INSTRUCTIONS FOR COMPLETION OF THE APPLICATION FOR PROTOCOL AMENDMENT FORM DHCS 5135

Submit completed form electronically to <u>DHCSNTP@dhcs.ca.gov</u> or return completed form to the following address:

Department of Health Care Services Counselor & Medication Assisted Treatment Section, MS2603 <u>PO BOX 997413</u> Sacramento, CA 95899-7513

DO NOT USE staples on this form or on any attachments.

DO NOT USE correction tape, white out, or highlighter pen or ink of a similar type on this form. If you must make corrections, please line through, date, and initial in ink.

DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A

Facility Type

This section must be completed by all applicants.

Check the appropriate box for the type of facility.

Narcotic Treatment Program (NTP) – A licensed opioid use disorder treatment program, whether inpatient or outpatient, which offers all of the following: evaluation, maintenance treatment and/or detoxification treatment, and other services in conjunction with medication for opioid use disorder.

Medication Unit (MU) – A DEA registered facility established as part of, but geographically separate from, a narcotic treatment program, from which appropriately licensed program staff, contractors working on behalf of the program, or community pharmacists dispense or administer controlled medication for opioid use disorder, and which may provide other treatment services. Medication units are a brick-and-mortar location and do not include mobile narcotic treatment programs.

Office-Based Narcotic Treatment Network (OBNTN) – A network of providers, that are affiliated and associated with a primary NTP, offering one or more of the following: evaluation of medical, employment, alcohol, criminal, and psychological problems; screening for diseases that are disproportionately represented in the substance use disorder population; counseling by substance use disorder counselors that are evaluated through ongoing supervision; and professional medical, treatment, and behavioral health services, on-site or by referral.

SECTION B

Type of Amendment

This section must be completed by all applicants.

Check the appropriate box(es) for the type(s) of protocol amendment for which you are applying and complete the corresponding sections for each protocol amendment.

Relocation – A change of location of a facility or of any portion of the facility.

Change in Licensed Patient Capacity – An increase or decrease in the licensed capacity for detoxification or maintenance treatment.

Addition, Reduction or Termination of Services – Any addition, reduction or termination of services.

Name of Program Sponsor – Any change in the person or organization responsible for the operation of the NTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, treatment, behavioral health, or recovery support services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Change in Individual Pursuant to CCR, Title 9 §10035(a)(5) – Any change in partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

Change in Physical Structure – Any change to the physical structure or floor plan of the facility including expansions or modifications to dispensing stations.

Interim Treatment – Applying to for approval to provide interim treatment (9 CCR § 10023).

Other Providers – Applying to for approval for "other providers" to provide specified NTP services (9 CCR § 10031).

Other – All other changes in the protocol and supplemental written protocol.

SECTION C Existing Licensee Information

This section must be completed by all applicants.

License Number – Enter the NTP license number issued by the Department for the facility with the proposed protocol amendment(s).

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at https://nppes.cms.hhs.gov/#/contactUs

Name of Legal Entity – Enter the legal entity name.

PLEASE NOTE: Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: <u>Business Programs :: California Secretary of State</u>

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: <u>Business Programs :: California Secretary of State</u>

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: <u>Business Programs :: California Secretary of State</u>

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of NTP, MU or OBNTN – If different from legal entity name, enter the name of the facility or provider.

Tax Status – Check the box which applies to your business structure for tax purposes.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website: <u>https://tools.usps.com/go/ZipLookupAction_input</u>

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

An exact address can be verified at the United States Postal Service website: <u>https://tools.usps.com/go/ZipLookupAction_input</u>

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number assigned to the facility.

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Name of Program Sponsor – Enter the person or organization responsible for the operation of the NTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, treatment, behavioral health, or recovery support services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Name of Program Director – Enter the name of the person who has primary administrative responsibility for operation of the NTP.

Name of Medical Director – Enter the name of the physician licensed to practice medicine in California who is responsible for compliance and overseeing all medical and behavioral health services provided by the NTP.

SECTION D

NTP Services by Other Providers

This section must be completed by applicants applying for NTP services to be provided by other providers.

All medical and behavioral health services must be available at the primary NTP's location, except where the program sponsor has entered into a written agreement with a private or public agency, organization, health care provider, or institution such as a hospital, correctional facility, or long-term care facility ("other provider"), to provide specified services to patients enrolled in the NTP.

NTP Services by Other Providers – Check the box to indicate that a copy of the agreement containing the signatures of all providers of services is attached.

Check the box to indicate that the agreement contains all requirements in CCR, Title 9, Section 10031. The agreement with the other provider shall contain:

- The services that the other provider will provide to patients enrolled in the NTP.
- The conditions under which a patient will receive the services set forth in the agreement.
- Policies and procedures for the other provider to provide the services set forth in the agreement, including but not limited to, requirements to comply with all applicable federal and state laws on patient confidentiality and security of controlled medications.
- Policies and procedures for the other provider to provide documentation to the NTP of the services it provides to the NTP's patients.

SECTION E

Relocation

This section must be completed by applicants applying for program relocation.

PLEASE NOTE: Pursuant to CCR, Title 9, §10085(a)(2), the Department shall conduct a site visit prior to the approval of program facility relocation.

For relocation of a Department approved NTP location, additional documentation is required.

Written Statement Explaining Relocation – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the relocation of the program to the new location.
- The estimated impact that the relocation will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the relocation.

Facility and Geographical Area Form DHCS 5025 – Complete the Facility and Geographical Area form DHCS 5025 for the new NTP location and attach to this form.

County Certification Form DHCS 5027 – Complete the County Certification form DHCS 5027 for the new NTP location and attach to this form.

Letters of Community Support – Obtain written verification of support from the community for the new NTP location and attach to this form.

SECTION F

Change in Licensed Patient Capacity

This section must be completed by applicants applying for a change in licensed patient capacity.

PLEASE NOTE: Pursuant to CCR, Title 9, §10035(d), an amendment proposing an increase in the licensed patient capacity for detoxification or maintenance treatment at a program shall be subject to the Department's determination that the program is currently in compliance with applicable State and federal laws and regulations.

For a change in the Department approved maximum licensed patient capacity, additional documentation is required.

Written Statement Explaining Change in Licensed Patient Capacity – Check box to indicate that a written statement is attached to this form.

Statement must include:

• The proposed effective date of the change in licensed patient capacity.

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- The estimated impact that the change in licensed patient capacity will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in licensed patient capacity.

Current Licensed Patient Capacity – Enter the Department approved maximum licensed patient capacity for maintenance and detoxification treatment.

Amount of Licensed Patient Capacity Increase or Decrease – Enter the amount of licensed patient capacity increase or decrease for maintenance and detoxification treatment.

Requested Licensed Patient Capacity – Enter the requested total licensed patient capacity for maintenance and detoxification treatment.

Number of Deaths Reported – Enter the number of patient deaths reported in the last 90 days as required by CCR, Title 9, §10195. This information will be verified against Department records for purposes of verifying compliance.

Current Program Census – Enter the total number of patients currently receiving maintenance or detoxification treatment at the NTP.

Proposed Counselor to Patient Ratio – Enter the number of counselors per patient with the additional capacity.

Example: If the program has a current total capacity of 100 patients and 10 counselors. The ratio would be 1:10.

Updated Facility Map – If any change has been made to the facility map previously provided to the Department in the protocol, attach an updated map of the NTP location.

Section G Addition, Reduction or Termination of Services

This section must be completed by applicants applying for an addition, reduction or termination of services.

PLEASE NOTE: This section must be completed for a change in hours of operation, including services provided via telehealth.

For a change in Department approved services including the addition, reduction or termination of services additional documentation is required.

Written Statement Explaining Addition, Reduction or Termination of Services – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the addition, reduction or termination of services.
- The estimated impact that the addition, reduction or termination of services will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.

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• Any other portion of the previously Department approved protocol affected by the addition, reduction or termination of services.

Section H

Change in Program Sponsor

This section must be completed by applicants applying for change in Program Sponsor.

Name of Current Program Sponsor – Enter the person or organization currently responsible for the operation of the NTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, treatment behavioral health, or recovery support services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Name of New Program Sponsor – Enter the person or organization that, if approved by the Department, will be responsible for the operation of the NTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, treatment, behavioral health, or recovery support services at the program or any of its medication units and OBNTNs. The new program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Business Address of New Program Sponsor – Enter the business address of the new program sponsor.

Telephone Number of New Program Sponsor – Enter the telephone number of the new program sponsor, include an extension if applicable.

Email Address of New Program Sponsor – Enter the email address of the new program sponsor.

PLEASE NOTE: For a change in program sponsor additional documentation is required.

Written Statement Explaining Change in Program Sponsor – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in program sponsor.
- The estimated impact that the change in program sponsor will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in program sponsor.

New Program Sponsor Resume – Check box to indicate that the proposed program sponsor's resume is attached to this form.

Section I Change in Individual Pursuant to CCR, Title 9, §10035(a)(5)

This section must be completed by applicants applying for change in individual pursuant to CCR, Title 9, §10035(a)(5).

Name of Individual – Enter the name of the partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

Telephone Number – Enter the telephone number and extension if applicable of the partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

Email Address – Enter the email address of the partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

Individual Live Scan Fingerprinting Date – Enter the date that the partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, had individual live scan fingerprinting.

PLEASE NOTE: For any change in personnel pursuant to CCR, Title 9, §10035(a)(5), additional documentation is needed.

Written Statement Explaining Change in Individual – If applying for a change in partner, officer, board of director's member, or 10 percent or greater shareholder, check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in individual.
- The estimated impact that the change in individual), will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in individual.

Organizational Responsibility Form DHCS 5031 – If applying for a change in partner, officer, board of director's member, or 10 percent or greater shareholder, complete the Organizational Responsibility form DHCS 5031 and attach to this form.

Written Statement Explaining Change in Individual – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in individual.
- The estimated impact that the change in individual will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in individual.

Staff Information Form DHCS 5026 – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete the Staff Information form DHCS 5026 and attach to this form.

Written Documentation of Medical Licensure – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, obtain written documentation of medical licensure and attach to this form.

Procedure for Replacement – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete a written statement describing the procedure of replacement of such staff member in the event of death, retirement, or prolonged sickness and attach to this form.

Procedure to Assure Appropriate Staff Time – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete a written statement describing the procedure to assure that appropriate staff time will be provided to the program in the event of a short-term emergency, vacation, or sickness and attach to this form.

Resume – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, attach a resume to this form.

Section J

Change in Physical Structure

This section must be completed by applicants applying for change in physical structure.

For a change in physical structure, additional documentation is required.

Written Statement Explaining Change in Physical Structure – Check box to indicate that a written statement is attached to this form.

Statements must include:

- The proposed effective date of the change in physical structure.
- A narrative describing the changes in physical structure.
- The estimated impact that the change in physical structure will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in physical structure.

Facility and Geographical Area Form 5025 – Complete the Facility and Geographical Area form DHCS 5025 to include the change in physical structure and attach to this form.

Updated Facility Map – Complete an updated facility map that includes the change in physical structure for which you are applying for and attach to this form.

Section K

Interim Treatment

This section must be completed by applicants applying for approval to provide interim treatment.

Interim treatment means that on a temporary basis, not to exceed 180 days in any 12-month period, a patient may receive medication for opioid use disorder from a NTP while awaiting access to comprehensive treatment. The NTP must be compliant with the requirements specified in California Code of Regulations, Title 9, Chapter 4, Section 10023:

Written Protocol for Interim Treatment – Check box to indicate that a written statement is attached to this form.

Protocol must include:

- Criteria for establishing the priority of admitting patients into interim treatment and transferring
 patients from interim treatment into comprehensive treatment, which shall prioritize the
 admission and transfer of pregnant patients; and
- Evidence that the NTP's provision of interim treatment will not reduce the capacity of the NTP to admit patients into comprehensive treatment.

Section L

Declaration

This section must be completed by all applicants.

Print Name – Enter the name of the program sponsor.

Title – This field has been pre-filled by the Department to reflect that the form must be signed by the program sponsor.

Signature – Program sponsor's signature.

Date – Enter the date that the application is signed by the program sponsor.

Section A	Facility Type		
Check one box: Narcotic Treatment Program (NTP) CCR, Title 9, §10030 Medication Unit (MU) CCR, Title 9, §10020 Office-Based Narcotic Treatment Network (OBNTN) CCR, Title 9, §10021			
Section B	Type of Amendment		
Check all that apply:			
 Relocation CCR, Title 9, §10035(a)(1) Change in Licensed Patient Capacity CCR, Title 9, §10035(a)(2) Addition, Reduction or Termination of Services CCR, Title 9, §10035(a)(3) Program Sponsor CCR, Title 9, §10035(a)(4) Any change in partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code CCR, Title 9, §10035(a)(5) Any change to the physical structure of the facility or floor plan including expansions or modifications to dispensing stations CCR, Title 9, §10035(a)(6) Other CCR, Title 9, §10035(b) or 10031(d) 			
Section C	Existing Licensee Information		
License Number:	National Provider Identifier (NPI):		
Name of Legal Entity:			
Name of NTP, MU or OBNTN (if o	different than name of legal entity):		

Section C (Continued)	Existing Licens	ee Information		
Tax Status:				
Corporation Nonprofit				
Corporation				
Limited Liability Company				
Partnership/Limited Partner	ship			
Sole Proprietor				
Governmental Agency				
Facility Street Address (if applicab	le Room/Suite/Unit):		
City:	County:		Zip Code:	
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):				
City:	County:		Zip Code:	
Telephone Number:		Fax Number:		
Name of Program Sponsor:				
Name of Program Director:				
Name of Medical Director:				
Section D N1	TP Services by Ot	her Providers		
Attach the following:				
A copy of the agreement containing the signatures of all providers of services.				
Agreement contains requirements in CCR, Title 9, Section 10031(b).				

Section E	Relocatio	on			
Attach the following:	Attach the following:				
Written Statement Explain	ing Relocation				
Facility and Geographical	Area Form DHCS 5	025			
County Certification Form	DHCS 5027				
Letters of Community Sup	port				
Section F (Complete section	Change in License E if application is fo				
Attach the following:					
Written Statement Explaining Change in Licensed Patient Capacity					
Current Licensed Patient Capacit	y:				
Amount of Licensed Patient Capa	acity Increase or De	crease:			
Requested Licensed Patient Cap	acity:				
Number of Deaths Reported in th	e last 90 days as re	quired by CCR	, Title 9, §10195:		
Current Program Census:		Proposed Co	unselor to Patient Ratio:		
Updated Facility Map Attached: Yes N/A					
Section G Addition, Reduction or Termination of Services					
Attach the following:					
Written Statement Explaining Addition, Reduction or Termination of Services					
Section H	Change in Progr	ram Sponsor			
Name of Current Program Sponsor:					
Name of New Program Sponsor:					
Business Street Address of New Program Sponsor:					
City:	County:		Zip Code:		

Section H (Continued)	Change in Program Sponsor					
Telephone Number of New Program	n Sponsor:	Email Address of New Program Sponsor:				
Attach the following:	Attach the following:					
Written Statement Explaining Change in Program Sponsor						
New Program Sponsor Resume						
)	Individual Purs	suant to CCR, Title 9, §10035(a)(5)				
Name of Individual:						
Telephone Number:		Email Address:				
Individual Live Scan Fingerprinting [Date:					
Attach the following for a change in partner, officer, board of director's member, or 10 percent or greater shareholder: Written Statement Explaining Change in Individual Organizational Responsibility Form DHCS 5031						
Attach the following for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code:						
Written Statement Explaining Change in Individual						
Staff Information Form DHCS 5026						
Written Documentation of Medical Licensure						
Procedure for Replacement						
Procedure to Assure Appropriate Staff Time						
Resume						

Section J Change in	Physical Structure				
Attach the following documents:					
Written Statement Explaining Change	in Physical Structure				
Facility Geographical Area Form DHC	S 5025				
Updated Facility Map					
Section K Interim	Treatment				
Attach the following document: Written Statement Explaining Change in Physical Structure					
Section L Dec	laration				
I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate, and complete to the best of my knowledge and belief. I hereby further declare that I will abide by all State and federal laws and regulations governing narcotic treatment programs. I declare that I am authorized to sign this application.					
Print Name:	Title:	Program Sponsor			
Signature:	Date:				
Priv	acy Statement				
PRIVACY STATEMENT (Civil Code Section 1798 et seq.) All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department) by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10055. The consequences of not supplying the mandatory information requested is that review of the application shall be terminated, which may result in lapse of licensure and/or imposition of fines. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the CMATS Officer of the Day at (916) 322-6682.					