

DEPARTMENT OF ALCOHOL AND DRUG PROGRAMS

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**ADP BULLETIN**

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| Title: PROGRAM PHYSICIAN REQUEST FOR A TEMPORARY EXCEPTION TO TITLE 9 REGULATIONS | | Issue Date:10-20-00 Expiration Date: Until Notified | Issue No. 00-33 |
| Acting Deputy Director Approval: (signed by) Joy A. Jarfors Quality Assurance Division | <input type="checkbox"/> Function: <input type="checkbox"/> Information Management <input checked="" type="checkbox"/> Quality Assurance <input type="checkbox"/> Service Delivery <input type="checkbox"/> Fiscal <input type="checkbox"/> Administration | Supersedes Letter to Narcotic Treatment Program Directors, Executive Directors, and County Alcohol & Drug Program Administrators, dated July 3, 1998 | |

PURPOSE

The purpose of this bulletin is to notify all narcotic treatment programs (NTPs) of major revisions to procedures related to Form ADP 8045 - *Physician Request for a Temporary Exception to Regulations*. Changes include the following:

- a. Waiver of Federal and State approvals for over 100 milligram take-homes.
- b. Clarification of approvals for over seven- and over fourteen-day take-home supplies.
- c. Differences between Federal and State urinalysis exception requests.
- d. Documentation of NTP's attempt to arrange for courtesy dosing.
- e. Clarification regarding conditions of State approvals.

DISCUSSION

Pursuant to California Health and Safety Code (HSC) Section 11876(a)(7), the Director of ADP may grant an exception to the State's Title 9 regulations governing narcotic treatment when it is determined that the 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, applicable federal laws and regulations.

The Narcotic Treatment Program Licensing Branch has amended the enclosed Form ADP 8045 (rev 09/2000). Following is an explanation of each change:

- a. **Waiver of Federal and State approvals for over 100 Milligram Take-homes:** In response to an ADP request, the U.S. Food and Drug Administration (FDA) has granted a statewide waiver to Title 21 of the Code of Federal Regulations (CFR), Section 91.505(d)(6)(v)(D), for all narcotic treatment programs licensed by the State of California. This specific rule requires

that an NTP receive prior approval from FDA, with concurrence by ADP, before a program physician grants more than one take-home per week to a maintenance treatment patient whose daily medication dosage level exceeds 100 milligrams. FDA granted this waiver in accordance with 21 CFR 291.505(d)(11)(i). In turn, ADP has granted a statewide waiver to the corresponding California Code of Regulations (CCR) 10370(c), effective the date of this bulletin. Therefore, an NTP no longer needs to submit Form ADP 8045 prior to dispensing take-homes at a dosage level over 100 milligrams.

- b. Clarification of Approvals for Over Seven- & Over Fourteen-Day Take-home Supplies:** Federal regulation 21 CFR 291.505(d)(6)(vi)(A) already allows a program physician to order a take-home medication schedule for those patients with a chronic medical condition or physical disability, and State regulation CCR 10385(a)(1) limits this schedule to not more than a two-week supply of take-home medication at one time. Therefore, this option has been eliminated from the form. The over seven- and over fourteen-day waiver requests on this form should be for exceptional circumstances requiring a one-time take-home supply.
- c. Differences Between Federal and State Urinalysis Exception Requests:** There are differences between the Federal and State requirements for frequency of urinalyses. As a result, programs are not always sure when a Federal exception of regulations should be obtained before seeking State approval. A State exception to urinalysis regulations will always be needed since CCR 10310(e) requires monthly testing (or testing once each calendar week in accordance with CCR 10360(c)(2) during a pregnancy).
- d. Documentation of NTP's Attempt to Arrange for Courtesy Dosing:** CCR 10385(a)(2) states that "when the patient must travel out of the program area, the program shall attempt to arrange for the patient to receive his or her medication at a program in the patient's travel area." Therefore, Form ADP 8045 has been revised so that the program may clearly document why its attempt to arrange for courtesy dosing was not successful. ADP will use this information, along with the program physician's rationale of why it would be a hardship to the patient if he or she were not allowed to travel out of the program area, as the basis for approving the program physician's request for a temporary exception to the regulations.
- e. Clarification Regarding Conditions of State Approvals:** The Department has placed additional conditions on certain requests for temporary waivers to regulations. By signing ADP Form 8045, the program physician acknowledges and accepts these conditions when submitting the request. Following is an explanation of these conditions:
 - 1. *Approval does not exempt the program from complying with all other applicable state, federal, and foreign country laws and regulations.*

The Department can only grant temporary exceptions to those regulations under its jurisdiction, and does not have the means to determine with certainty how other laws may apply.

2. Prior to granting take home exceptions, patients are to be informed that use and possession of methadone may violate other laws (e.g., commercial motor vehicle and opiate importation restrictions).

The Department cautions that its approval of take-home narcotic medication supplies does not exempt either the program physician or the patient from the drug possession laws of any destination or the qualifications for operating vehicles. Therefore, the program has the responsibility to counsel the patient that possession of the take-homes may conflict with other legal provisions. For example,

- a. In the Federal Highway Administration's Regulatory Guidance for Physical Qualifications for Drivers (Section 391.41), published in the *Federal Register* on April 4, 1997, it states that methadone "is not an allowable drug for operators of CMVs" (commercial motor vehicles).

- b. Laws regarding importation of methadone vary widely from country to country. For more information regarding travel restrictions, refer to the web-site <http://home/muenster.net/~indro/travel.htm>.

3. *A urinalysis exception is only valid as long as the patient's condition that makes the exception necessary continues to exist.*

The Department has seen an increase in requests for urinalysis waivers tied to chronic or end-stage medical conditions. These same conditions also interfere with a patient's ability to attend the clinic. The reduced clinic attendance and elimination of drug-screens impacts a program's ongoing task to insure that a patient continues to be responsible in handling narcotic drugs. Therefore, the Department requests that the program physician review these exceptions on an annual basis and re-submit those that continue to be required.

4. *All documentation concerning this exception will be filed in the patient's record.*

As previously required by the Department, the program shall file in the patient's record the approved exception and all related documentation; including evidence of prior treatment failures, travel tickets, or primary care medical diagnoses.

Once the exception request form is completed by the program and sent by facsimile (FAX) to the Branch at (916) 323-5086, the exception request will be reviewed. The program may be contacted for additional information in order to continue processing the exception request. Upon determination that the exception can be approved, the exception form will be signed and returned to the program via FAX. The Department will retain the signed hard copy.

REFERENCES

California Health and Safety Code, Sections 11875 to 11896
California Code of Regulations, Sections 10000 to 10425
Code of Federal Regulations, Title 21, Section 291.505

HISTORY

This new form replaces and supersedes Form ADP 8045 (rev. 5/98) that was mailed to the field on July 3, 1998.

QUESTIONS/MAINTENANCE

If you have any questions or require additional information, please call the Narcotic Treatment Program Licensing Branch at (916) 322-6682.

EXHIBITS

1. Physician Request for a Temporary Exception to Regulations
Form ADP 8045 (rev. 09/00)

DISTRIBUTION

Narcotic Treatment Program Executive Directors
Narcotic Treatment Program Directors and Medical Directors
County Alcohol and Drug Program Administrators
Director's Advisory Council
Wagerman Associates, Inc.