Administration (SAMHSA); February 2, 2015

¹⁴ Luis Sordo, Gregorio Barrio, Maria Bravo, Iciar Indave, Lucas Wiessing, Marica Ferri, Roberto Pastor-Barriuso; Morality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies; British Medical Journal April 26, 2017

¹⁵ Timothy Kinlock, Michael Gordon, Robert Schwartz, and Kevin O'Grady; A Study of Methadone Maintenance for Male Prisoners; Criminal Justice and Behavior, 2008: 35(1): 34-47.

MAT is underutilized in the US civilian populations but is even more underutilized in prisoners. MAT substitution based therapy is provided to only 34% of the US addicted population¹⁶ but only 0.4% of the incarcerated population. According to a US Department of Justice report using data from 2007-2009, 0.4% of state prisoners who met drug dependence criteria received maintenance drug therapy and only 28.5 % received any drug treatment.¹⁷ No inmates in CDCR receive maintenance drug therapy despite its known benefits and despite widespread drug use in CDCR.

Drug interdiction efforts in CDCR have not been successful to date based on overdose death rates within CDCR. A recent study showed that drug use within CDCR is about as high as use in the civilian population.¹⁸ Drug treatment programs within CDCR have not been successful to date. These programs have been hampered by lack of involvement of medical and mental health clinical staff and by failure to use medical assisted therapies. It is our opinion that as a result of availability of illegal drugs and less effective drug treatment, overdose deaths continue to rise.

We recommend the following steps in an attempt to reduce the excessive morbidity and mortality due to injection drug use within CDCR, reduce morbidity and mortality from hepatitis C, and to bring therapy of drug addiction and hepatitis C in line with community standards.

- Make naloxone available to injection drug users in CDCR for their personal use as permitted by regulation in the state of California. This can be provided by using nasal naloxone to avoid the need to use needles.
- Train custody staff in the use of naloxone for use in the event of a suspected overdose.
- Consider how to reasonably integrate medical substitution therapy (methadone, buprenorphine, and naltrexone) as clinically appropriate into chronic disease management for all willing injecting drug users in combination with cognitive behavioral therapy programs consistent with services provided by Medi-Cal for Medicaid recipients.
- Review the effectiveness of substance abuse therapy programs in CDCR with respect to the current excessive overdose deaths and consider improvements including medical substitution therapy.
- Dissociate drug abuse therapy from punitive custodial practice and place medical substitution therapy and substance abuse treatment under medical and mental health supervision.

¹⁶ Nora Volkow, Thomas Frieden, Pamela Hyde, Stephen Cha; Perspective- Medication Assisted Therapies- Tackling the Opioid Overdose Epidemic; New England Journal of Medicine April 23 1014

¹⁷ Jennifer Bronson, Jessica Stroop, Stephanie Zimmer, Marcus Berzofsky: Drug Use, Dependence, and Abuse Among State Prisoners and Jail Inmates, 2007-2009, Special Report. US Department of Justice, Bureau of Justice Statistics NCJ 250546, June 2017.

¹⁸ Steven Raphael, Magnus Lofstrom, Brandon Martin; The Effects of California's Enhanced Drug and Contraband Interdiction Program on Drug Abuse and Inmate Misconduct in California Prisons; Goldman School of Public Policy, University of California Berkeley, April 29, 2017 as found at https://www.cdcr.ca.gov/Reports/docs/External-Reports/Effects-Drug-Contraband-Interdiction-Report_April-29-2017.pdf

- Provide naloxone and ensure referral for substitution therapy and drug therapy as indicated for all known opiate-addicted inmates about to be discharged from CDCR to prevent mortality.
- Consider providing clean needles to injecting drug users in CDCR as promoted by the California Department of Health for civilians with injecting drug use habits.
- CDCR should intensify drug interdiction strategies at all prisons, prioritizing prisons with the highest rates of drug overdose.