INITIAL STATEMENT OF REASONS

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 (CFR), 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.

This regulatory action sets forth in the CCR the most current versions of the provider enrollment forms that the Department previously amended through provider bulletin, pursuant to WIC section 14043.75. These forms apply to DMC providers, as well as other provider types as specified by the forms.

<u>Anticipated Benefits or Goals of the Regulations</u>

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.

REGULATORY SECTIONS and FORMS

This regulatory action will update and expand definitions and rules (standards of participation) for enrollment into the DMC program; and amend related enrollment criteria for the Medi-Cal program. Applicants/providers who wish to enroll or continue enrollment in the DMC program must meet the program requirements and demonstrate an established place of business. These participation standards will be used to identify and screen out those providers and applicants whose business practices do not meet these standards. To assist the Department in verifying that program requirements are

met, applicants/providers are required to complete specified forms to participate and continue to participate as a provider in the Medi-Cal (including the DMC) program. Medi-Cal (including DMC) program forms allow the Department to effectively gather comprehensive and accurate information from applicants/providers that wish to participate in these programs. These forms include criteria related to an applicant's/provider's: qualifications (i.e. licensing/certification), facilities/clinic locations, and services rendered, among others. It is critical that the Department obtain all of this information, including documentation/verification (as applicable), as well as assurances that the applicant/provider is aware of the responsibilities for program participation. This information is necessary so that the Department can determine if an applicant/provider meets the standards to participate in these programs and when participating that the applicant/provider is held to these standards. Ensuring that applicants/providers meet program participation requirements and are held to these requirements is necessary to curtail and prevent provider fraud and abuse under these programs. As described under each section below, the proposed amendments are necessary to enhance the fiscal integrity of the Medi-Cal (including DMC) program by curtailing and preventing provider fraud and abuse.

The specific purpose and rationale for necessity for the proposed changes to Title 22, CCR, are identified below.

Section 51000

As currently adopted, the definition defines an "agent" as a person who has been delegated the authority to obligate or act on behalf of an applicant or provider. The Department proposes to amend this section to clarify that for substance use disorder clinics "agent" includes the substance use disorder medical director and any physician making determinations of medical necessity for treatment. This amendment is necessary to ensure that substance use disorder clinics, as well as their substance use disorder medical directors and physicians, understand that the physician is performing the treatment medical necessity determinations on behalf of the clinic. Through its investigations, the Department has determined that substance use disorder medical directors and other physicians working for the substance use disorder clinics have played a major role in the alleged fraud and abuse carried out by DMC providers. Only a physician can determine whether the services offered by the clinic are medically necessary for the beneficiary and thus eligible for payment under the Medi-Cal program. They also prescribe the course of treatment for the beneficiary. Clinics have attempted to avoid liability for the wrongful acts of their medical directors who falsely certify that a service is medically necessary by asserting that the doctor is an independent contractor and the clinic cannot be liable for any fraud resulting from that false certification. The proposed change makes clear that in making the medical necessity determination for treatment services, the physicians, whether or not they are the designated substance use disorder medical director, are the agent for the clinic.

Section 51000.7

The Department proposes to amend Section 51000.7 in order to clarify that for the purposes of provider enrollment of substance use disorder clinics in the Medi-Cal program, the terms “enrolled,” “enrollment,” and “certification” have the same meaning. This is necessary because, as described above in detail in the Statement of Purpose and Rationale Being Addressed, the Department is proceeding through the process of applying already established Medi-Cal Provider Enrollment statutes and regulations to the enrollment of substance use disorder clinics. In the past, the statutes and regulations governing substance use disorder clinics were expressed in terms of “certification” rather than “enrollment” in the Medi-Cal program. By making clear that the words mean the same thing for purposes of provider enrollment, the Department can continue to utilize as much as possible of the existing Substance Use Disorder (SUD) statutory and regulatory law already in place while still integrating these providers into the existing Medi-Cal Provider Enrollment structure.

Section 51000.9.5

The Department proposes to adopt Section 51000.9.5 in order to provide a definition for the designation “Licensed Substance Use Disorder Treatment Professional.” It was necessary for the Department to include this definition for a number of reasons:

- The definition specifies the provider types which require a professional license that are set forth in California’s State Plan Amendment 13-038, Supplement 3 to Attachment 3.1-A, pages 5-6, January 1, 2014, which can be found at http://www.dhcs.ca.gov/formsandpubs/laws/Documents/CA_SPA_13-038_Approved_Package_Redacted.pdf.
- The term “Licensed Substance Use Disorder Treatment Professional” is being added as a “Provider” in the amendment to Section 51051(b) proposed within this regulatory action.
- The definition allows the Department to refer to the specifically identified professionals in a shortened form in proposed amendments to Sections 51000.30, 51000.35, 51000.40, 51000.45, and 51000.75.
- The addition of this definition will add clarity to the regulations and support the intent of increased provider compliance.

Section 51000.15.5

The Department proposes to adopt Section 51000.15.5 to provide a definition of a “perinatal residential substance use disorder services program.” It is necessary for the Department to include this definition because the term is used and would apply in other sections of the Provider Enrollment regulations under this chapter. The Department offers enrollment in the DMC program to licensed perinatal residential clinics wishing to also receive reimbursement for DMC services. A clinic may provide substance use disorder treatment services in a residential or outpatient setting, however residential clinics must be licensed pursuant to Health and Safety Code (HSC) Sections 11834.01 and 11834.30 and Title 9, CCR, Section 10505. Clinics desiring to provide services in a

perinatal residential setting must obtain a residential license prior to being granted approval to be reimbursed for providing DMC services.

Section 51000.20

The Department proposes to amend Section 51000.20 to provide a definition of "provider number" for purposes of substance use disorder clinics. Substance use disorder clinics have multiple numbers assigned to them and they currently refer to their DMC provider number as their "provider number." Effective May 23, 2007, applicants and providers are required to submit their national provider identifier (NPI) with each Medi-Cal provider application package. Implementation of the NPI is a requirement of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, Title II, Sections 1175 and 1178), herein referred to as HIPAA. Therefore, effective May 23, 2007, in the FFS Medi-Cal program, "provider number" means NPI number, unless the applicant is atypical. It is necessary for the Department to include this definition to clarify that for purposes of substance use disorder clinics the term "provider number," as used in the Provider Enrollment regulations, shall mean the NPI number.

Section 51000.24.3

The Department proposes to adopt Section 51000.24.3 in order to provide a definition for the term "Substance Use Disorder Clinic." It was necessary for the Department to include this definition because it is used in other sections of the proposed Provider Enrollment regulations to refer to those facilities that receive reimbursement from the Medi-Cal program for substance use disorder treatment services. The addition of this definition will result in regulation text that is more specific and easier to read, therefore resulting in increased provider compliance.

Section 51000.24.4

The Department proposes to adopt Section 51000.24.4 to provide a definition of "Substance Use Disorder Medical Director." It is currently a program requirement that each substance use disorder clinic have a substance use disorder medical director. Through its investigations, the Department has determined that substance use disorder medical directors and other physicians working for the substance use disorder clinics have played a major role in the alleged fraud and abuse carried out by DMC providers. These medical directors have certified that beneficiaries have a substance use disorder diagnosis necessitating medical treatment, when there was no evidence of facts to justify such diagnosis. Further information regarding the necessity for amending the regulations to include a Substance Use Disorder Medical Director as defined, is set forth in this Initial Statement of Reasons in Sections 51000.70 and 51341.1.

Section 51000.24.4.1

The Department proposes to adopt Section 51000.24.4.1 in order to provide a definition for the designation of a "Substance Use Disorder Nonphysician Medical Practitioner." It was necessary for the Department to include this definition for a number of reasons:

- The definition implements the non-licensed provider types that are set forth in California's State Plan Amendment 13-038, Supplement 3 to Attachment 3.1-A, pages 5-6a, effective January 1, 2014, which can be found at: http://www.dhcs.ca.gov/formsandpubs/laws/Documents/CA_SPA_13-038_Approved_Package_Redacted.pdf.
- The term "Substance Use Disorder Nonphysician Medical Practitioner" is being added as a "Provider" in the amendment to Section 51051(b) in this regulatory action.
- The definition allows the Department to refer to the specifically identified practitioners in a shortened form in proposed amendments to Sections 51000.30, 51000.35, 51000.45, and 51000.75. Notably, a "Substance Use Disorder Nonphysician Medical Practitioner" is not subject to the proposed amendments in Section 51000.40, thus the need for a separate identification definition from "Licensed Substance Use Disorder Treatment Professional."
- The addition of this definition will add clarity to the regulations and support the intent of increased provider compliance.

Section 51000.24.5

The Department proposes to adopt Section 51000.24.5 to provide a definition for the designation "Substance Use Disorder Treatment Professional." It is necessary for the Department to include this definition for a number of reasons:

- The definition implements non-licensed provider types that are set forth in California's State Plan Amendment 13-038, Supplement 3 to Attachment 3.1-A, pages 5-6, effective January 1, 2014, which can be found at: http://www.dhcs.ca.gov/formsandpubs/laws/Documents/CA_SPA_13-038_Approved_Package_Redacted.pdf.
- This definition allows the Department to refer to the specifically identified professionals in a shortened form in proposed amendments to Sections 51000.30 and 51000.40. However, the professionals identified in this definition are not being added as a "Provider" in the amendment to Section 51051(b) proposed in this regulation package and therefore are not subject to the proposed amendments in Sections 51000.35, 51000.45, and 51000.75, regarding enrollment, provider agreement, and disclosure.
- The addition of this definition will add clarity to the regulations and support the intent of increased provider compliance.

Section 51000.24.8

The Department proposes to adopt Section 51000.24.8 to provide a definition for the term "Substance Use Disorder Treatment Services." It is necessary for the Department to include this definition because it is used in other sections of the proposed Provider

Enrollment regulations to refer to the type of services reimbursed by the Medi-Cal program. All authorized DMC substance use disorder treatment services are contained in Section 51341.1.

Section 51000.30

The Department proposes to amend Section 51000.30 to establish additional requirements that shall be met as a condition for enrollment, or continued enrollment, in the Medi-Cal program. The requirements of this section apply to all new applicants and to current providers who wish to continue participating in the Medi-Cal program.

Section 51000.30, Subsection (c)(3)(F)

The Department proposes to amend Section 51000.30(c)(3)(F) to update the "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician and Allied Providers" DHS 6216 (07/05) form, which was previously incorporated by reference in this section. The application title and revision date is updated to read: "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers," DHCS 6216 (Rev. 2/15). "Dental" was included to the application title, the revision date was updated to (2/15) and the form name beginning with "DHS" has been updated to "DHCS." This form has been amended via a provider bulletin pursuant to WIC Section 14043.75 since its initial implementation in regulations. Although the Department implemented the revised form via provider bulletin an explanation of all of the amendments have been included in this statement of reasons for purposes of clarity for the affected public.

As a result of the structure and appearance of the form, the existing version of the form is repealed in its entirety and is replaced with the newly adopted version. The only amendments on the newly adopted version that differ from the existing version are described below. All other provisions remain the same. The following amendments were made to the now titled: "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers," DHCS 6216 (Rev. 2/15), form and are hereby incorporated by reference:

The following instructions have been added to the application:

- The title was amended and now includes "Dental" providers. This is a universal amendment, the title now reads, "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers." Dental providers now use the same form for enrolling their providers; therefore they have been incorporated into the application.

- In the introduction paragraph, the applicant/provider is additionally advised that if corrections are made, to line through, initial in ink, date and not to leave any question, boxes, lines, etc. blank. The applicant is instructed to enter N/A if not

applicable. These revisions were made to assist the Department in the application review process.

- The phrases “part of,” “applicants and providers must also provide additional information and documentation,” and “and providers,” have been added to existing instructions for clarity.

- The introduction paragraph is amended and the phrase “if you are completing this form, you will not need to submit a disclosure statement or provider agreement” was removed, as well as the definition of rendering provider that originally followed that sentence. The provider agreement and disclosure statement was added to the “Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers,” DHCS 6216 (Rev. 2/15), therefore, a separate provider agreement and disclosure statement is not needed.

- Instructions for rendering provider have been removed as they are no longer necessary. The applicant or provider should reference the regulations for definitions of terms when filling out the application.

- Applicant is advised that they must attach copies of Centers for Medicare Services/National Plan and Provider Enumeration System (CMS/NPPES) confirmation for each NPI submitted with the application package. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI was required pursuant to HIPAA.

- “New rendering physician/allied provider” was amended and now includes “dental” providers as they now use the “Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers,” DHCS 6216 (Rev. 2/15) to enroll. In addition, new instructions were included to inform the applicant/provider to check the box if the applicant is not currently enrolled with the Medi-Cal program “as a provider with an active provider number,” instead of “and would like to have a Medi-Cal provider number issued.” This amendment is due to implementation of the NPI requirement pursuant to HIPAA. The Department no longer issues provider numbers unless the applicant is atypical.

- Instructions have been adopted for “National Provider Identifier” to instruct the applicant/provider to enter their current NPI. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI was required pursuant to HIPAA.

- Number 3 was amended and now the applicant/provider enters their gender instead of checking a box. This amendment was done to be consistent with other sections of the application.

- Number 4 was renumbered to number 6, however, the Social Security Number is now mandatory. This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR Parts 405,424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). This revision is also necessary for compliance with 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- Numbers 5 through 12 were renumbered as follows: Number 12, "Residence Address," was renumbered and now is number 4; numbers 5 through 11 were re-numbered and are now 7 through 13, in the same chronological order. This change allows the applicant to read and understand the instructions before completing the application and was restructured for ease in form usage by the applicant/provider.

- Number 5 adopted "mailing address" to instruct the applicant/provider to enter the mailing address where correspondence may be sent to as defined in Section 51000.11. This information is inputted into the Department's database system and is used to mail updates and other correspondence to the applicant/provider.

- Number 8 has been amended to include commas for clarification throughout the sentence.

- Number 9 has been amended to change the sequential order of "street name" and "number" to match the form portion of the application. This change was made for consistency.

- Number 10 has been amended to clarify a "beeper" number to match the definition in Section 51000.4 and the form portion of the application.

- Number 14 adopts instructions for "Provider number of Group being joined" to instruct the applicant/provider to enter the NPI or Denti-Cal provider number of the Medi-Cal Group Provider that the individual named in number 1 is joining. This assists the Department during the application review period to ensure that the group to which the rendering provider is requesting enrollment at is enrolled in the Medi-Cal program. The group must be enrolled in the Medi-Cal program in order to bill for services provided by the rendering provider.

- Number 15 adopts "proof of professional liability insurance" to instruct the applicant/provider to enter the name of the insurance company, policy number,

date the policy was issued, expiration date of the policy and the agents' name, telephone number, fax number and email address. The applicant/provider is also instructed to submit a copy of the applicant/providers certification of insurance. Submission of professional liability insurance is required pursuant to Sections 51000.30(f)(3) and 51000.60(c)(6). In addition, this information assists the Department during the application review period to ensure the applicant/provider meets enrollment criteria.

Disclosure Information

Numbers 1 through 9 contain the same information/reporting requirements but were slightly reworded for clarification purposes. The following amendments were made to assist the applicant or provider with completing this section accurately and to help eliminate confusion with sentence structure:

- Number 1 instructs the applicant/provider to additionally provide the date of conviction if applicable. This information is required pursuant to Section 51000.35.

- Number 2 instructs the applicant/provider to additionally provide the date of final judgment if applicable. This information is required pursuant to Section 51000.35.

- Number 3 instructs the applicant/provider to additionally provide the date of settlement if applicable. This information is required pursuant to Section 51000.35.

- Number 4 was amended to include "provider number," instead of "Medi-Cal numbers," this is to be consistent with the term "provider number" as used by the Department and defined in Section 51000.20.

- Number 5 was amended to match the sequential order of the form. This change was made for consistency and clarification purposes. In addition, "Medi-Cal" and "NPIs" were added due to the fact that "Medi-Cal" was erroneously left out of the initially drafted question. "NPIs" were established pursuant to HIPAA and therefore has been added to the application.

- Number 7 was amended to instruct the applicant/provider to attach written confirmation "from the licensing authority" that professional privileges have been restored. This was added for clarification purposes and to aid the applicant/provider in submitting a complete application package with the correct supporting documents.

- Number 8 no longer instructs the applicant/provider to check the appropriate box and, if applicable, complete the requested information. This section has been amended to be more consistent with other instructions by providing detailed

information. The applicant/provider is advised to check the appropriate box and, if applicable, list the state(s) where the applicant's or provider's license, certificate, or other approval to provide health care was lost or surrendered while a disciplinary hearing was pending and the effective dates of those actions and to attach a written confirmation from the licensing authority that professional privileges have been restored. This is necessary in order for a provider to be compliant with Section 51000.35(c)(4).

- Number 10, "residence address" was moved from the "Disclosure Information" section and is now Number 4 in the previous section. Number 10 is adopted to instruct the applicant/provider to enter the name, title/position, email address and telephone number of the individual who can be contacted by staff to answer questions regarding the application package. The applicant/provider is advised that failure to include this information may result in the application package being returned deficient for items that can be remediated via fax or telephone. This information assists the Department in the application review period by being able to contact an individual to remediate deficiencies by fax, or answer clarifying questions.

Provider Agreement

- Number "29." was removed from this section as it was incorrect. There was never a number 29. in the form portion of the application therefore this correction is necessary. The term "physician" was changed to "applicant" because this application is used for enrollment of more provider types. In addition, all prospective providers are referred to as "applicants." Section 51000.30(a)(2)(B) was adopted and the applicant/provider is instructed to review this section to determine whether they have the authority to sign the application. This will assist the applicant in determining who can sign the application.

- Additional boxes were added to remind the applicant/provider to submit all applicable documents with the application. Added boxes include verification of reinstatement, written confirmation for licensing authority that professional privileges have been restored, copies of payment arrangement documents, notary public certificate, certificate of insurance, drug enforcement agency certificate, anesthesia permit, conscious sedation permit and NPI verification. This will assist the applicant/provider is submitting the required supporting documents with their application package and will assist the Department in making a determination.

The following has been added/amended to the form portion of the application:

- The PO Box and nine-digit ZIP code for the existing provider enrollment address was updated to 95899-7412. This amendment was made to ensure the application package is forwarded to the correct place. In addition, the address

and phone number for Denti-Cal was added since dental provider types now use the “Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers,” DHCS 6216 (Rev. 2/15), form to enroll. These applications are additionally reviewed and processed by Denti-Cal.

- The “preferred provider status” section was amended to include the correct citation. WIC Section 14043.26(c) was incorrectly used and now correctly states Section 14043.26(d).

- The applicant/provider is additionally advised not to use correction fluid or tape on the application. This was added to be consistent with information listed in the instruction portion of the application.

- The “National Provider Identifier (NPI)” section has been adopted to instruct the applicant/provider to list their NPI. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- “Registered Dental Hygienist Alternative Practice” and “Dentist” were added as provider types. These provider types now use this application to enroll in the Medi-Cal program and have been incorporated into the application.

- Number 4 instructs the applicant/provider to list their residence address, city, state, and nine-digit ZIP code. This information was originally asked in the “Disclosure Information” portion of the form and has moved from number 10 to number 4.

- Number 5 instructs the applicant/provider to list their mailing address, city, state, and nine-digit ZIP code. This information is necessary in order to submit correspondence and updated information to the provider.

- Numbers 4 through 11 were renumbered and are now numbers 6 through 13 in the same chronological order.

- Number 6 now advises the applicant/provider that the Social Security Number is now required. This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). This revision is also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- Number 8 was amended to include “certificate/permit” in the license effective and expiration boxes. This amendment was done to be consistent with the instruction portion of the application. “Dentist” was added to the List of Specialty(ies). This provider type now uses this application to enroll in the Medi-Cal program and has been incorporated into the application.

- Number 14 instructs the applicant/provider to list the provider number (NPI or Denti-Cal Provider Number as applicable) of the group being joined. This information is requested to ensure that the group that the rendering provider is joining is enrolled as a Medi-Cal provider. The group is required to be enrolled in the Medi-Cal program in order to bill for services provided by the rendering individual.

- Number 15 Proof of Liability Insurance was added to instruct the applicant/provider to attach a copy of the applicant/provider’s certificate of insurance and to enter the name of the insurance company, insurance policy number, date policy issued, expiration date of policy, insurance agent’s name, telephone number, fax number and email address. Submission of professional liability insurance is required pursuant to Sections 51000.30(f)(2) and 51000.60(c).

Disclosure Information

- Number 4 was amended and “NPI” number was included to the existing table. The applicant/provider is now instructed to list their NPI and/or provider number(s). This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- Number 5 was amended and “NPI” number was included to the existing table. The applicant/provider is now instructed to list their NPI and/or provider number(s). This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- Numbers 6, 7, and 8 were amended to include “action(s) taken” in the column provided. These amendments are necessary in order for a provider to be compliant with Section 51000.35(c)(4) and (5).

- Number 8 was amended and additionally instructs the applicant/provider that if they answer yes to being disciplined by a licensing authority, the applicant/provider is required to attach a copy of the written confirmation from the licensing authority decision(s) including any terms and conditions for each decision. They shall also provide the information required on the preceding chart. This information is required in order to be compliant with Section 51000.35.

- Number 10 has been relocated and is now number 4 of the form portion of the application.

Provider Agreement

The provider agreement is designed to educate providers about the Provider Enrollment Division (PED) laws and regulations. It is expected that the applicant will read the provisions contained in the agreement. By signing the "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers," DHCS 6216 (Rev. 2/15) form, the applicant or provider agrees to comply with all applicable provisions of Chapters 7 and 8 of WIC (commencing with Sections 14000 and 14200), and any applicable rules or regulations as long as he/she maintains a Medi-Cal provider number. This section was amended and requires the applicant/provider to attest to the following:

- The applicant/provider declares under penalty of perjury under the laws of the State of California that the foregoing information and the information on all attachments is true, accurate, and complete to the best of their knowledge and belief and that they are authorized to sign this application pursuant to Section 51000.30(a)(2)(B).

- The applicant/provider understands that the failure to disclose the required information, or the disclosure of false information, shall, prior to any hearing, result in the denial of the application for enrollment or shall be grounds for termination of enrollment status and suspension from the Medi-Cal program, which shall include deactivation of all provider numbers used to obtain reimbursement from the Medi-Cal program. The applicant/provider is required to provide this information pursuant to Section 51000.35.

- The applicant/provider understands they must report changes in the foregoing information within 35 days to the Department of Health Care Services, Provider Enrollment Division. This amendment is required pursuant to Section 51000.40(a).

- The applicant/provider further declares that they will abide by all Medi-Cal laws and regulations and the Medi-Cal program policies and procedures as published in the Medi-Cal Provider Manual, including the requirements for record keeping and the disclosure of information. The applicant/provider understands that compliance with all Medi-Cal laws and regulations is a condition for participation as a provider in the Medi-Cal program.

- The applicant/provider agrees to make available, during regular business hours, all pertinent financial records, all records of the requisite insurance coverage, and all records concerning the provision of health care services to beneficiaries to

any duly authorized representative of the Department, the California Attorney General's Medi-Cal Fraud Unit ("AG"), and the Secretary of the United States Centers for Medicare and Medicaid Services. The applicant/provider must further agree to provide if requested by any of the above, copies of the records and documentation, and that failure to comply with any request to examine or receive copies of such records shall be grounds for immediate suspension of applicant/provider from participation in the Medi-Cal program. The applicant/provider will be reimbursed for reasonable copy costs as determined by the Department or AG. This amendment is required pursuant to Section 51476(g).

- The applicant/provider agrees that the Department and/or AG may make unannounced visits to the applicant/provider, at any of applicant's/provider's business locations, before, during or after enrollment, for the purpose of determining whether enrollment, continued enrollment, or certification is warranted, to investigate and prosecute fraud against the Medi-Cal program, to investigate complaints of abuse and neglect of patients in health care facilities receiving payment under the Medi-Cal program, and/or as necessary for the administration of the Medi-Cal program and/or the fulfillment of the AGs powers and duties under Government Code Section 12528. Premises subject to inspection include billing agents, as defined in WIC Section 14040.1. Failure to permit inspection by the Department or AG, or any agent, investigator or auditor thereof, shall be grounds for immediate suspension of applicant/provider from participation in the Medi-Cal program, which is consistent with WIC Section 14124.2(b)(1).

- Number 10 instructs the applicant/provider to provide the "Contact Person's Information," identify if this individual is the same individual identified in item 1, and provide the contact person's name, title/position, email address, and telephone number. This information is necessary to assist the Department during the application review process when clarification is needed.

- The privacy statement was amended to specify that all information is mandatory and the telephone number for Denti-Cal was additionally included since this application now includes dental provider types.

Section 51000.30, Subsection (c)(3)(H)

The Department proposes to amend this section to incorporate the "Drug Medi-Cal Substance Use Disorder Clinic Application," DHCS 6001 (Rev. 12/14) form by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. PED forms are available on the Department's internet website at http://files.medi-cal.ca.gov/pubsdoco/prov_enroll.asp#Forms. Please refer to the applicable areas of this Statement of Reasons for an explanation of necessity for the

newly adopted sections/subsections that are referenced throughout this discussion of necessity pertaining to the “Drug Medi-Cal Substance Use Disorder Clinic Application,” DHCS 6001 (Rev. 12/14).

An introductory cover letter has been included with the application:

- The introduction paragraph of the cover letter has been adopted to include the Department’s address where the application package must be returned to. This will assist the applicant/provider in sending the application package to the correct address.

- Applicants/providers are advised that they are required to submit their NPI with each Medi-Cal provider application package. Applicants are required to attach a copy of the CMS/National Plan and Provider Enumeration System (CMS/NPPES) confirmation for each NPI listed in the application package. If providers are not eligible to receive an NPI, they should instead enter the word "atypical" in any NPI fields. These "atypical providers" will receive a unique Medi-Cal provider number once the application is approved. Implementation of the NPI, is a requirement of HIPAA and has therefore been added to the application cover letter.

- The cover letter advises the applicant/provider that they are required to submit an application fee or proof of payment for enrollment with Medicare or other state Medicaid programs. Effective January 1, 2013, the Department requires certain applicants and providers to submit an application fee when requesting an enrollment action. The application fee collected is used to offset the cost 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. This adoption is necessary in order to be compliant with these federal requirements.

- The applicant is advised that it is their responsibility to report any modifications to information previously submitted to the Department within 35 days from the date of the change. This adoption is necessary and required pursuant to Section 51000.40(a). The applicant is advised that most changes can be reported via the “Medi-Cal Supplemental Changes,” DHCS 6209, (Rev. 12/14) form. This adoption is necessary as it is required pursuant to Section 51000.40(b).

- The applicant is advised that if they are planning on selling their business or buying an existing business, they may find it helpful to visit the Medi-Cal website for more information at http://www.medi-cal.ca.gov/.The applicant/provider is advised that the Provider Enrollment page contains information about enrollment options available when there is a sale or purchase of a Medi-Cal enrolled

provider or business, including the option to submit a "Successor Liability with Joint and Several Liability" (DHCS 6217) agreement. This information is necessary because it will assist the applicant/provider if they are planning to sell or purchase a Medi-Cal enrolled provider or business.

- The applicant/provider is advised that enrollment forms are available at http://www.medi-cal.ca.gov/ and for more information about the forms and the regulatory requirements for participation in the Medi-Cal program, to visit the Department's Website at http://www.medi-cal.ca.gov/ and to click the "Provider Enrollment" link. Through experience the Department has found that this addition is necessary to give the applicant/provider the tools to read and understand requirements before completing the application.

- The applicant/provider is advised that if they have any additional enrollment questions, to contact the Provider Enrollment Message Center at (916) 323-1945, or via email at DHCSDMCRecert@dhcs.ca.gov. This will assist the applicant/provider in easily being able to contact the Department for clarification or assistance.

The following instructions have been included in the application:

- The applicant/provider is advised not to use staples on the form or any attachments, not to use correction tape, white out, or highlighter pen or ink of a similar type on the form. The applicant/provider is advised that if corrections are necessary, to line through, date, and initial. These adoptions were made to assist the Department in the application review process and to ensure the integrity of the form.

- The applicant/provider is advised to not leave any question, boxes, lines, etc. blank and to enter N/A if not applicable. This adoption was added to assist the applicant/provider in submitting a complete application by bringing to their attention that every question needs to be answered to ensure completion. Providing complete and accurate information is required pursuant to Section 51000.30(a)(2)(A) and is consistent with the definition of "applicant" under Section 51000.1.1. This information was added to assist the applicant/provider in understanding program requirements.

- The introduction paragraph has been adopted to include an explanation that the "Drug Medi-Cal Substance Use Disorder Application" is for the enrollment or continued enrollment of a provider in the Medi-Cal program. Applicants are informed that additional information and documentation may be required and that they may be subject to an onsite inspection. In accordance with WIC Section 14043.7(a), the Department's A&I Branch may conduct an onsite inspection of the applicant/providers place of business.

- The applicant/provider is advised that the "Medi-Cal Disclosure Statement," DHCS 6207 (Rev. 2/15)) and the "Drug Medi-Cal Provider Agreement," DHCS 6009 (Rev. 12/14) must be completed for enrollment and continued enrollment. These forms and additional information can be found at the Medi-Cal web site, Provider Enrollment link, at http://www.medi-cal.ca.gov/. This adoption is necessary as a Medi-Cal Disclosure Statement and Drug Medi-Cal Provider Agreement are required pursuant to Sections 51000.35(a) and 51000.45(d).

- The applicant/provider is advised that omission of any information or documentation on this form or failure to sign any of the documents may result in any of the denial actions identified in the Section 51000.50. This information assists the applicant/provider in understanding program requirements and the Department's authority to deny an incomplete application package, before completing the application.

- Instructions for the Provider Number (NPI) have been adopted to instruct the applicant to enter the NPI for the business address indicated in item 5. This information is necessary as it is required pursuant to Section 51000.30(d)(1) and as defined under Section 51000.20.

- Instructions for "Date" have been adopted to instruct the applicant to enter the date that they completed the application. This field is standard information that is requested across all Department applications and it assists the Department in determining when the application was completed.

- Instructions for the "Enrollment Action Requested" have been adopted to instruct the applicant to specify the action(s) they are requesting by checking the appropriate box(es) within a type of action category. These categories are "New provider" meaning that the applicant is not currently enrolled in the Medi-Cal program; "Change of business address'" meaning a current provider is requesting to relocate to a new business address; "Additional business address," meaning the applicant is currently enrolled in the Medi-Cal program and is requesting enrollment for an additional business address; "New taxpayer ID number," meaning a new taxpayer identification number (TIN) has been issued by the IRS to a currently enrolled provider; "Change of Ownership," meaning there is a change in ownership as defined in Section 51000.6; "Acceptance of Successor Liability with Joint and Several Liability'" meaning a provider transferor joins a transferee applicant to its Medi-Cal provider agreement, including its rights to use the provider number issued for that location; "Cumulative change of 50 percent or more in person(s) with ownership or control interest," meaning there is a cumulative change of 50 percent or more in person(s) with ownership or control interest; "Sale or transfer of assets," meaning there has been a sale or transfer of assets (an item of economic value owned by an individual or corporation); and "Continued enrollment," meaning the applicant is currently enrolled as a Medi-Cal provider and has been requested by the Department to

apply for continued enrollment in the Medi-Cal program, and the applicant must identify if the applicant intends to use their current provider number to bill for services delivered at the location listed on the application while the application request is pending. This action places the provider on provisional provider status. This information will assist the Department during the application review period in determining the purpose for the applicant/provider submitting an application package.

- Instructions for the "Medi-Cal Application Fee" have been adopted to instruct the applicant to check the appropriate box(es) and specify which fee categories apply. These categories are: the applicant is currently enrolled in the program at the business address listed on page 6, item 5 of the application; the applicant is currently enrolled in another State's Medicaid or Children's Health Insurance Program (CHIP) at the business address listed on the application; the applicant has paid the application fee to a Medicare contractor or another State's Medicaid or CHIP for the same business address; or the applicant has included an application fee check and/or an application fee waiver with the application. Applicants must provide verification if they meet any of the exemptions above. The applicant is advised that the Department can only accept a cashier's check as payment of the application fee made payable to the State of California, Department of Health Care Services. The Department established the Medi-Cal application fee requirements to implement Title 42 CFR Section 455.460. These requirements are necessary to comply with the February 2, 2011, Final Rule published by CMS in the Federal Register (Title 42 CFR Parts 405, 424, 447 et al., 76 Federal Register 5862-5971 [Feb. 2, 2011]), which implements provisions of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively known as the Affordable Care Act or ACA). The requirement to submit payment via a cashier's check is required via the regulatory provider bulletin, "Medi-Cal Application Fee Requirements for Compliance with 42 Code of Federal Regulations Section 455.460." In addition, the cashier's check is necessary because it is the safest method of payment and avoids lag time of personal checks clearing or bouncing, which also subjects the Department to penalty fees, and the Department does not have a system in place to accept credit card payments.

I. Applicant Information

- Instructions for "Type of entity" have been adopted to instruct the applicant to identify their business structure. If the business structure is a partnership, the applicant must attach a legible copy of the partnership agreement. If "Other" is checked, the applicant must list the type of entity. This information is necessary as it is required pursuant to Section 51000.30(d)(2). In addition, a partnership agreement is required pursuant to Section 51000.30(d)(2).

- Number 1, “Provider legal name” has been adopted to instruct the applicant to provide their legal name, which means the name that is listed with the Internal Revenue Service (IRS). This information is necessary as it is required to be reported on the application pursuant to Section 51000.30(d)(3).

- Number 2, “Business name” has been adopted to instruct the applicant to enter the name of the applicant or provider if different from the listed legal name. If this is a Fictitious Business Name, the applicant must provide the Fictitious Business Name Statement/Permit number and effective date, and must attach a legible copy of the recorded/stamped Fictitious Business Name Statement/Permit to the application. This information is necessary as it is required to be reported on the application pursuant to Sections 51000.30(d)(3) and 51000.30(e).

- Number 3, “Type of location” has been adopted to instruct the applicant to enter the type of location the applicant is providing services at (clinic, doctor’s office, residential, etc.). This information will assist the Department during the application review period in determining the practice type of the substance use disorder clinic and to make sure the service modalities provided are consistent with the practice type. For example, if the applicant is requesting DMC residential services but indicates on the application that they are a doctor’s office; the Department would have some insight on how the applicant is practicing. This information may also serve as a fraud indicator.

- Number 4, “business telephone number” have been adopted to instruct the applicant to provide the primary business telephone number used at the business address. A beeper number, cell phone, answering service, pager, facsimile, biller or billing service phone, or answering machine shall not be used as the primary business telephone. This information is necessary as it is required to be reported on the application pursuant to Section 51000.30(d)(5) and as defined under Section 51000.4.

- Number 5 ,“Business address” has been adopted to instruct the applicant to provide the business address, which is the actual location where services are rendered, including the street name and number, room or suite number or letter, city, county, state, and nine-digit ZIP code. A post office or commercial box is not acceptable. This information is necessary in order to determine whether the applicant/provider meets established place of business requirements pursuant to Section 51000.60. Furthermore, the applicant/provider is required to enroll at each location where services are required and each business address is kept on file with the Department.

- Number 6, “Mailing address” has been adopted to instruct the applicant to enter the address at which the applicant or provider wishes to receive Medi-Cal correspondence. The mailing address, as defined in Section 51000.11 is

necessary in order for the Department to send out general correspondence, such as information updates, to the provider.

- Number 7, “Previous business address” has been adopted to instruct the applicant to provide the previous business address at which they were previously enrolled. The applicant must enter N/A if the applicant is not submitting an application for a change of location. If the provider is requesting a change of address, the previous business address is needed so the Department can properly update the provider’s file.

- Number 8 has been adopted to instruct the applicant to submit their Taxpayer Identification Number (TIN) or Social Security Number (SSN) if they do not have a TIN and to submit verification. These forms include but are not limited to the IRS Form 941, Form 8109-C, Form 147-C, Form SS-4 (Confirmation Notification) or Form 2363. This adoption is necessary as it is required pursuant to Sections 51000.30(d)(3) and 51000.30(d)(12).

- Number 9 has been adopted to instruct the applicant to list their 6-digit CalOMS number. This adoption assists the Department during the application review period and is used as a tool to see if the applicant is currently enrolled in the Medi-Cal program.

- Number 10 has been adopted to instruct applicant to enter any local business license or permit numbers for any city and/or county in which business is conducted and to attach copy(ies) to the application for verification of information. This amendment is necessary as it is required pursuant to Sections 51000.30(e) and 51000.60(c)(4).

- Number 11 has been adopted to instruct the applicant/provider to enter their current DMC number, if applicable. This adoption assists the Department during the application review period and is used as a tool to see if the applicant is currently enrolled in the Medi-Cal program.

- Number 12 has been adopted to instruct the applicant to enter each taxonomy code associated with the NPI and to attach additional sheets if necessary. The taxonomy code is to be reported on the application in accordance with HIPAA, therefore, it has been added to the application.

- Number 13 has been adopted to instruct the applicant to provide requested information on liability insurance and attach to the application legible copy(ies) of the applicant’s current certificate of insurance for comprehensive liability insurance that covers premises and operation for the business address. This adoption is necessary as it is required pursuant to Sections 51000.30(f)(2) and 51000.60(c)(9)(D).

- Number 14 has been adopted to instruct the applicant to check the appropriate box that indicates whether the applicant has worker's compensation insurance as required by state law. The applicant must attach verification if applicable. It is required that the applicant/provider show evidence of workers compensation insurance pursuant to Sections 51000.30(f)(1) and 51000.60(c)(5), therefore, instructions have been incorporated into the application.

II. Service Modalities

- Number 15 has been adopted to instruct the applicant to enter all services to be provided by the substance use disorder clinic, including existing services and additional services or program types being requested by the application. The applicant/provider is required to list the service modalities they provide pursuant to Section 51000.30(d)(22)(E), therefore, instructions have been incorporated in to the application to assist the applicant/provider.

III. Residential Substance Use Disorder Services

- Instructions have been adopted to instruct the applicant that applicants for residential services must first obtain a residential license issued by the Department, or another governmental agency, prior to application submission for DMC residential services. The applicant is advised that the Department of Social Services may be contacted at http://www.cdss.ca.gov/cdssweb/PG69.htm for all licensing requirements and procedures. The applicant/provider is required to submit a copy of their valid residential license with the application pursuant to Section 51000.30(d)(22)(C), therefore, instructions have been adopted to assist the applicant/provider.

- Number 16 has been adopted to instruct the applicant to indicate whether they provide residential services at the business location; whether there are any other entities that provide residential services at the business address; to indicate if the facility is licensed by the Department, or another governmental agency, and to provide the residential license number and a valid copy; the applicant is instructed to check no and provide an explanation if not applicable. The applicant/provider is required to submit a copy of their valid residential license with the application pursuant to Section 51000.30(d)(22)(C). This information will assist the Department in determining what type of residential program the applicant/provider is. If the applicant/provider is a residential program, not licensed by the Department, and does not wish to provide DMC residential services then they do not have to obtain a residential license from the Department. This will assist the Department in determining the proper course of action to take on the application.

IV. Substance Use Disorder Treatment Professionals, Licensed Substance Use Disorder Treatment Professionals, and Substance Use Disorder Nonphysician Medical Practitioners

- Number 17 has been adopted to instruct the applicant to enter the name, provider number (NPI, if applicable), license/certification/registration information, and licensing authority for all substance use disorder nonphysician medical practitioners, licensed substance use disorder treatment professionals, and substance use disorder treatment professionals providing services at the clinic, and to attach additional sheets if necessary. This adoption is necessary as it is required pursuant to Section 51000.30(d)(22)(A), and 2.

V. Substance Use Disorder Medical Director Information

- Number 18, “Legal Name” has been adopted to instruct the applicant to print the last, first, and middle name of the substance use disorder medical director of the clinic. This adoption is necessary as it is required pursuant to Section 51000.30(d)(22)(G)1.

- Number 19 has been adopted to instruct the applicant to list the substance use disorder medical director’s medical license number and to attach a legible copy. This adoption is necessary as it is required pursuant to Section 51000.30(d)(22)(G)2.

- Number 20 has been adopted to instruct the applicant to provide the substance use disorder medical director’s provider number (NPI). This adoption is necessary as it is required pursuant to Section 51000.30(d)(22)(G)3.

VI. Information About Authorized Individual Signing This Application

- Number 21 has been adopted to instruct the applicant/provider to print the legal name of the individual signing on behalf of the applicant. This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B).

- Number 22 has been adopted to instruct the individual signing to list their gender. This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B).

- Number 23 has been adopted to instruct the individual signing to enter the driver’s license or state-issued identification card number and state of issuance. The driver’s license or state-issued identification number shall be issued within the 50 United States or the District of Columbia. This information is needed to

confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B). The driver's license of the individual signing is required pursuant to Section 51000.30(d)(9), therefore instructions have been added to the application to assist the applicant/provider.

- Number 24 has been adopted to instruct the individual signing to enter their date of birth. This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B), therefore, instructions have been adopted to assist the applicant/provider.

- Number 25 has been adopted to instruct the individual signing to enter their Social Security Number, which is mandatory. This adoption is necessary pursuant to the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). This adoption is also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- Number 26 has been adopted to instruct the applicant to provide an original signature of the individual listed in Number 21 and include the title of the person signing the application, city, state, and date where and when the application was signed. This adoption is necessary as it is required pursuant to Section 51000.30(a)(2)(C).

- Number 27 has been adopted to instruct the applicant that individuals signing on behalf of the applicant or provider that are licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code (BPC), the Osteopathic Initiative Act, or the Chiropractic Initiative Act, are not required to have this application notarized. If the application must be notarized, the Certificate of Acknowledgement signed by the Notary Public must be in the form specified in Section 1189 of the Civil Code. This information assists the Department in mitigating fraud and abuse by verifying the legitimacy of the signatory. In addition, notarization is required pursuant to Section 51000.30(a)(2)(D) and WIC Section 14043.25(c), and therefore, instructions have been added to the application.

- Number 28 has been adopted to instruct the applicant to provide contact information for the provider or other authorized person designated for Provider Enrollment staff to contact for clarification. Failure to include this information may result in the application package being returned deficient for item(s) that an applicant can readily provide by fax or telephone. This assists the expediency of

the review and keeps the application process from being delayed in the event the Department needs more or missing information from the applicant.

- Instructions for a checklist have been adopted to remind the applicant of the required forms, if applicable, that must to be attached to the application. The checklist includes: National Provider Identifier (NPI) verification (CMS/NPPES verification); proof of application fee payment to a Medicare contractor or another State's Medicaid/CHIP; TIN verification; Fictitious Business Name Statement or Fictitious Business Name Permit; applicable certifications, licensure, and/or registration for all listed professionals; driver's license or state-issued identification of the individual signing the application; business licensure or evidence of an exemption; certificate of comprehensive liability insurance; Medical license for the substance use disorder medical director; proof of worker's compensation insurance; Medicare enrollment verification; Successor Liability Agreement; Residential licensure issued by the Department or authorized governmental agency; signed Medi-Cal Disclosure Statement; and signed Drug Medi-Cal Provider Agreement. This information will assist the applicant/provider in being able to easily identify the items needed in order to provide a complete application package.

- "Approved Certifying Organizations" list has been adopted to inform the applicant on which organizations have been approved for certifying counselors, that are in compliance with Title 9, CCR, Section 13035(c), including California Consortium of Addiction Programs & Professionals (CCAPP); California Association of Alcohol/Drug Educators (CAADE); California Association of Drinking Driver Treatment Programs (CADDTP); and American Academy of Health Care Providers in the Addictive Disorder (AAHCPAD). This information will assist the applicant/provider in being able to easily identify approved certifying organizations as specified in Title 9, CCR, Section 13035(a) and (b).

The following additions are made to the application portion of the "Drug Medi-Cal Substance Use Disorder Clinic Application," DHCS 6001 (Rev.12/14):

- The applicant is advised to read all instructions before completing the application, to type or print clearly in ink, and to line through, date, and initial in ink if corrections are necessary. These adoptions were made to assist the Department in the application review process and ensure the integrity of the application.

- The applicant is advised to return completed forms to the Department of Health Care Services, Provider Enrollment Division, MS 4704, PO Box 997412 in Sacramento, CA, 95899-7412 and the Department's telephone number is additionally provided. This will assist the applicant/provider in sending the application package to the correct address.

- The applicant is advised not to use staples on the form or on any attachments and to not leave any questions, boxes, lines, etc. blank. The applicant is advised to enter N/A if not applicable. These adoptions were made to assist the Department in the application review process.

- The “Provider Number” (NPI) section instructs the applicant to enter the NPI. This information is necessary as it is required pursuant to Section 51000.30(d)(1) and as defined under Section 51000.20.

- The “Date” section instructs the applicant to enter the date the application is being completed. This field is standard information that is requested across all Department applications and assists the Department in determining when the application was completed.

- The “Enrollment Action Requested” section instructs the applicant to specify the action(s) it is requesting by checking the appropriate box(es) within a type of action category. These categories are “New Provider,” meaning that the applicant is not currently enrolled in the Medi-Cal program; “Change of business address,” meaning the applicant is requesting to relocate to a new business address; “Additional business address,” meaning the applicant is currently enrolled in the Medi-Cal program and is requesting enrollment for an additional business address; “New Taxpayer ID,” meaning a new Taxpayer Identification Number (TIN) has been issued by the IRS; “Change of Ownership,” meaning there is a change in ownership as defined in Section 51000.6; “Acceptance of Successor Liability with Joint and Several Liability,” meaning a provider transferor joins a transferee applicant to its Medi-Cal provider agreement, including its rights to use the provider number issued for that location; “Cumulative change of 50 percent or more in person(s) with ownership or control interest,” meaning there is a cumulative change of 50 percent or more in person(s) with ownership or control interest; “Sale or transfer of assets,” meaning there has been a sale or transfer of assets (an item of economic value owned by an individual or corporation); and “Continued Enrollment,” meaning the applicant is currently enrolled as a Medi-Cal provider and has been requested by the Department to apply for continued enrollment in the Medi-Cal program, and the applicant must identify if the applicant intends to use their current provider number to bill for services delivered at the located listed on the application while the application request is pending. This action places the provider on provisional provider status. This information will assist the Department during the application review period in determining the purpose for the applicant/provider submitting an application package.

- The “Medi-Cal Application Fee” section instructs the applicant to check the appropriate box(es) and specify which fee categories apply. These categories are “I am currently enrolled in the Medicare program at this business address and under this legal name. (Attach verification)”; “I am currently enrolled in

another State's Medicaid or Children's Health Insurance Program (CHIP) at this business address and under this legal name. (Attach Verification)"; "I have paid the application fee to a Medicare contractor or another state's Medicaid or CHIP for this business address, and under this legal name. (Attach proof of payment)"; and "I have included an application fee check and/or an application fee waiver with this application." In accordance with the CMS, the Department is to establish the Medi-Cal application fee requirements to implement Title 42 CFR Section 455.460. These requirements are necessary to comply with the February 2, 2011, Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR Parts 405, 424, 447 et al.), which implements provisions of the ACA.

Section I Applicant Information.

The "Applicant Information" section has been adopted to instruct the applicant to supply pertinent information pertaining to the applicant/provider. This information includes:

- The "Type of entity" section instructs the applicant to check only one type of business. The categories include, "Sole proprietorship," "Partnership," "Government Entity," "Corporation (including corporate number and state incorporated)," "Limited Liability Company (LLC) (including LLC number, and state registered/filed)," "Nonprofit Corporation (including type of nonprofit)," and "Other." This information is necessary and required pursuant to Section 51000.30(d)(2). In addition, a partnership agreement is required pursuant to Section 51000.30(d)(2).

- Number 1 instructs the applicant to provide the legal name by which the applicant/provider is listed with the Internal Revenue Service. This information is necessary as it is required to be reported on the application pursuant to Section 51000.30(d)(3).

- Number 2 instructs the applicant to provide the business name if different than the legal name listed in Number 1. The applicant must identify if a fictitious business name is being used. If so, the applicant must provide the fictitious business name statement/permit number, effective date, and attach a copy of the recorded/stamped fictitious business name statement/permit. This information is necessary as it is required to be reported on the application pursuant to Sections 51000.30(d)(3) and 51000.30(e).

- Number 3 instructs the applicant to list the type of business location (clinic, doctor's office, residential, etc.). This information will assist the Department during the application review period in determining what the practice type of the substance use disorder clinic is and to make sure that the service modalities provided are consistent with the practice type.

- Number 4 instructs the applicant to provide the telephone number at the business location. This information is necessary and required to be reported on the application pursuant to Section 51000.30(d)(5) and as defined in Section 51000.4.

- Number 5 instructs the applicant to list the business address, which is the actual location where services are rendered. This information is necessary in order to determine whether the applicant/provider meets established place of business requirements pursuant to Section 51000.60. Furthermore, the applicant/provider is required to enroll at each location where services are required and each business address is kept on file with the Department.

- Number 6 instructs the applicant to list the mailing address at which the applicant wishes to receive Medi-Cal correspondence. The mailing address, as defined in Section 51000.11 is necessary in order for the Department to send out general correspondence, such as information updates, to the provider.

- Number 7 instructs the applicant to provide the previous business address if there has been a change in the business location where services are rendered. If the provider is requesting a change of address, the previous business address is needed so the Department can properly update the provider's file.

- Number 8 instructs the applicant to provide the taxpayer identification number (TIN) or Social Security Number and attach a legible copy of the IRS form. This adoption is necessary as it is required pursuant to Sections 51000.30(d)(3) and 51000.30(d)(12).

- Number 9 instructs the applicant to enter the 6 digit CalOMS number if applicable. This adoption assists the Department during the application review period and is used as a tool to see if the applicant is currently enrolled in the Medi-Cal program. This adoption assists the Department during the application review period and is used as a tool to see if the applicant is currently enrolled in the Medi-Cal program.

- Number 10 instructs the applicant to provide any local business license/permit numbers and attach a legible copy. This amendment is necessary as it is required pursuant to Sections 51000.30(e) and 51000.60(c)(4).

- Number 11 instructs the applicant to provide the current DMC number (if applicable). This adoption assists the Department during the application review period and is used as a tool to see if the applicant is currently enrolled in the Medi-Cal program.

- Number 12 instructs the applicant to provide the primary taxonomy code. The taxonomy code is to be reported on the application in accordance with HIPAA, therefore, it has been added to the application.

- Number 13 instructs the applicant to provide proof of liability insurance including the name of the insurance company, insurance policy number, date the policy was issued, the expiration date of the policy, the insurance agent's name, telephone number, fax number, email address and to attach a copy of the certificate of insurance for the business address. This adoption is necessary as it is required pursuant to Sections 51000.30(f)(2) and 51000.60(c)(9)(D).

- Number 14 instructs the applicant to identify if they have worker's compensation as required by state law and to attach proof of maintenance of worker's compensation insurance, if applicable. It is required that the applicant/provider show evidence of worker's compensation insurance pursuant to Sections 51000.30(f)(1) and 51000.60(c)(5), therefore, instructions have been incorporated into the application.

Section II Service Modalities

- Number 15, the "Service Modalities" section, has been adopted to instruct the applicant to identify which service modalities they are provided and identify the treatment component (non-perinatal, or perinatal) requested for the business site. Applicants for perinatal residential services are required to first obtain a residential license issued by the Department prior to application submission for DMC residential services. Applicants are advised that a narcotic treatment program license issued by the Department is required to provide Narcotic Treatment Program (NTP) services. The applicant/provider is required to list the service modalities they provide pursuant to Section 51000.30(d)(22)(E).

- The service modalities include NTP and the license number, Intensive Outpatient Treatment (IOT), Outpatient Drug Free (ODF), Residential License number, and Naltrexone. The applicant/provider is required to submit a copy of their valid residential license with the application pursuant to Section 51000.30(d)(22)(C).

Section III Residential Substance Use Disorder Services

- Section (a) has been adopted to instruct the applicant to indicate whether they provide residential substance use disorder treatment services at the business address identified in item 5. The applicant/provider is required to submit a copy of their valid residential license with the application pursuant to Section 51000.30(d)(22)(C). This information will assist the Department in determining what type of residential program the applicant/provider is. If the applicant/provider is a residential program, not licensed by the Department, and does not wish to provide DMC residential services then they do not have to obtain a residential license from

the Department. This will assist the Department in determining the proper course of action to take on the application.

- Section (b) instructs the applicant to provide an explanation if the clinic is separately licensed by the Department, or another governmental agency, and include the license number. If not applicable, the applicant is instructed to check “no” and provide an explanation. The applicant/provider is required to submit a copy of their valid residential license with the application pursuant to Section 51000.30(d)(22)(C). This information will assist the Department in determining what type of residential program the applicant/provider is. If the applicant/provider is a residential program, not licensed by the Department, and does not wish to provide DMC residential services then they do not have to obtain a residential license from the Department. This will assist the Department in determining the proper course of action to take on the application.

- Section (c) instructs the applicant to identify if there is another entity at the business address that provides residential services. The applicant/provider is required to submit a copy of their valid residential license with the application pursuant to Section 51000.30(d)(22)(C). This information will assist the Department in determining what type of residential program the applicant/provider is. If the applicant/provider is a residential program, not licensed by the Department, and does not wish to provide DMC residential services then they do not have to obtain a residential license from the Department. This will assist the Department in determining the proper course of action to take on the application.

- The applicant is advised that they must first obtain a residential license prior to application submission for DMC residential services. The applicant/provider is required to submit a copy of their valid residential license with the application pursuant to Section 51000.30(d)(22)(C). This explanation was provided for additional clarification to the applicant/provider.

<u>Section IV Substance Use Disorder Treatment Professionals, Licensed Substance Use Disorder Treatment Professionals, and Substance Use Disorder Nonphysician Medical Practitioners</u>

- Number 17, the “Substance Use Disorder Treatment Professionals, Licensed Substance Use Disorder Treatment Professionals, and Substance Use Disorder Nonphysician Medical Practitioners” section has been adopted to instruct the applicant to supply pertinent information pertaining to all substance use disorder treatment professionals, licensed substance use disorder treatment professionals, and substance use disorder nonphysician medical practitioners providing services at the clinic. This information includes the name, provider number, license, certification, and registration information, and license or certification number. Certified and registered individuals must attach a legible copy of registration or certification. This adoption is necessary as it is required pursuant to Section 51000.30(d)(22)(A)1 and 2.

Section V Substance Use Disorder Medical Director Information

The “Substance Use Disorder Medical Director Information” section has been adopted to instruct the applicant to supply information pertaining to the substance use disorder medical director. This information includes:

- Number 18 instructs the applicant to provide the legal name of the substance use disorder medical director. This adoption is necessary as it is required pursuant to Section 51000.30(d)(22)(G)1.

- Number 19 instructs the applicant to provide the substance use disorder medical director’s license number and attach a legible copy. This adoption is necessary as it is required pursuant to Section 51000.30(d)(22)(G)1.

- Number 20 instructs the applicant to provide the substance use disorder medical director’s provider number (NPI). This adoption is necessary as it is required pursuant to Section 51000.30(d)(22)(G)3.

Section VI Information About the Authorized Individual Signing This Application

The “Information About the Authorized Individual Signing This Application” section has been adopted to instruct the applicant to supply pertinent information for the individual signing the application. This information includes:

- Number 21 instructs the applicant/provider to enter the legal name of the individual signing the application. This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B).

- Number 22 instructs the applicant/provider to enter the gender of the individual signing the application. This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B).

- Number 23 instructs the applicant/provider to provide the driver’s license or state-issued identification card number and state of issuance and attach a legible copy. This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B). The driver’s license of the individual signing is required pursuant to Section 51000.30(d)(9).

- Number 24 instructs the applicant to provide the date of birth. This information is needed to confirm the identity of the individual signing and to ensure the individual is

authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B).

- Number 25 instructs the applicant/provider to provide the Social Security Number. This adoption is necessary pursuant to the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). This adoption is also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- Number 26 instructs the applicant/provider to declare under penalty of perjury under the laws of the State of California that the foregoing information in the document, in the attachments, the disclosure statement, and provider agreement are true, accurate, and complete to the best of his/her knowledge and belief. The individual signing the application declares that he/she has the authority to legally bind the applicant or provider pursuant to Section 51000.30(a)(2)(B). This adoption is necessary to demonstrate who the individual is who is responsible for the contents of the application.

- Number 27 instructs the applicant to refer to the instructions under 27 for individuals who must have the application signed by a Notary Public in the form specified by Section 1189 of the Civil Code. This information assists the Department in mitigating fraud and abuse by verifying the legitimacy of the signatory. In addition, notarization is required pursuant to Section 51000.30(a)(2)(D) and WIC Section 14043.25(c) and therefore has been added to the application.

- Number 28 instructs the applicant to provide the “Contact Person’s Information,” identify if this individual is the same individual identified in item 21, and provide the contact person’s name, title/position, email address, and telephone number. This assists the Department in being able to contact the applicant/provider for application remediation or clarification. Failure to provide this information may result in the application package being returned deficient for item(s) that an applicant can readily provide by fax or telephone. This assists the expediency of the review and keeps the application process from being delayed in the event the Department needs more or missing information from the applicant.

- The statement added to the end of the application instructs the applicant/provider that all information requested on the application, the disclosure statement, and the provider agreement is mandatory. The information provided is required by the Department of Health Care Services, Provider Enrollment Division, by the authority of WIC Section 14043.2(a); and Section 51536. The consequences of not supplying the mandatory information requested are denial of enrollment as a Medi-Cal provider or denial of continued enrollment as a provider and deactivation of all provider

numbers used by the provider to obtain reimbursement from the Medi-Cal program. Any information may also be provided to the State Controller's Office, the California Department of Justice, the Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, fiscal intermediaries, managed care plans, the Federal Bureau of Investigation, the Internal Revenue Service, Medicare Fiscal Intermediaries, Centers for Medicare and Medicaid Services, Office of the Inspector General, Medicaid, and licensing programs in other states. The applicant/provider is advised that for more information or access to records containing their personal information maintained by the Department, to contact the Provider Enrollment Division at (916) 323-1945.

Section 51000.30, Subsection (c)(3)(I)

The Department proposes to amend this section to incorporate 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) form by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. PED forms are available on the Department's internet website at http://files.medi-cal.ca.gov/pubsdoco/prov_enroll.asp#Forms. Please refer to the applicable areas of this Statement of Reasons for an explanation of necessity for the newly adopted sections/subsections that are referenced throughout this discussion of necessity pertaining to 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).

The following instructions have been included on the application:

- The introduction paragraph has been adopted to include an explanation that 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" is for the sole purpose of enrollment as a substance use disorder medical director, licensed substance use disorder treatment professional, or substance use disorder nonphysician medical practitioner. This information was added to provide clarification on who is required to use this application for enrollment purposes.

- The applicant/provider is instructed to not use staples on the form or any attachments and to not use correction tape, white out, or highlighter pen or ink of a similar type or form. The applicant is instructed to line through, date and initial in ink if corrections are made. These adoptions were made to assist the Department in the application review process consistent with the processing of all Medi-Cal provider applications and to ensure the integrity of the form.

- The applicant/provider is advised to not leave any question, boxes, lines, etc. blank and to enter N/A if not applicable. This adoption was added to assist the applicant/provider in submitting a complete application by bringing to their attention that every question needs to be answered to ensure completion. Providing complete and accurate information is required pursuant to Section 51000.30(a)(2)(A) and is consistent with the definition of “applicant” under Section 51000.1.1. This information was added to assist the applicant/provider in understanding program requirements.

- Applicants and providers are informed that enrollment as a substance use disorder medical director, licensed substance use disorder treatment professional, or substance use disorder nonphysician medical practitioner does not allow the Medi-Cal program to reimburse the applicant/provider for services provided. The applicant/provider is not reimbursed directly from the Department or county; instead, the substance use disorder clinic is reimbursed for services provided. Therefore, this information was added for clarification purposes. The applicant/provider is advised that they may be subject to an onsite inspection and to unannounced visits prior to enrollment or approval of continued enrollment in a program in accordance with WIC Section 14043.7(a). The Department’s website is provided for additional information.

- Omission of any information on this form, or the failure to provide required documentation or signature in ink on any of these documents may result in denial of the application as provided in Section 51000.50. This information assists the applicant/provider in understanding program requirements and the Departments authority to deny an incomplete application package, before completing the application.

- Applicant/provider is advised that they must attach copies of Centers for Medicare Services/National Plan and Provider Enumeration System (CMS/NPPES) confirmation for each NPI submitted with the application package. Implementation of the NPI is a requirement of HIPAA and has therefore been added to the application cover letter.

- Instructions for “Provider Number (NPI)” have been adopted to instruct the applicant or provider to enter their NPI. This information is necessary as it is required pursuant to Section 51000.30(d)(1) and defined under Section 51000.20.

- Instructions for “Provider Type” have been adopted to instruct the applicant or provider to enter their provider type pursuant to Section 51051. This information assists the Department in determining which provider type the applicant/provider is requesting enrollment as.

- Instructions for “Date” have been adopted to instruct the applicant or provider to enter the date they are completing the application. This field is standard information that is requested across all Department applications and assists the Department in determining when they application was completed.

- Instructions for the “Enrollment Action Requested” have been adopted to instruct the applicant to specify the action(s) they are requesting by checking the appropriate box(es) within a type of action category. These categories are “Add New,” meaning that the applicant is not currently enrolled in the Medi-Cal program as a substance use disorder medical director, substance use disorder nonphysician medical practitioner, or a licensed substance use disorder treatment professional, or “Continued Enrollment,” meaning the applicant is currently enrolled as a Medi-Cal provider and has been requested by the Department to apply for continued enrollment in the Medi-Cal program. This information will assist the Department during the application review period in determining the purpose of the applicant/provider submitting an application package.

Section I Identifying Information

- Number 1, instructions for “Legal name” have been adopted to instruct the applicant to provide their legal name, which means the name that is listed on the applicant’s or provider’s professional license. This information is needed so the Department knows who the applicant/provider is requesting enrollment for.

- Number 2, instructions for “Date of Birth” have been adopted to instruct the applicant to enter the date of birth of the applicant or provider. This information is necessary for compliance with Section 51000.30(d)(8).

- Number 3, instructions for “Gender” have been adopted to instruct the applicant to enter the gender of the applicant or provider. This information is necessary for compliance with Section 51000.30(d)(8).

- Number 4, instructions for “Residence address” have been adopted to instruct the applicant to provide the applicant’s or provider’s residence address. This information is requested by the Department in case the application contains more personal information, such as the applicant/provider being under investigation by the Department, and the application needs to go back directly to the applicant/provider instead of going back to the contact person at the business location.

- Number 5, instructions for “Mailing address” have been adopted to instruct the applicant to enter the address at which the applicant or provider wishes to receive Medi-Cal correspondence. The mailing address, as defined in Section 51000.11 is necessary in order for the Department to send out general correspondence, such as information updates, to the provider.

- Number 6, instructions for “Social Security Number” have been adopted to instruct the applicant to enter the Social Security Number of the applicant or provider. This field is mandatory. This adoption is necessary pursuant to the Final

Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). This adoption is also necessary for compliance with 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- Number 7, instructions for "Driver's license number or state-issued identification card number and state of issuance" have been adopted to instruct the applicant of the type of identification information that needs to be submitted with the application. The applicant is also instructed to attach a current and legible copy of either the driver's license or state-issued identification card number to the application form. This adoption is necessary for compliance with Section 51000.30(d)(9).

- Number 8 has been adopted to instruct the applicant/provider to include both the effective date and the expiration date of the professional license/certification number and to provide a legible copy. This adoption is necessary for compliance with Section 51000.30(d)(10).

- Number 9, "Business address" has been adopted to instruct the applicant/provider to provide the business address, which is the actual location where services are rendered, including the street name and number, room or suite number or letter, city, county, state, and nine-digit ZIP code. A post office or commercial box is not acceptable. This information is necessary so the Department can conduct background research on the clinic to ensure the clinic and the applicant/provider meet Medi-Cal program requirements. The Department also needs to know which clinic the applicant/provider is providing services at so all files are current.

To mitigate fraud and abuse and assist the Department in verifying the identity of the substance use disorder clinic as a current Medi-Cal provider, the following are adopted:

- Number 10, instructions for "Name of entity at which services are provided" have been adopted to instruct the applicant/provider to provide the substance use disorder clinic sites legal name, which means the name that is listed with the Internal Revenue Service. This information is necessary in order to verify that the substance use disorder clinic is currently enrolled in the Medi-Cal program and to determine which clinic the substance use disorder medical director oversees.

- Number 11, instructions for "Provider number (NPI) of substance use disorder clinic site at which services are being provided" have been adopted to instruct the applicant to supply the provider number (NPI) for the entity listed in item number 10 on this application. This information is necessary in order to verify that the substance use disorder clinic is currently enrolled in the Medi-Cal program and to

determine which clinic(s) the substance use disorder medical director oversees. This information is additionally necessary to assist the Department during the application review period in identifying any potential issues. For example, if the substance use disorder director oversees twenty different substance use disorder clinics, and most are under investigation, the Department would do a more in-depth review and most likely subject the applicant to an onsite inspection.

- Number 12, instructions have been adopted to instruct the applicant/provider, if the applicant or provider is a substance use disorder medical director, to list the name(s) and location(s) of any other substance use disorder clinics currently being supervised by the listed substance use disorder medical director along with the number of hours worked per week at each location. This information is necessary in order to determine that the substance use disorder medical director is providing quality care for the amount of clinics being overseen. Depending on the applicant's/provider's answer, the Department may initiate an onsite review to ensure all clinics are being properly overseen by the substance use disorder medical director.

- Number 13, instructions have been adopted for the applicant/provider to provide requested information on liability insurance and attach to the application legible copy(ies) of the applicant's current certificate of insurance for professional liability insurance. This information is necessary as it is required pursuant to Sections 51000.30(f)(3) and 51000.60(c)(6).

Section II Disclosure Information

This information is necessary to mitigate fraud and abuse under the Medi-Cal program, specifically these requirements will provide the Department with relevant information and documentation that demonstrates the past and current status of a provider related to licensing, certification and participation and/or disciplinary action in other programs.

- Number 1 has been adopted for the applicant/provider to check whether they have been convicted of any felony or misdemeanor involving fraud or abuse in any government program within the last ten years. The applicant or provider must provide the date of conviction if applicable. This information is necessary as it is required by Title 42 CFR, Section 455.106; and Section 51000.35(a) and (b).

- Number 2 has been adopted for the applicant/provider to check the box whether they have been found liable for fraud or abuse involving a government program in any civil proceeding. The applicant or provider must provide the date of the final judgment if applicable. This information is necessary as it is required by Title 42 CFR, Section 455.106 and Section 51000.35(a) and (b).

- Number 3 has been adopted for the applicant/provider to check the box whether they have entered into a settlement in lieu of conviction for fraud or abuse

involving a governmental program. The applicant or provider must provide the date of settlement if applicable. This information is necessary as it is required by Section 51000.35(a) and (b).

- Number 4 has been adopted to instruct applicant/provider to check the appropriate box and complete the requested information indicating if they have participated in the Medi-Cal program or another state's Medicaid program. This information is necessary as it is required by Section 51000.35(a) and (b). This information notifies the Department that past information about this applicant/provider may be available for review.

- Number 5 has been adopted to instruct the applicant/provider to check the appropriate box and, if applicable, provide the effective date(s) of suspension(s) date(s) of reinstatement and Medicare or Medicaid provider number. This information is necessary as it is and required by Section 51000.35(a) and (b).

- Number 6 has been adopted to instruct the applicant/provider to check the appropriate box and, if applicable, list the state(s) where their license to provide health care was suspended or revoked and the effective dates of those actions, along with confirmation that professional privileges have been restored. This information is necessary in order to be compliant with Section 51000.35(a) and (b).

- Number 7 has been adopted for the applicant/provider to check the appropriate box and, if applicable, list the state(s) where the substance use disorder medical director's license to provide health care was lost or surrendered while a disciplinary hearing was pending and the effective dates of those actions, along with written confirmation that professional privileges have been restored. This information is necessary in order to be compliant with Section 51000.35(a) and (b).

- Number 8 has been adopted to instruct the applicant/provider to check the appropriate box and, if applicable, complete the requested information. This information is necessary in order to be compliant with Section 51000.35(a) and (b).

- Number 9 has been adopted to instruct the applicant/provider to list all fines/debts due and owing to any federal, state, or local government that relate to Medicare, Medicaid, and all other federal and state health care programs that have not been paid and what arrangements have been made to fulfill the obligation(s). Copies of all documents pertaining to the arrangement including terms and conditions must be submitted with the application. This information is necessary in order to be compliant with Section 51000.35(a) and (b).

<u>Section III Provider Agreement</u>

- Instructions have been adopted to instruct the applicant/provider to print their legal name and to provide their original signature. This information is needed to ensure an authorized individual is signing the application. The applicant/provider is also instructed to include the applicant's/provider's e-mail address and contact phone number in the event the Department needs to contact them for remediation.

- Instructions have been adopted to instruct the applicant/provider to provide contact information for the provider or other authorized person designated for Provider Enrollment staff to contact for further information or clarification. Failure to include this information may result in the application package being returned deficient for item(s) that an applicant can readily provide by fax or telephone. This assists the expediency of the review and keeps the application process from being delayed in the event the Department needs more or missing information from the applicant.

- Instructions for a checklist have been adopted to remind the applicant/provider of the required attachments that must to be attached to the application. The checklist includes: Driver's license or state-issued identification card, professional license certification (pocket license), National Provider Identifier (NPI) verification, and professional liability insurance. This checklist is necessary to assist the applicant/provider in being able to easily identify all supporting documents that are required in order for the application package to be complete.

- An additional checklist has been adopted to remind the applicant/provider of the required attachments, if applicable, that includes: verification of reinstatement, written confirmation from licensing authority that your professional privileges have been restored, written confirmation from the licensing authority that includes the terms and conditions of the disciplinary action taken and the status of the licensure and copies of all documents related to fulfilling all fines/debts. This checklist with assist the applicant/provider in being able to easily identify all supporting documents that may be required in order for the application package to be complete.

The following information is included on the application portion of 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).

- The applicant is advised to read all instructions before completing the application, type or print clearly in ink, and to line through, date and initial if corrections are made. These adoptions were made to assist the Department in the application review process and to ensure the integrity of the application.

- The applicant is instructed to return completed forms to: Department of Health Care Services, Provider Enrollment Division, MS 4704, P.O. Box 997412, Sacramento, CA, 95899-7412. This information will assist the applicant/provider in submitting a complete application package to the correct address.

- Instructions have been adopted to instruct the applicant on how to complete the form, and not to staple the form or any attachments and not to leave any questions, boxes, lines, etc. blank, and to enter N/A if not applicable. These adoptions were made to assist the Department in the application review process and to ensure all necessary information is provided.

- The "Provider Number (NPI)" section instructs the applicant to enter the NPI as applicable. This information is necessary and required pursuant to Section 51000.30(d)(1) and as defined under Section 51000.20.

- The "Provider Type" Section instructs the applicant to list their provider type. This information assists the Department in determining which provider type the applicant/provider is requesting enrollment as.

- The "Date" section instructs the applicant to enter the date the application is being completed. This field is standard information that is requested across all department applications and assists the Department in determining when the application was completed.

- The "Enrollment Action Requested" section instructs the applicant to specify the action(s) it is requesting by checking the appropriate box(es) within a type of action category. These categories are "New Substance Use Disorder Medical Director," meaning that the applicant is not currently enrolled in the Medi-Cal program as a substance use disorder medical director, "New Licensed Substance Use Disorder Treatment Professional," meaning that the applicant is not currently enrolled in the Medi-Cal program as a substance use disorder treatment professional, "New Substance Use Disorder Nonphysician Medical Practitioner," meaning the applicant is not currently enrolled in the Medi-Cal program as a substance use disorder nonphysician medical practitioner; or "Continued Enrollment," meaning the applicant is currently enrolled as a Medi-Cal provider and has been requested by the Department to apply for continued enrollment in the Medi-Cal program. This information will assist the Department during the application review period in determining the purpose of the submission of the application package by the applicant/provider.

<u>Section I Identifying Information</u>

The "Identifying Information" section has been adopted to instruct the applicant to supply pertinent information pertaining to the applicant/provider. This information is necessary during the application process for identification and verification purposes and

to ensure providers are eligible to participate in the Medi-Cal program. This information includes:

- Number 1 instructs the applicant/provider to provide the legal name as it appears on their professional license. This information is needed so the Department knows who the applicant/provider is requesting enrollment for.

- Number 2 instructs the applicant/provider to include the date of birth. This information is necessary for compliance with Section 51000.30(d)(8).

- Number 3 instructs the applicant/provider to specify their gender. This information is necessary for compliance with Section 51000.30(d)(8).

- Number 4 instructs the applicant/provider to include their residence address. This information is requested by the Department in case the application contains more personal information, such as the applicant/provider is under investigation by the Department, and the application needs to go back directly to the applicant/provider instead of going back to the contact person at the business location ensuring the protection of applicant privacy.

- Number 5 instructs the applicant/provider to list the mailing address at which the applicant/provider wishes to receive Medi-Cal correspondence. The mailing address, as defined in Section 51000.11 is necessary in order for the Department to send out general correspondence, such as information updates, to the provider.

- Number 6 instructs the applicant/provider to include their Social Security Number. This adoption is necessary pursuant to the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR Parts 405, 424, 447 et al.). This adoption is also necessary for compliance with Title 42 CFR Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- Number 7 instructs the applicant/provider to provide the driver's license number or state-issued ID and state of issuance and attach a current and legible copy. This adoption is necessary to ensure compliance with Section 51000.30(d)(9).

- Number 8 instructs the applicant/provider to provide their professional license/certification/permit number and attach a current and legible copy. This adoption is necessary for compliance with Section 51000.30(d)(10).

- Number 9 instructs the applicant/provider to list the business address, which is the actual location where services are rendered. This information is necessary so the Department can conduct background research on the clinic to ensure the clinic and the applicant/provider meets program requirements. The Department also needs to

know which clinic the applicant/provider is providing services at so all files are current.

- Number 10 instructs the applicant/provider to provide the legal name of the entity at which services are being provided. This information is necessary in order to verify that the substance use disorder clinic is currently enrolled in the Medi-Cal program and to determine which clinic the substance use disorder medical director oversees.

- Number 11 instructs the applicant/provider to provide the national provider identifier number for the entity listed in item 10 business addresses that includes street address, city, state, and zip code. This information is necessary in order to verify that the substance use disorder clinic is currently enrolled in the Medi-Cal program and to determine which clinic the substance use disorder medical director oversees.

- Number 12 instructs the applicant, if they are a substance use disorder medical director, to provide all the substance use disorder clinics currently supervised by the applicant/provider including the clinic name(s), business address(es), and provider numbers (NPI). If the applicant is not a substance use disorder medical director, they are instructed to proceed to number 13. This information is necessary in order to determine that the substance use disorder medical director is providing quality care based off the amount of clinics being overseen. Depending on the applicant's/provider's answer, the Department may initiate an onsite review to ensure that all clinics are being properly overseen by the substance use disorder medical director.

- Number 13 instructs the substance use disorder medical director to provide proof of professional liability insurance including the name of the insurance company, insurance policy number, date policy was issued, expiration date of policy, insurance agent's name, and telephone number. The applicant must attach a copy of their certificate of malpractice insurance. This information is necessary as it is required pursuant to Sections 51000.30(f)(3) and 51000.60(c)(6).

<u>Section II Disclosure Information:</u>

This information is necessary to mitigate fraud and abuse under the Medi-Cal program by ensuring that the Department is provided with the information necessary to assess the past and current status of an applicant/provider related to licensing/certification and participation and/or disciplinary action in other programs.

- Number 1 inquires if the applicant/provider has been convicted of any felony or misdemeanor involving fraud or abuse in any government program within ten years of the date of the statement. If yes, the applicant/provider must list the date of conviction. This information is necessary and required by Section 51000.35(a) and (b).

- Number 2 inquires if the applicant/provider has been found liable for fraud or abuse involving a government program in any civil proceeding within ten years of the date of the statement. If yes, the applicant/provider must list the date of final judgment. This information is necessary as it is required by Section 51000.35(a) and (b).

- Number 3 inquires if the applicant/provider entered into settlements in lieu of conviction for fraud or abuse involving a government program within ten years of the statement. If yes, the applicant/provider must list the date of settlement. This information is necessary and required by Section 51000.35(a) and (b).

- Number 4 inquires if the applicant/provider currently participates or has ever participated as a provider in the Medi-Cal program or in another state's Medicaid program. If yes, the applicant/provider must list the state, name, and provider number with which they participated. This information is necessary as it is required by Section 51000.35(a) and (b).

- Number 5 inquires if the applicant/provider has ever been suspended from a Medicare, Medicaid, or Medi-Cal program. If yes, the applicant/provider must indicate which program(s), their provider number, and effective and end dates of the suspension as well as provide verification of reinstatement. This information is necessary as it is required by Section 51000.35(a) and (b).

- Number 6 inquires if the applicant/provider license to provide health care has ever been suspended or revoked. If yes, the applicant/provider must list where the action was taken and the effective date(s) of the licensing authority's action(s), as well as attach written confirmation from the licensing authority that professional privileges have been restored. This information is necessary as it is required by Section 51000.35(a) and (b).

- Number 7 inquires if the applicant/provider has ever lost or surrendered their license, certificate, or other approval to provide health care while a disciplinary hearing was pending. If yes, the applicant/provider must indicate where the action was taken and the effective date(s) of the licensing authority's action(s), as well as attach a copy of the written confirmation from the licensing authority that professional privileges have been restored. This information is necessary as it is required by Section 51000.35(a) and (b).

- Number 8 inquires if the applicant/provider license, certificate, or other approval to provide health care ever been disciplined by any licensing authority. If yes, the applicant/provider must list where the action was taken, what the action was, and the effective dates of the actions. This information is necessary as it is required by Section 51000.35(a) and (b).

- Number 9 instructs the applicant to list all fines/debts due and owing by the applicant/provider to any federal, state or local government that relate to Medicare,

Medicaid and all other federal and state health care programs that have not been paid and what arrangements have been made to fulfill the obligation(s). The applicant/provider must submit copies of all documents pertaining to the arrangements including terms and conditions. This information is necessary as it is required by Section 51000.35(a) and (b).

Section III Provider Agreement

This information is necessary to ensure that the authorized individual signing the application is aware of and acknowledges the requirements and stipulations within this application. The agreement provides the following information:

- The applicant understands that this type of enrollment does not allow the Medi-Cal program to reimburse the applicant/provider for services provided, because payment for the services provided are distributed to the substance use disorder clinic and not to the individual applicant directly.

- The applicant/provider declares under penalty of perjury under the laws of the State of California that the foregoing information and all attachments are true, accurate, and complete to the best of the applicant's/provider's knowledge and belief. This statement is necessary as the provider is agreeing that all information and attachments are true and accurate. A provider agreement is required pursuant to Section 51000.45(e).

- The applicant/provider agrees that incorrect or inaccurate information may affect their eligibility to receive Medi-Cal reimbursement and that changes in the information on the application must be reported within 35 days to the California Department of Health Care Services, Provider Enrollment Division. This adoption is necessary as providers are required to report changes within 35 days pursuant to Section 51000.40(a). This information will additionally assist the applicant/provider in understanding and agreeing that they will submit any changes to the Department within 35 days.

- The applicant/provider agrees to abide by all Medi-Cal laws and regulations and the Medi Cal program policies and procedures as published in the Medi-Cal Provider Manual and understands that it is their responsibility to read the manual and its updates. A provider agreement is required pursuant to Section 51000.45(e).

- The applicant/provider agrees the Department, the County, and/or Attorney General (AG) may make unannounced visits to the applicant/provider, at any of the applicant's/provider's business locations, before, during and after enrollment, for the purpose of determining whether enrollment, continued enrollment, or certification is warranted, to investigate and prosecute fraud against the Medi-Cal program, to investigate complaints of abuse and neglect of patients in health care facilities receiving payment under the Medi-Cal program, and/or as necessary for the

administration of the Medi-Cal program and/or fulfillment of the AGs powers and duties under Government Code Section 12528. Premises subject to inspection are defined in WIC Section 14040.1. The applicant/provider agrees that failure to permit inspection by the Department, the County, or AG, or any agent, investigator or auditor thereof, shall be grounds for immediate suspension of Applicant/Provider from participation in the Medi-Cal program pursuant to WIC Section 14124.2(b)(1). On site visits are necessary for the Department to ensure Medi-Cal (and DMC) program integrity. In addition, a provider agreement is required pursuant to Section 51000.45(e).

- The applicant/provider certifies that they are an individual practitioner who is applying for the sole purpose of enrolling as a substance use disorder medical director, licensed substance use disorder treatment professional, or substance use disorder nonphysician medical practitioner. The applicant/provider understands that this enrollment type does not allow the Medi-Cal program to reimburse the applicant/provider for services provided. The applicant/provider is not reimbursed directly from the Department or county; instead, the substance use disorder clinic is reimbursed for services provided by the applicant/provider. Therefore, it is necessary to include this information and to help the applicant/provider attest to understanding this information for the purposes of transparency and clarity.

- The applicant/provider is instructed to enter the name, e-mail address, and telephone number of the applicant/provider. This serves as an additional tool if the contact person is not available and the Department needs clarification on parts of the application package; or if clarification is needed on personal information provided. This assists the expediency of the review and keeps the application process from being delayed in the event the Department needs more or missing information from the applicant.

- By providing an original signature the applicant/provider declares under penalty of perjury under the laws of the State of California that the foregoing information in the document, in the attachments, the disclosure statement, and provider agreement are true, accurate, and complete to the best of his/her knowledge and belief. The individual signing the application declares that he/she has the authority to legally bind the applicant or provider pursuant to Section 51000.30(a)(2)(B). Location of execution is requested to assist the Department in determining the validity of the signature provided.

- “Contact Person’s Information” instructs the applicant/provider to identify if this individual is the same individual identified in item 1, and provide the contact person’s name, title/position, email address, and telephone number. This will assist the Department in being able to contact the applicant/provider for clarification or remediation’s that can be done via fax.

- The applicant/provider is advised that all information requested on the application, the disclosure statement, and the provider agreement is mandatory. This information is required by the Department of Health Care Services, Provider Enrollment Division, by the authority of WIC Section 14043.2(a) and Title 22, California Code of Regulations, Section 51536. The consequences of not supplying the mandatory information requested are denial of enrollment as a Medi-Cal provider or denial of continued enrollment as a provider and deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program. Any information may also be provided to the State Controller's Office, the California Department of Justice, the Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, fiscal intermediaries, managed care plans, the Federal Bureau of Investigation, the Internal Revenue Service, Medicare Fiscal Intermediaries, Centers for Medicare and Medicaid Services, Office of the Inspector General, Medicaid, and licensing programs in other states. Pursuant to the California Public Records Act and Government Code Section 6253, the information provided is public unless specifically protected by law from disclosure, such as Social Security Numbers. Further, each identified entity above has its own legal authority for obtaining the information as it is necessary to the performance of that entity's responsibilities. In addition, the applicant/provider is advised for more information or access to records containing the applicant's/provider's personal information maintained by the Department, to contact the Provider Enrollment Division at (916) 323-1945.

Section 51000.30, Subsection (d)(22)

The Department proposes to adopt this subsection to set out application requirements specific to substance use disorder clinics. This section also cross-references Sections 51341.1, 51490.1, and 51516.1 of the CCR that currently regulate the DMC program. To enhance program integrity and decrease the risk of fraud, waste and abuse, it is necessary to set out enrollment criteria specific to substance use disorder clinics, within these sections and within the "Drug Medi-Cal Substance Use Disorder Clinic Application," DHCS 6001 (Rev. 12/14), as described.

Section 51000.30, Subsection (d)(22)(A)

The Department proposes to adopt Section 51000.30(d)(22)(A) to require all substance use disorder treatment professionals, licensed substance use disorder treatment professionals, and substance use disorder nonphysician medical practitioners to be listed on the application. It is necessary for a substance use disorder clinic to disclose these individuals who provide the actual services to beneficiaries so that the Department can ensure that the individuals meet all programmatic requirements. The applicant/provider must list whether the staff member is licensed, certified, or registered, and the licensing, certifying, or registering organization with the effective and expiration dates. This information will help the Department verify licenses, certification, and registration on the appropriate sites during application review. Additionally, this

information is required to verify that the training occurred in an approved program. Counseling staff shall be licensed, certified, or registered to ensure beneficiaries are receiving quality health care services. In addition, Title 9, CCR, Section 13010 requires that at least thirty percent of staff providing counseling services in the Drug Medi-Cal program to be licensed or certified. This requirement is necessary to verify that the counselors meet the established licensure, registration, and certification standards required pursuant to Title 9, CCR, Section 13010.

Section 51000.30, Subsection (d)(22)(A)1 - 2.

The Department proposes to adopt Section 51000.30(d)(22)(A)1 - 2. to require all certified or registered individuals rendering services on behalf of the applicant or provider, to submit proof of certification, or registration. This requirement is necessary in order to mitigate fraud, abuse, and waste in the Medi-Cal program. Because certified and registered staff are not required to enroll in the Medi-Cal program, it is difficult for the Department to verify the status of registered and certified staff during the application review process as required pursuant to Title 42 CFR, Section 455.412. By requiring the substance use disorder clinic to provide this information, the Department will be able to verify certification and registration during its review of the application. The Department is not requiring licensed staff to submit proof of their professional license with the clinic application because all licensed staff will be required to enroll and will submit proof of their professional license at the time they request to enroll.

Section 51000.30, Subsection (d)(22)(A)3.

The Department proposes to adopt this subsection to require that the substance use disorder clinic disclose the NPI of each licensed substance use disorder treatment professional, substance use disorder nonphysician medical practitioner, and if applicable, each substance use disorder treatment professional. This requirement is necessary in order to mitigate fraud, abuse, and waste in the Medi-Cal program by allowing the Department to verify that each substance use disorder professional is currently enrolled in the Medi-Cal program as a substance use disorder professional.

Section 51000.30, Subsection (d)(22)(B) -(C)

The Department proposes to adopt Section 51000.30(d)(22)(B) -(C) to require the applicant or provider to indicate whether they provide residential services, or perinatal residential substance use disorder treatment services at the business address. This requirement is necessary in order to mitigate fraud, abuse, and waste in the Medi-Cal program by providing the Department with relevant knowledge regarding the type of services a provider is authorized to offer. In addition, this information will give the Department an understanding of the type of services offered by the applicant or provider prior to the Department conducting an onsite review of the location. In addition, pursuant to HSC Sections 11834.01 and 11834.30 and Title 9, CCR, Section 10505, substance use disorder clinics providing perinatal residential services must be licensed

by the Department or another governmental agency prior to requesting to enroll in the DMC program. If an application is received from a substance use disorder clinic that provides perinatal residential substance use disorder treatment services but does not have a valid license, their application for enrollment cannot be processed. On the current application that is used for enrollment in the DMC program, the question solely asks whether the applicant or provider provides residential services. There is not a distinction between perinatal residential and non-perinatal residential programs.

Section 51000.30, Subsection (d)(22)(D)

The Department proposes to adopt Section 51000.30(d)(22)(D) to require the NTP licensure number to be listed on the application, along with proof of licensure. Programs providing NTP services must be licensed by the Department pursuant to HSC Sections 11217, 11839.3, and 11839.5 and Title 9, CCR, Section 10010. This amendment is necessary so that the Department can determine whether the NTP has the appropriate licensure to provide narcotic treatment services.

Section 51000.30, Subsection (d)(22)(E)

The Department proposes to adopt Section 51000.30(d)(22)(E) to require the applicant or provider identify the service modalities provided for the service address indicated on the application. Substance use disorder clinic providers are paid for each service modality they provide. Counties contract with DMC providers for specific services and plan funding for services via the contract. Therefore, it is required that the applicant or provider list all service modalities that will be provided. This amendment is necessary so that the Department can determine whether the service modalities offered by the substance use disorder clinic are being properly administered in accordance with the applicable statutes and regulations.

Section 51000.30, Subsection (d)(22)(F)

The Department proposes to adopt Section 51000.30(d)(22)(F) to require the applicant or provider to submit a copy of the board minutes upon the Department's request. When the signature on the application is not clear, this document serves as a tool to validate that the individual signing on behalf of the applicant or provider is an authorized individual. This information is necessary to increase program integrity and decrease the risk of fraud, waste, and abuse by ensuring an authorized individual is making decisions on behalf of the applicant or provider.

Section 51000.30, Subsection (d)(22)(G)1-3.

The Department proposes to adopt Section 51000.30(d)(22)(G)1-3. to specify the information that must be disclosed with respect to the substance use disorder medical director. This adoption is necessary to increase program integrity and decrease the risk of fraud, waste and abuse in the DMC program. This subsection specifies the

information that will assist the Department in identifying potentially fraudulent substance use disorder medical directors. The applicant/provider shall provide with the application:

1. The legal name of the substance use disorder medical director overseeing the substance use disorder clinic. This information is necessary for the Department to verify the identity of the substance use disorder medical director and combat potential fraud and abuse in the Medi-Cal program.
2. In order to mitigate fraud, abuse, and waste in the Medi-Cal program, the substance use disorder clinic must submit the medical license number and a copy of the professional license issued by the Medical Board of California or the Osteopathic Board of California for the substance use disorder medical director. This information is necessary for the Department to verify if the substance use disorder medical director has a current medical license. Additionally, this requirement will help ensure beneficiaries are receiving quality care at the oversight or direction of the substance use disorder medical director.
3. In order to mitigate fraud, abuse, and waste in the Medi-Cal program, the substance use disorder medical director's NPI must be submitted with the application package. This information must be provided to verify whether the substance use disorder medical director is currently enrolled in the Medi-Cal program and to ensure no state or federal sanctions have been placed on the substance use disorder medical director, thus disqualifying the substance use disorder clinic applicant or provider from enrollment in the Medi-Cal program.

<u>Section 51000.30, Subsection (d)(23)</u>

The Department proposes to adopt Section 51000.30(d)(23) to set out application requirements specific to the substance use disorder medical director. Through its investigations, the Department has determined that substance use disorder medical directors have played a major role in the fraud and abuse carried out by DMC providers. Only a physician can determine whether the services offered by the clinic are medically necessary for the beneficiary and thus eligible for payment under the Medi-Cal program. They also prescribe the course of treatment for the beneficiary. All medical services provided by the substance use disorder clinic must be under the direction of the substance use disorder medical director; therefore, to ensure public safety, it is necessary that the substance use disorder medical director be an enrolled provider. To enhance program integrity and decrease the risk of fraud, waste and abuse, it is necessary to set out enrollment criteria specific to substance use disorder medical director. The substance use disorder medical director shall provide the name and address of each substance use disorder clinic for which they provide medical oversight. This information is an essential tool during the Department's review of the substance use disorder medical director's application.

Section 51000.31. Medi-Cal Provider Group or Rendering Provider Application for Enrollment, Continued Enrollment or Enrollment at a New, Additional or Change in Location.

Section 51000.31, Subsection (b)

The Department amended Section 51000.31(b) to include the updated application title, form name and revision date for the "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers, DHCS 6216 (Rev. 2/15)" form which has been implemented via a provider bulletin, pursuant to WIC Section 14043.75, and was previously incorporated by reference above. Refer to prior explanation of specific amendments to this form.

Section 51000.35. Disclosure Requirements.

Section 51000.35 was last revised in 2005. The ACA made a number of changes to the Medicaid program that enhanced the provider and supplier enrollment process to improve the integrity of the programs to reduce fraud, waste, and abuse in the programs. The Department has implemented these changes through statute as well as by provider bulletins issued pursuant to its authority under WIC Section 14043.75. This regulation section does not include the changes made by the regulatory provider bulletin, so an update of the regulations are needed to reflect those changes as well as the proposed changes for enrollment of DMC providers. To do so, the Department significantly revises the text of Section 51000.35, through reorganization as well as additions, deletions and modifications of language. In some instances, the only way to clearly show the proposed language changes was to strike out entire provisions and set forth the new language. See below for further information.

Section 51000.35, Subsection (a)(1)-(6)

As described above Section 51000.35(a) is separated into multiple paragraphs for clarity. This amended subsection contains language that already exists in the section as well as additional language as explained in detail below. The phrase, under subsection (a) "'Medi-Cal Disclosure Statement,' DHS 6207 (Rev. 02/05) or the 'Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied Providers,' DHS 6216 (07/05) incorporated by reference herein, and submit the disclosure statement with the application required by Sections 51000.30 and 51000.40.," has been amended to read, "following forms incorporated by reference herein, using whichever form is applicable, and shall submit the disclosure statement with the application required by Sections 51000.30 and 51000.40," to provide clarity given that there are three different disclosure statements that must be submitted depending on the provider type.

Section 51000.35(a)(1)

The Department proposes to adopt this subsection, and to move the "Medi-Cal Disclosure Statement, DHS 6207 (Rev. 02/05)" from subsection (a) to subsection (a)(1), for purposes of clarity. In addition, the department designation in the form title is revised from "DHS" to "DHCS" and the date is revised from "02/05" to "2/15." This form has been amended via a provider bulletin pursuant to WIC Section 14043.75 since its initial implementation in regulations. Although the Department implemented the revised form via provider bulletin an explanation of all of the amendments have been included in this statement of reasons for purposes of clarity for the affected public.

As a result of the structure and appearance of the form, the existing version of the form is repealed in its entirety and is replaced with the newly adopted version. The only amendments on the newly adopted version that differ from the existing version are described below. All other provisions remain the same. The following amendments were made to the now entitled "Medi-Cal Disclosure Statement, DHCS 6207 (Rev. 2/15), and are herein incorporated by reference:

- The cover page has been amended to clarify that for new applicants, a failure to disclose complete and accurate information may result in denial of enrollment and a three-year reapplication bar. While for currently enrolled providers, failure to disclose may result in denial, deactivation of all business addresses and a three-year reapplication bar, this amendment was made for clarification purposes to distinguish which actions will be taken for applications versus currently enrolled providers. The provider is advised that the Department is required to report the termination of participation in the Medi-Cal program to the Centers for Medicare and Medicaid Services and to other States' Medicaid and Children's Health Insurance Programs pursuant to Title 42, United States Code, Sections 1396a(kk)(6) and 1902 (kk)(6); and Title 42 CFR, Section 1002.3(b).

- The table of contents has been amended. Section VI, Incontinence Supplies was moved from page 11 to page 13; Section VII, Pharmacy Applicants or Providers was moved from page 12 to page 14; Section VIII, Declaration and Signature Page was moved from page 13 to page 15. These amendments were made to reflect the correct pages as the reporting information in each section grew. In addition, Section V. "Subcontractor" was changed to "Subcontractor Information and Significant Business Transactions" to match the form portion of the disclosure.

General Instructions for Completing the Medi-Cal Disclosure Statement

- The instructions, "Do not leave any questions, boxes, lines, etc. blank" was amended and now additionally instructs the applicant/provider to check or write N/A if not applicable. This was done due to the Department receiving many incomplete disclosure statements and to better assist the applicant in providing complete responses.

Section I: Applicant/Provider Information

- Number 1 was adopted and replaces existing language that is no longer applicable, to advise the applicant/provider that all applicants and providers must complete Section I unless they are eligible to use the "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers," DHCS 6216), or the "Medi-Cal Ordering/Referring/Prescribing Provider Application/Agreement/Disclosure Statement for Physician and Nonphysician Practitioners," (DHCS 6219). This amendment was made because the disclosure statement is already included in the above applications; therefore they are not required to submit a separate disclosure statement.

- Number 2 was amended to clarify that rendering providers joining a group who are not eligible to use the "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers," DHCS 6216 (Rev. 2/15) should leave parts E–H blank if part D is checked. This clarification was needed to distinguish between the different rendering provider types in the Medi-Cal FFS program. If a rendering provider is not eligible to use the "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers," DHCS 6216 (Rev. 2/15), which is dependent on how they are practicing and their provider type, then they must submit a separate application form, along with a complete disclosure statement.

- Number 3 was adopted to advise the applicant that if they lease the location where services are being rendered or provided, a copy of a current signed lease agreement must be attached. A signed lease agreement is required pursuant to Section 51000.60(c)(9)(A). This amendment is necessary in order to determine that applicants/providers meet program requirements of having an established place of business.

- Number 4 was adopted to advise the applicant or provider that in California, a domestic or foreign limited liability company is not permitted to render professional services, as defined in Corporations Code Sections 13401, subdivision (a) and 13401.3. See California Corporations Code Section 17701.04(e). The Department has received many application packages where the entity structure is not set up appropriately for professional services and it was determined that it would be helpful to the applicant/provider to clarify that domestic or foreign limited liability companies are not permitted to render professional services in California.

Section II: Unincorporated Sole-Proprietor or Individual Rendering Provider Adding to a Group

- The Social Security Number is now mandatory. This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and

specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). This revision is also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

Section III. Ownership Interest and/or Managing Control Information (Entities)

- Number 1 was amended to include an example of how to determine percentage of ownership. The applicant/provider is advised, if A owns 10 percent of a note secured by 60 percent of the applicant's or provider's assets, A's interest in the provider's assets equates to 6 percent and shall be reported pursuant to the Section 51000.35, Conversely, if B owns 40 percent of a note secured by 10 percent of the applicant's or provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported. This example is necessary to assist the applicants or providers with completing the form accurately.

- Number 2 was amended to include an example of how to determine indirect ownership interest. The applicant/provider is advised, if A owns 10 percent of the stock in a corporation which owns 80 percent of the stock of the applicant or provider, A's interest equates to an 8 percent indirect ownership interest in the applicant or provider and shall be reported pursuant to Section 51000.35. Conversely, if B owns 80 percent of the stock of a corporation, which owns 5 percent of the stock of the applicant or provider, B's interest equates to a 4 percent indirect ownership interest in the applicant or provider and need not be reported. This example is necessary to assist the applicants or providers with completing the form accurately. Title 42 CFR Section 455.102 provides the basis of the formula used for the examples in numbers 1 and 2 above.

- Number 3 was amended to change "disclosing entity" to "applicant or provider." The words "disclosing entity" was removed and replaced with "applicant or provider" for clarity and to avoid confusion on who's ownership interest needs to be reflected on the disclosure statement.

- Number 5 was added and advises the applicant/provider to list the National Provider Identifier (NPI) of each listed corporation, unincorporated association, partnership, or similar entity having 5% or more (direct or indirect) ownership or control interest, or any partnership interest, in the applicant/provider identified in Section I. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- Number 6 was adopted and advises the applicant/provider that corporations with ownership or control interest in the applicant or provider must provide all corporate business addresses and the corporation Taxpayer Identification Number (TIN) issued by the IRS. For verification, a legible copy of the IRS Form 941, Form 8109-

C, Letter 147-C, or Form SS-4 (Confirmation Notification) must be included. This will assist the Department during the application review period as the Department will be able to enter the entities taxpayer identification numbers to see if they are enrolled into the program. The TIN verification is requested to additionally confirm the TIN number was entered on to the disclosure statement correctly.

Section IV: Ownership Interest and/or Managing Control Information (Individuals)

- Number 1 was amended to advise the applicant or provider to also refer to the definitions for clarity.

- Number 3 was amended and now includes a definition for agent. The applicant/provider is advised that an agent means a person who has been delegated the authority to obligate or act on behalf of an applicant or provider. This definition was added to provide clarity for the applicant/provider. This change is necessary to provide a clear and consistent description of this term as it is used on this form.

- Number 4 was amended and now includes a definition for managing employee. Previously, the applicant/provider was solely advised all management employees must be included in this section. However, due to confusion with completing this section of the disclosure statement, a definition was added for clarity. This change is necessary to provide a clear and consistent description of this term as it is used on this form.

- Number 5 was added and advises the applicant/provider to list the National Provider Identifier (NPI) of each individual with ownership or control interest or any partnership interest, in the applicant/provider identified in Section I. In addition, all officers of the corporation, directors, agents and managing employees of the applicant/provider must be reported in Section IV. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- Number 6 was amended; disclosure of the Social Security Number is no longer optional. The word “optional” was replaced with “mandatory,” so the applicant/provider is advised to see the Privacy Statement which is now on page 15. This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). This revision is also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

Section V: Subcontractor Information and Significant Business Transactions

- “Significant business transactions” was added to the title of this section to better reflect the questions that are being asked in this section for clarity purposes. There has been some confusion among providers understanding this term, therefore, it is necessary that it is included.

- Numbers 1 through 5 were removed from this section and moved to other sections of the disclosure statement to better match the information that is being asked of the applicant/provider.

- Number 7, “Subcontractor” was renumbered to number 1. Subsection “c” was removed. This amendment was done as the previous definitions are no longer in this section.

- Number 6, “Significant business transaction” was renumbered to number 2. This amendment was done as the previous definitions are no longer in this section.

- Number 3 was added to include the definition of a wholly owned supplier, which is a supplier whose total ownership interest is held by an applicant or provider or by a person, persons, or other entity with an ownership or control interest in an applicant or provider. Providers/applicants have been confused by this section and therefore, the definition has been added for more clarification. There has been some confusion among providers understanding this term, therefore, it is necessary that it is included.

<u>Section VIII: Declaration and Signature Page</u>

- Number 3 was amended to advise the applicant or provider to see Section 51000.30(a)(2)(B). This is necessary to clearly point the provider/applicant to the description of the person who must sign the form.

- Number 5 was amended to include “Dentists” to those that are excluded from the notarization requirement. Dentists now use the disclosure statement and have therefore been included.

The following amendments were made to the disclosure portion of the previously titled “Drug Medi-Cal Disclosure Statement” DHS 6207, Rev. 2/05:

- Item B, “if applicable” was removed and item B now instructs the applicant/provider that “if not applicable/check the box.” This amendment was made to provide clear instructions to the applicant/provider and is necessary as applicants/providers tend to leave this section blank, but not mark the box.

- Item C was amended and the term “Medi-Cal provider number(s) (if applicable)” was changed to “provider numbers.” In addition, the applicant/provider is instructed that

the NPI or Denti-Cal provider number used at the business address in item G should be listed as applicable. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA. In addition, Denti-Cal Provider Number was added to the disclosure statement as Denti-Cal applicants/providers now use this disclosure statement for enrollment into their program.

- Item D was amended and the phrase “marked with *asterisk below” was added for additional clarification and to better instruct the applicant/provider where to proceed from.

- Item E was amended and “if applicable” was removed. If not applicable, the applicant/provider is required to mark N/A. Therefore, “if applicable” is not necessary and was removed.

- Item F was amended and “if applicable” was removed. If not applicable, the applicant/provider is required to mark N/A. Therefore, “if applicable” is not necessary and was removed.

- Item G was amended and applicant/provider is now instructed to list their nine-digit ZIP code. This is also a universal update and “ZIP code” has been amended to “nine-digit ZIP code” throughout the disclosure statement.

- Item G(2) was amended and the applicant/provider is now instructed to enclose a copy of the current signed lease agreement, including any sublease agreements entered into by the applicant or provider at the business address on the application. This information is necessary to assist the applicants or providers with completing the forms accurately. In addition, a valid lease agreement is required pursuant to Section 51000.60(c)(9)(A) and has therefore been added to the disclosure statement.

- Item H has been amended and now instructs the applicant/provider to enclose Articles of Incorporation and Statement of Information if the applicant/provider is a corporation. This assists the Department during the application review period in verifying if the applicant/provider is a professional corporation, which is required when providing professional services as defined in Corporations Code Section 13401(b) and required in BPC Section 2406.

- Item J was amended and reworded to instruct the applicant or provider to list the name and address of all health care providers, participating or not participating in the Medi-Cal program, in which the applicant/provider, listed in Part A, also has an ownership or control interest. If none, check N/A. If additional space is needed, attach additional page (label “Additional Section I, Part J”). “Listed in Part A” was added to existing instructions to assist applicants and providers with completing the

form accurately. In addition, the “nine-digit” ZIP Code was added pursuant to WIC Section 14043.1(j) and Title 22, CCR, Section 51000.10.1. Furthermore, “See CCR, Title 22, Section 51051(b) for provider types” was removed from this section as the regulation is irrelevant to this section.

- Section I, Item K, Number 4 was amended to include “NPI and/or” to the existing table. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- Section I, Item K, Number 5 was amended to include “NPI and/or” to the existing table. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- Section I, Item K, Number 6 was amended to instruct the applicant/provider if they mark yes, to include copies of licensing authority decision(s) for each decision and written confirmation from them that their professional privileges have been restored and provide the action(s) taken in the table provided. This amendment is necessary as copies of “licensing authority decisions” and “actions taken” are required pursuant to Section 51000.35(c)(4).

- Section I, Item K, Number 7 was amended to add “action(s) taken” in the table provided. This amendment is necessary and required pursuant to Section 51000.35(c)(4).

- Section I, Item K, Number 8 was amended to instruct the applicant/provider if they mark yes, to include copies of licensing authority decision(s) for each decision, including any terms and conditions for each decision, and provide the action(s) taken in the table provided. This amendment is necessary as copies of “licensing authority decisions” and “actions taken” are required pursuant to Section 51000.35(c)(4).

<u>Section II. Unincorporated Sole-Proprietor or Individual Rendering Provider Adding to a Group</u>

- Item B was amended and “nine-digit” ZIP code was added pursuant to WIC Section 14043.1(j) and Title 22, CCR Section 51000.10.1.

- Item C was amended and the applicant/provider is advised that the Social Security Number is required. The social security number is no longer “optional” and is now “mandatory.” This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security

Numbers (SSNs). This revision is also necessary for compliance with 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

Section III. Ownership Interest and/or Managing Control Information (entities)

- The chart in Item A was amended to include a column for the listed entities to include their NPI if applicable. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- Item B, Number 3 was amended to include “nine-digit” ZIP code pursuant to WIC Section 14043.1(j) and Title 22, CCR, Section 51000.10.1. In addition, an “*asterisk” was added to instruct the entity to list their primary business address and attach a list of all business location addresses and PO Box addresses of the corporation, if the applicant/provider is a corporation. This information will assist the Department during the application review period by being able to link all businesses together and for the discovery of any potential fraud in the program.

- Item B, Number 4 through 6 were renumbered and are now 5 through 7. Number 4 now instructs the applicant/provider to list the taxpayer identification number issued by the IRS and attach a legible copy, if they are a corporation. This information will assist the Department during the application review period by being able to link all businesses together and for the discovery of any potential fraud in the program.

- Item C, Numbers 4 and 5 were amended to include “NPI AND/OR” to the existing tables. This change was made to better assist the Department during the applicable review period in determining whether any listed entities are enrolled in the Medi-Cal program. The Department can then do background research on the listed entities quicker to make sure they meet program requirements for participation.

- Item C, Number 6 was amended to include the nine-digit ZIP code, which is required pursuant to WIC Section 14043.1(j) and Title 22, CCR, Section 51000.10.1. In addition, “See CCR, Title 22, Section 51051(b) for provider types” has been removed as it is irrelevant to the question being asked. “Proceed to Section IV” has been removed because it is unnecessary and for purposes of clarity.

Section IV. Ownership Interest and/or Managing Control Information (Individuals)

- The word “agents” was added as an individual that must be reported in this section. This amendment is necessary as “agents” are included in the definition of “applicant”

pursuant to Section 51000.1 and therefore shall be listed in this section of the disclosure statement.

- The chart in Item A was amended to include “NPI number (if applicable).” This change was made to better assist the Department during the applicable review period in determining whether any listed individuals are enrolled in the Medi-Cal program. The Department can then do background research on the listed individuals quicker to make sure they meet program requirements for participation.

- The chart in Item B was amended to include a column for the listed individuals to include their NPI if applicable.

- Item B was amended and now advises the applicant/provider that this section is for identification information and is for individuals with ownership or control interest, officers, directors, managing employ(s), partners and/or agents of the partnership, group association, corporation, institution or entity. This amendment is necessary for clarification purposes and to better assist the applicant/provider in completing the disclosure statement properly.

- Item B, Number 2 was amended to include the nine-digit ZIP code to the residence address listed. A nine-digit ZIP code is required pursuant to WIC Section 14043.1(j); and Title 22, CCR, Section 51000.10.1.

- Item B, Number 3 was amended to indicate that the Social Security Number is required. This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). This revision is also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- Item B, Number 6 was amended and now includes page 7 and Section IV for clarity.

- Item B, Number 7 and 8, the word “agent” was added because many applicant business structures do not include “owners” or individuals with “managing control.” Non-profit corporations have board members and agents instead. The addition of this term allows for these business structures to disclose all required information.

- Item C, Number 4 and 5 was amended to include “NPI and/or” to the existing tables. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- Item C, Number 6 was amended to include the word “above” to the existing question. This was done for clarification purposes so the question is completed for the right individual. In addition, “action(s) taken” was added to the existing table and the applicant/provider is advised to include copies of licensing authority decision(s). These amendments are necessary and required pursuant to Section 51000.35(c)(4).

- Item C, Number 7 was amended to include the words “above individual” and “his or her” in the existing question. This was done for clarification purposes so the question is completed for the right individual. In addition, “action(s) taken” was added to the existing table provided. This amendment is necessary and required pursuant to Section 51000.35(c)(4).

- Item C, Number 8 was amended to include the words “above individual” and “his or her” in the existing question. This was done for clarification purposes so the question is completed for the right individual. In addition, the applicant/provider is instructed that if they mark yes, to include copies of the licensing authority decision(s) for each decision and terms and conditions for each decision and “action taken” was added to the existing table. These amendments are necessary and are required pursuant to Section 51000.35(c)(4).

- Item C, Number 9 has been amended and “See CCR, Title 22, Section 51051(b) for provider types” has been removed as it is irrelevant to the question being asked. “Proceed to Section V” has been removed as it is unnecessary and for clarity purposes.

<u>Section V. Subcontractor Information and Significant Business Transactions</u>

This section is necessary to assess conflict of interest and to prevent fraud.

- Part A was amended and some existing language was removed and replaced with language as described below. This section now instructs the applicant/provider to check the yes or no box on whether the applicant/provider (as named in Section I Part A on Page 1 of this form) has direct or indirect ownership of 5 percent or more in any of its subcontractors that provide health care services or goods. This amendment is necessary and required pursuant to Section 51000.35(b)(1).

    - The applicant/provider is instructed to check the yes or no box on whether any of the entities named in Section III, Part A on Page 5 of the disclosure statement have direct or indirect ownership of 5 percent or more in any of the applicant’s/provider’s subcontractors that provide health care services or goods. This amendment is necessary and required pursuant to Section 51000.35(b)(1).

    - The applicant/provider is instructed to check the yes or no box on whether any of the individuals named in Section IV, Part A on Page 7 of this form have

direct or indirect ownership of 5 percent or more in any of the applicant's/provider's subcontractors that provide health care services or goods. This amendment is necessary and required pursuant to Section 51000.35(b)(1).

- The applicant/provider is instructed to proceed to Section V, Part C on the next page if they answered no to all of the above questions in Part A. This amendment was added for clarification, to assist the applicant/provider in providing a complete disclosure statement. If Part A does not apply, the applicant/provider is still required to complete the following pages.

- The applicant/provider is instructed to complete the table about the subcontractor and attach a copy of any written agreement(s) that the applicant/provider has with the subcontractor that relate to its functions/responsibilities. The chart instructs the applicant to list the subcontractor's full legal name, subcontractor's telephone number, subcontractor's address (number, street), City, State, and nine-digit ZIP code, subcontractor's federal employer identification number if applicable, and subcontractor's corporation number if applicable. This amendment is necessary to assist the Department during the application review period to ensure all individuals are checked and meet program requirements for participation.

- The applicant/provider is instructed that if there is more than one subcontractor, provide a separate sheet with all required information (label "Additional Section V, Part A") and check the box indicating additional sheets have been attached. This amendment is necessary to clarify that if there is more than one subcontractor, they still need to be disclosed on a separate piece of paper since there is room for only one subcontractor to be listed.

- Part B, was amended and some existing language was removed and replaced with the language as described below. This section now instructs the applicant/provider to list the following information for any person or entity, other than the applicant/provider, with 5 percent or more ownership and/or control interest in any subcontractor listed in Part A. This information is necessary and required pursuant to Section 51000.35(b)(1).

  - Name of subcontractor in Part A, full legal name of person or entity with ownership or control interest in the subcontractor, phone number, address (number, street), City, State, nine-digit and ZIP code. The applicant/provider is instructed to check all applicable boxes that describe the individuals roll with the subcontractor reported in Part A. Boxes include 5% or more owner with percentage of ownership, director/officer with title listed, partner, managing employee, and/or other (specify). This information is required and

necessary pursuant to Section 51000.35(b)(1) and will additionally assist the Department during the application review period.

- The applicant/provider is instructed to mark yes or no for whether the above individual is related to any individual listed in Section IV, Table A (Page 7). If yes, the applicant/provider is instructed to check the appropriate box and list the name of the related individuals. Boxes include spouse, parent, child, sibling, and other (explain). This information is required and necessary pursuant to Section 51000.35(b)(2).

- If there is more than one subcontractor, the applicant/provider is instructed to provide a separate sheet with all required information (label "Additional Section V, Part B") and check the box indicating additional sheets have been attached, with the number of attached sheets listed. This amendment is necessary to clarify that if there is more than one subcontractor, they still need to be disclosed on a separate piece of paper since there is room for only one subcontractor to be listed.

- Part C has been amended and some existing language was removed and replaced with the language as described below. This section now instructs the applicant/provider to mark yes or no on whether they have had any significant business transactions with any wholly owned supplier or with any subcontractor (not listed on Part A) during the 5-year period immediately preceding the date of the Application. This information is necessary and required pursuant to Section 51000.35(b)(5).

  - The applicant/provider is advised that "significant business transaction" means any business transaction or series of transactions that involve health care services, goods, supplies, or merchandise related to the provision of services to beneficiaries that, during any one fiscal year, exceed the lesser of $25,000 or 5 percent of an applicant's or provider's total operating expenses. This information is necessary and required pursuant to Section 51000.35(b)(4) and (5).

  - The applicant/provider is advised that "wholly owned supplier" means any business transaction or series of transactions that involve health care services, goods, supplies, or merchandise related to the provision of services to beneficiaries that, during any one fiscal year, exceed the lesser of $25,000 or 5 percent of an applicant's or provider's total operating expenses. This information is necessary as there has been some confusion with providers not understanding how to properly complete this section. Wholly owned supplier is currently defined in Section 51000.26.
  - The applicant/provider is advised that "subcontractor" means an individual, agency, or organization to which an applicant or provider has contracted or delegated some of its management functions or responsibilities of providing

health care services, equipment, or supplies to its patients; or an individual, agency or organization with whom an applicant or provider has entered into a contract, agreement, purchase order, lease, or leases of real property, to obtain space, supplies, equipment, or services provided under the Medi-Cal program. This information is necessary as there has been some past confusion with providers not understanding how to properly complete this section. Subcontractor is currently defined in Section 51000.24.

- The applicant/provider is instructed to proceed to Section V, Part D on the next page if "no." This amendment was added for clarification, to assist the applicant/provider in providing a complete disclosure statement. If this section does not apply, the applicant/provider is still required to complete the following pages.

- If yes, the applicant/provider is instructed to provide the subcontractor's or supplier's full legal name, phone number, address (street, number), City, State, nine-digit ZIP code, and to describe the transaction(s). This information is necessary and required pursuant to Section 51000.35(b)(4) and (5).

- The applicant/provider is instructed that if there is more than one subcontractor or supplier, provide a separate sheet with all required information (label "Additional Section V, Part C"), check the box indicating additional sheets have been attached, with the number of attached sheets listed. This amendment is necessary to clarify that if there is more than one subcontractor, the other subcontractors still need to be disclosed on a separate piece of paper since there is room for only one subcontractor to be listed.

- Part D was added and instructs the applicant/provider to list the name and address of each person(s) with an ownership or control interest in any subcontractor (listed in Part C) 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 totals 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. If there is more than one subcontractor, the applicant/provider is instructed to provide a separate sheet with all required information. (Label "Additional Section V, Part D"). This information is required and necessary pursuant to Section 51000.35(b)(4).

    - The applicant/provider is instructed to check a box if no subcontractors are listed in Part C or if the applicant/provider has had no business transactions with subcontractors 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. The applicant is advised to proceed to Section VI if the box is checked. This amendment was added for clarification, to assist the applicant/provider in providing a complete disclosure statement. If this section does not apply, the applicant/provider is still required to complete the following pages.

- The applicant/provider is instructed to check the box if additional sheet(s) are attached and to list the number of additional pages in relation to the question asked in Part D. This amendment is necessary to clarify that if there is more than one subcontractor, they still need to be disclosed on a separate piece of paper since there is room for only one subcontractor to be listed.

- The applicant/provider is instructed to list the full legal name of person or entity with ownership or control interest, phone number, address (number, street), City, State, and nine-digit ZIP code. This information is necessary and required pursuant to Section 51000.35(b)(1).

Section VI. Incontinence Supplies

- Item A was amended to include the nine-digit ZIP code pursuant to WIC Section 14043.1(j) and Title 22, CCR, Section 51000.10.1.

Section VII. Pharmacy Applicants or Providers

- Item A was amended to provide clarification, "of licensing authority decision(s)" was added to existing language to clearly specify that the copy of the written confirmation includes the licensing authority decision, so the Department knows that privileges to provide services have been restored.

- Item B has been amended and "while a disciplinary hearing on his or her license was pending" was added to the existing question and "action(s) taken" was added to the existing table. These amendments are necessary pursuant to Section 51000.35(c)(4).

- Item C has been amended and the applicant/provider is instructed to include copies of licensing authority decision(s) including any terms and conditions and provide the information in the existing chart, if they answer yes. In addition, "action(s) taken" was added to the existing table. These amendments are necessary pursuant to Section 51000.35(c)(4).

Section VIII.

- This section was amended and Section 51000.30(a)(2)(B) was added to the declaration. This regulation section was added to provide clarification to the applicant/provider on who is authorized to sign the disclosure statement.

- Number 2 was amended to include, “with authority to legally bind the applicant or provider,” for clarification purposes. The change allows the applicant to read and recognize that an individual who is legally authorized has to sign the disclosure statement to make it official.

- Number 3 was amended to include “of the applicant, provider or the person with authority to legally bind the applicant or provider (in ink)” has been added for clarification purposes. The change allows the applicant to read and recognize that an individual who is legally authorized has to sign the disclosure statement to make it official.

- The Privacy statement was amended and the applicant/provider is advised that all information requested on the Application, the disclosure statement, and the provider agreement is mandatory. This information is required by the Department and any other California State Departments that are delegated responsibility to administer the Medi-Cal program, by the authority of the WIC Sections 14043 through 14043.75, Title 22, CCR Sections 51000 through 51451 and Title 42 CFR Part 455. The applicant/provider is advised that the consequences of not supplying the mandatory information requested are denial of enrollment as a Medi-Cal provider or denial of continued enrollment as a provider and deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program. Some or all of this information may also be provided to the California State Controller’s Office, the California Department of Justice, the California Department of Consumer Affairs, the California Department of Corporations, the California Franchise Tax Board or other California state or local agencies as appropriate, fiscal intermediaries, managed care plans, the Federal Bureau of Investigation, the Internal Revenue Service, Medicare Fiscal Intermediaries, Centers for Medicare and Medicaid Services, Office of the Inspector General, Medicaid, or as required or permitted by law. The applicant/provider is advised that for more information or access to records containing their personal information maintained by the Department, to contact the Provider Enrollment Division at (916) 323-1945 or contact Denti-Cal at (800) 423-0507. This privacy statement is consistent across all applications and forms and is necessary to ensure that the applicant/provider understands that all information requested is mandatory, and the bodies of law that are used to administer the Medi-Cal program. The Department also gives its due diligence by advising the applicant/provider of the consequences of not providing the required information. This privacy statement also advises the applicant/provider of additional entities that information may be shared with, as required or permitted by law. The applicant/provider is given PED’s and Denti-Cal’s telephone number for more information or to access records. This information is necessary as it is essential that the applicant/provider understands the Department’s right to share information, and with whom, and the telephone number they may use to attain additional information.

<u>Section 51000.35(a)(2)</u>

The Department proposes to adopt this subsection, and to move the "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied Providers, DHS 6216 (07/05)" from subsection (a) to subsection (a)(2) for clarity. In addition, the Department designation in the form title is revised from "DHS" to "DHCS," the word "Dental" is included in the form title, and the date is revised from "07/05" to "2/15." The Department implemented existing federal and state requirements via a regulatory provider bulletin pursuant to WIC Section 14043.75. Refer to prior explanation for Section 51000.30(c)(3)(F) regarding specific amendments to this form.

Section 51000.35(a)(3)

The Department proposes to adopt this subsection to require the substance use disorder medical director, licensed substance use disorder treatment professional, and substance use disorder nonphysician medical practitioner to disclose information that would help the Department in determining risk level. Section 51000.35 requires an applicant or provider to disclose all information required by federal Medicaid regulations and any other information required by the Department. Title 42 CFR Part 455, requires each state Medicaid agency to require providers of Medicaid services to disclose specified information as a condition for enrollment into the Medicaid program. Since the substance use disorder medical director, licensed substance use disorder treatment professionals, and substance use disorder nonphysician medical practitioners are required to enroll in the Medi-Cal program, they shall be required to disclose all pertinent information.

Section 51000.35, Subsection (b)

The Department proposes to amend Section 51000.35(b), the contents of which were previously located at Section 51000.35(a). This section has been redesignated and amended for clarity.

Section 51000.35, Subsection (b)(1)(A)-(D)

The Department proposes to amend Section 510000.35(b)(1)(A)-(D), which was previously located at Section 51000.35(a)(1), and has been redesignated and amended for clarity. The Department proposes to amend Section 51000.35(b)(1)(A) to add the requirement that providers disclose managing employees. WIC Section 14043.1(b) and (o) respectively define "applicant" and "provider" to include the "managing employees." Therefore, it is necessary that the managing employees be disclosed on the Medi-Cal Disclosure Statement. This requirement is applicable to Medi-Cal FFS applicants and providers, as well as the substance use disorder clinic applicants and providers. The Department proposes to amend Section 51000.35(b)(1)(D) to require disclosure of "board members and officers, if the applicant or provider is a non-profit entity." The purpose of the Medi-Cal Disclosure Statement is to obtain information regarding the individuals who exercise control over the entity in order to combat fraud and abuse in

the Medi-Cal program. With respect to non-profit entities, the board members and officers are legally and financially responsible for the conduct of the organization and these individuals must be disclosed in order for the Department to properly screen each applicant and provider.

Section 51000.35, Subsection (b)(2)

The Department proposes to amend Section 51000.35(b)(2), which was previously located at Section 51000.35(a)(2) and has been redesignated for clarity.

Section 51000.35, Subsection (b)(3)

The Department proposes to amend Section 51000.35(b)(3)(A)-(C), which was previously located at Section 51000.35(a)(3) and has been redesignated for clarity. The Department proposes to amend Section 51000.35(b)(3) to include the phrase "a managing employee, board member, officer." The purpose of the Medi-Cal Disclosure Statement is to obtain information regarding the individuals who exercise control over the entity in order to combat fraud and abuse in the Medi-Cal program. With respect to non-profit entities, the board members and officers are legally and financially responsible for the conduct of the organization. In addition WIC Section 14043.1(b) and (o) respectively define "applicant" and "provider" to include the "managing employees." This amendment is necessary to combat fraud and abuse in the Medi-Cal program because it provides the Department with information regarding the health care providers in which the managing employees, board members, and officers have an ownership or control interest. This requirement is applicable to Medi-Cal FFS applicants and providers, as well as the substance use disorder clinic applicants and providers.

Section 51000.35, Subsection (b)(4)-(6)(C)

Previous subsections (a)(4)-(6)(C) in Section 51000.35, have been redesignated to subsections (b)(4)-(6)(C).

Section 51000.35, Subsection (c)

The Department proposes to amend Section 51000.35(c) which was previously located at Section 51000.35(b) and has been redesignated for clarity. The Department proposes to amend Section 51000.35(c)(1) to change the phrase, "on the Medi-Cal Disclosure Statement, DHS 6207 (Rev. 02/05)" and replace it with "applicable application identified in subsection (a)." This amendment was necessary to provide clarity given that there are three different disclosure statements that must be submitted depending on provider type.

Section 51000.35, Subsection (d)

Previous subsection (c) has been redesignated to subsection (d).

Section 51000.40. Reporting of Additional or Changed Information to Provider Applications.

Section 51000.40, Subsection (b)

The Department proposes to amend Section 51000.40(b) to include the updated "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form that previously had a revision date of 11/05 and was previously referred to as the "DHS 6209." This form has been amended via a provider bulletin pursuant to WIC Section 14043.75 since its initial implementation in regulations. Although the Department implemented the revised form via provider bulletin an explanation of all of the amendments have been included in this statement of reasons for purposes of clarity for the affected public.

As a result of the structure and appearance of the form, the existing version of the form is repealed in its entirety and is replaced with the newly adopted version. The only amendments on the newly adopted version that differ from the existing version are described below. All other provisions remain the same. The following amendments have been made to this form and are herein incorporated by reference:

The following cover letter has been added to the application:

- The introduction paragraph of the cover letter has been adopted to include the Departments address where the application package must be returned to. This information was added for additional clarification and to assist the provider in submitting to form to the correct address.

- The provider is advised to read all the instructions included in the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form carefully and complete each item requested. Incomplete forms will be returned. The Department receives many incomplete forms and has determined that it is necessary to offer a reminder to providers that incomplete forms cannot be processed.

- Applicants and providers are advised that they are required to submit their NPI with each Medi-Cal provider application package. Applicants are required to attach a copy of the CMS/National Plan and Provider Enumeration System (CMS/NPPES) confirmation for each NPI listed in the application package. If providers are not eligible to receive an NPI, they should instead enter the word "atypical" in any NPI fields. "Atypical providers" will receive a unique Medi-Cal provider number once the application is approved. Implementation of the NPI, is a requirement of HIPAA and has therefore been added to the application cover letter.

- The cover letter advises the provider that it is their responsibility to report to the Department any modifications to information previously submitted within 35 days

from the date of the change. The provider is advised that most changes may be reported on the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form. However, the provider must complete a new application package if the provider is reporting a change of ownership of 50 percent or more, a change of business address, or one of the other changes identified in Section 51000.30(a) and (b). This information was added for clarification purposes and is necessary to assist the provider in updating their information with the correct form/application.

- The cover letter advises the provider that if they are planning to sell their business or buy an existing business, they may find it helpful to refer to the Medi-Cal Provider Enrollment page at http://www.medi-cal.ca.gov/. The Provider Enrollment page contains information about enrollment options available whenever there is a sale or purchase of a Medi-Cal enrolled provider or business, including the option to submit a "Successor Liability with Joint and Several Liability" agreement. This information is necessary because it will assist the applicant/provider if they are planning to sell or purchase a Medi-Cal enrolled provider or business.

- The cover letter also instructs the provider to contact the Provider Enrollment Message Center at (916) 323-1945, or submit question(s) to the PO Box address listed or via email at PEDCorr@dhcs.ca.gov. This information is necessary to assist the provider in being able to contact the Provider Enrollment Division if clarification is needed.

- The provider is advised to visit the Medi-Cal website at http://www.medi-cal.ca.gov/ for information on submitting claims electronically. A submitter number is not transferable. The provider is advised that a new submitter number must be obtained each time a new Medi-Cal provider number is issued by the Department. The provider is advised that if they have any questions about obtaining an electronic billing submitter number to call the Telephone Service Center at (800) 541-5555 and select the option for Computer Media Claims. This information was added for clarification purposes and to assist the provider in being able to contact the Telephone Service Center for billing questions.

The following amendments were made to the newly titled "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14):

- The header has been amended and now states the "Department of Health Care Services." The Department's name has changed from the Department of Health Services to the Department of Health Care Services pursuant to SB 162 (Stats of. 2006, Ch. 241); therefore, the header has been amended for accuracy. In addition, Toby Douglas is no longer the Director of the Department, so the header was updated to include the new Director, Jennifer Kent.

- The introduction paragraph was amended and the provider is no longer advised not to use staples on the form or any attachments; instead, the provider is instructed that if corrections are necessary, to line through, initial, and date in ink. This amendment will assist the Department during the application review period by ensuring all corrections are made by the applicant/provider and to ensure the integrity of the application.

- The provider is no longer advised that omission of any required information may result in any denial actions pursuant to Section 51000.50, instead the provider is advised that omissions of any required information or documents on the form, including not signing the form, may result in the records with the Medi-Cal program not being updated as requested. This amendment is necessary as the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form is not an application and therefore, cannot be denied. The Department simply cannot update the provider's information if the form is not complete.

- The provider is advised that they must attach copies of CMS/NPPES confirmation for each NPI submitted with this form. The form was revised to accommodate the NPI. Implementation of the NPI is a requirement of HIPAA and is therefore a necessary addition to this form.

- The provider is additionally instructed to enter the (NPI or Denti-Cal provider number). Implementation of the NPI, is a requirement of HIPAA and has therefore been added to the form. In addition Denti-Cal providers now additionally use this form to update their information and have therefore been incorporated.

- "Deactivate provider number" was added to advise the provider that marking this box will result in deactivation of all enrolled locations using the provider number submitted. The provider is instructed that in order to deactivate an enrolled provider type or location, the provider should attach a cover letter specifying the deactivation request. This amendment is consistent with the requirement on the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form pursuant to Section 51000.40(b)(9). This amendment is necessary to assist the provider while completing the form and it is important that the provider knows that all enrolled locations under that NPI will be deactivated unless a cover letter is provided specifying specific locations.

- The instructions were amended to reflect the correct boxes (40-45) and (46) that the provider must complete if the provider is adding, changing, or deleting, or completing the action requested. As more fields were added to the form, the numbering was altered for clarity. This change allows the provider to read the instructions in the right order, before completing the form portion. In addition, "number" was changed to "box" for consistency throughout this sentence.

General Information

- Universal edit – numbers 1 through 4 were amended to include the word “enter” to existing language and now instructs the provider to “enter” the requested information. This amendment was made to properly instruct the provider to enter the information requested and was done for clarity purposes.

- Number 3, “Pay-to address” was amended to instruct the provider that only one pay-to address may be assigned per NPI. The Department’s payment system only allows one pay-to address per NPI. One payment is made per NPI and sent to one location. In addition, substance use disorder clinic sites may not use the form to update their pay-to address. Since substance use disorder clinics contract through the County for payment, their pay-to address will need to be updated with the County; therefore, the Department has no use for the substance use disorder clinic’s pay-to address. In addition, the original instructions were restructured to match the form portion where the provider enters their information, for purposes of consistency and clarity.

- Number 6 was amended and no longer instructs the provider to list their Medicare billing number. Number 6 now instructs the provider to insert any additional NPI for the entity indicated in number 1 and attach an NPI confirmation for each. Providers not eligible to receive an NPI must submit their Medicare billing number. The form was revised to accommodate the NPI. Implementation of the NPI is a requirement of HIPAA and is therefore a necessary amendment. In addition, the word “should” was changed to “must,” submit their Medicare billing number. The providers Medicare billing number is required to be listed if the provider does not have an NPI. The Medicare billing number is required pursuant to Section 51000.40(b)(5).

- Number 8 was amended and the order of the words were switched to “license, permit, and certificate number” to match the form portion and is therefore a necessary amendment.

- Number 9 was amended and now has a subsection (a) and (b). Subsection (a) instructs the provider to insert the specialty codes to be added or deleted and instructs the provider to see page 14 for codes. This change is necessary since the codes are no longer on page 9 and have moved to page 14. In addition, subsection (b) is added, and instructs the provider to insert the provider’s taxonomy code(s) to be added or deleted from their NPI. The provider is advised that the taxonomy codes must already be registered with CMS/NPPES prior to submission to the Medi-Cal program and to attach additional sheets if necessary. The provider enters each taxonomy code that they used in their original application to CMS/NPPES associated with their NPI and this amendment allows the provider to update their taxonomy code via the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14). This information is necessary in order to be

in compliance with Section 51000.30(d)(13)(A). In addition, specialty codes are used for billing and therefore, need to be listed in the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14). Furthermore, taxonomy codes are 10-digit codes used to identify a provider's specialty area(s). Taxonomy codes are required to be submitted pursuant to the Medi-Cal Regulatory provider bulletin "Provider Enrollment Application Changes Due to NPI," effective February 15, 2008.

- The subheader, "Change of Ownership or Control Interest" was added above number 10 for clarification purposes. This amendment is necessary in order to be consistent with the form portion of the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) and to assist the provider in being able to easily read applicable instruction sections.

- The subheader, "Change in Hours of Operation" was added above number 11 for clarification purposes. This amendment is necessary in order to be consistent with the form portion of the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) and to assist the provider in being able to easily read applicable instruction sections.

- The subheader, "For Durable Medical Equipment and Pharmacy Providers Only" was added above number 12 for clarification purposes. This amendment is necessary in order to be consistent with the form portion of the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) and to assist the provider in being able to easily read applicable instruction sections.

- Number 12 was amended to instruct the provider to check the appropriate box indicating whether the applicant provides "custom rehabilitation equipment" and "custom rehabilitation technology services" to beneficiaries. The provider is instructed that if they answer yes, to check the appropriate box whether the provider has on staff, either as an employee or independent contractor, or the applicant has a contractual relationship with, a "qualified rehabilitation professional" who was directly involved in determining the specific custom rehabilitation equipment needs of the patient and was directly involved with, or closely supervised, the final fitting and delivery of the custom rehabilitation equipment. This information is necessary and the requirement is specified by WIC Section 14105.485.

The provider is instructed that "Custom rehabilitation equipment" means any item, piece of equipment, or product system, whether modified or customized, that is used to increase, maintain, or improve functional capabilities with respect to mobility and reduce anatomical degradation and complications of individuals with disabilities. The provider is advised that custom rehabilitation equipment includes, but is not limited to, nonstandard manual wheelchairs, power wheelchairs and seating systems, power scooters that are specially configured, ordered, and measured based on patient height,

weight, and disability, specialized wheelchair electronics and cushions, custom bath equipment, standers, gait trainers, and specialized strollers. This information was added to assist the provider in determining what meets the definition of custom rehabilitation equipment. This definition is consistent with the definition as specified in WIC Section 14105.485(c)(1).

The provider is advised that “custom rehabilitation technology services” means the application of enabling technology systems designed and assembled to meet the needs of a specific person experiencing any permanent or long-term loss or abnormality of physical or anatomical structure or function with respect to mobility. The provider is advised that these services include, but are not limited to, the evaluation of the needs of a patient with a disability, including an assessment of the patient for the purpose of ensuring that the proposed equipment is appropriate, the documentation of medical necessity, the selection, fit, customization, maintenance, assembly, repair replacement, pickup and delivery, and testing of equipment and parts, and the training of an assistant caregiver and of a patient who will use the equipment or individuals who will assist the client in using the equipment. This information was added to assist the provider in determining what meets the definition of custom rehabilitation technology. This definition is consistent with the definition as specified in WIC Section 14105.485(c)(2).

The provider is advised that “Qualified rehabilitation professional” means an individual to whom any one of the below applies. This information was added to assist the provider in determining what a “qualified rehabilitation professional” is and it is consistent with the definition as specified in WIC Section 14105.485(c)(3).

- The individual is a physical therapist licensed pursuant to the Business and Professions Code, occupational therapist licensed pursuant to the Business and Professions Code, or other qualified health care professional recognized by the Department.

- The individual is a registered member in good standing of the National Registry of Rehabilitation Technology Suppliers, or other credentialing organization recognized by the Department.

- The individual has successfully passed one of the following credentialing examinations administered by the Rehabilitation Engineering and Assistive Technology Society of North America:

  - The Assistive Technology Supplier examination.
  - The Assistive Technology Practitioner examination.
  - The Rehabilitation Engineering Technologist examination.

- Number 14, “Geographic area(s) served,” was renumbered and is now number 15. Number 14 now instructs the provider to check the appropriate boxes and

complete all requested information. The sequential order was changed as more information was added to the form.

- The subheader, "For Transportation Providers Only" was added above number 15 for clarification purposes. This amendment is necessary in order to be consistent with the form portion of the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) and to assist the provider in being able to easily read applicable instruction sections.

- Numbers 15 through 28 were renumbered to numbers 16 through 29 in the same chronological order. The sequential order was changed as more information was added to the form.

- Number 16, “Driver” was amended and “Driver’s license year of expiration” and “DMV DL-51 effective and expiration dates” were added to the checklist. This information is necessary in order to be consistent with the form portion of the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form, and this information is additionally required pursuant to Section 51000.30(d)(18)(D)2.

- Number 17, “Pilot,” checklist was amended to match the information as recorded on the form portion of the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14), for consistency purposes. This change allows the provider to easily identify the items that needs to be submitted with the form to update their file. Pilot’s driver’s license number or state issued identification card; pilot’s license number with year of expiration; copy of FAA pilot’s license for each pilot; copy of pilots driver’s license or state issued identification card were added to the checklist. This information is necessary to ensure the safety of beneficiaries by verifying that the pilot is licensed as such. In addition, this information is necessary in order for the Department to be in compliance with Section 51000.30(d)(18)(D).

- Number 18, “Litter and/or wheelchair van” has been amended as follows: “Litter and/or wheelchair van” was changed to “Vehicle Information (litter and/or wheelchair van)” with the following checklist additional items to be attached: DMV registration, proof of vehicle insurance, brake lamp certificate and special vehicle permit (if applicable). In addition, “Driver” was changed to “Driver Information” with the following checklist of items to be attached: DMV driving record printout for each driver, certificates for first aid and CPR for each driver, standard pre-employment drug and alcohol tests lab results for each driver, California driver’s license for each driver, special driver’s permit (if applicable), and DMV DL-51 form signed by a physician for each driver. These amendments have been made to match the information as recorded on the form portion of the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form for consistency purposes. These changes also allow the provider to easily identify the items that

need to be submitted with the form to update their file. This information is required in order to be in compliance with Sections 51000.30(d)(18)(A) and (D).

- The subheader, “For Pharmacies Only” was added above number 19 for clarification purposes. This amendment is necessary in order to be consistent with the form portion of the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) and to assist the provider in being able to easily read applicable instruction sections.

- Number 19 was amended and the order of the legal name (first, middle, and last) was changed to (last, first, middle). This change was done to be consistent with the form portion of the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form.

- Number 20 has been amended and the provider is no longer instructed to view the privacy statement. This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). These revisions are also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- Number 21 has been amended to instruct the provider to attach a legible copy of license and renewal, if applicable. This amendment is necessary to match the form portion of the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form and for consistency.

- Numbers 23 through 28 have been redesignated from numbers 22-27 and the provider is directed to number 29, which has been redesignated from number 28.

- Number 29 has been amended and the existing language removed and replaced with language that the provider is now instructed to provide all details to any answers for numbers 23 through 28, which has been redesignated from numbers 22-27.

- The header, “Providers of Substance Use Disorder Treatment Services Only” and subheader “New Substance Use Disorder Medical Director or Physician Making Medical Necessity Determinations” were added above number 30 for clarification purposes. This amendment is necessary in order to be consistent with the form portion of Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) and to assist the provider in being able to easily read applicable instruction sections.

- Existing numbers 30 through 36 have been redesignated in the same chronological order and are now numbers 39 through 45.

- Number 30 is added to instruct the provider to insert the last, first, and middle name of the substance use disorder medical director or physician determining medical necessity at the business location. This information is necessary in order to report a change in substance use disorder medical director pursuant to Section 51000.40(b)(14)(A) and to ensure that the Department is aware of who this person is, to ensure qualified providers provide care to beneficiaries.

- A new number 31 is added to instruct the provider to provide the (NPI), and attach a legible copy, of the substance use disorder medical director or physician determining medical necessity. This information is necessary in order to report a change in a substance use disorder medical director or physician pursuant to Section 51000.40(b)(14)(A). This information is requested for verification purposes as the Department will need the NPI to look up the substance use disorder medical director or physician determining medical necessity in the Department's internal system. Furthermore, requiring the provider to list their NPI and provide a legible copy is a HIPAA requirement as therefore has been added to the form.

- A new number 32 is added to instruct the provider to provide the medical license number of the substance use disorder medical director or physician determining medical necessity and to attach a legible copy. This information is necessary in order to report a change in the substance use disorder medical director pursuant to Section 51000.40(b)(14)(A) and will help the Department determine that the substance use disorder medical director or the physician determining medical necessity is properly licensed to provide quality care to beneficiaries. A copy of the license is required for verification purposes.

- A new number 33 is added to instruct the provider to provide the full legal name, NPI, provider type, license, certification, or registration number (and attach a legible copy), for each substance use disorder treatment professional or licensed substance use disorder treatment professional and to check whether the individual is being deleted or added. This information is necessary in order to report a change in an individual that provides counseling services pursuant to Section 51000.40(b)(14)(C) and it will assist the Department in determining that the substance use disorder treatment professionals and licensed substance use disorder treatment professionals are in compliance with all laws and regulations. This is necessary to ensure quality care is provided to beneficiaries. A copy of the license is required for verification purposes.

- A new number 34 is added to instruct the provider to enter all services to be provided by the substance use disorder clinic, including existing services and additional services or program types being requested by this application. The

provider is advised that non-perinatal residential services require a residential alcoholism or drug use recovery treatment facility license issued by the Department. The provider is advised that a Narcotic Treatment Program (NTP) license issued by the Department is required to provide NTP services and that facility licensing and NTP information and applications are available online at www.dhcs.ca.gov/provgovpart/Pages/SUD-ProvPartners.aspx. This information is necessary in order for the provider to update their service modalities accurately by using the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form pursuant to Section 51000.40(b)(14)(B). This information is necessary so the Department can track current information about services provided and required to be provided at DMC clinics.

- The subheader, "National Provider Identifier (NPI) Subparting" was added above number 35 for clarification purposes. This amendment is necessary in order to be consistent with the form portion of the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) and to assist the provider in being able to easily read applicable instruction sections.

- A new number 35 is added to instruct the provider to see instructions for sub-parting information. This information is required if requesting to change the NPI assigned to one or more locations and has therefore been added to the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form. A Subpart is a component of a health care organizational provider, such as a provider group, that is not a person. Subparting is a requirement of HIPAA.

- A new number 36 is added to instruct the provider to check the appropriate box. This amendment is necessary in order for the Department to be clearly notified if the provider is updating their information via the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form.

- A new number 37 is added to instruct the provider to provide all details regarding the additions or changes if "yes" was answered to the previous question. This amendment is necessary in order for the Department to be clearly notified if the provider is updating their information via the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form.

- Number 38 instructs the provider to check the appropriate box. This amendment is necessary in order for the Department to be clearly notified if the provider is updating their information via the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form.

- Number 39 instructs the provider to provide all details regarding the addition(s) or change(s) if yes was answered to the previous question. This amendment is necessary in order for the Department to be clearly notified if the provider is

updating their information via the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form.

- The sub-header, “Information About Provider” was added above number 40 for clarification purposes. This amendment is necessary in order to be consistent with the form portion of the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) and to assist the provider in being able to easily read applicable instruction sections.

- Numbers 41 through 45 contain universal amendments and the cross reference to number 30 was changed to number 40. Number 43 additionally instructs the provider to see the privacy statement on page 13, instead of page 8. SSNs are necessary pursuant to the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of SSNs. These revisions are also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the Department perform routine checks on Federal databases.

- Number 45 has been amended and the provider is instructed to “see CCR, Title 22, Section 51000.30(a)(2)(B) to determine whether they have the authority to sign the form.” This information is necessary to notify the provider that only certain individuals are authorized to sign the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form in order for it to be valid.

- Number 47 has been adopted to instruct the provider that in order to assist in the timely processing of the application package, enter the name, gender, title/position, e-mail address, and telephone number of the individual who can be contacted by Provider Enrollment staff to answer questions regarding the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form. The provider is advised that failure to include this information may result in the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form being returned deficient for item(s) that an applicant can readily provide by fax or telephone. This information is necessary and supports the timely review of applications for the Department during the review period when an item needs to be clarified or remediated.

- The provider is advised to attach additional items if applicable, additions to this listing include: NPI verification, Medical Director License, Medicare enrollment verification, residential license issued by the Department (if applicable), narcotic treatment program license issued by the Department (if applicable) and substance use disorder medical director or physician determining medical necessity, professional license and the license, certification, and/or registration of the substance use disorder treatment professional or licensed substance use disorder treatment professional providing counseling services. This checklist was

amended to assist providers in remembering to submit all attachments needed to update their file.

The following changes have been made to the application portion of the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form:

- The form was amended and the Department's name has been updated as were the P.O. Box and ZIP code for the Provider Enrollment Division due to the Department using a different address. The mailing address and phone number for Denti-Cal was added to the form as this form is now being used by Denti-Cal providers.

- The provider is no longer instructed to not staple the form or any attachments or to not leave any questions, boxes, etc. blank or to enter N/A if not applicable. Instead, the provider is instructed that this form is not the correct form for reporting a change in business address. This information was added and the previous language removed for clarification purposes as a complete application package is required for a change in business address, and not all fields need to be completed on the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14). In addition, this change was done because not all questions, boxes, etc. need to be completed in order for the provider to update their information. Unlike applications, disclosures, and provider agreements, the provider is only required to complete specific fields related to the action they are requesting.

- The form has been amended to instruct the provider to list their provider number (NPI or Denti-Cal provider number) instead of "Medi-Cal provider number." Effective May 23, 2007, applicants and providers are required to submit their NPI. This revision was necessary to comply with the Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). Implementation of the NPI is a requirement of HIPAA.

- "Provider Type" has been amended to include dentist, substance use disorder clinic, and registered dental hygienist alternative practice as provider type options. Substance use disorder clinics, registered dental hygienist alternative practices, and dentists now use this form to notify the Department of a change in information and therefore have been added as provider types.

- "Action requested" portion of the form has been amended under "Add" to include "Taxonomy code" and "service modalities" and "other NPI" was added to "Medicare" box; "service modalities" has been included as an option under both "Add" and "Delete"; "NPI," "business activities," "other information previously submitted with the application package," and "substance use disorder medical director or physician making medical necessity determinations" has been included as an option under "Change"; and "deactivate provide type/location (attach letter specifying change)," and "Issuance (new PIN) Note: Providers of

substance use disorder treatment services may not use this form for PIN issuance" has been included under "Miscellaneous." This information is necessary as it contains all of the changes the provider may report to the Department with the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14). It also assists the Department during the application review period as the Department will have an understanding of what the provider is requesting to update.

- "See page 12" was included under "Change." This amendment is necessary to refer the provider to the page where the provider will include the NPI assigned to one or more locations. In addition, this section was amended to include "pilot or geographic area served," "Substance use disorder medical director or physician making medical necessity determinations (substance use disorder clinics only)" and "Substance use disorder treatment professional or licensed substance use disorder treatment professional providing counseling services (substance use disorder clinics only)" as options. This information is necessary to assist the Department in being able to easily determine and process the provider's request.

- Provider is instructed to complete only the boxes specific to the action requested and to complete boxes 40-45 and box 46, if applicable. This amendment is necessary in order to refer the provider to the correct pages that require information about the provider.

General Information

- Number 3 was amended and the pay-to address now includes the street "name, room, suite or", this information was added for clarification purposes and to assist the provider in providing a complete address on this form.

- Number 9 was changed to 9a and the phrase "if applicable" was added for clarification.

- A new number 9b was added to instruct the provider to list their taxonomy codes to be added or deleted and attach additional sheets if necessary. This amendment is necessary because Taxonomy Codes are a requirement of HIPAA. Healthcare Provider Taxonomy Codes are designated to categorize the type, classification, and/or specialization of health care providers and are required when providers apply for an NPI.

Change of Ownership or Control Interest

Number 10 was amended and now describes a change of ownership as less than 50% to match the instructions. This was done for clarification and consistency purposes. In addition, the provider is advised to "attach a legible copy of agreement" if they are a

partnership. This information is necessary pursuant to Section 51000.30(d)(2) and serves as verification of a current partnership.

For Durable Medical Equipment and Pharmacy Providers Only

- Number 12 was renumbered and is now number 14 (as described below). A new number 12 now instructs the provider to mark “yes” or “no” for whether they provide custom rehabilitation equipment and custom rehabilitation technology services to beneficiaries. The provider is advised to mark “yes” or “no” for whether they have staff, either as an employee or independent contractor, or if they have a contractual relationship with, a qualified rehabilitation professional who was directly involved in determining the specific custom rehabilitation equipment needs of the patient and was directly involved with, or closely supervised, the final fitting and delivery of the custom rehabilitation equipment. WIC Section 14105.485 requires that this type of provider be available to provide these rehabilitative services, so the Department needs to verify this information to be compliant with state law.

- Number 14 (previously number 12) was amended by removing the first part of the sentence to specifically ask the provider whether they sell, rent, or lease durable medical equipment, incontinence medical supplies and/or supply items. The part of the sentence that was removed in the first sentence was added to another question if the provider checks the “yes box.” This information is required in order to determine if the provider is in compliance with Section 51000.30(d)(16)(A). The phrase “and is readily available” was removed because it was not necessary.

For Transportation Providers Only

- “For Transportation Providers only” was previously numbered 14 through 17 and is now renumbered 15 through 18 in the same chronological order. These redesignations are necessary due to previous redesignations.

- Number 15 was amended and additionally advised the provider to attach a copy of their permit/license. This amendment was necessary to be consistent with instructions and to provide verification of this information.

- Number 16 has been amended to include the title “Ambulance and Driver Information – see instructions (attach a separate sheet if necessary).” This sentence has been added for clarification purposes to assist the provider in completing the correct fields for their provider type and for notifying the Department of specific changes. The term “plate” was added between the term “license” and “number” to clarify that this information is related to the ambulance. Additionally the chart in this section was amended for the provider to enter the “ambulance driver certificate number.” This amendment was made to be

consistent with current instructions. In the instructions, the provider was advised to enter this information; however; this information was missing from this chart.

- Number 17 has been amended to additionally instruct the provider to attach a driver's license or state issued identification card and to enter the driver's license number or state issued identification number in the pre-existing table. Specifically this information will allow the Department to confirm the pilot's identity.

- Number 18 has been amended to include a title "Vehicle Information" for clarity and "plate" has been added for clarification purposes to instruct the provider to enter their "license plate number." In addition, the DMV driving record printout, certificates for first aid and CPR, standard pre-employment drug tests, special driver permit, California driver's license, and DMV DL-51 form as signed by a physician – for each new driver have been added to the checklist portion. These additions are necessary to assist the provider in providing a complete "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form and to provide the Department with verification of this information.

<u>For Pharmacies Only</u>

- Numbers 18 through 28 were re-numbered and are now numbers 19 through 29. These amendments are necessary to accommodate previous redesignations and to refer the provider to the correct pages/sections. In addition, existing number 29 was renumbered to 14.

- Number 20 has been amended and the phrase "(Optional - see the privacy statement on page 8)" has been removed. This amendment was necessary to refer the provider to the correct page. This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). These revisions are also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- The provider is advised if they answer yes to questions 23 through 28 to give details in newly redesignated number 29. These amendments are necessary to refer the provider to the correct pages/sections.

- New number 29, the provider is advised to provide details for questions 23 through 28. These amendments are necessary to refer the provider to the correct pages/sections and to capture information about the pharmacist in charge.

<u>Providers of Substance Use Disorder Treatment Services Only</u>

This section was added to allow substance use disorder clinics to update their files via a shortened mechanism (short form). Currently, substance use disorder clinics are required to submit a complete application package for a change in service modalities and/or a change in the substance use disorder medical director because section 51000.40(a) requires the provider to notify the Department of a change in any information reported on the application within 35 days. Use of the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) will allow the provider to notify the Department of a change in those providing counseling services via a short form, instead of being required to submit a complete application package.

"New Substance Use Disorder Medical Director or Physician Making Medical Necessity Determinations" was added as a sub-header. This amendment is necessary to direct providers to the correct section in which they need to complete if they are reporting a change in the substance use disorder medical director or physician determining medical necessity.

- Numbers 30 through 32 are added to instruct the provider to include the legal name (last, first, middle), NPI and medical license number with an attached legible copy of the medical license. This information is necessary in order for the provider to notify the Department of a change pursuant to Sections 51000.40(a) and 51000.40(b)(14)(A) and it provides the Department with current and verifiable information about the Medical Director or physician, which supports the provision of quality care for beneficiaries by qualified providers.

- The provider is advised that if the substance use disorder medical director or physician making medical necessity determinations is not currently enrolled as such, a "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) must be submitted to the Department for that individual. This addition is necessary because these individuals are required to enroll in the Medi-Cal program pursuant to Sections 51000.70 and 51000.75 and to ensure the provider is continuing to meet Medi-Cal program requirements.

- Number 33 was added to instruct the provider to provide the full legal name, NPI, provider type, license, certification, or registration (and attach a legible copy), for each substance use disorder treatment professional or licensed substance use disorder treatment professional and to check whether the individual is being deleted or added. This information is necessary so the provider can report a change in an individual that provides counseling services pursuant to Section 51000.40(b)(14)(C). This will assist the Department in determining if the substance use disorder treatment professionals or licensed substance use disorder treatment professionals are in compliance with all laws and regulations.

Providing a copy of the license/certification/registration provides verification of this information.

- Number 34 was added to instruct the provider to identify the service modality(ies) and treatment component(s) (non-perinatal or perinatal) requested for the site and to include service modality(ies) and treatment component(s) that the provider wishes to continue as well as those to be added. This information is necessary in order for the provider to notify the Department of a change pursuant to Sections 51000.40(a) and 51000.40(b)(14)(B). This is necessary so the Department can maintain complete, current, and accurate information as well as meet Section 51000.40(a) and 51000.40(b)(14)(B) requirements. The applicant is also advised that applicants for residential services must first obtain a residential license issued by the Department prior to applicant submission for DMC residential services. This is required pursuant to Title 22, CCR, Section 51000.30(d)(22)(D) and is therefore necessary as it provides clarification to the applicant on the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form. In addition, the applicant is also advised that a Narcotic Treatment Program (NTP) licensed by the Department is required pursuant to Section 51000.30(d)(22)(D) and is therefore necessary as it provides clarification to the applicant on the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form.

National Provider Identifier (NPI) Subparting

This addition is necessary as it is a requirement of HIPAA. It is necessary for the Department to have this information about subparting because subpart determination ensures that entities within a health care provider that need to be uniquely identified in HIPAA standard transactions obtain unique NPIs for that purpose. The Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162) provides guidance to covered organization health care providers in determining subparts and whether or not they should have NPIs. A subpart that conducts any of the HIPAA standard transactions separately from the "parent" must have its own unique NPI. Therefore, the following has also been added:

- The provider is instructed that the table provided on the form is intended for applicants and providers who have subparted and wish to change an NPI assigned to one or more Medi-Cal enrolled locations. An applicant or provider must determine whether or not to subpart based on their business practices, billing practices and federal requirements including Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162). This amendment is necessary as it is a requirement of HIPAA.

- The provider is instructed that a subpart is a component of a health care organizational provider, such as a provider group, that is not a person. A subpart furnishes health care and might conduct standard transactions, be

required by Federal regulations to have a Federal billing number, be certified/licensed separately from the covered organization, have a location different from the covered organization, be a member of a chain, or be Durable Medical Equipment, Prosthetics, Orthotics and Supplies provider. This addition is necessary as it is a requirement of HIPAA.

- The provider is instructed that if they are an individual sole proprietor (unincorporated) health care provider such as a physician, dentist, nurse, chiropractor, etc., they do not qualify to subpart**.** The provider is instructed that when they receive their NPI they will be identified with an Entity Type Code 1 (Health care providers who are individual human beings, including sole proprietors.). This addition is necessary as it is a requirement of HIPAA.

- The provider is instructed that if they are an organization, they may subpart. The provider is advised that when they receive their NPI they will be identified with an Entity Type Code 2 (Health care provider who is other than an individual human being). Examples of organizations are hospitals; individuals who have incorporated; home health agencies; clinics; nursing homes; residential treatment centers; laboratories; emergency and nonemergency medical transportation companies; group practices; suppliers of durable medical equipment; prosthetics and orthotics providers; and pharmacies. This addition is necessary as it is a requirement of HIPAA.

- The provider is advised for additional information to see the Centers for Medicare and Medicaid Services website at: https://www.cms.hhs.gov/NationalProvIdentStand/ for comprehensive information regarding subparting and general NPI implementation. This information is necessary to assist providers in determining this ability to subpart, and to ensure it is done correctly.

- Number 35, “Enrolled business location,” the provider is instructed that they must be currently enrolled at this location. “NPI currently on file” the provider is instructed to indicate the NPI assigned to the enrolled business location at the time the form is submitted. “New NPI being assigned to the location” the provider is instructed to indicate the new NPI that they wish to have assigned to the enrolled business location listed on the form. This addition is necessary as it is a requirement of HIPAA. The provider is reminded to attach additional sheets if necessary and to attach verification for any new NPIs assigned. If the change is for an enrolled location, the confirmation must reflect the enrolled location’s address. This is necessary to ensure all required information is submitted to the Department in a timely manner for review.

Other Information

- Number 36, the provider is instructed to mark “yes” or “no” whether they are reporting any addition(s) or change(s) in information to a pending application. This addition is necessary to assist the Department during the application review period to ensure that the Department is aware of all information that needs to be reviewed.

- Number 37, the provider is instructed to explain, if they answered “yes” to the prior question. This addition is necessary to assist the Department during the application review period in order to determine why a complete application package and a “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form were both submitted to the Department and so the Department is aware of what specific information needs to be reviewed.

- Number 38, the provider is instructed to mark “yes” or “no” whether they are reporting any addition(s) or change(s) in information submitted in a prior application package other than information covered elsewhere in this form that does not require the submission of a new application package. This addition is necessary to assist the Department during the application review period and to ensure the Department is aware of all information that needs to be reviewed.

- Number 39, the provider is instructed to explain if they answered “yes” to the prior question. This addition is necessary to assist the Department during the application review period in order to understand specifically what the provider is reporting.

<u>Information About Provider</u>

- Existing numbers 30 through 36 were renumbered and are now numbers 40 through 46 to accommodate prior redesignations and to clearly organize the information.

- New number 44 has been amended, the phrase “(optional – see privacy statement below),” was changed to “(required – see privacy statement below).” This amendment was necessary to refer the provider to the correct page. This revision is necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). These revisions are also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- New number 45 has been amended to include a cross reference to Section 51000.30(a)(2)(B). This information is necessary to notify the provider that only

certain individuals are authorized to sign the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev. 12/14) form in order for it to be valid.

- New number 46 has been amended and now instructs the provider to see instructions under number 46 (as redesignated) and includes a cross reference to Civil Code Section 1189 which specifies requirements related to notarizing public signatures. Updating the reference to number 46 is necessary to lead the applicant to the current location of the instructions and including the Civil Code reference is necessary to clearly lead the provider to the additional requirements to ensure appropriate signatures.

- Number 47 is added to instruct the provider to check the box if the contact person is the same person identified in item 39 and to provide that person’s email address and phone number. If the box is not checked, enter the contact person’s name (last, first, middle), title/position, email address, and telephone number of the contact person. This information is necessary in order for the Department to be able to contact the provider if an item needs to be remediated or clarified during the review process and to facilitate a timely review.

- The Privacy Statement was amended and is consistent with the Department’s other applications and forms and to provide current information for providers related to privacy. This amendment is necessary in order to be in compliance with the Department’s current authority to administer the Medi-Cal program (WIC Section 14043). Disclosure of the Social Security Number is no longer optional and is now federally required. These revisions are necessary for implementation of the Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) and specifically for compliance with Title 42 CFR, Section 455.104(b), which mandates disclosure of Social Security Numbers (SSNs). These revisions are also necessary for compliance with Title 42 CFR, Section 455.436, which mandates that the State Medicaid Agency perform routine checks of Federal databases.

- The Physician/Nonphysician Medical Practitioner Specialty Codes chart was amended to correctly reflect “Osteopathic Physicians,” instead of “Osteopaths.” This amendment is the result of stakeholder feedback and is necessary because there is a distinction in the way the two groups of individuals are defined. An Osteopath is a nonphysician that is trained in a foreign country; therefore, this section was amended to reflect the correct provider type, which is a osteopathic physician.

<u>Section 51000.40, Subsection (b)(1)</u>

The Department proposes to amend Section 51000.40(b)(1) to prohibit substance use disorder clinics from using the “Medi-Cal Supplemental Changes,” DHCS 6209 (Rev.

12/14) form to update their pay-to address. This amendment is necessary to clarify that because substance use disorder clinics bill through a different payment system, the pay-to address is not collected during the application review process. Therefore, this provider type does not have a pay-to address that would require updating.

Section 51000.40, Subsection (b)(10)

The Department proposes to amend Section 51000.40(b)(10) to prohibit substance use disorder clinics from using the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form to obtain reissuance of their PIN. Substance use disorder clinics bill through a different payment system and receive a separate PIN from their respective counties, which is not the same PIN issued by the Department. This amendment is necessary to clarify that the PIN issued by the Department would not be useful because substance use disorder clinics receive direct payment from a different payment system.

Section 51000.40, Subsection (b)(14)(A)

The Department proposes to adopt Section 51000.40(b)(14)(A) to require substance use disorder clinics to submit a "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form to notify the Department of a change in the substance use disorder medical director or physicians making medical necessity determinations for beneficiaries. Due to the amount of alleged fraud related to the substance use disorder medical director and physicians that determine medical necessity, this adoption is necessary to assist the Department in monitoring the substance use disorder medical director and other physicians working at a substance use disorder clinic, thus mitigating the potential for fraud and abuse of the Medi-Cal program. This amendment is also necessary to clarify that a substance use disorder clinic can inform the Department of these changes using this form rather than having to submit a complete application package, thus allowing the substance use disorder clinic to report these changes in a less cumbersome manner

Section 51000.40, Subsection (b)(14)(B)

The Department proposes to adopt Section 51000.40(b)(14)(B) to require substance use disorder clinics to submit a "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form to notify the Department of an addition or deletion of service modalities. This amendment is necessary to clarify that a substance use disorder clinic can inform the Department of these changes using this form rather than having to submit a complete application package. This allows the substance use disorder clinic to report these changes in a less cumbersome manner and assists the Department in keeping information on file current, thus mitigating the potential for fraud and abuse of the DMC program.

Section 51000.40, Subsection (b)(14)(C)

The Department proposes to adopt Section 51000.40(b)(14)(C) to require substance use disorder clinics to submit a "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form to notify the Department of a change of any substance use disorder treatment professional or licensed substance use disorder treatment professional providing counseling services. This amendment is necessary to clarify that a substance use disorder clinic can inform the Department of these changes using this form rather than having to submit a complete application package. This allows the substance use disorder clinic to report these changes in a less cumbersome manner and assists the Department in keeping information on file current, thus mitigating the potential for fraud and abuse of the DMC program.

Section 51000.40, Subsection (d)

This section has been amended to include the updated "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) form. The department designation and revision date has been amended, as described in Section 51000.40(b) above. The Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) was amended, via a provider bulletin December 2014 pursuant to WIC Section 14043.75.

Section 51000.45. Provider Agreement.

Section 51000.45, Subsection (c)

The Department proposes to amend this subsection to update the application title and revision date of this form to read: "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers," DHCS 6216 (Rev. 2/15)." "Dental" was included to the application title, the revision date was updated to (2/15) and the form name beginning with "DHS" has been updated to "DHCS." This form has been amended via a provider bulletin pursuant to WIC Section 14043.75 since its initial implementation in regulations. Refer to the prior explanation for specific amendments to this form in Section 51000.30(c)(3)(F).

Section 51000.45, Subsection (d)

The "Drug Medi-Cal Provider Agreement," DHCS 6009 (Rev. 12/14) form is currently a requirement as of October 24, 2014 to participate in the DMC program. This agreement is required pursuant to Title 42 CFR Section 431.107, and WIC Sections 14043.2, and 14043.25. The Department implemented existing federal and state requirements via a provider bulletin pursuant to WIC Section 14043.75.

Subsection (d) has been adopted to incorporate the "Drug Medi-Cal Provider Agreement," DHCS 6009 (Rev. 12/14) form by reference. This form is incorporated by reference because it would be too cumbersome to print it directly in the CCR. PED forms are available on the Department's internet website at http://files.medi-cal.ca.gov/pubsdoco/prov_enroll.asp#Forms. Please refer to the applicable areas of this

Statement of Reasons for an explanation of necessity for the newly adopted sections/subsections that are referenced throughout this discussion of necessity pertaining to the “Drug Medi-Cal Provider Agreement,” DHCS 6009 (Rev. 12/14).

The following has been incorporated by reference:

- Instructions have been adopted to instruct the applicant on how to complete the agreement, and not to staple the form or any attachments, to type clearly in ink, and to line through incorrect responses and initial in ink, and to enter N/A if not applicable. These adoptions were made to ensure the integrity of the form, to assist the Department in the application review process and to assist the applicant/provider in submitting a complete application by bringing to their attention that every question needs to be answered. Providing complete and accurate information is required pursuant to Section 51000.30(a)(2)(A) and as defined under Section 51000.1.1.

- The “Date” section instructs the applicant to enter the date the application is being completed. This field is standard information that is requested across all Department applications and assists the Department in determining when the application was completed.

- “Legal name of applicant or provider” has been adopted to instruct the applicant to provide their legal name. This information is necessary and required to be reported on the application pursuant to Section 51000.30(d)(3).

- “Business name (if different than legal name)” has been adopted to instruct the applicant to enter their business name, if different from the listed legal name. This information is necessary for identification purposes and is required to be reported on the application pursuant to Sections 51000.30(d)(3) and 51000.30(e).

- “Provider number (NPI)” has been adopted to instruct the applicant to enter the National Provider Identifier (NPI) number in the application package. This information is necessary for identification purposes and is required pursuant to Section 51000.30(d)(1) and as defined under Section 51000.20.

- “Business Telephone Number” has been adopted to instruct the applicant to provide the primary business telephone number used at the business address. This information is necessary and required to be reported on the application pursuant to Section 51000.30(d)(5) and as defined under Section 51000.4.

- “Business address (number, street)” has been adopted to instruct the applicant to provide the business address, which is the actual location where services are rendered, including the street name and number, city, state, and nine-digit ZIP code. A post office or commercial box is not acceptable. This information is

necessary in order to determine that the provider agreement is for the correct location, as listed on the corresponding application. Furthermore, the applicant/provider is required to enroll at each location where services are rendered and each business address is kept on file with the Department.

- "Mailing address (number, street, P.O. box number)" has been adopted to instruct the applicant to enter the address at which the applicant or provider wishes to receive Medi-Cal correspondence. The mailing address, as defined Section 51000.11, is necessary in order for the Department to send out general correspondence, such as information updates, to the provider.

- "Previous Business address (number, street)" has been adopted to instruct the applicant to provide the previous business address, which is the actual location where services were previously rendered, including the street name and number, city, state, and nine-digit ZIP code. A post office or commercial box is not acceptable. If the provider is requesting a change of address, the previous business address is needed so the Department can properly update the provider's file and to ensure that the provider agreement is for the correct location.

- "Taxpayer Identification Number (TIN)" has been adopted to instruct the applicant to provide the taxpayer identification number. This adoption is necessary and required pursuant to Section 51000.30(d)(12).

The following information is specified on the agreement portion of the "Drug Medi-Cal Provider Agreement," DHCS 6009 (Rev. 12/14):

- Applicant/provider is informed that execution of this agreement between the provider and the Department is mandatory for participation or continued participation in the Medi-Cal program. A provider agreement is required pursuant to Section 51000.45. In accordance with the United States Code, Title 42, Section 1396a(a)(27), Title 42 CFR Section 431.107, WIC Section 14043.2 and Title 22, CCR Section 51000.30(a)(2), in order to be enrolled as a provider or for enrollment as a provider to continue, an applicant or provider is required to sign a provider agreement and shall disclose all information as required in federal Medicaid regulations and other information required by the Department. Therefore, the applicant/provider is informed that a provider agreement is required and mandatory.

- Number 1, "Term and Termination" informs the applicant/provider that the agreement will be effective from the date the applicant is enrolled as a provider, or the date the provider is approved for continued enrollment. The provider may terminate the provider agreement by providing the Department written notice and the Department may immediately terminate the provider agreement if the provider is suspended/excluded for any of the reasons set forth in Paragraph

22(a), which will result in the provider's immediate disenrollment and exclusion (without formal hearing under the Administrative Procedure Act) from further participation in the Medi-Cal program. During any period in which the provider is on provisional provider status or preferred provisional provider status, the Department may terminate the agreement for any of the grounds stated in WIC Section 14043.27(c). This information was added to the provider agreement to assist the applicant/provider in understanding, and attesting to understand, program requirements prior to signing the provider agreement to become a provider in the Medi-Cal program. This information is necessary to ensure that applicants understand their responsibilities and liabilities as a Medi-Cal provider.

- Number 2, "Compliance with Laws and Regulations" informs the applicant that as a provider they shall comply with all applicable provisions of Chapters 7 and 8 of WIC (commencing with Sections 14000 and 14200), and any applicable rules or regulations promulgated by the Department. The provider agrees that if there is any violation of provisions the provider may be subject to all sanctions available to the Department. This information was added to the provider agreement to assist the applicant/provider in understanding, and attesting to understand, program requirements prior to signing the provider agreement and requesting to become a provider in the Medi-Cal program. This information is consistent with other provider agreements used by the Department and is necessary to ensure that applicants understand their responsibilities and liabilities as a Medi-Cal provider.

- Number 3, "National Provider Identifier (NPI)" informs the applicant that as a provider they shall use an NPI that is appropriately registered with CMS and the provider is in compliance with all NPI requirements established by CMS. The provider shall additionally report any change to the Department. Implementation of the NPI is a requirement of the HIPAA and has therefore been added to the provider agreement to assist the applicant/provider in understanding program requirements prior to signing the provider agreement.

- Number 4, "Forbidden Conduct" informs the applicant that the applicant shall not engage in conduct inimical to the public health, morals, welfare and safety of any beneficiary, or the fiscal integrity of the Medi-Cal program. This statement was included to ensure public welfare and safety for all beneficiaries and to maintain the fiscal integrity of the Medi-Cal program. This information is necessary because the Department is prohibited from maintaining an active relationship with providers in violation of WIC Sections 14043.27 and 14043.36.

- Number 5, "Nondiscrimination" informs the applicant that as a provider they shall not exclude or deny aid, care, service or other benefits available under the Medi-Cal program or in any other way discriminate against a person. In addition, the provider shall provide the service in the same manner, by the same methods, and at the same scope, level, and quality as provided to the general public. This

statement was included to ensure equity in the provision of care and to ensure public welfare and safety for all beneficiaries.

- Number 6, "Scope of Health and Medical Care" informs the applicant that as a provider they shall provide health care services that may include diagnostic, preventive, corrective, and curative services provided by qualified personnel for conditions that cause suffering, endanger life, result in illness or infirmity, interfere with capacity for normal activity, including employment, or for conditions which may develop into some significant handicap or disability. This statement was included to ensure the provision of necessary health care for beneficiaries and for public welfare and safety for all beneficiaries.

- Number 7, "Licensing" informs the applicant that as a provider they shall possess and maintain valid and unexpired license(s), certificate(s), or other approval(s) to provide health care services, for the term of this provider agreement, if required by the state or locality in which the provider is located, or by the Federal Government. The provider further agrees that the Department shall automatically suspend the provider if any approval(s) to provide health care services are subsequently revoked or suspended by a federal, California, or another state's licensing, certification, or approval authority. This information was added to the provider agreement to assist the applicant/provider in understanding, and attesting to understand, program requirements prior to signing the provider agreement to become a provider in the Medi-Cal program. This information reiterates the Department's authority in Section 51000.53(a)(5) to assist the applicant/provider in understanding the Department's program requirements and authority. Licensing requirements support the provision of care under the Medi-Cal program by qualified personnel and assists in curtailing fraud and abuse in the Medi-Cal program. This information is necessary because the Department is prohibited from maintaining an active relationship with providers in violation of WIC Section 14043.6.

- Number 8, "Insurance" informs the applicant that as a provider they shall possess and maintain liability insurance for the business address and, if a licensed practitioner, professional liability (malpractice) insurance throughout the term of the provider agreement. Professional liability insurance is required pursuant to Sections 51000.30(f)(3) and 51000.60(c)(6) and was added to the provider agreement to assist the applicant/provider in understanding, and attesting to understand, program requirements prior to signing the provider agreement to become a provider in the Medi-Cal program. This information is necessary to ensure the provider has appropriate liability insurance.

- Number 9, "Record Keeping and Retention" informs the applicant that as a provider they shall, keep and maintain in a systematic and orderly manner, and have readily retrievable, such records as are necessary to fully disclose the type and extent of all services, provided to beneficiaries. Such records shall be

retained by the provider in the form in which they are regularly kept for a period of three years from the date the goods, or supplies, were delivered or the services rendered. This information was added to the provider agreement to assist the applicant/provider in understanding, and attesting to understand, program requirements prior to signing the provider agreement to become a provider in the Medi-Cal program. This maintenance of records is consistent with existing requirements under Section 51476 and Title 42 CFR Section 431.107. The words, “as amended” were added to accommodate any future changes in the federal rule. The maintenance of records is also necessary for verification of services provided and to protect the Medi-Cal program from fraud and abuse.

- Number 10, "DHCS, AG, County, and Secretary Access to Records; Copies of Records" informs the applicant that as a provider, during regular business hours, they shall make all pertinent financial records, all records of the requisite insurance coverage, and all records concerning the provision of health care services available to beneficiaries available to any duly authorized representative of the Department, an authorized representative of their respective County, the California Attorney General’s Medi-Cal Fraud Unit (“AG”), and the Secretary of the United States Centers for Medicare and Medicaid Services (Secretary) pursuant to Section 51476. This information was added to the provider agreement to provide clarification to the applicant/provider on the Department’s authority and program requirements and to ensure access to records that are necessary to ensure appropriate participation in the Medi-Cal program and to protect the Medi-Cal program from fraud and abuse.

- Number 11, "Confidentiality of Beneficiary Information" informs the applicant that as a provider all records of beneficiaries made or acquired by the provider shall be confidential and shall not be released without the written consent of the beneficiary or his/her personal representative, or as otherwise authorized by law as specified by HIPAA requirements. This information was added to provide reassurance to the applicant/provider and to the beneficiaries that all of their records are confidential and will not be shared.

- Number 12, "Disclosure of Information to DHCS" informs the applicant that as a provider they shall disclose all information as required in Federal Medicaid laws and regulations and any other information required by the Department, and to respond to all requests from the Department for information. The provider further agrees that the failure to disclose the required information or the disclosure of false information will result in the denial of the application for enrollment or shall be grounds for termination of enrollment status or suspension from the Medi-Cal program, which will include deactivation of all provider numbers. In accordance with Title 42 CFR Section 455.105(a), and WIC Sections 14043.2 and 14043.26, in order to be enrolled as a provider or for enrollment as a provider to continue, an applicant or provider is required to sign a provider agreement and shall disclose all information as required in federal Medicaid regulations and any other

information required by the Department. Therefore, the applicant/provider is informed that all information shall be disclosed to the Department. This disclosure of information requirement is necessary so the Department can fully assess all information necessary to ensure the provision of necessary and high-quality care to beneficiaries.

- Number 13," Information Regarding Subcontractors and Suppliers" informs the applicant that as a provider they must submit, within 35 days of the date on a request by the Secretary or the Medicaid agency, full and complete information about the ownership of any subcontractor with whom the provider has had business transactions totaling more than $25,000 during the 12-month period ending on the date of the request; and any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-month period ending on the date of the request. This information is required to be reported within 35 days of the request pursuant to Sections 51000.40(a), 51000.35(a)(4), and Title 42 CFR Section 455.105(b), and was added to the provider agreement to provide clarification to the applicant/provider. This information requirement is necessary to ensure that the agencies have timely access to information to ensure appropriate business practices.

- Number 14, "Background Check" informs the applicant/provider that the Department may conduct a background check for the purpose of verifying the accuracy of the information provided in the application and in order to prevent fraud or abuse under the Medi-Cal program. The Department has the authority to conduct background checks pursuant to WIC Section 14043.37; therefore this information was added to the provider agreement to assist the applicant/provider in understanding the Department's authority prior to signing the provider agreement. This requirement is also necessary so the Department and other agencies can ensure the appropriate provision of health care services to beneficiaries and to combat fraud and abuse under the Medi-Cal program.

- Number 15, "Unannounced Visits by DHCS, AG, County, and Secretary" informs the applicant/provider that the Department, the County, AG and/or Secretary may make unannounced visits to the provider, at any of the provider's business locations, before, during or after enrollment, for the purpose of determining whether enrollment, continued enrollment, or certification is warranted, to investigate and prosecute fraud against the Medi-Cal program, to investigate complaints of abuse and neglect of patients in health care facilities receiving payment under the Medi-Cal program, and/or as necessary for the administration of the Medi-Cal program and/or the fulfillment of the AGs powers and duties under Government Code Section 12528. The Department has the authority to make unannounced visits pursuant to WIC Section 14043.7; therefore, this information was added to the provider agreement to assist the applicant/provider in understanding the Department's authority prior to signing the provider

agreement. This requirement is also necessary so the Department and other agencies can ensure the appropriate provision of health care services to beneficiaries and to combat fraud and abuse under the Medi-Cal program.

- Number 16, "Provider Fraud and Abuse" informs the applicant that as a provider they shall not engage in or commit fraud or abuse. The definitions used for “fraud” and “abuse” are consistent with WIC Section 14043.1 and Title 42 CFR, Section 455.2. Engaging in fraud or abuse prohibits enrollment or continued enrollment into the Medi-Cal program pursuant to WIC Section 14043.36. This information was added so the provider is fully aware what constitutes fraud and abuse and that these actions are prohibited under the Medi-Cal program. This information is necessary because the Department is prohibited from maintaining an active relationship with providers in violation of WIC Sections 14043.27 and 14043.36.

- Number 17, "Investigations of Provider for Fraud or Abuse" informs the applicant that as a provider they certify that at the time this provider agreement was signed, they were not under investigation for fraud or abuse pursuant to Title 42 CFR Subpart A (commencing with Section 455.12) of Part 455 or under investigation for fraud or abuse by any other government entity. The provider further agrees to notify the Department within ten business days of learning that they are under investigation for fraud or abuse. Pursuant to WIC Section 14043.36, the Department shall not enroll a provider if the provider is under investigation for fraud or abuse; therefore, number 17 was added to the provider agreement to assist the applicant/provider in understanding, and attesting to understand, program requirements prior to signing the provider agreement to become a provider in the Medi-Cal program. This information is necessary because the Department is prohibited from maintaining an active relationship with providers in violation of WIC Sections 14043.27 and 14043.36.

- Number 18, "Provider Fraud or Abuse Convictions and/or Civil Fraud or Abuse Liability" informs the applicant that as a provider they certify that neither they nor their owners, officers, directors, substance use disorder medical directors, employees, and agents, have been convicted of any felony or misdemeanor involving fraud or abuse in any government program, abuse of any patient, or substantially related to the qualifications, functions, or duties of a provider; or in any civil proceeding within the last ten years. The provider further agrees that the Department shall not enroll the provider if within the last ten years the provider has been convicted of any felony or any misdemeanor involving fraud or abuse in any government program, has entered into a settlement in lieu of conviction for fraud or abuse, or has been found liable for fraud or abuse in any civil proceeding. This information is required to be disclosed pursuant to Section 51000.35(a)(6) and prohibits the applicant from enrollment into the Medi-Cal program pursuant to WIC Section 14043.36. Number 18 was added to the provider agreement to assist the applicant/provider in understanding, and

attesting to understand, program requirements prior to signing the provider agreement to become a provider in the Medi-Cal program. This information is necessary because the Department is prohibited from maintaining an active relationship with providers in violation of WIC Sections 14043.27 and 14043.36.

- Number 19, "Changes to Provider Information" informs the applicant that as a provider they shall keep their application for enrollment in the Medi-Cal program current by informing the Department's Provider Enrollment Division, in writing on the "Drug Medi-Cal Substance Use Disorder Clinic Application," DHCS 6001, (Rev. 12/14) and the "Medi-Cal Disclosure Statement," DHCS 6207 (Rev. 2/15), and/or the "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14) within 35 days of any changes to the information contained in the application for enrollment, the disclosure statement, this provider agreement, and/or any attachments to these documents. The provider is required to report a change within 35 days pursuant to Section 51000.40(a), therefore, this information was added to the provider agreement to assist the applicant/provider in understanding, and attesting to understand, program requirements prior to signing the provider agreement to become a provider in the Medi-Cal program. This requirement is necessary so the Department has all necessary information at all times, to ensure that a provider qualifies to provide goods and services to beneficiaries.

- Number 20, "Prohibition of Rebate, Refund, or Discount" informs the applicant that as a provider they shall not offer, give, furnish, or deliver any rebate, refund, commission preference, patronage dividend, discount, or any other gratuitous consideration, in connection with the rendering of health care services to any beneficiary. In addition, the provider shall not solicit, request, accept, or receive, any rebate, refund, commission preference, patronage dividend, discount, or any other gratuitous consideration, in connection with the rendering of health care services to any beneficiary. This information was added to the provider agreement because the listed activities are prohibited pursuant to Section 51478, WIC Section 14107.2, and Title 42 CFR Section 447.10(f)(2). Number 20 was added to provide clarification to the provider about these Medi-Cal program requirements. This requirement is also necessary so the Department can ensure appropriate billing activity and to combat fraud and abuse under the Medi-Cal program.

- Number 21, "Termination of Provisional Provider or Preferred Provisional Provider Status" informs the provider that, while in provisional provider status or preferred provisional provider status, the provider will be subject to immediate termination of its provisional provider status or preferred provisional provider status and disenrollment from the Medi-Cal program. The Department has the authority to terminate provisional provider status pursuant to WIC Section 14043.27 for the circumstances below. This information has been added to assist the provider in understanding the Department's authority and requirements for

continued participation in the Medi-Cal program. Circumstances were added in numbers 1 through 12 to additionally assist the provider in understanding the Department's authority and circumstances that will terminate the provider's provisional provider status. This authority is necessary so the Department can ensure qualified providers participate in the Medi-Cal program and to protect the program from fraud and abuse.

- Number 1, the provider, persons with an ownership or control interest in the provider, or persons who are directors, officers, or managing employees of the provider have been convicted of any felony, or convicted of any misdemeanor involving fraud or abuse in any government program, related to neglect or abuse of a patient in connection with the delivery of a health care item or service, or in connection with the interference with, or obstruction of, any investigation into health care related fraud or abuse, or have been found liable for fraud or abuse in any civil proceeding, or have entered into a settlement in lieu of conviction for fraud or abuse in any government program within 10 years of the date of the application package. This provision is consistent with WIC Section 14043.27(c)(1) and is therefore necessary.

- Number 2, there is a material discrepancy in the information provided to the Department, or with the requirements to be enrolled, that is discovered after provisional provider status or preferred provisional provider status has been granted and that cannot be corrected. This provision is consistent with WIC Section 14043.27(c)(2) and is therefore necessary.

- Number 3, the provider has provided material information that was false or misleading at the time it was provided. This provision is consistent with WIC Section 14043.27(c)(3) and is therefore necessary.

- Number 4, the provider failed to have an established place of business at the business address for which the application package was submitted at the time of any onsite inspection, announced or unannounced visit, or any additional inspection or review conducted pursuant to this article or a statute or regulation governing the Medi-Cal program. This provision is consistent with WIC Section 14043.27(c)(4) and is therefore necessary.

- Number 5, the provider meets the definition of a clinic under HSC Section 1200 but is not licensed as a clinic pursuant to Chapter 1 (commencing with Section 1200) of Division 2 of the HSC and fails to meet the requirements to qualify for at least one exemption pursuant to HSC Sections 1206 or 1206.1. This provision is consistent with WIC Section 14043.27(c)(5) and is therefore necessary.

- Number 6, the provider performs clinical laboratory tests or examinations, but it or its personnel do not meet certificate of compliance and accreditation (CLIA), and the regulations adopted there under, and the state clinical laboratory law, do not possess valid CLIA certificates and clinical laboratory registrations or licenses pursuant to Chapter 3 (commencing with Section 1200) of Division 2 of the BPC, or are not exempt from licensure as a clinical laboratory under BPC Section 1241. This provision is consistent with WIC Section 14043.27(c)(6) and is therefore necessary.

- Number 7, the provider fails to possess either of the following.
  - Item (a), the appropriate licenses, permits, certificates, or other approvals needed to practice the profession or occupation, or provide the services, the provider identified in the application package approved by the Department when the provisional provider status or preferred provisional provider status was granted and for the location for which the application was submitted.
  - Item (b), the business or zoning permits or other approval necessary to operate a business at the location identified in its application package approved by the Department when the provisional provider status or preferred provisional provider status was granted.

  This provision is consistent with WIC Section 14043.27(c)(7) and is therefore necessary:

- Number 8, the provider, or if the provider is a clinic, group, partnership, corporation, or other association, any officer, director, or shareholder with a 10 percent or greater interest in that organization, commits two or more violations of the federal or state statutes or regulations governing the Medi-Cal program, and the violations demonstrate a pattern or practice of fraud, abuse, or provision of unnecessary or substandard medical services. This provision is consistent with WIC Section 14043.27(c)(8) and is therefore necessary.

- Number 9, the provider commits any violation of a federal or state statute or regulation governing the Medi-Cal program or of a statute or regulation governing the provider's profession or occupation and the violation represents a threat of immediate jeopardy or significant harm to any beneficiary or to the public welfare. This provision is consistent with WIC Section 14043.27(c)(9) and is therefore necessary.

- Number 10, the provider submits claims for payment that subject a provider to suspension under WIC Section 14043.61. This provision is consistent with WIC Section 14043.27(c)(10) and is therefore necessary.

- Number 11, the provider submits claims for payment at a location other than the enrolled location where provisional provider status was granted. This provision is consistent with WIC Section 14043.27(c)(11) and is therefore necessary.

- Number 12, the provider has not paid its fine or has debt due to owing, including overpayments and penalty assessments to any federal, state or local government entity that relates to Medicare, Medicaid, Medi-Cal, or any other federal or state health care program. This provision is consistent with WIC Section 14043.27(c)(12) and is therefore necessary.

- Number 22, "Provider Suspension; Appeals Rights; Reinstatement" informs the applicant that as a provider they shall be subject to the suspension actions listed. The provider further agrees that the suspension by the Department of the provider will include deactivation of the provider's entire provider numbers used in the Medi-Cal program. The Department has the authority to automatically suspend a provider pursuant to WIC Sections 14043.6 and 14043.61 for the circumstances below. This information has been included to assist the provider in understanding the Department's authority and requirements for continued participation in the Medi-Cal program. Circumstances were added in items "a" through "c" to additionally assist the provider in understanding the Department's authority and circumstances that will cause automatic suspension. This authority is necessary so the Department can ensure qualified providers participate in the Medi-Cal program and to protect the program from fraud and abuse. The applicant/provider is advised that the Department will automatically suspend the provider under the following circumstances:

  - Item a, "Automatic Suspensions/Mandatory Exclusions" informs the provider that the Department will automatically suspend or exclude for the following:

    - Number 1, upon notice from the Secretary of the United States Department of Health and Human Services that the provider has been excluded from participation in the Medicare or Medicaid programs. This provision is consistent with WIC Section 14123(b).
    - Number 2, if the provider has license(s), certificate(s), or other approval(s) to provide health care services, revoked or suspended by a federal, California, or another state's licensing, certification, or approval authority, has otherwise lost that/those license(s), certificate(s), or approval(s), or has surrendered that/those license(s), certificate(s), or approval(s) while a disciplinary hearing on that license, certificate, or approval was pending. This provision is consistent with WIC Section 14043.6, and is therefore necessary.

- Number 3, if the provider is convicted of any felony or any misdemeanor involving fraud, abuse of the Medi-Cal program or any patient, or otherwise substantially related to the qualifications, functions, or duties of a provider of service. Suspension following conviction is not subject to the proceedings under WIC Section 14123(c). However, the director may grant an informal hearing at the request of the provider to determine in the director's sole discretion if the circumstances surrounding the conviction justify rescinding or otherwise modifying the suspension. This provision is consistent with WIC Section 14123(b), and is therefore necessary.

- Item b, "Permissive Suspensions/Permissive Exclusions" informs the provider that the Department may suspend or exclude for the following:

  - Number 1, the provider violates any of the provisions of Chapter 7 of the WIC (commencing with Section 14000 except for Sections 14043–14044), or Chapter 8 (commencing with Section 14200) or any rule or regulation promulgated by the Department pursuant to those provisions. Administrative appeal pursuant to HSC Section 100171. This provision is consistent with WIC Section 14123(a) and (c), and is therefore necessary.
  - Number 2, the provider fails to comply with the Department's request to examine or receive copies of the books and records pertaining to services rendered to beneficiaries. This provision is consistent with WIC Section 14124.2, and is therefore necessary.

- Item c, "Temporary Suspension" informs the provider that the Department may temporarily suspend the provider under the following circumstances:

  - Number 1, the provider fails to disclose all information as required in federal Medicaid regulations or any other information required by the Department, or discloses false information. Administrative appeal pursuant to WIC Section 14043.65. This provision is consistent with WIC Section 14043.2(a), and is therefore necessary.
  - Number 2, if it is discovered that the provider is under investigation for fraud or abuse. Administrative appeal pursuant to WIC Section 14043.65. This provision is consistent with WIC Section 14043.36(a), and is therefore necessary.
  - Number 3, the provider fails to remediate discrepancies discovered as a result of an unannounced visit to a provider. Administrative appeal pursuant to WIC Section 14043.65. This provision is consistent with WIC Section 14043.7(c), and is therefore necessary.

- Number 4, the director determines that prior to a hearing, it is necessary to protect the public welfare or the interests of the Medi-Cal program. Administrative appeal pursuant to HSC Section 100171. This provision is consistent with WIC Section14123(c), and is therefore necessary.
- Number 5, provider submits claims to the County or Department for payment under any provider number from an individual or entity that is suspended, excluded or otherwise ineligible. This includes a provider on the Suspended and Ineligible Provider List or any list published by the Office of the Inspector General or the Department of Health and Human Services. Appeal pursuant to WIC Section 14043.65. This provision is consistent with WIC Section 14043.61, and is therefore necessary.
- Number 6, provider fails to comply with the Department's request to examine or receive copies of books and records pertaining to services rendered to beneficiaries. This provision is consistent with WIC Section 14124.2, and is therefore necessary.

- Number 23, "Liability of Clinic Providers" informs the applicant/provider that as a provider each person with an ownership or control interest in the clinic, agent, and managing employee is jointly and severally liable for any breach in this provider agreement, and that action by the Department against any of the providers in the provider clinic may result in action against all of the persons with ownership, control interest, agents, and managing employees of the clinic. This information was added to the provider agreement for clarification. As defined in Section 51000.1, persons with ownership, control interest, agents, and managing employees meet the definition of "applicant" and "provider" pursuant to Section 51051. Therefore, they are all responsible for compliance with the provider agreement. This information is necessary so the provider understands who is liable, and so the Department can ensure qualified providers participate in the Medi-Cal program and to protect the program from fraud and abuse.

- Number 24, "Legislative and Congressional Changes" informs the applicant/provider that this provider agreement is subject to any future additional requirements, restrictions, limitations, or conditions enacted by the California Legislature or the United States Congress which may affect the provisions, terms, conditions, or funding of this provider agreement in any manner. This information was added to the provider agreement to assist the applicant/provider in understanding that requirements and restrictions may be changed pursuant to the legislature or United States Congress that will affect the provider agreement and providers shall be held to these conditions.

- Number 25, "Provider Capacity" informs the applicant/provider that the provider, and the officers, directors, employees, and agents of the provider, in the performance of this provider agreement, shall act in an independent capacity and

not as officers, employees, or agents of the State of California. This information was added to the provider agreement for clarification. As defined in Section 51000.1, persons with ownership, control interest, agents, and managing employees meet the definition of “applicant” and “provider” pursuant to Section 51051. Therefore, they are all responsible for compliance with the provider agreement. This provision is necessary to provide a clear understanding of the provider’s role and responsibilities in the event of a legal discrepancy.
In addition, this information was added so the Department can ensure qualified providers participate in the Medi-Cal program and to protect the program from fraud and abuse.

- Number 26, "Indemnification" informs the applicant that as a provider they agree to indemnify, defend, and save harmless the State of California, its officers, agents, and employees, from any and all claims and losses accruing or resulting to any and all persons, firms, or corporations furnishing or supplying services, materials, or supplies in connection with the provider’s performance of this Agreement, and from any and all claims and losses accruing or resulting to any beneficiary, or to any other person, firm, or corporation who may be injured or damaged by the provider in the performance of this Agreement. This information is necessary to provide a clear understanding of the provider’s role and responsibilities in the event of a legal discrepancy.

- Number 27, "Governing Law" informs the applicant/provider that the provider agreement is governed and interpreted in accordance with the laws of the State of California and was added for clarification. It is necessary to incorporate this information so that applicants/providers understand the authority used to develop and maintain this agreement.

- Number 28, "Venue" informs the applicant/provider that the venue for all actions, including federal actions, concerning the provider agreement, lies in Sacramento County, California, or in any other county in which the California Department of Justice maintains an office. This information was added for clarification to the applicant/provider of where all actions will be taken place.

- Number 29, "Titles" informs the applicant/provider that the titles of the provisions of the provider agreement are for convenience and reference only and are not to be considered in interpreting this provider agreement. This information was added for clarification and to assist the applicant/provider in understanding the purpose of titles throughout this agreement. It is necessary to incorporate this information to provide a common understanding of the titles and their purposes in the event of a legal discrepancy.

- Number 30, "Severability" informs the applicant/provider that if one or more of the provisions of the provider agreement shall be invalid, illegal, void, or unenforceable, the validity, legality, and enforceability of the remaining provisions

shall not in any way be affected or impaired. This information was added for clarification and to assist the provider in understanding that if one provision is no longer applicable due to a change in law, all other provisions will still apply. It is necessary to incorporate this information to provide a clear understanding of the separate parts of the agreement in the event of a legal discrepancy.

- Number 31, "Waiver" informs the applicant/provider that any action or inaction by the Department or any failure of the Department on any occasion, to enforce any right or provision of the provider agreement, shall not be interpreted to be a waiver by the Department of its rights hereunder and shall not prevent the Department from enforcing such provision or right on any future occasion. This information was added for clarification and to assist the provider in understanding that the Department has the right to enforce any provision of the provider agreement at any time. It is necessary to incorporate this information to provide a clear understanding of the separate parts of the agreement in the event of a legal discrepancy.

- Number 32, "Complete Integration" informs the applicant/provider that the Provider Agreement, including any attachments or documents incorporated herein by express reference, is intended to be a complete integration and there are no prior or contemporaneous different or additional agreements pertaining to the subject matter of the provider agreement. This information was added for clarification for the provider. It is necessary to incorporate this information to provide a clear understanding of the separate parts of the agreement in the event of a legal discrepancy.

- Number 33, "Amendment" informs the applicant/provider that no alteration or variation of the terms or provisions of this provider agreement shall be valid unless made in writing and signed by the parties to the provider agreement. This statement will help the Department confirm that the applicant/provider attests that no alteration or variation of the provider agreement will be valid unless both parties sign written agreement/alteration. It is necessary to incorporate this information to provide a clear understanding of the separate parts of the agreement in the event of a legal discrepancy.

- Number 34, "Provider Attestation" informs the applicant that as a provider they agree that all information it submits on the application form for enrollment, this provider agreement, and all attachments or changes to either, is true, accurate, and complete to the best of the provider’s knowledge and belief. This statement will help the Department confirm that the applicant/provider attests that all information is true, accurate, and complete to the best of their knowledge. It is necessary to incorporate this information to provide a clear understanding of the separate parts of the agreement in the event of a legal discrepancy.

- The provider agrees that compliance with the provisions of the provider agreement is a condition precedent to payment to the provider. This statement is necessary to help the Department confirm that the applicant/provider has read and understands that payment is contingent upon compliance with the provider agreement.

- The Department and the provider agree that the provider agreement is a legal and binding document and is fully enforceable in a court of competent jurisdiction. The provider signing the agreement warrants that he/she has read this agreement and understands it. This statement is necessary to help the Department confirm that the applicant/provider has read and understands all information in the provider agreement and that the agreement is binding.

- The provider declares under penalty of perjury under the laws of the State of California that the foregoing information is true, accurate, and complete to the best of their knowledge and belief. This statement has been adopted as legal protection for the Department, ensuring that the applicant is responsible for all information listed on the submitted form and acknowledges that all information provided is true, accurate, and complete to the best of their knowledge. Complete and accurate information is necessary so the Department can ensure that qualified providers offer services under the Medi-Cal program.

The provider declares that they are the provider or they have the authority to legally bind the provider, which is an entity and not an individual person and that they are eligible to sign the provider agreement under Section 51000.30(a)(2)(B). This statement was added to bring attention to the fact that the individual signing needs to be an authorized individual.

- Number 1, “Printed legal name of provider” has been adopted to instruct the applicant/provider to print their legal name. A provider agreement shall be submitted for each provider, therefore, the legal name of the applicant/provider is necessary to confirm whom the provider agreement is between.

- Number 2, “Printed name of person signing this declaration on behalf of provider (if an entity or business name is listed in Item 1 above)” has been adopted to instruct the applicant to print the name of the person that has the authority to legally bind the applicant/provider, which is an entity and not an individual person and that is eligible to sign the agreement under Section 51000.30(a)(2)(B). This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B).

- Number 3, “Original signature of provider or representative if this provider is an entity other than an individual person as sole proprietor” has been adopted to instruct the applicant/provider to sign the name of the person that has the

authority to legally bind the provider, which is an entity and not an individual person and that is eligible to sign the agreement under Section 51000.30(a)(2)(B). This information is needed to confirm the identity of the individual signing and to ensure the individual is authorized to sign on behalf of the applicant/provider pursuant to Section 51000.30(a)(2)(B).

- Number 4, “Title of person signing this declaration” has been adopted to instruct the applicant/provider to provide the title of the person that has the authority to legally bind the provider, which is an entity and not an individual person and that is eligible to sign the agreement under Section 51000.30(a)(2)(B). This information was adopted to help the Department during the application review period to additionally confirm that the individual signing is an authorized individual and/or doesn’t need notarization.

- Number 5, “Executed at (City) (State) (Date)” has been adopted to instruct the applicant/provider to provide the City, State, and Date of where and when the original signature took place. This has been added to assist the Department in identifying the applicant’s location at the time of signing and provides record for signatory validation.

- Number 6, “Notary Public” instructs the applicant/provider to provide the name of the Notary Public who witnessed the signature. This information assists the Department in mitigating fraud and abuse by verifying the legitimacy of the signatory. In addition, notarization is required pursuant to Section 51000.30(a)(2)(D) and WIC Section 14043.25(c).

- “Privacy Statement” has been adopted to inform the applicant/provider that all the information is mandatory, including the Social Security Number. The applicant/provider is advised that all information requested on the application, the disclosure statement, and the provider agreement is mandatory. This information is required by the Department’s Provider Enrollment Division (PED), by the authority of WIC Section 14043.2(a). The consequences of not supplying the mandatory information requested are denial of enrollment as a Medi-Cal provider or denial of continued enrollment as a provider and deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program. Any information may also be provided to the State Controller’s Office, the California Department of Justice, the Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, fiscal intermediaries, managed care plans, the Federal Bureau of Investigation, the Internal Revenue Service, Medicare Fiscal Intermediaries, Centers for Medicare and Medicaid Services, Office of the Inspector General, Medicaid, and licensing programs in other states. For more information or access to records containing the applicant/provider’s personal information maintained by the Department, contact the Provider Enrollment Division at (916) 323-1945. The applicant/provider is advised that for more information or access to records

containing their personal information maintained by the Department, to contact the Provider Enrollment Division at (916) 323-1945 or contact Denti-Cal at (800) 423-0507. This privacy statement is consistent across all applications and forms and is necessary to ensure that the applicant/provider understands that all information requested is mandatory, and the bodies of law that are used to administer the Medi-Cal program. The Department also gives its due diligence by advising the applicant/provider of the consequences of not providing the required information. This privacy statement also advises the applicant/provider of additional entities that information may be shared with, as required or permitted by law. The applicant/provider is given PED's and Denti-Cal's telephone number for more information or to access records. This information is necessary as it is essential that the applicant/provider understands the Department's right to share information, and with whom, and the telephone number they may use to attain additional information.

Section 51000.45, Subsection (e)

The Department proposes to adopt this subsection to require the substance use disorder medical director, licensed substance use disorder treatment professional, and substance use disorder nonphysician medical practitioner to complete a provider agreement, which is required by each provider enrolled into the Medi-Cal program, pursuant to Title 42 CFR Section 455.105(a), and WIC Sections 14043.2, and 14043.26. The provider agreement is included in the "Drug Medi-Cal Substance Use Disorder Medical Director Application/Licensed Substance Use Disorder Treatment Professional/Substance Use Disorder Nonphysician Medical Practitioner/ Application/Agreement/Disclosure Statement," DHCS 6010 (Rev. 12/14) incorporated by reference above in Section 51000.30. Further discussion related to the necessity of this form is included under Section 51000.30 above.

Section 51000.60. Established Place of Business Requirements.

The Department proposes to amend the title of Section 51000.60 to include the word "Requirements" for clarity, as this section specifies what is required to be an established place of business.

Section 51000.60, Subsection (c)(9)(A)

The Department proposes to amend Section 51000.60(c)(9)(A) to require the applicant or provider to obtain verification from the space owner if they are located on donated space. It is not uncommon for substance use disorder clinics to be located on donated space, such as churches or unused local facilities. Typically, all Medi-Cal providers must be located on space that is either owned or leased by the applicant or provider, however, substance use disorder clinics located on donated space would not be able to meet this requirement. Therefore, this amendment was necessary to create an exemption for substance use disorder clinics that do not lease or own the location

where they are providing services and allows the Department to ensure that use of the donated space has been verified.

Section 51000.60, Subsection (c)(9)(B) and (C)

The Department proposes to amend Section 51000.60(c)(9)(B) and (C) to exempt substance use disorder clinics from being required to have signage identifying them as a health care provider or posted business hours. This amendment is necessary because due to privacy restraints (Title 42, CFR, Part 2, Sections 2.12(a) and 2.13(c)(1)) some substance use disorder clinics may not be able to meet this requirement, including applicants and providers that are located on donated space.

Section 51000.70. Substance Use Disorder Medical Director.

The Department proposes to adopt Section 51000.70 to set forth the requirement that in order for a DMC clinic to enroll in the Medi-Cal program, the clinic must have a substance use disorder medical director meeting specifically listed criteria. The first paragraph of Section 51000.70 requires that the substance use disorder medical director be a licensed physician whom is an agent of the substance use disorder clinic. It is necessary that the substance use disorder medical director be a licensed physician because they are responsible for the medical services provided in the clinic as described in the proposed amendments under Section 51341.1. The first paragraph also specifies that the substance use disorder medical director shall be the agent of the clinic. This addition is necessary because clinics have attempted to avoid liability for fraudulent billings by claiming that any fraud was due to the wrongful acts of their medical directors who falsely certify that a service is medically necessary and assert that the clinic cannot be liable for any fraud resulting from that false certification. A DMC clinic shall be responsible for the wrongful acts of its medical director, and will have to reimburse the Medi-Cal program for any fraudulent billing arising from the medical director's work at the clinic. This will incentivize clinics to monitor the performance of their substance use disorder medical directors.

Section 51000.70, Subsection (a)

The Department proposes to adopt Section 51000.70(a) to implement the requirements in WIC Sections 14043.36(b) and 14043.61 that the substance use disorder medical director not be excluded from participating in any State or Federal Medicare or Medicaid program, meaning the substance use disorder medical director is in good standing with those programs. The Department has experienced many cases of alleged fraud in which the substance use disorder medical director was excluded or temporarily suspended from participation in a State or Federal Medicare program. This proposed subsection is necessary to aid in the protection of public health, safety, and general welfare by requiring the substance use disorder medical director to be in good standing with any State or Federal Medicare program.

Section 51000.70, Subsection (b)

The Department proposes to adopt Section 51000.70(b) to require the substance use disorder medical director to be enrolled in the Medi-Cal program as a substance use disorder medical director. This amendment is necessary to ensure that substance use disorder medical directors comply with all applicable statutes and regulations regarding the standards for participation in the Medi-Cal program. Through its investigations, the Department has determined that substance use disorder medical directors and other physicians working for the substance use disorder clinics have played a major role in the alleged fraud and abuse carried out by DMC providers. Only a physician can determine whether the services offered by the clinic are medically necessary for the beneficiary and thus eligible for payment under the Medi-Cal program. They also prescribe the course of treatment for the beneficiary. This amendment is necessary to ensure that substance use disorder medical directors meet all requirements of the Medi-Cal program prior to being able to treat beneficiaries. It also provides the Department clear authority to take direct action against substance use disorder medical directors who do not meet the Medi-Cal program requirements.

Section 51000.70, Subsection (c)

The Department proposes to adopt Section 51000.70(c) to require that the substance use disorder medical director act in compliance with all laws and requirements of the Medi-Cal program. This section is necessary to specify that in order for the substance use disorder clinic and the substance use disorder medical director to meet program requirements and continue enrollment in the Medi-Cal program, the substance use disorder medical director must comply with all of the Medi-Cal laws and requirements. Furthermore, by holding the substance use disorder medical director to this standard, the Department has a greater ability to combat fraud and abuse in the DMC program and ensure that beneficiaries receive quality care.

Section 51000.75. Licensed Substance Use Disorder Treatment Professional and Substance use Disorder Nonphysician Medical Practitioner Utilization.

The Department proposes to adopt Section 51000.75 to require 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 using the “Drug Medi-Cal Substance Use Disorder Clinic Application,” DHCS 6001 (Rev. 12/14). This requirement is necessary to combat fraud and abuse during the application review process. The Department will be able to verify that each licensed substance use disorder treatment professional and substance use disorder nonphysician medical practitioner is enrolled and is in good standing. Further discussion related to the necessity of this form is included under Section 51000.30 above.

Section 51000.75, Subsection (a)

The Department proposes to adopt Section 51000.75(a) to implement the requirements in WIC Sections 14043.36(b) and 14043.61 that the licensed substance use disorder treatment professional and all substance use disorder nonphysician medical practitioners not be excluded from participating in any State or Federal Medicare or Medicaid program. This section is necessary to combat fraud and abuse in the Medi-Cal program and to aid in the protection of public health, safety and general welfare by allowing the Department to verify that each licensed professional is in good standing with any State or Federal Medicare or Medicaid program.

Section 51000.75, Subsection (b)

The Department proposes to adopt this section to require each licensed substance use disorder treatment professional and substance use disorder nonphysician medical practitioner to be enrolled in the Medi-Cal program by using the appropriate form. This amendment is necessary to ensure that licensed substance use disorder treatment professionals and substance use disorder nonphysician medical practitioners comply with all applicable statutes and regulations regarding the standards for participation in the Medi-Cal program. This amendment is also necessary to allow the Department greater authority to take action on clinics with licensed substance use disorder treatment professionals and substance use disorder nonphysician medical practitioners who do not meet program requirements that are established to ensure quality care is provided to beneficiaries.

Section 51051. Provider.

Section 51051, Subsection (b)

The Department proposes to amend Section 51051(b) to include licensed substance use disorder treatment professionals, substance use disorder clinics, substance use disorder medical directors, and substance use disorder nonphysician medical practitioners as “providers” under the Medi-Cal program. This amendment is necessary because substance use disorder clinics, substance use disorder medical directors, licensed substance use disorder treatment professionals, and substance use disorder nonphysician medical practitioners are considered to be providers under the Medi-Cal program, as described throughout this Statement of Reasons.

Section 51341.1. Drug Medi-Cal Substance Use Disorder Services.

Section 51341.1, Subsection (b)(28)

The Department proposes to amend Section 51341.1(b), which includes definitions and requirements for DMC Substance Use Disorder Services, to add a definition, responsibilities and requirements of a “Substance Use Disorder Medical Director.”

The definition for a “Substance Use Disorder Medical Director” cross-references to the definition under Section 51000.24.4 and also specifies the role and responsibilities of the substance use disorder medical director.

In most instances a substance use disorder clinic’s substance use disorder medical director is also its sole physician, but a clinic may also utilize both a substance use disorder medical director and a physician(s). The regulations were drafted to address both scenarios.

In the course of investigating the DMC Clinics, the Department has determined that physicians/substance use disorder medical directors have played a major role in the alleged abuses and that there has been a general lack of medical oversight at the clinics. Recent amendments to Section 51341.1, which were made through a previous regulatory action, addressed the role of physicians but did not address the definition, responsibilities and requirements of substance use disorder medical directors. This proposed amendment sets forth the requirements and responsibilities of medical directors. It will provide the Department with greater authority to take disciplinary action against substance use disorder medical directors who do not meet Medi-Cal program requirements. By making substance use disorder medical directors responsible for ensuring that services provided by physicians and nonphysician medical practitioners meet the applicable standard of care, subsection (b)(28)) will address the lack of medical oversight and enhance the Department’s ability to enforce standard of care requirements.

During investigations, the Department has observed fraudulent or abusive practices, which have likely resulted in the provision of unnecessary and/or inappropriate care to beneficiaries. In some instances, apparently for financial considerations, physicians have diagnosed beneficiaries with a substance use disorder and made findings of medical necessity when there was inadequate evidence to support the diagnosis or finding. In other instances, the substandard diagnoses and medical necessity determinations appear to be the result of physicians’ and substance use disorder medical directors’ lack of competence in substance use disorder medicine or the improper delegation of medical necessity determinations to nonphysician medical practitioners. These amendments are necessary to address these issues and to support the provision of necessary and quality care to beneficiaries as well as to help curtail fraud and abuse in the DMC Program.

Section 51341.1, Subsection (b)(28)(A)

The Department proposes to adopt subsection (b)(28)(A) to specify that provisions (b)(28)(A)(i) - (iii) apply to a substance use disorder medical director for an outpatient drug free, day care habilitative, perinatal residential or naltrexone treatment services program. This amendment is necessary since there are different requirements that apply to a substance use disorder medical director of a narcotic treatment program.

Section 51341.1, Subsection (b)(28)(A)(i)

The Department proposes to adopt subsection (b)(28)(A)(i) to specify the responsibilities of the substance use disorder medical director. This provision establishes the substance use disorder medical director's role as the party responsible for the medical care provided by the clinic. The requirements in provisions (a) - (f) are necessary to address specific issues that the Department encountered during its investigations related to the lack of oversight and substandard provision of care in the clinics. These amendments make a substance use disorder medical director responsible for ensuring that services provided by physicians and nonphysician medical practitioners at the clinic meet the applicable standards of care, and in turn, will enhance the Department's ability to enforce those standards of care requirements.

Section 51341.1, Subsection (b)(28)(A)(i)(a)

The Department proposes to adopt subsection (b)(28)(A)(i)(a) to require a substance use disorder medical director to ensure that physicians meet the applicable standards of care in performing their duties. This is necessary to address the substandard performance of physician duties at clinics, which the Department observed during its investigations and is evidenced by the lack of documentation in beneficiary's records to support diagnoses and the medical necessity of treatment plans. This subsection also requires the substance use disorder medical director to ensure that nonphysician medical practitioners meet the applicable standards of care. This is necessary to address the lack of medical oversight at the clinics.

Section 51341.1, Subsection (b)(28)(A)(i)(b)

The Department proposes to adopt subsection (b)(28)(A)(i)(b) to require a substance use disorder medical director to ensure that physicians do not improperly delegate their duties to nonphysician medical practitioners. The Department has observed blank treatment plans signed by physicians. By signing blank treatment plans, the physician effectively delegates determination of medical necessity to a non-physician. This is because initial diagnoses are performed by non-physician personnel and treatment plans are prepared by non-physician personnel and the physician's signature on a beneficiary's treatment plan indicates that the physician agrees with the beneficiary's diagnosis and that the services identified in the treatment plan are medically appropriate and necessary for the beneficiary. This amendment is necessary to address the practice of physicians' signing blank treatment plans.

Section 51341.1, Subsection (b)(28)(A)(i)(c)

The Department proposes to adopt subsection (b)(28)(A)(i)(c) to require a substance use disorder medical director to develop and implement medical policies and standards. These policies and standards are needed to address medical issues that occur at the clinics, such as beneficiary psychiatric and medical crises and the safeguarding and

securing of beneficiary medication in perinatal residential and day care habilitative programs. This requirement is necessary since the Department has observed that in some clinics there are no policies or procedures.

Section 51341.1, Subsection (b)(28)(A)(i)(d)

The Department proposes to adopt subsection (b)(28)(A)(i)(d) to require the substance use disorder medical director to ensure that physicians and nonphysician medical practitioners follow the policies and standards implemented under subsection (b)(28)(A)(i)(c). This requirement is necessary because the Department has observed that in some clinics the established policies and procedures were not being followed.

Section 51341.1, Subsection (b)(28)(A)(i)(e)

The Department proposes to adopt subsection (b)(28)(A)(i)(e) to require a substance use disorder medical director to ensure that physician decisions, including substance use disorder diagnoses and medical necessity determinations for treatment services, are not influenced by financial considerations. This requirement is necessary because based on Department observations, it appears that some physicians have diagnosed beneficiaries with a substance use disorder and made findings of medical necessity so the clinics can continue to treat and bill for a beneficiary's treatment, when this treatment is not medically necessary.

Section 51341.1, Subsection (b)(28)(A)(i)(f)

The Department proposes to adopt subsection (b)(28)(A)(i)(f) to require a substance use disorder medical director to ensure that physicians receive adequate training to perform their duties. This provision is necessary because based on Department observations it appears that physicians working in clinics have inadequate training in addiction medicine. Training in this specialty area is necessary to support the provision of medically necessary and quality care to beneficiaries.

Section 51341.1, Subsection (b)(28)(A)(ii)

The Department proposes to adopt subsection (b)(28)(A)(ii) to allow a substance use disorder medical director to delegate his/her responsibilities to a physician, consistent with the clinic's policies and standards. This provision is necessary because a substance use disorder medical director is sometimes not available to perform services at the clinic due to illnesses, vacations, maternity leave, bereavement leave, etc., so a viable option for delegation is necessary to ensure the provision of health care services to beneficiaries by a physician. However, this provision states that the substance use disorder medical director is still responsible to ensure that delegated duties were performed appropriately. This is necessary because the Department needs to be able to hold the substance use disorder medical director responsible for medical oversight at the clinics, as discussed in subsection (b)(28)(A)(i) above.

Section 51341.1, Subsection (b)(28)(A)(iii)

The Department proposes to adopt subsection (b)(28)(A)(iii) to require the substance use disorder medical director to receive a minimum of five hours of continuing medical education in addiction medicine each year. This provision is necessary because based on Department observations it appears that physicians and substance use disorder medical directors working in clinics have inadequate training in substance use disorder medicine. This requirement is based on a recommendation from Elinore McCance-Katz, MD, Chief Medical Officer, Substance Abuse and Mental Health Services Administration. (See "Requirements for DMC Program Physicians," which is prepared by Elinore McCance-Katz, MD.) Addiction medicine is a specialty and it is not unreasonable to require a minimum of 5 hours of continuing medical education in addiction medicine each year.

Section 51341.1, Subsection (b)(28)(B)

The Department proposes to adopt subsection (b)(28)(B) to refer to existing requirements for a substance use disorder medical director of a narcotic treatment program. The cross reference to these requirements are included in subsection (b)(28)(B) to make it easy for the regulated public to locate those requirements and to clearly indicate that the existing requirements for substance use disorder medical directors of narcotic treatment programs are unchanged.

Section 51341.1, Subsections (b)(29)-(31)

Subsections (b)(28) through (b)(30) have been redesignated to (b)(29) through (b)(31).

AUTHORITY STATEMENT

WIC Sections 10725, 14043.75, and 14124.5 authorize the director of the Department to adopt, amend, or repeal regulations as necessary and proper to carry out the purpose and intent of the statutes governing the Medi-Cal program.

DOCUMENTS RELIED UPON (In order of appearance)

1. "DHCS Tightens Oversight of Drug Medi-Cal Centers," News Release, July 18, 2013, available at: http://www.dhcs.ca.gov/formsandpubs/publications/opa/Documents/2013/13-07DHCS-WICDMC7-18-13.pdf.

2. "Drug Medi-Cal Program Limited Scope Review," November 2013, available at: http://www.dhcs.ca.gov/dataandstats/reports/Documents/DMCLtdScopeRvw.pdf.

3. "Implementation Plan for Drug Medi-Cal Program Limited Scope Review," available at: http://www.dhcs.ca.gov/dataandstats/reports/Documents/ImpPlanforAuditRecom.pdf.

4. California's State Plan Amendment 13-038, Supplement 3 to Attachment 3.1-A, pages 5-6, January 1, 2014, which is available at: http://www.dhcs.ca.gov/formsandpubs/laws/Documents/CA_SPA_13-038_Approved_Package_Redacted.pdf.

5. Final Rule published by CMS on January 23, 2004, in Volume 69, Number 15 of the Federal Register (Title 45 CFR, Part 162) which is available at: https://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/downloads/npifinalrule.pdf

6. Final Rule published by CMS on February 2, 2011, in Volume 76, Number 22 of the Federal Register (Title 42 CFR, Parts 405, 424, 447 et al.) which is available at: http://www.gpo.gov/fdsys/pkg/FR-2011-02-02/pdf/2011-1686.pdf

7. Medi-Cal Regulatory Provider Bulletin, "Medi-Cal Application Fee Requirements for Compliance with 42 Code of Federal Regulations Section 455.460," which is available at: http://files.medi-cal.ca.gov/pubsdoco/prov_enroll.asp#Forms

8. Medi-Cal Regulatory Provider Bulletin "Provider Enrollment Application Changes Due to NPI," effective February 15, 2008 which is available at: http://files.medi-cal.ca.gov/pubsdoco/prov_enroll.asp#Forms

9. "Requirements for DMC Program Physicians," by Elinore McCance-Katz, MD Ph.d., Chief Medical Officer, Substance Abuse and Mental Health Services Administration.

DOCUMENTS INCORPORATED BY REFERENCE

The following forms, which are incorporated by reference in Sections 51000.30 and 51000.45, have been adopted to require information that shall be reported to the Department:

- "Drug Medi-Cal Substance Use Disorder Clinic Application," DHCS 6001 (Rev. 12/14);
- "Drug Medi-Cal Provider Agreement," DHCS 6009 (Rev. 12/14); and
- "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).

These forms have been incorporated by reference because it would be too cumbersome to publish the forms directly in the CCR. PED forms are available on the Department's internet website at: http://files.medi-cal.ca.gov/pubsdoco/prov_enroll.asp.

The following forms, which were previously incorporated by reference, have also been amended through this regulatory action, and are available at the website noted above:

- "Medi-Cal Disclosure Statement," DHCS 6207 (Rev. 2/15);
- "Medi-Cal Supplemental Changes," DHCS 6209 (Rev. 12/14); and
- "Medi-Cal Rendering Provider Application/Disclosure Statement/Agreement for Physician/Allied/Dental Providers," DHCS 6216 (Rev. 2/15).

STATEMENTS OF DETERMINATION

(a) ALTERNATIVES CONSIDERED

The Department has determined 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 this regulatory action was taken, would be as effective and less burdensome to affected private persons than the regulatory 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 Medi-Cal program are located in Title 22, CCR, Division 3. Using this regulatory proposal to make amendments and adoptions to existing requirements that govern the Medi-Cal program is the most effective and convenient way to provide current and updated information directly to those impacted providers, physicians, beneficiaries.

This regulatory action is necessary, pursuant to WIC Section 14043.75, to take 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 field reviews conducted by the Department.

(b) 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.

(c) 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.

(d) 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.

(e) HOUSING COSTS DETERMINATION

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