

DEPARTMENT OF ALCOHOL AND DRUG PROGRAMS

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**ADP BULLETIN**

Title	Issue Date:	Issue No.
Narcotic Treatment Programs: Step Level Take-Home Supply, Physician Exception To Take-Homes, and Electronic Submission for Program Physician Request For a Temporary Exception to Title 9, California Code of Regulations, Division 4, Chapter 4	June 6, 2012	12 - 10
	Expiration	
	Date: N/A	
Deputy Director Approval	Function:	Supersedes Bulletin/ADP
<i>MILLICENT GOMES</i> <i>Acting Deputy Director</i> <i>Licensing and Certification Division</i>	<input type="checkbox"/> Information Management <input type="checkbox"/> Quality Assurance <input checked="" type="checkbox"/> Service Delivery <input type="checkbox"/> Fiscal <input type="checkbox"/> Administration <input type="checkbox"/>	Letter No. 02-5 00-33 Section B 98-33

PURPOSE

The purpose of this bulletin is to notify all Narcotic Treatment Programs (NTP) of a change in the Department of Alcohol and Drug Programs' (ADP) policy for the following:

1. Exception to the number of take-homes for patient step levels, Title 9, California Code of Regulations (CCR), Chapter 4, Section (§)10375(a)(1-6).
2. Elimination of the physicians' authority to grant exceptions for take-home medication for patients with medical or exceptional circumstances making daily attendance a hardship, Title 9, CCR, Chapter 4, §10385(a)(1,2).
3. Elimination of the ADP 8045 – Physician Request for a Temporary Exception to Regulations. ADP will use the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment's (CSAT) electronic Exception Request and Record of Justification SMA 168 form (Exhibit 1) via the SAMHSA/CSAT Opioid Treatment Program Extranet.

DISCUSSION

Pursuant to California Health and Safety Code (H&S), §11839(a)(7) the director may grant exceptions to the regulations adopted under this chapter if he or she determines that this action would improve treatment services or achieve greater protection to the health and safety of patients, the local community, or the general public. No exception may be granted if it is contrary to, or less stringent than, the federal laws and regulations which govern narcotic treatment programs. The identified exceptions or changes are effective the date of this bulletin.

1. The following take-home medication step levels identify the maximum number of take-homes that will be allowed by this exception to Title 9, CCR, §10375(a)(1-6)(Exhibit 2):
 - Step I Level –Admission a single take home if determined responsible for State approved Holidays §10380.
 - Step II Level –After 90 days of continuous maintenance treatment, the medical director or program physician may grant the patient not more than a two-day take-home supply of medication. The patient shall attend the program at least five times a week for observed ingestion. *Plus one (1) if State holiday.
 - Step III Level –After 180 days of continuous maintenance treatment, the medical director or program physician may grant the patient not more than a three-day take-home supply of medication. The patient shall attend the program at least four times a week for observed ingestion. *Plus one (1) if State holiday.
 - Step IV Level –After 270 days of continuous treatment, the medical director or program physician may grant the patient not more than a six-day take-home supply of medication. The patient shall attend the program at least one (1) time a week for observed ingestion. *Plus one (1) if State holiday.
 - Step V Level –After one year of continuous treatment, the medical director or program physician may grant the patient not more than a two-week supply of medication. The patient shall attend the program at least two times a month for observed ingestion. *Plus one (1) if State holiday.
 - Step VI Level –After two years of continuous treatment, the medical director or program physician may grant the patient not more than a one month take-home supply of medication. The patient shall attend the program at least one time a month for observed ingestion per CCR Title 9§10380(b)(1).

2. Title 9, CCR, §10385(a)(1-2) gives physicians the authority to make exceptions to take-homes for patients with medical or exceptional circumstance which make daily attendance a hardship is **eliminated**. This section does not comply with H&S §11839(a) (7). No exception may be granted if it is contrary to, or less stringent than, the federal laws and regulations which govern narcotic treatment programs. May 18, 2001, 42 Code of Federal Regulations (CFR) Part 8 replaced 21 CFR Part 291 §291.505; 42 CFR Part 8 does not allow the medical director or program physician to make this exception and requires submission of the SMA 168 form.

3. The Physician Request for a Temporary Exception to Regulations (ADP 8045 form) has been **discontinued**. Effective the date of this bulletin all providers shall submit requests electronically for exceptions to Title 9, CCR utilizing the SAMHSA, Exception Request and Record of Justification (SMA 168 form), <http://otp-extranet.samhsa.gov/REQUEST>.

The NTP fax number (916) 323-5086 may be used during an emergency when electronic submission is not available; however, programs will still use the SMA 168 form for the submission of the exception to regulations request.

REFERENCES

Health and Safety Code 11839
Title 9, CCR, 10000 – 10425
21, CFR, Section 291.505
42, CFR, Part 8

BACKGROUND

Title 9, CCR, take-home medication regulations have limited the ability of the medical director or program physician(s) to determine the appropriate number of take homes without submitting exceptions to the State. This bulletin allows the medical director or program physician(s) additional take-home medication options for patients.

Title 9, CCR, Section 10385(a)(1,2), when written, was based on Title 21, CFR, Section 291.505 which was rescinded when SAMHSA became the federal governing body over Opioid Treatment Programs. SAMHSA's regulations do not allow physicians to make exceptions to take-homes without approval from SAMHSA; therefore, the State can not allow physicians to make exceptions to take-homes that are less stringent than SAMHSA's regulations.

The ADP 8045 form, Physician Request for a Temporary Exception to Regulations, has been used for regulation exceptions which frequently are simultaneously sent to SAMHSA via electronic submission on the SMA 168 form. By utilizing the SAMHSA, SMA 168 form, we are eliminating duplication of effort for providers and ADP. ADP will use the SAMHSA/CSAT Opioid Treatment Program Extranet for data collection.

QUESTIONS

Attached is a set of frequently asked questions (Exhibit 3). If you need additional information please contact Reneeka Williams, Licensing Analyst, Licensing and Certification Division, (916) 445-5529 or Reneeka.Williams@adp.ca.gov. This bulletin is available on the ADP web page at www.adp.ca.gov/ADPLTRS/bulletin_letter.shtml.

EXHIBITS

Exhibit 1 – [Exception Request and Record of Justification Under Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Form SMA 168](#)

Exhibit 2 – [Take-Home Medication Criteria and Quick-Glance Sheet](#)

Exhibit 3 – [Frequently Asked Questions: Step Level Take-Home Supply; Physician Exception To Take-Homes; and, Electronic Submission for Program Physician Request For A Temporary Exception to Title 9, California Code of Regulations, Division 4, Chapter 4](#)

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