

Provisions of the Drug Medi-Cal Regulation

On August 17, 2015, revisions and additions to the California Code of Regulations (CCR), Title 22, Division 3, become effective as state law. These revisions and additions apply to the enrollment of Drug Medi-Cal providers in Medi-Cal, and include new definitions, provider application submission requirements and fraud prevention provisions. Set forth below is a brief summary list of the changes in CCR that become effective August 17, 2015, in numerical order. A more detailed explanation of the changes, as well as the language of the revised regulations, can be found on the Department of Health Care Services (DHCS) [website](#).

Definitions

Section 51000 adds the substance use disorder medical director and any physician making determinations of medical necessity for treatment.

Section 51000.7 adds “Drug Medi-Cal certification” to mean the same as “enrolled or enrollment in the Medi-Cal Program.”

Section 51000.9.5 defines “Licensed Substance Use Disorder Treatment Professional.”

Section 51000.15.5 defines “Perinatal Residential Substance Use Disorder Services Program.”

Section 51000.20 defines “provider number” as the National Provider Identifier (NPI) number for purposes of substance use disorder clinics.

Section 51000.24.3 defines “Substance Use Disorder Clinic.”

Section 51000.24.4 defines “Substance Use Disorder Medical Director.”

Section 51000.24.4.1 defines “Substance Use Disorder Non-Physician Medical Practitioner.”

Section 51000.24.5 defines “Substance Use Disorder Treatment Professional.”

Section 51000.24.8 defines “Substance Use Disorder Treatment Services.”

Medi-Cal Provider Application for Enrollment, Continued Enrollment or Enrollment at a New, Additional or Change in Location

Section 51000.30(c) replaces subsection (a) for subsection (a)(2).

Section 51000.30(c)(3)(F) sets forth the revised application name and date “Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied Dental Providers.” DHCS 6216 (Rev. 2/15).

Section 51000.30(c)(3)(H) adds the “Drug Medi-Cal Substance Use Disorder Clinic Application,” DHCS 6001 (Rev. 12/14).

Section 51000.30(c)(3)(I) adds 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).

Section 51000.30(d)(22) adds the compliance requirements for the substance use disorder clinic with Sections 51341.1, 51490.1, 51516.1 and the submission of a “Drug Medi-Cal Substance Use Disorder Clinic Application” DHCS 6001 (Rev. 12/14) with information and documentation listed.

Section 51000.30(d)(22)(A) requires the submission of a list of all substance use disorder treatment professionals, licensed substance use disorder treatment professionals and substance use disorder Nonphysician-Medical Practitioners.

Section 51000.30(d)(22)(A)(1) requires the provider or applicant to disclose if the staff member is licensed, certified or registered, and if so, the licensing, certifying or registering organization.

Section 51000.30(d)(22)(A)(2) requires that the provider or applicant submit proof of certification or registration of all substance use disorder treatment professionals.

Section 51000.30(d)(22)(A)(3) requires the provider or applicant to list the NPI of each licensed substance use disorder treatment professional, and substance use disorder Nonphysician-Medical Practitioners, and if applicable, each substance use disorder treatment professional.

Section 51000.30(d)(22)(B) requires the provider or applicant to disclose whether it provides residential services at the business address.

Section 51000.30(d)(22)(C) requires the applicant or provider to disclose the residential license number and submit a valid residential license with the application if providing residential services..

Section 51000.30(d)(22)(D) requires the applicant or provider to disclose if it provides narcotic treatment services and to submit a copy of the valid Narcotic Treatment Program license.

Section 51000.30(d)(22)(E) requires the provider or applicant to disclose the service modalities it provides.

Section 51000.30(d)(22)(F) requires that any applicant or provider that is a governmental entity, corporation or limited liability company submit along with its application a copy of current board minutes that contains the name of the individual authorized to sign on behalf of the applicant or provider.

Section 51000.30(d)(22)(G) requires the applicant or provider to disclose the legal name, medical license number, a copy of the valid license and the NPI number of its Substance Use Disorder medical director.

Section 51000.30(d)(22)(G) requires substance use disorder medical directors to submit 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).

Section 51000.31 replaces DHS 6216 (07/05) with DHCS 6216 (rec. 2/15) and include "Dental" in the application name.

Section 51000.35(a) requires the applicant or provider to disclose all of the information required by 42, Code of Federal Regulations, Sections 455.104, 455.105 and 455.106, on whichever form is applicable, and the submission of the disclosure statement with the application required by Sections 51000.30 and 51000.40.

Section 51000.35(a)(1) adds the "Medi-Cal Disclosure Statement" DHCS 6207 (Rev. 2/15).

Section 51000.35(a)(2) adds the "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied Providers," DHCS 6216 (Rev. 2/15).

Section 51000.35(a)(3) adds the "Drug Medi-Cal Substance Use Disorder Medical Director/Licensed Substance Use Disorder Treatment Professional/Nonphysician Medical Practitioner Application/Agreement/ Disclosure Statement," DHCS 6010 (Rev. 12/14).

Section 51000.35(b)(1)(A) requires the disclosure statement submitted by the provider or applicant to include the name, address and title of the managing employee.

Section 51000.35(b)(1)(B) requires the disclosure statement submitted by the applicant or provider to include the name, address and title of any persons with an ownership or control interest in the applicant or provider and the percentage of that ownership or control.

Section 51000.35(a)(3)(b)(1)(C) requires the disclosure statement submitted by the applicant or provider to include the name, address and title of persons with an ownership or control interest in any subcontractors in which the applicant or provider has a direct or indirect ownership of 5 percent or more and the percentage of that ownership or control interest.

Section 51000.35(b)(1)(D) requires the disclosure statement submitted by the applicant or provider to include the name, address and title of the board members and officers if the applicant or provider is a nonprofit entity.

Section 51000.35(b)(1)(D)(2) requires the disclosure statement submitted by the applicant or provider to include whether any of the persons named in subsection (b) above is related to another such as a spouse, parent, child or sibling.

Section 51000.35(b)(1)(D)(3) requires the disclosure statement submitted by the applicant or provider to include the name and address of any other health care provider in which a managing employee, board member, officer or a person(s) with an ownership or control interest in the applicant or provider also has an ownership or control interest. This requirement applies to the extent that the applicant or provider can obtain this information by requesting it in writing from the health care provider.

Section 51000.35(b)(1)(D)(3)(A) requires the applicant or provider to keep copies of all these requirements and the responses to them.

Section 51000.35(b)(1)(D)(3)(B) requires the applicant or provider to make the copies of all these requirements and the responses to them available to the Department upon request.

Section 51000.35(b)(1)(D)(3)(C) requires the applicant or provider to advise the Department when there is no response to a request.

Section 51000.35(b)(1)(D)(4) requires that the applicant or provider disclose the name and address of each person(s) with an ownership or control interest in any subcontractor with whom the applicant or provider has had business transactions involving health care services, goods, supplies or merchandise related to the provision of services to a beneficiary that total more than \$25,000 during the 12-month period immediately preceding the date of the application, or immediately preceding the date on the Department's request for such information.

Section 51000.35(b)(1)(D)(5) requires the applicant or provider to disclose any significant business transactions between the applicant or provider and any wholly owned supplier, or between the applicant or provider and any subcontractor, during the 5-year period ending on the date of the application, or ending on the date of the written request by the Department for such information.

Section 51000.35(b)(1)(D)(6)(A) requires the applicant or provider to disclose and identify any person(s) who has an ownership or control interest in the applicant or provider, or is an agent or managing employee of the applicant or provider, who has within the previous ten years of the date of the application package been convicted of any felony or misdemeanor involving fraud or abuse in any government program.

Section 51000.35(b)(1)(D)(6)(B) requires the applicant or provider to disclose and identify any person(s) who has ownership or control interest in the applicant or provider, or is an agent or managing employee of the applicant or provider, who has within the previous ten years of the date of the application package been found liable in any civil proceeding involving fraud or abuse in any government program

Section 51000.35(b)(1)(D)(6)(C) requires the applicant or provider to disclose and identify any person(s) who has ownership or control interest in the applicant or provider, or is an agent or managing employee of the applicant or provider, who has within the previous ten years of the date of the application package entered into a settlement in lieu of conviction involving fraud or abuse in any government program.

Section 51000.35(c) replaces "Medi-Cal Provider Disclosure Statement, DHS 6207(Rev. 02/05)" with applicable application identified in subsection (a).

Section 51000.40(b) replaces "DHS 6209 (Rev. 11/05)" with DHCS 6209 (Rev. 12/14).

Section 51000.40(b)(1) adds "unless the provider is a substance use disorder clinic."

Section 51000.40(b)(10) adds "unless the provider is a substance use disorder clinic."

Section 51000.40(b)(14)(A) requires a substance use disorder clinic to complete and submit the form "Medi-Cal Supplemental Changes, DHCS 6209 (Rev. 12/14)" when there is a change in the

clinic's substance use disorder medical director or physicians making medical necessity determinations for beneficiaries.

Section 51000.40(b)(14)(B) requires a substance use disorder clinic to complete and submit the form "Medi-Cal Supplemental Changes, DHCS 6209 (Rev. 12/14)" whenever there is a deletion or addition of service modalities.

Section 51000.40(b)(14)(C) requires a substance use disorder clinic to complete and submit the form "Medi-Cal Supplemental Changes, DHCS 6209 (Rev. 12/14)" whenever there is a change of any substance use disorder treatment professional or licensed substance use disorder treatment professional providing counseling services.

Section 51000.40(d) replaces "DHS 6209 (Rev. 11/05)" with DHCS 6209 (Rev. 12/14).

Section 51000.45(c) revises the application name and date to "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied Dental Providers." DHCS 6216 (Rev. 2/15).

Section 51000.45(d) includes "Drug Medi-Cal Provider Agreement," DHCS 6009 (Rev. 12/14), as one of the possible provider agreements required to be signed and submitted.

Section 51000.45(e) includes, "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) as one of the possible provider agreements required to be signed and submitted.

Section 51000.60(c)(9)(A) adds, "if the applicant or provider is a substance use disorder clinic located on space donated at no cost, the applicant or provider has obtained verification from the space owner that it is authorized to use the space to provide substance use disorder services."

Section 51000.60(c)(9)(B) adds, "unless the applicant or provider is a substance use disorder clinic."

Section 51000.60(c)(9)(C) adds, "unless the applicant or provider is a substance use disorder clinic."

Section 51000.70 requires that each substance use disorder clinic have a licensed physician designated as the substance use disorder medical director who is an agent of the substance use disorder clinic.

Section 51000.70(a) requires that the clinic's substance use disorder medical director not be excluded from participation in any State or Federal Medicare or Medicaid program.

Section 51000.70(b) requires that the clinic's substance use disorder medical director be enrolled in Medi-Cal as a substance use disorder medical director.

Section 51000.70(c) requires that the substance use disorder medical director be acting in compliance with all laws and requirements of the Medi-Cal program.

Section 51000.75 requires each substance use disorder clinic to list all licensed substance use disorder treatment professionals and substance use disorder Nonphysician-Medical Practitioners utilized at the business address on the "Drug Medi-Cal Substance Use Disorder Clinic Application," DHCS 6001 (Rev. 12/14).

Section 51000.75(a) requires that the clinic's licensed substance use disorder treatment professional(s) or a substance use disorder Nonphysician-Medical Practitioner(s) not be excluded from participation in any State or Federal Medicare or Medicaid program.

Section 51000.75(b) requires that any licensed substance use disorder treatment professional or substance use disorder Nonphysician-Medical Practitioner be enrolled in Medi-Cal as a licensed substance use disorder treatment professional or a substance use disorder Nonphysician-Medical Practitioner.

Section 51051(b) includes licensed substance use disorder treatment professionals, substance use disorder clinics, substance use disorder medical directors, and substance use disorder Nonphysician-Medical Practitioners.

Section 51341.1(b)(28) gives “Substance Use Disorder Medical Director” the same meaning as in Section 51000.24.4.

Section 51341.1(b)(28)(A) adds requirements to outpatient drug free, day care habilitative, perinatal residential and naltrexone treatment services programs.

Section 51341.1(b)(28)(A)(i) identifies the responsibilities of a substance use disorder medical director.

Section 51341.1(b)(28)(A)(i)(a) requires that the substance use disorder medical director ensures that medical care provided by a clinic’s physicians, registered nurse practitioners and physician assistants meets the applicable standard of care.

Section 51341.1(b)(28)(A)(i)(b) requires that the substance use disorder medical director ensures that physicians do not delegate their duties to non-physician personnel.

Section 51341.1(b)(28)(A)(i)(c) requires that the clinic’s substance use disorder medical director develop and implement medical policies and standards for the provider.

Section 51341.1(b)(28)(A)(i)(d) requires that the substance use disorder medical director ensure that the clinic’s physicians, registered nurse practitioners and physician assistants follow the provider’s medical policies and standards.

Section 51341.1(b)(28)(A)(i)(e) requires that the substance use disorder medical director ensures that the medical decisions made by clinic physicians are not influenced by fiscal considerations.

Section 51341.1(b)(28)(A)(i)(f) requires that the substance use disorder medical director ensures that the clinic’s physicians are adequately trained to perform diagnosis of substance use disorders for beneficiaries, determine the medical necessity of treatment for beneficiaries and perform other physician duties, as outlined in this section.

Section 51341.1(b)(28)(A)(ii) allows the provider’s substance use disorder medical director to delegate his/her responsibilities to a physician consistent with the provider’s medical policies and standards; however the substance use disorder medical director shall remain responsible for ensuring all delegated duties are properly performed.

Section 51341.1(b)(28)(A)(iii) requires that the provider’s substance use disorder medical director receive a minimum of five (5) hours of continuing medical education in addiction medicine each year.

Section 51341.1(b)(28)(B) requires that the substance use disorder medical director of narcotic treatment programs meet the requirements specified in Section 10110 of Title 9, CCR.

Section 51341.1(b)(28) is amended to read Section 51341.1(b)(29).

Section 51341.1(b)(29) is amended to read Section 51341.1(b)(30).

Section 51341.1(b)(30) is amended to read Section 51341.1(b)(31).