FINDING OF EMERGENCY

This regulatory action adopts and amends the following sections under Title 22, California Code of Regulations (CCR): 51000, 51000.7, 51000.9.5, 51000.15.5, 51000.20, 51000.24.3, 51000.24.4, 51000.24.4.1, 51000.24.5, 51000.24.8, 51000.30, 51000.31, 51000.35, 51000.40, 51000.45, 51000.60, 51000.70, 51000.75, 51051, and 51341.1. This regulatory action will revise definitions and enrollment requirements related to the Drug Medi-Cal (DMC) program; and amend related enrollment criteria under the Medi-Cal program. This regulatory action is necessary to enhance the fiscal integrity of the DMC program by curtailing and preventing provider fraud and abuse and this action will also enhance provider accountability and the Department of Health Care Services' (Department's) ability to enforce these requirements. These regulations must be adopted as an emergency and will provide for the official regulatory publication of these enrollment requirements.

Welfare and Institutions Code (WIC) Section 14043.75, subdivision (a), provides as follows:

> The director may, in consultation with interested parties, by regulation, adopt, readopt, repeal, or amend additional measures to prevent or curtail fraud and abuse. Regulations adopted, readopted, repealed, or amended pursuant to this section shall be deemed emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). These emergency regulations shall be deemed necessary for the immediate preservation of the public peace, health and safety, or general welfare. Emergency regulations adopted, amended, or repealed pursuant to this section shall be exempt from review by the Office of Administrative Law. The emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and publication in the California Code of Regulations.

The deeming of the regulations as an emergency by the Legislature implies the need for immediate action to effectuate the statutes being implemented through this action.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The California Department of Health Care Services' (Department) mission is to provide Californians with access to affordable high-quality health care, including medical, dental, mental health, substance use treatment services, and long-term care. In support of this mission, the Department administers and oversees many health care programs, including the recently absorbed Drug Medi-Cal (DMC) program.

The DMC program directs statewide prevention and treatment programs that address the use and abuse of alcohol and other drugs (AOD). Its core function is to provide medically necessary substance use disorder treatment services to Medi-Cal eligible beneficiaries. Substance use disorder treatment services include outpatient drug-free group and

individual counseling, residential services for pregnant and postpartum women, and medication services for opiate addicted beneficiaries.

Statement of Purpose and Rationale Being Addressed

Assembly Bill (AB) 106 (Chapter 32, Statutes of 2011) transferred California's DMC program from the Department of Alcohol and Drug Programs (ADP) to the Department effective July 1, 2012. The transfer of the DMC program from ADP to the Department was part of a consolidation effort.

In addition, AB 75 (Committee on Budget, Chapter 22, Statutes of 2013) approved the transfer of the remaining substance use disorder ADP programs and staff to the Department and the Department of Public Health effective July 1, 2013. Since that time, the Department has worked diligently to address fraud, waste, and abuse in the DMC program and has been taking sustainable steps toward resolving fraud-related issues affecting the DMC program. In July 2013, the Department began performing field reviews of DMC providers suspected of committing fraud and abuse. See Department news release entitled, "DHCS Tightens Oversight of Drug Medi-Cal Centers," July 18, 2013, available at: http://www.dhcs.ca.gov/formsandpubs/publications/opa/Documents/2013/13-07DHCS-DMC7-18-13.pdf.

As a continuation of the Department's internal Business Process Reengineering efforts that began in early 2012, to ensure a smooth transition of the DMC program to the Department, the Department's Audits and Investigations (A&I) Division worked collaboratively with management and staff to perform a "top-to-bottom" assessment and "gap analysis" of the DMC program. Based on the review conducted, A&I prepared a report entitled, "Drug Medi-Cal Program Limited Scope Review," November 2013, that outlines programmatic issues in the DMC program, available at: http://www.dhcs.ca.gov/dataandstats/reports/Documents/DMCLtdScopeRvw.pdf.

"Gaps" were defined as internal control weaknesses, inefficient or ineffective business practices and lack of sufficient statutory or regulatory authority to meet performance expectations to ensure DMC program integrity and effectively mitigate financial or legal risks to the Department. The assessment was completed on November 18, 2013, and includes 33 recommendations to effectively address and remediate all identified gaps and weaknesses in the DMC program. "Implementation Plan for Drug Medi-Cal Program Limited Scope Review," is available at: http://www.dhcs.ca.gov/dataandstats/reports/Documents/ImpPlanforAuditRecom.pdf.

Furthermore, the Department initiated a continued certification review of all actively billing DMC providers to ensure current providers continue to meet DMC program requirements. As part of the continued certification effort, a total of 1,063 informational letters were mailed to active DMC billers informing them of the need to be recertified. To date, the Department has decertified 238 locations due to lack of response in complying with the continued certification review.

As of May 20, 2014, 275 providers, totaling 547 individual sites, have been visited for review. As a result of these investigations, 73 providers (about 27 percent of total providers visited) have been suspended due to a credible allegation of fraud. All of these cases have been referred to the State Department of Justice for criminal investigation and prosecution where warranted.

AB 106 transferred the administration of the DMC program to the Department, whose goal is to utilize existing Provider Enrollment statutes and regulations, Welfare and Institutions Code (WIC) Sections 14043 through 14045 and Title 22, California Code of Regulations (CCR), Division 3, used to regulate fee-for-service (FFS) Medi-Cal providers, and apply them to all DMC applicants and providers. This will better ensure public safety, DMC program integrity, as well as protect public funds, and reduce the risk of fraud and abuse in the DMC program.

In an effort to meet this goal, the Department is updating existing regulations used to regulate the FFS Medi-Cal program to accommodate the needs of the DMC provider type, including added enrollment criteria for DMC applicants and providers. The Department's existing enrollment authority, outlined in WIC Sections 14043 through 14045, also includes the ability to take action if noncompliance is recognized. Actions include:

- The ability to bar providers from program participation for failure to disclose required information;
- The ability to deny and deactivate for noncompliance, or failure to remediate deficient applications; and
- The ability to establish enrollment criteria through provider bulletin.

The Department's existing regulations and statutes also ensure provider integrity and accountability by requiring that DMC providers meet minimum application requirements and provide evidence of an established place of business. Such application requirements include:

- A complete provider agreement;
- Verifications such as general liability insurance, workers compensation insurance, and a business license;
- Notarization of the representative's signature on the DMC application; and
- A complete and accurate disclosure statement listing all owners and managing employees.

Regulation amendments and adoptions are methods and criteria for identifying fraud, waste, and abuse as required pursuant to Title 42, Code of Federal Regulations, Section 455.13(a). These regulations amend and establish new enrollment criteria and will serve as a means for the Department to verify that providers are practicing lawfully and maintaining high standards of care. Therefore, businesses practicing in accordance with State and local laws and ordinances will not be impacted adversely.

This emergency regulatory action is authorized by and implements WIC Section 14043.75. The purpose of Section 14043.75 is to authorize the Department to take steps to prevent

and curtail provider fraud and abuse through the adoption of regulations. The Department anticipates that the proposed regulatory amendments will enhance the fiscal integrity of the DMC program by curtailing and preventing provider fraud and abuse. More specifically, the amendments will enhance provider accountability and the Department's ability to enforce the requirements.

This regulatory action is also authorized by WIC Section 14124.26 and implements WIC Section 14124.24. The purpose of WIC Section 14124.24(a) and (b) is for the Department to administer delivery of the specified substance use disorder services to beneficiaries. The Department anticipates the regulatory amendments will clarify provider obligations, which should make it easier for providers to comply with DMC program requirements. In addition, the amendments will improve the effectiveness of some treatments and enhance physician oversight.

Anticipated Benefits or Goals of the Regulations

This regulatory action will address the matter of updating and expanding the rules for enrollment in the DMC program, and put in regulation the enrollment forms that have already been adopted by the Department through provider bulletin. This proposal will directly benefit DMC providers and beneficiaries through the provision of current DMC program standards, which in turn will facilitate the delivery of these vital services. Additionally, establishing these standards and rules in regulations will accomplish the following:

- Assist in preventing fraud, waste, and abuse;
- Improve access to alcohol and drug treatment services for beneficiaries, including a focus on recovery and rehabilitative services;
- Improve access to high-quality care;
- Safeguard public funds;
- Increase openness and transparency in business and government; and
- Protect the health, welfare, and safety of California residents.

These regulations not only meet the goals of the authorizing statutes, as specified above, but the regulations ensure the proper and efficient administration of the Medi-Cal program, in accordance with the federal and state laws that govern the DMC program's rules of participation and funding. Additionally, the regulations set out enrollment criteria and will serve as a means for the Department to verify that providers are practicing lawfully and maintaining high standards of care.

Stakeholder Involvement in Preparation of the Regulations

The Department acknowledges the importance of education and outreach and has committed to engage in stakeholder meetings to introduce these regulatory changes to the affected providers. In mid-January 2015, the Department invited the DMC and FFS Medi-Cal community to the first in a series of stakeholder meetings. The invitation included the proposed amended regulation text and proposed applications, and encouraged participant feedback. On January 27, 2015, the Department held a stakeholder meeting to review the proposed amendments as well as existing authorities that govern the FFS Medi-Cal program. The goal of this initial stakeholder engagement and opportunity to comment was to introduce DMC providers to the enrollment requirements already in place for FFS Medi-Cal providers and to address how the implementation of these regulations is intended to increase DMC program integrity and create continuity in the application process across all provider types. There was an opportunity for stakeholders to present comments to the Department following this stakeholder meeting. The Department took the limited comments received under consideration while finalizing this regulatory action.

Consistency and Compatibility with Existing State Regulations

The Department has conducted an evaluation of the related existing state regulations under Title 22, CCR, Division 3 and Title 9, CCR, Division 4 and has determined that the regulations are consistent with and compatible with those regulations. An automated search of Title 22, CCR, Division 3 and Title 9, CCR, Division 4 using the following keywords “Drug Medi-Cal Substance Use Disorder Services, Day Care Habilitative Services, Narcotic Treatment Program, and Postservice Postpayment Utilization Review” was conducted via Westlaw and yielded no conflicting state regulations.

Regulatory Sections

The changes to Title 22, CCR include the adoption or amendment of the following Sections: 51000, 51000.7, 51000.9.5, 51000.15.5, 51000.20, 51000.24.3, 51000.24.4, 51000.24.4.1, 51000.24.5, 51000.24.8, 51000.30, 51000.31, 51000.35, 51000.40, 51000.45, 51000.60, 51000.70, 51000.75, 51051, and 51341.1.

This emergency regulatory action specifically accomplishes the following:

- Adds substance use disorder medical director and physicians determining medical necessity to the definition of agent.
- Clarifies that the definition of enrolled or enrollment in the Medi-Cal program must have the same meaning as Drug Medi-Cal certification for substance use disorder clinics.
- Defines licensed substance use disorder treatment professional.
- Defines perinatal residential substance use disorder services program.
- Clarifies, for substance use disorder clinics that provider number means national provider identifier (NPI) number.
- Defines a substance use disorder clinic.
- Defines a substance use disorder medical director.
- Defines a substance use disorder nonphysician medical practitioner.
- Defines a substance use disorder treatment professional.

- Defines substance use disorder treatment services.
- Adopts and incorporates by reference the “Drug Medi-Cal Substance Use Disorder Clinic Application,” DHCS 6001 (Rev. 12/14), “Drug Medi-Cal Provider Agreement,” DHCS 6009 (Rev. 12/14) and the “Drug Medi-Cal Substance Use Disorder Medical Director/Licensed Substance Use Disorder Treatment Professional/Substance Use Disorder Nonphysician Medical Practitioner Application/Agreement/Disclosure Statement,” DHCS 6010 (Rev. 12/14) forms.
- Amends forms currently incorporated by reference including the: “Medi-Cal Disclosure Statement,” DHCS 6207 (Rev. 2/15), the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) and the “Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers,” DHCS 6216 (Rev. 2/15) forms.
- Adds the “Drug Medi-Cal Substance Use Disorder Clinic Application,” DHCS 6001 (Rev. 12/14) and the “Drug Medi-Cal Substance Use Disorder Medical Director/Licensed Substance Use Disorder Treatment Professional/Substance Use Disorder Nonphysician Medical Practitioner Application/Agreement/ Disclosure Statement,” DHCS 6010 (Rev. 12/14) to the application/enrollment criteria.
- Adds the requirement for the substance use disorder medical director, licensed substance use disorder treatment professional, and substance use disorder nonphysician medical practitioner to disclose mandatory information on the “Drug Medi-Cal Substance Use Disorder Medical Director/Licensed Substance Use Disorder Treatment Professional/Substance Use Disorder Nonphysician Medical Practitioner Application/Agreement/Disclosure Statement,” DHCS 6010 (Rev. 12/14).
- Specifies when a substance use disorder clinic must use the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form.
- Requires the substance use disorder clinic to submit the “Drug Medi-Cal Provider Agreement,” DHCS 6009 (Rev. 12/14) or the “Drug Medi-Cal Substance Use Disorder Medical Director/Licensed Substance Use Disorder Treatment Professional/Substance Use Disorder Nonphysician Medical Practitioner Application/Agreement/Disclosure Statement,” DHCS 6010 (Rev. 12/14) if the applicant or provider is a substance use disorder medical director, licensed substance use disorder treatment professional, or substance use disorder nonphysician medical practitioner.
- Adds exemptions for substance use disorder clinics that will not be able to meet all established place of business requirements due to the nature of services they provide.
- Establishes DMC program requirements and duties specific to the substance use disorder medical director.
- Establishes program requirements specific to licensed substance use disorder treatment professionals and substance use disorder nonphysician medical practitioners.
- Adds substance use disorder clinics, substance use disorder medical directors, licensed substance use disorder treatment professionals, and substance use disorder nonphysician medical practitioners to the definition of provider.

- Sets forth in regulation the currently existing versions of the provider enrollment forms that were previously amended by the Department through Provider Bulletin pursuant to WIC Section 14043.75. As noted on the forms, the updated forms are applicable to the DMC program as well as other Medi-Cal programs as specified.

AUTHORITY:
Section 20, Health and Safety Code; and Sections 10725, 14015, 14021, 14021.3, 14021.30, 14021.5, 14021.51,14021.6, 14043.37, 14043.4, 14043.45, 14043.47(c), 14043.75, 14100.1, 14124.1, 14124.24, 14124.26 and 14124.5, Welfare and Institutions Code; Section 700, Insurance Code; Statutes of 2011, Chapter 32, and Statutes of 2012, Chapter 36.

REFERENCE:
Section 1206, Business and Professions Code; Section 1250(k), Health and Safety Code; Sections 14021, 14021.3, 14021.5, 14021.6, 14021.33, 14021.51, 14043, 14043.1, 14043.15, 14043.2, 14043.25, 14043.26, 14043.27, 14043.29, 14043.36, 14043.37, 14043.4, 14043.45, 14043.6, 14043.62, 14043.65, 14043.7, 14043.75, 14053, 14100.1, 14105, 14105.3, 14107, 14107.11, 14115.6, 14123.25(a), 14124.1, 14124.2, 14124.20, 14124.21, 14124.24, 14124.25, 14124.26, 14124.5, 14125.8, 14131, 14132, 14132.21, 14132.39, 14132.4, 14132.44, 14132.905, 14133, 14133.1, and 14134.5, Welfare and Institutions Code; 42, U.S.C., Sections 1320a-3, 1320a-7, 1396a(a)(38), and 1396b(i)(2); 42, Code of Federal Regulations, Parts 431 and 455; Title 45, Code of Federal Regulations, Sections 162.408 and 162.412; Section 33, Chapter 456, Statutes of 1990; Title 42 United States Code, Section 263a; Sections 436.122, 456.21, 456.22 and 456.23, Title 42, Code of Federal Regulations; Statutes of 1996, Chapter 162, Items 4200-101-0001 and 4200-102-0001; and Statutes of 2011, Chapter 32, and Statutes of 2012, Chapter 36.

FISCAL IMPACT STATEMENT:

A. Costs to any Local Agency or School District that is not reimbursable by the State: None

   Costs to any Local Agency or School District that is required to be reimbursed Under Part 7 (commencing with Section 17500), Division 4 of the Government Code: None

B. Costs or Savings to any State Agency: Fiscal impact in FY 2015-16 of $675,000 one-time.

C. Costs or Savings in Federal Funding to the State: Fiscal impact in FY 2015-16 of $725,000 one-time.

D. Other Nondiscretionary Costs or Savings Including Revenue Changes Imposed on State or Local Governments: None.

Cost Impacts on a Representative Private Person or Business:

This regulatory action will impact providers who choose to participate in the Medi-Cal program including the Drug Medi-Cal program. See below "Impact on Jobs and Businesses" for discussion related to potential cost impact for some providers.

DETERMINATIONS

LOCAL MANDATE DETERMINATION
The Department has determined that the regulations would not impose a mandate on local agencies or school districts nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500), Division 4 of the Government Code. County participation in the DMC program is voluntary, and not all counties offer DMC services.

ECONOMIC IMPACT ANALYSIS/ASSESSMENT
The Department has made an initial determination that the regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The Department has determined that the regulations would not significantly affect the following:

- The creation or elimination of jobs within the State of California.
- The creation of new businesses or the elimination of existing businesses within the State of California.
- The expansion of businesses currently doing business within the State of California.

Impact on Jobs and Businesses
This regulatory action will impact providers who choose to participate in the Medi-Cal program, including the DMC providers who offer substance use disorder services to beneficiaries.

The Department has made an initial determination that the requirements related to the DMC provider application process, as specified in this regulatory action, may impose additional costs ranging from approximately $542 - $2000 per provider, per year dependent on the provider type. Substance use disorder clinics that do not qualify for an exemption, will incur an estimated $542 application fee. The application fee is collected to offset the Department's costs of conducting the required screening as specified in Title 42 CFR 455 Subpart E. Please reference the Medi-Cal Regulatory Provider Bulletin, "Medi-Cal Application Fee Requirements for Compliance with 42 Code of Federal Regulations Section 455.460," for further information. Substance use disorder medical directors, substance use disorder nonphysician medical practitioners, and licensed substance use disorder treatment professionals, who are now required to apply for enrollment, may incur an estimated cost of $2000 to obtain and provide proof of Professional Liability Insurance.

These potential additional fees are considered to be a negligible cost of doing business and being a certified provider under the DMC program. For the substance disorder clinics, this nominal cost will be offset by the clinic's opportunity to be enrolled in the DMC program and provide services to an expanded beneficiary population, for which the clinic will receive reimbursement. Therefore, these costs are not anticipated to have a significant impact on the creation or elimination of jobs, the creation of new businesses, the elimination of existing businesses or the expansion of businesses in California.

These regulations support the provision of appropriate and high quality health care services for beneficiaries, as provided by providers who are in compliance with local, county, state, and federal requirements. The regulations may have an economic impact on applicants and providers who are found to be out of compliance with current federal regulations, and state and local laws and ordinances regarding business licensing and operations. However, the Department has determined that the regulations will offset any potential and negligible economic impacts by protecting public funds and supporting the development of highly qualified Medi-Cal providers rendering valued services to beneficiaries.

In addition, the regulations will eliminate existing unlawful or potentially fraudulent providers by excluding them from participation in the Medi-Cal program for fraud, waste, abuse, failure to meet program requirements, or failure to disclose required information.

Benefits of the Proposed Regulation

The Department has determined that the regulations would not specifically affect worker safety or the state's environment. However, the regulations will benefit the health and welfare of California residents by maintaining the continuity of the Medi-Cal program through the provision of quality health care services (including DMC program services) to beneficiaries. These regulations will also ensure public safety, Medi-Cal and DMC program integrity, as well as protect public funds, and reduce fraud and abuse under the Medi-Cal program.

EFFECT ON SMALL BUSINESSES

The Department has determined that the regulations would only affect small businesses that choose to provide services under the Medi-Cal program, including those that provide substance use disorder services to beneficiaries.

HOUSING COSTS DETERMINATION

The Department has made the determination that the regulations would have no impact on housing costs.