SECOND 15-DAY PUBLIC COMMENT PERIOD
LIST OF COMMENTERS

Commenter #1 (submitted 01-16-20)
Brad Shapiro, MD, FASAM
UCSF Professor, Psychiatry and Family and Community Medicine
Medical Director, Opiate Treatment Outpatient Program

Commenter #2 (submitted 01-16-20)
Philip Peters, MD
Office of AIDS Medical Officer
California Department of Public Health

Commenter #3 (submitted 01-23-20)
Phillip Hernandez, SUDCC III
Program Manager – Substance Use Disorder Services
Sutter-Yuba Behavioral Health

Commenter #4 (submitted 01-23-20)
Brenda del Castillo
Director of Contracts and Compliance
Clare Matrix

Commenter #5 (submitted 01-28-20)
Joan Bates
Department of Veteran Affairs
VA Long Beach Healthcare System

Commenter #6 (submitted 02-10-20)
Brion Phipps, LCSW, Quality Assurance Specialist Supervisor
Alameda County Behavioral Health Care Services
Quality Assurance

Section 10000(a)(2)

Comment #5L

(2) Buprenorphine. “Buprenorphine” means a semisynthetic narcotic analgesic that is derived from thebaine and is administered in the form of its hydrochloride $C_{29}H_{41}NO_4 \cdot HCl$ ~~intravenously or intramuscularly~~ to ~~treat~~ control moderate to severe pain and ~~sublingually to~~ treat opioid dependence. AGREE

Response #5L

This comment was considered, however, the regulations were not amended. The commenter stated their agreement with the proposed changes. The Department appreciates your comment of support.

Section 10000(a)(2)

Comment #5B

2. Division 4, Title 9, California Code of Regulations.

(1) Amendment. “Amendment” means written changes in the protocol.

(2) Buprenorphine. “Buprenorphine” means a semisynthetic narcotic analgesic that is derived from thebaine and is administered in the form of its hydrochloride C29H41NO4·HCl transdermal to treat control moderate to severe pain and sublingual tablets and films as well subcutaneous injection to treat opioid use disorder ~~dependence~~.

Response #5B

This comment was considered, however, the regulations were not amended. The commenter proposed to add the methods of administering buprenorphine and change “dependence” to “use disorder.” This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #2A from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10000(a)(3)

Comment #5C

(3) Buprenorphine Products. “Buprenorphine products” means buprenorphine combination products approved by the United States Food and Drug Administration (FDA) for maintenance treatment or detoxification of opioid use disorder ~~dependence~~.

Response #5C

This comment was considered, however, the regulations were not amended. The commenter proposed to change “dependence” to “use disorder.” This comment was outside the scope of this 15-day public comment period, which was limited to proposed

amendments to Sections 10056 and 10056.5. Please refer to the discussion of Section 10000, Subsection (a)(3) from the Initial Statement of Reasons for additional information.

Section 10000(a)(5)

Comment #5D
(4) Department. “Department” means the Department of Health Care Services.

(25) Detoxification Treatment. “Detoxification treatment” means the treatment modality, whereby replacement narcotic therapy is used in decreasing, medically determined dosage levels for a period not more than 21 days, to treat physical dependence reduce or eliminate ~~opiate~~ opioid addiction, while the patient is provided a comprehensive range of treatment services.

Response #5D
This comment was considered, however, the regulations were not amended. The commenter proposed keeping the phrase “reduce or eliminate opioid addiction.” This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #1A from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10000(a)(10)

Comment #5E
3. NOTE: Levoalphacetylmethadol (LAAM) was discontinued for being used in USA due to QTC prolongation years ago.

(610) Levoalphacetylmethadol (LAAM). “Levoalphacetylmethadol (LAAM)” also known as Levo-Alpha-Acetyl-Methadol or levomethadyl acetate hydrochloride, means the substance that can be described chemically as levo-alpha-6-dimethylamino-4, 4-diphenyl-3-heptyl acetate hydrochloride.

Response #5E
This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #4AK and Response #6AW from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10000(a)(13)

Comment #5F
4. Maintenance Treatment. “Maintenance treatment” means the treatment modality whereby replacement narcotic therapy is used in sustained, stable, medically determined dosage levels for a period in excess of 21 days, to reduce or eliminate chronic **opiate use disorder**, while the patient is provided a comprehensive range of treatment services.

Response #5F
This comment was considered, however, the regulations were not amended. The commenter proposed the phrase “to reduce or eliminate chronic opiate use disorder…” This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #2D from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10000(a)(15)(B)

Comment #5G
915) Medication. “Medication” means any opioid agonist medications that have been approved for use in replacement narcotic therapy, including:

(A) Methadone;, and

(B) Levoalphacetylmethadol (LAAM) as mentioned previously, this medication is no longer available for Clinical Use in USA.

Response #5G
This comment was considered, however, the regulations were not mended. The comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #4AK and Response #6AW from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10000(a)(15)(C)

Comment #5H
(C) Buprenorphine and buprenorphine products. approved by the federal Food and Drug Administration for maintenance treatment or detoxification treatment of opioid **use disorder**

Response #5H
This comment was considered, however, the regulations were not amended. The commenter proposed to replace “addiction” with “use disorder.” This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #2D from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10000(a)(20)

Comment #5M

(20) Office-Based Narcotic Treatment Network (OBNTN). :Office-Based Narcotic Treatment Network (OBNTN). "Office-Based Narcotic Treatment Network (OBNTN)" means a network of providers, that are affiliated and associated with a primary narcotic treatment program, 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 ~~opioid abusing~~ substance use disorder population; counseling by addiction counselors that are evaluated through ongoing supervision; and professional medical, social work, and mental health services, on-site or by referral. *SUBSTANCE USE*

Response #5M

This comment was considered, however, the regulations were not amended. The commenter's request was unclear. The scope of this 15-day public comment period was limited to proposed amendments to Sections 10056 and 10056.5.

Section 10000(a)(21)

Comment #5I

Note: I recommend to use the word Opioid instead of opiate.

1. While subtle, the distinction between opioids and opiates is significant. An opiate is a drug naturally derived from the flowering opium poppy plant. Examples of opiates include heroin, morphine and codeine.

On the other hand, the term opioid is a broader term that includes opiates and refers to any substance, natural or synthetic, that binds the brain's opioid receptors.

Response #5I

This comment was considered, however, the regulations were not amended. The scope of this 15-day public comment period was limited to proposed amendments to Sections 10056 and 10056.5. Further, the requested change was already incorporated as part of the Department's original proposal. Please refer to the discussion of Section 10000, Subsection (a)(21) from the Initial Statement of Reasons for additional information.

Section 10000(a)(22)

Comment #5N

(22) Opioid. “Opioid” means any psychoactive chemical that resembles morphine in pharmacological effects, including opiates and synthetic/semisynthetic agents that exert their effects by binding to highly selective receptors in the brain where morphine and endogenous opioids affect their actions. *good*

Response #5N

This comment was considered, however, the regulations were not amended. The commenter stated their agreement with the proposed changes. The Department appreciates your comment of support.

Section 10000(a)(23)

Comment #5O

(~~15~~23) ~~Opiate~~Opioid Addiction. “~~Opiate~~Opioid Addiction,” and the related term “addiction to ~~opiates~~opioids,” means a condition characterized by compulsion and lack of control that lead to illicit or inappropriate ~~opiate~~opioid-seeking behavior, including an ~~opiate~~ opioid addiction that was acquired or supported by the misuse of a physician’s legally prescribed narcotic medication. *Simpler Word*

Response #5O

This comment was considered, however, the regulations were not amended. The commenter’s request was unclear. The scope of this 15-day public comment period was limited to proposed amendments to Sections 10056 and 10056.5.

Comment #5J

2. I recommend to use the phrase opioid use disorder instead of opiate addiction.

Response #5J

This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #2D from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10000(a)(32)

Comment #5K

3. I recommend to use the term Medication Assisted Treatment (MAT) instead of Replacement Narcotic Therapy. MAT is a combination of Pharmacological treatment plus psychosocial/psychotherapy services.

Response #5K
This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #5D from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information

Section 10010

Comment #5P
10010. License Requirement.
All narcotic treatment programs operating in ~~the State of~~ California shall be licensed by the Department of ~~Alcohol and Drug Programs~~ in accordance with the provisions of this article.

Response #5P
This comment was considered, however, the regulations were not amended. The commenter proposed to delete the phrase “the State of”. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5.

Section 10015

Comment #5Q
10015. Licensure of Separate Facilities. ~~If there is to be a centralized organizational structure, consisting of a primary program facility and other program facilities, whether inpatient or outpatient, all of which provide treatment services which exceed the administering or dispensing of medications and the collection of patient body specimens for testing or analysis of samples for illicit drug use, both the primary program and each other program facility must be licensed as separate programs, even though some services may be shared, such as the same hospital or treatment referral services.~~ *good*

Response #5Q
This comment was considered, however, the regulations were not amended. The commenter stated their agreement with the proposed changes. The Department appreciates your comment of support.

Section 10045(d)

Comment #5R
~~(d) The Department shall process applications in a timely manner, consistent with the Department’s responsibility to protect the health and safety of the patients and the public. As of April 1, 1983, the Department’s experience in processing an application from initial submission of the application to the final determination is as follows:~~
~~(1) median time is 96 days.~~
~~(2) minimum time is 27 days.~~

~~(3) maximum time is 388 days.~~
okay

Response #5R
This comment was considered, however, the regulations were not amended. The commenter stated their agreement with the proposed changes. The Department appreciates your comment of support.

Section 10240

Comment #3A
In the proposed regulation under Patient Identification: I would suggest that under Patient Identification and/or other location(s) in the proposed regulation that the patient be required to provide the NTP Provider "Proof of Residency". Proof of County Residency would be verified by a utility bill, lease or bed or homeless shelter agreement. Verifying residency by Medi-Cal and/or a Driver's License and/or Identification Card is insufficient since persons are often not required to update these items when re-locating. This often leads to Counties being responsible for NTP costs they would not be responsible for under the County of Residency system. Requiring "Proof of Residency" , in the above outlined manner, will especially protect small counties from excessive NTP expenditures which in turn negatively impacts the ability to provide Outpatient Drug Free (ODF) services.

Response #3A
This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5.

Section 10270(a)(2)

Comment #1A
Section 10270

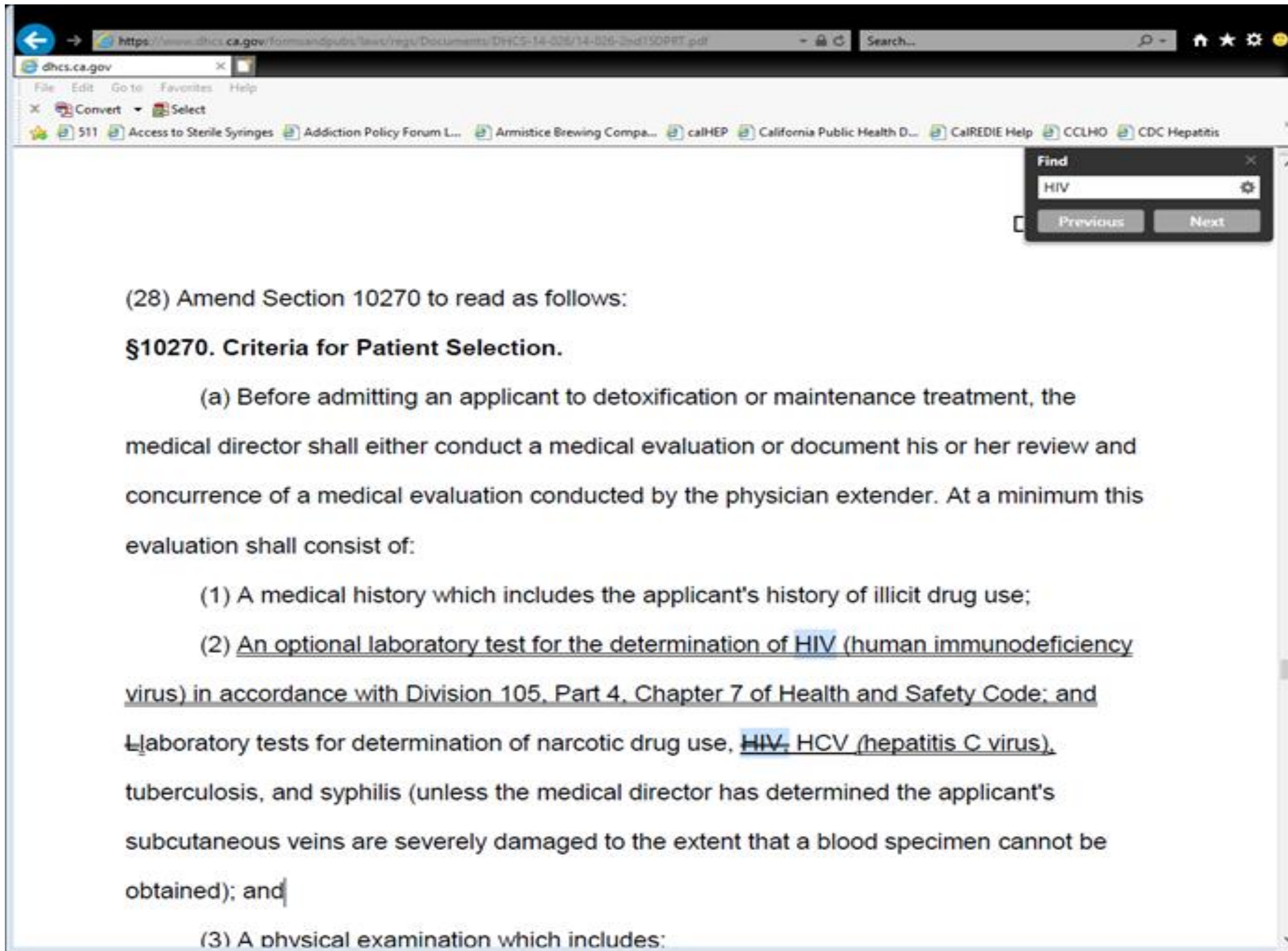
(a) (2) I appreciate that DHCS wants to make sure that patients are tested (and hopefully treated) for HIV and HCV. At our clinic, we have an opt-out approach to testing. That said, mandatory HIV testing is a terrible choice clinically and is not legal in this setting. See H&S Code Section 120990 requiring that a patient be advised that he or she has the right to decline the HIV test. The issue here is that all patients should be offered HIV and HCV testing routinely and barriers to testing (cost) should be eliminated, but HIV testing cannot legally be mandated at intake. HCV testing has a different legal status, but should also be voluntary. There are patients who are not emotionally prepared to test on the day of intake and not prepared to get the results in the early induction period. It might be helpful to include the following 4 points as guidance on HIV testing (adapted here from CDPH, Office of AIDS 2009 publication on California HIV/AIDS Laws:

> "In General California law has eliminated the requirement for separate, written consent for HIV testing. H&S Code Section 120990 requires a medical care provider, prior to ordering an HIV test, to:
> • Inform the patient that an HIV test is planned;

• Provide information about the HIV test;
• Inform the patient that there are numerous treatment options available for a patient who tests positive for HIV and that a person who tests negative for HIV should continue to be routinely tested;
• **Advise the patient that he or she has the right to decline the HIV test**; and if the patient declines the HIV test, document that fact in the patient's medical file" [emphasis is mine]

Response #1A
This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #1H and Response #4W from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Comment #2A
Section 10270(a)(2)
Rachel McLean pointed out some changes in the Narcotic Treatment Program regs related to HIV (see below).
I'm confused as to why HIV testing would be optional but HCV, TB, and syphilis would be routine.
Also I'm not sure if the intent is that the person has the option to receive an HIV test or the medical director has the option to offer an HIV test?



(28) Amend Section 10270 to read as follows:

§10270. Criteria for Patient Selection.

(a) Before admitting an applicant to detoxification or maintenance treatment, the medical director shall either conduct a medical evaluation or document his or her review and concurrence of a medical evaluation conducted by the physician extender. At a minimum this evaluation shall consist of:

(1) A medical history which includes the applicant's history of illicit drug use;

(2) An optional laboratory test for the determination of HIV (human immunodeficiency virus) in accordance with Division 105, Part 4, Chapter 7 of Health and Safety Code; and ~~L~~laboratory tests for determination of narcotic drug use, ~~HIV,~~ HCV (hepatitis C virus), tuberculosis, and syphilis (unless the medical director has determined the applicant's subcutaneous veins are severely damaged to the extent that a blood specimen cannot be obtained); and

(3) A physical examination which includes:

Response #2A

This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #1H and Response #4W from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10270(a)(3)(C)

Comment #1B

(a) (3) (C) The inclusion of a mandatory breast exam is both clinically unwarranted and potentially harmful, particularly given the high rates of sexual abuse and exploitation experienced by women seeking treatment. There is no medical reason for a breast exam in this setting and the requirement needs to be eliminated. There is also no reason for a thyroid exam, and I would recommend eliminating this as well.

Response #1B

This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #4Y from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10315(a) and (b)

Comment #1C

Section 10315

(a) (6) (b) In patients taking buprenorphine, samples should not be routinely analyzed for methadone metabolite (EDDP). Generally certified labs will offer a separate panel for buprenorphine maintained patients. With that panel, methadone will be analyzed and reported as a drug of abuse rather than an expected result. There is no purpose for having an EDDP result in that panel.

Response #1C

This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #4AF from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10355(d)(3)

Comment #1D

Section 10355(d)(3) Remove the need for justification for dosages above 100mg for methadone.

Response #1D

This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #4AI from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10360(a)(1-2)

Comment #1E

(a) (1-2) Some patients will not or cannot engage in prenatal care. The forced choice here for OTP physicians to either accept medical responsibility for prenatal care (which many Medical Directors are not qualified to do based on their training and available clinic resources and materials) or verify that they are under the care of another physician is problematic. Should I discharge the patient from treatment if I can't do either of these things? I would hope that is not what DHCS would want. Also the language in (2) should be expanded to include NPs, PAs and CNMs as acceptable prenatal care providers at any rate.

Response #1E

This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #6AP and #4AJ from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Section 10380(b)

Comment #5S

~~(3) The~~a *A* medical director or program physician has included the patient within a list of all patients that, in his or her clinical judgment, have been determined currently not responsible in handling narcotic medications, based on consideration of the criteria specified in Section 10370(a). This list shall be maintained with the daily reconciliation dispensing record for the holiday or Sunday closure.

Response #5S

This comment was considered, however, the regulations were not amended. The commenter proposed to capitalize the word "a" prior to the phrase "medical director or program physician…" This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5.

ADDITIONAL COMMENTS

Comment #5A

Be aware that certain terminology use in this document is not anymore in use. Opioid Treatment Program (OTP) certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and registered with the Drug Enforcement Administration (DEA) as an Narcotic Treatment Program (NTP), (hereinafter OTP) is the term that it is use today.
In our facility (LBVA), we do not have an OTP program. We do not dispense methadone. What we have is an Office Based Buprenorphine Treatment for Opioids Use disorder.

Response #5A
This comment was considered, however, the regulations were not amended. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5. Please refer to Response #1B from the FSOR Addendum I – Responses to 45-Day Public Comments for additional information.

Comment #4A
Can someone please help assist me on how I can get our OTP Program listed on this site?

Response #4A
This comment was considered, however, the regulations were not amended. The commenter was inquiring how to get their OTP Program included on a list of providers enrolled in Medicare. This comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5.

LATE COMMENT

Comment #6A
I know the public comment period has passed, however I noticed a potential inconsistency in the proposed 14-026 rule making, particularly around short and long-term detoxification services for OTPs. From what I can tell, since ADP 01-21, OTP detoxification services were expanded to include 21 and 180 detoxification services. And on the DHCS OTP/NTP FAQ page under *Phases of a Narcotic Replacement Therapy* there is a clear reference to both short and long-term detoxification services. This was an expansion of 9 CCR, Ch. 4 which previously only specified 21 day detox and ongoing maintenance treatment services. The 14-026 proposed regulations do not incorporate the 21/180 detox services as indicated by ADP 01-21.

Response #6A
This comment was considered, however, the regulations were not amended. The comment was submitted after the close of the 15-day public comment period. Furthermore, the comment was outside the scope of this 15-day public comment period, which was limited to proposed amendments to Sections 10056 and 10056.5.