State of California—Health and Human Services Agency
Department of Health Care Services

TOBY DOUGLAS
Director

EDMUND G. BROWN JR.
Governor

NOTICE OF RULEMAKING AFTER EMERGENCY ADOPTION

SUBJECT: Drug Medi-Cal Program Integrity, DHCS-14-006E

NOTICE IS HEREBY GIVEN that the Department of Health Care Services (Department) has adopted the regulations in California Code of Regulations (CCR), Title 22, Division 3, Subdivision 1, Chapter 3, Article 4, Section 51341.1 on an emergency basis. These emergency regulations became effective on June 25, 2014, and will remain in effect for a period of 180 days. The purpose of this rulemaking is to adopt the emergency regulations on a permanent basis.

PUBLIC HEARING

The Department will conduct a public hearing, during which time any interested person or his or her duly authorized representative may present statements or arguments relevant to the regulatory action described in this notice. The hearing will be held as follows:

Date: September 5, 2014
Time: 10:00 am
Location: Auditorium, East End Complex (Building 172)
1500 Capitol Avenue
Sacramento, CA 95814

Attendees wishing to speak at the public hearing will be heard on a first-come, first-serve basis. Speakers may be limited to ten minutes or less, depending on the number of attendees requesting to speak. The hearing will close after all attendees present and wishing to speak have provided their testimony or at 5:00 p.m., whichever comes first. Comments will not be discussed or debated by the Department, nor will speakers be cross-examined. A certified court reporter will be present to record the proceedings. Written comments may be submitted for the record at the public hearing.

WRITTEN COMMENT PERIOD

Any interested person or his or her duly authorized representative may submit written comments to the Department relevant to the regulatory action described in this notice.

Please label any comments as pertaining to Drug Medi-Cal Program Integrity, DHCS-14-006E and submit using any of the following methods:

Mail Delivery:	Department of Health Care Services Office of Regulations, MS 0015 P.O. Box 997413 Sacramento, CA 95899-7413
Hand Delivery:	Department of Health Care Services Office of Regulations 1501 Capitol Avenue, Suite 5084 Sacramento, CA 95814
FAX:	(916) 440-5748
Email:	regulations@dhcs.ca.gov

The written comment period closes at **5:00 pm on September 8, 2014**, any written comments, regardless of the method of transmittal must be received by the Office of Regulations by **5:00pm** on this date, for consideration.

Written comments should include the author's contact information so the Department can provide notification of any further changes to the regulation proposal.

The Department shall consider all comments received regarding the proposal equally, whether submitted in writing or through oral testimony at a public hearing.

AUTHORITY AND REFERENCE

These regulations are being proposed under the following authorities:

Section 20, Health and Safety Code; Sections 10725, 14021, 14021.3, 14021.5, 14021.6, 14021.30, 14021.51, 14043.75, 14124.1, 14124.24, 14124.26, and 14124.5, Welfare and Institutions Code; Statutes of 2011, Chapter 32, and Statutes of 2012, Chapter 36.

These regulations implement, interpret, or make specific the following:

Sections 14021, 14021.3, 14021.5, 14021.6, 14021.33, 14021.51, 14043.7, 14053, 14107, 14124.1, 14124.2, 14124.20, 14124.21, 14124.24, 14124.25, 14124.26, 14131, 14132.21, 14132.905, 14133 and 14133.1, Welfare and Institutions Code; 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.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Background

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 many health care programs including California's State Medicaid program, which is known as the Medi-Cal Program.

Welfare and Institutions Code (WIC) Section 14113 authorizes the Department to enter into agreements with other state departments to administer Medi-Cal funding and requirements for services particular to their fields of expertise. In 1980 the Department entered into an agreement with the California Department of Alcohol and Drug Programs (ADP) to administer the Drug-Medi-Cal (DMC) program. In July 2012, pursuant to Assembly Bill 106 (Chapter 32, Statutes of 2011), administration of the DMC program was transferred from ADP back to the Department.

The DMC program offers a range of services including outpatient counseling and therapy, residential services for pregnant and postpartum women and medication services for opiate addicted beneficiaries. The Department oversees county and provider compliance with State and Federal statutes, regulations and other requirements. A part of this oversight is the Department's performance of postservice postpayment (PSPP) reviews of providers, which, among other things, focus on whether services provided to beneficiaries are medically necessary.

In July 2013, the Department began performing targeted 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, which is available at http://www.dhcs.ca.gov/formsandpubs/publications/opa/Documents/2013/13-07DHCS-DMC7-18-13.pdf). As of early April 2014 the Department was still conducting targeted field reviews.

In addition to the targeted field reviews, the Department's Audit and Investigations Division conducted a review of the DMC program, and prepared a report entitled, "Drug Medi-Cal Program Limited Scope Review," November 2013, which is available at http://www.dhcs.ca.gov/dataandstats/reports/Documents/DMCLtdScopeRvw.pdf. Among other things, this review focused on the lack of sufficient regulatory authority to ensure program integrity and ensure providers meet performance expectations. This review resulted in a series of recommendations and the Department prepared a plan to implement those recommendations. (*See* "The Implementation Plan for Drug Medi-Cal Program Limited Scope Review," which is available at http://www.dhcs.ca.gov/dataandstats/reports/Documents/ImpPlanforAuditRecom.pdf)

Related Existing Laws and Regulations

Welfare and Institutions Code Section 14021(c) authorizes the Department to provide outpatient substance use disorder services. (*See* also WIC Section 14131) Welfare

and Institutions Code Section 14132(u) authorizes the Department to provide comprehensive perinatal services. Welfare and Institutions Code Section 14124.24(a) defines the substance use disorder services offered by the DMC program, which must be consistent with the California State Medicaid Plan and approved Plan amendments. (The services offered by the DMC program include perinatal services.)

Welfare and Institutions Code Section 14124.26(c) authorizes the Department to adopt emergency regulations to implement Article 3.2, Chapter 7, Part 3, Division 9 of the WIC, which includes Section 14124.24. So, the Department has authority to adopt emergency regulations that implement the DMC program services set forth in Section 14124.24.

Title 22, California Code of Regulations (CCR) Section 51341.1 is the primary implementing regulation for the DMC program. It addresses numerous topics including the substance use disorder services offered by the program; provider requirements; PSPP reviews of providers by the Department; and the basis for recovery of payments from providers. In some instances ambiguities in the regulations have inhibited Department enforcement efforts.

Welfare and Institutions Code Section 14043.75 authorizes the Department to adopt and amend regulations to prevent and curtail fraud and abuse by Medi-Cal providers. Fraud and abuse are defined in WIC Section 14043.1. Fraud is defined as "an intentional deception or misrepresentation," knowingly made to obtain an unauthorized benefit. Abuse is defined as either "Practices that are inconsistent with sound fiscal or business practices and result in unnecessary cost to the federal Medicaid and Medicare programs…"; or "Practices that are inconsistent with sound medical practices and result in reimbursement by the federal Medicaid and Medicare programs … for services that are unnecessary or for substandard items or services that fail to meet professionally recognized standards for health care."

Statement of Purpose/Problem to be Addressed

This regulatory action amends Title 22, CCR Section 51341.1 to address abusive and fraudulent practices identified during the targeted field reviews and PSPP reviews conducted by the Department. The regulations also implement some of the recommendations contained in the "Drug Medi-Cal Program Limited Scope Review" and remove ambiguities from the regulations that have inhibited Department enforcement efforts in the past. Additionally, the amendments implement, interpret and make specific the DMC services, which are defined in WIC Section 14124.24(a) and (b) and described in the California State Medicaid Plan, State Plan Amendments 12-005 and 11-037b.

Anticipated Benefits of the Regulations

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 Section 14124.24(a) and (b) is for the Department to administer delivery of the specified substance use disorder services to Medi-Cal beneficiaries. The Department anticipates the regulatory amendments will clarify provider obligations, which should make it easier for providers to comply with program requirements. In addition, the amendments will improve the effectiveness of some treatments and enhance physician oversight.

Consistency and Compatibility with Existing State Regulations

The Department has conducted an evaluation of the related existing state regulations under Title 22 California Code of Regulations (CCR), Division 3 and Title 9, Division 4 and has determined that the regulations are consistent with and compatible with those regulations. An automated search of Title 22, Division 3 and Title 9, 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.

Regulation Section

This emergency regulatory action amends Section 51341.1 to accomplish the following:

- Define additional terms and phrases under the DMC program.
- Prohibit minors from participating in group counseling sessions with adults.
- Require group counseling sessions for day care habilitative services to be conducted with between two and twelve participants.
- Amend requirements for group counseling sign-in sheets.
- Require that group and individual counseling sessions are conducted in a confidential setting.
- Require beneficiaries, counselors, therapists and physicians to type or legibly print their name and date treatment plans, progress notes and discharge plans.
- Revise the physical examination requirements applicable during the intake process.
- Require physicians to review beneficiaries' personal, medical and substance use histories during the intake process.
- Require beneficiary treatment plans to include beneficiary diagnoses and goals related to physical examinations and medical illnesses.
- Require beneficiaries to participate in preparation of, review and sign their treatment plans.
- Specify when counselors and therapists must prepare progress notes.

- Require physicians to review additional documents in determining whether continued services are medically necessary for a beneficiary.
- Establish the requirement for providers to prepare beneficiary discharge plans, including what shall be included in the plans and documentation requirements.
- Require providers to produce all documents the Department relies on in performing PSPP reviews while Department personnel are on site conducting the review.
- Clarify the basis for the Department to withhold overpayments in a PSPP review.
- Non-substantive amendments to achieve clear and consistent language, including accurate punctuation, grammar, sentence structure and designations.

DISCLOSURES REGARDING THE RULEMAKING

The Department has made the following initial determinations:

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: None.

C. Costs or Savings in Federal Funding to the State: None.

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 Drug Medi-Cal program and to provide a particular type of service, group counseling day care habilitative services. See below “Impact on Jobs and Businesses” for discussion related to potential cost impacts for some providers.

Mandates on Local Agencies or School Districts

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) of Division 4 of the Government Code.

County participation in the DMC program is voluntary, and currently not all counties offer the five DMC services: day care habilitative therapy, residential-based therapy, narcotic treatment therapy, and counseling in both an individual and group setting. The

proposed amendments limit the number of participants allowed in a group counseling session for day care habilitative service, to twelve. No county-operated provider has billed in excess of the proposed group size of 12, so the proposed amendments will not have an economic impact on counties.

Significant Statewide Adverse Economic Impact Affecting Businesses
The Department has made an initial determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Results of the Economic Impact Assessment (Analysis)
In accordance with Government Code Section 11346.3(b)(1), the Department has made the following assessments and has determined that the proposed regulations would not significantly affect the following:

(1) The creation or elimination of jobs in California.
(2) The creation or elimination of businesses in California.
(3) The expansion of businesses currently doing business in California.

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

The Department has made an initial determination that the requirements related to group size for the day care habilitative service as proposed to be amended through these regulations will impact providers. In Fiscal Year 2011-2012, 79 providers billed for day care habilitative services. Of these 79, only 9 report a group size that exceeds the proposed limit of 12.

These 9 providers are likely to hire additional counselors to satisfy the new requirement and on average would have to absorb approximately $36,037 per year to continue offering day care habilitative services at the same capacity as before the reduction in group size. However, these additional 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.

County participation in the DMC program is voluntary, and currently not all counties offer the five DMC services: day care habilitative therapy, residential-based therapy, narcotic treatment therapy, and counseling in both an individual and group setting. Of the 79 providers of day care habilitative services, only 3 are county operated: Fresno, Humboldt, and Shasta. None of these counties have billed for group counseling services with more than 12 participants, so the proposed regulatory amendments will not have an economic impact on counties.

Benefits of the Proposed Regulation

The Department has determined that the regulations will not specifically affect worker safety or the state's environment. However, the regulations will benefit DMC providers through the provision of clear and comprehensive requirements for participation. This in turn will benefit the health and welfare of California residents by providing Medi-Cal beneficiaries the delivery of medically necessary and effective substance use disorder services that are provided under enhanced physician oversight.

This regulatory proposal ensures the proper and efficient administration of the Medi-Cal program, in accordance with federal and state laws. This is accomplished by improvements in the fiscal integrity of the DMC program through enhanced provider accountability and the Department's ability to enforce specific regulatory requirements.

Effect on Small Businesses

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

Housing Costs Determination

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

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Existing regulations related to the DMC program (substance use disorder services) are located in Section 51341.1. Using this regulatory proposal to make amendments to existing requirements and standards of the DMC program is the most effective and convenient way to provide (current/updated) information directly to those impacted (providers, physicians, beneficiaries).

This regulatory action is necessary pursuant to WIC Section 14124.26, which requires the Department to adopt emergency regulations. This action also implements WIC Section 14124.24, which requires the Department administer delivery of specified substance use disorder services. Additionally, this action is necessary to implement WIC Section 14043.75, by taking steps to prevent fraud and abuse related to substance use disorder services, under the Medi-Cal program. Specifically, this regulatory action will address abusive and fraudulent practices as identified in the targeted field reviews and PSPP reviews conducted by the Department, and will remove ambiguities from the existing regulations that have inhibited Department enforcement efforts in the past.

ASSISTIVE SERVICES

For individuals with disabilities, the Department can provide assistive services such as the conversion of written materials into Braille, large print, audiocassette and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takers, reading or writing assistance. To request these assistive services, please call (916) 440-7695 (or California Relay at 711 or 1-800-735-2929), email – regulations@dhcs.ca.gov, or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

The Department shall provide, upon request from a person with a visual disability or other disability for which effective communication is required under state or federal law, a narrative description of the additions to, and deletions from, the California Code of Regulations or other publication in a manner that allows for accurate translation by reading software used by the visually impaired. Providing this description may require extending the period of public comment for the proposed action pursuant to Government Code Section 11346.6.

CONTACT PERSONS

Inquiries regarding the substance of the regulations described in this notice may be directed to Marcia Yamamoto, Chief of the Substance Use Disorder Prevention, Treatment and Recovery Services Division, Performance Management Branch at (916) 322-6643.

All other inquiries concerning the regulatory action described in this notice may be directed to Jasmin Delacruz of the Office of Regulations, at (916) 440-7688, or to the designated backup contact person, Lynette Cordell, at (916) 440-7695.

AVAILABILITY OF TEXT OF REGULATIONS AND STATEMENT OF REASONS

The Department has prepared and has available for public review an initial statement of reasons for the regulations, all the information upon which the regulations are based, and the text of the regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the regulations (rulemaking file). In addition, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

The full text of any regulation which is changed or modified from the express terms of the emergency action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

Materials regarding the regulatory action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) are posted to the Department's Internet site at: http://www.dhcs.ca.gov/formsandpubs/laws/Pages/ProposedRegulations.aspx.

In order to request a copy of this public notice, the regulation text, and the initial statement of reasons be mailed to you, please call (916) 440-7695 (or California Relay at 711 or 1-800-735-2929), email regulations@dhcs.ca.gov, or write to the Office of Regulations at the address noted above.