



LICENSING ALERT

Anna Marie Sossong
Deputy Secretary for Quality Assurance

A handwritten signature in black ink, appearing to read "Anna Marie Sossong", written over the printed name.

May 2012

Division of Drug and Alcohol Program Licensure
Licensing Alert 04-12

USE OF BUPRENORPHINE RESIDENTIAL FACILITIES Requests for Exceptions to Regulations 28 Pa. Code Part V, Chapter 715

In May 2011, a workgroup assembled by the Pennsylvania Department of Health, which included representatives from the Departments of Health and Public Welfare, trade associations, and drug and alcohol providers, met to discuss 28 Pa. Code Chapter 715, Standards for Approval of Narcotic Treatment Programs regulations as it relates to buprenorphine. The intent of the Workgroup was to identify regulations for residential facilities that might be applicable for the exception process, and regulations for outpatient (nonresidential) facilities that should be removed from waiver eligibility. It was noted that the initial outpatient exception process (see Licensing Alert 01-08) was implemented to improve access to treatment. The initial exception request process did not apply to residential facilities.

As a result of this discussion, it was determined that relief from some of the existing regulations would improve retention of patients during their stay in treatment.

The Workgroup's recommendations were forwarded to the Secretary of Health for approval. The Secretary has determined pursuant to 28 Pa. Code § 701.11, that granting an exception to some of the requirements of 28 Pa. Code Chapter 715 to those residential and nonresidential facilities that desire to use buprenorphine will be in furtherance of sound program implementation and is consistent with the policy objectives of this part. (28 Pa. Code § 701.11(b)).

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This Alert addresses the use of buprenorphine by exception in a **residential** facility.

A licensed facility that desires to commence using buprenorphine in a residential setting may submit a request, along with documentation of governing body approval, for an exception from the requirements of Chapter 715 identified below. Acceptable documentation includes approved minutes of a Board of Directors meeting, a corporate resolution, a letter from the Board President or some other official document identifying approval by the governing body. Upon submission of the following information and following approval from the Department, the facility may commence with the use of buprenorphine.

As part of the exception process, the following information must be submitted, including the attached exception request form:

- a. The name of each physician.
- b. A copy of each physician's DEA card or letter from the Center for Substance Abuse Treatment (CSAT) indicating authorization to prescribe buprenorphine.
- c. Intent to provide maintenance (identified as other chemotherapy) and/or detoxification services and the maximum number of persons to be treated at any given time.
- d. Recommended length of stay for the activity or activities offered by the facility.

In addition, a facility that is granted an exception to use buprenorphine, to the extent necessary and applicable, must modify or develop policies and procedures found in Chapter 715 and policies and procedures regarding medication control. (See 28 Pa. Code §§ 709.32, 711.58, and 711.66). These policies and procedures do not need to be submitted to the Department at the time the request for exception is submitted. These policies and procedures will be reviewed by the Division of Drug and Alcohol Program Licensure at the facility's next scheduled annual licensure renewal inspection.

Facilities may seek exceptions to the following Chapter 715 regulations:

Residential Facilities

715.14(a) and (b) Urine testing. Current regulations require that urinalysis testing be conducted by an offsite federal and state approved laboratory. Due to the time needed for the return of the initial urinalysis results from the offsite laboratory, facilities have requested permission to utilize an onsite FDA approved urinalysis kit for the initial urine screen.

715.16(a)-(f) Take-home privileges. This section is not applicable since patients receive their care in an inpatient setting and do not leave the premises.

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715.20(4) Patient transfers. For buprenorphine patients who are transferred to other facilities, it is unnecessary for the transferring program to receive notification of the admission and date of the initial dose given the patient from the receiving program. It places an additional burden on facilities to monitor for receipt of information which does not affect the patient's plan and intended outcome of treatment with buprenorphine.

715.24(5)(v) Narcotic detoxification. No narcotic treatment program may provide long-term narcotic detoxification treatment to an individual until at least seven days after the conclusion of any previous detoxification treatment. Although the intent of this regulation is to discourage a continuous cycle of detoxification followed by maintenance, there is no clear purpose in withholding treatment until the seventh day after the previous narcotic detoxification treatment.

Guidelines for verbal orders for short term use of buprenorphine in a detoxification program during urgent situations

A primary goal of all detoxification programs is to provide safe medical treatment to adequately control withdrawal symptoms, minimize patients leaving against medical advice (AMA), and engage patients in a longer term process of recovery. Ideally all patients in a detoxification program should see a physician for a face-to-face evaluation before any medication, including buprenorphine, is given. Unfortunately, many detoxification programs do not have a physician on site 24 hours a day, but patients in a detoxification program may experience significant withdrawal symptoms during times when a physician is not present. If withdrawal symptoms are not adequately treated, this may result in the patient experiencing adverse medical symptoms and/or leaving AMA. Negative outcomes resulting from inadequately controlled withdrawal symptoms can be minimized if the patient receives psychological support from program staff. If psychological support is not enough, the patient will need to be evaluated by properly training nursing staff who can then report, by phone, to a physician who can provide necessary verbal orders to begin medication for the patient.

The following are guidelines that would allow the residential program to receive verbal orders for buprenorphine for detoxification from a buprenorphine physician during urgent situations in which delays in providing the treatment would put the patient at risk for a negative outcome.

1. Document psychological support given to patient.
2. Document effect of non-opioid medication, such as clonidine, on patient's condition.
3. Evaluate for need for opioid medication.
4. An assessment tool, completed by at minimum a registered nurse, should include documentation of past and current drug dependency and treatment, drug use status and history, including any prescription medications, licit or illicit, that may be contraindicated for buprenorphine, completion of a withdrawal scale such as the Clinical Opioid Withdrawal Scale, urine toxicology results, biographical data, and health and illness

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- patterns. The nurse, after reviewing the initial assessment, calls the physician and reviews the assessment findings with the physician.
5. A verbal order for buprenorphine should not be given unless the following three criteria are met:
 - a. The patient must be physiologically dependent on opioids and experiencing significant withdrawal symptoms that potentially put the patient at risk for a negative outcome;
 - b. The facility staff concludes that there is no appropriate alternative treatment other than buprenorphine available to adequately stabilize the patient; and,
 - c. There is no significant sedative-hypnotic physical dependence present. If the patient is dependent on alcohol or other sedative-hypnotics, such as benzodiazepines, the patient must be assessed personally by the physician.
 6. The physician approves or disapproves administration of buprenorphine. If a verbal order is given, the **physician** determines the initial dose. Only a single dose, or a dose divided in two, may be ordered verbally, and the verbal dose may not exceed 8 mg.
 7. The facility physician **must** see the patient within 24 hours and sign off on the verbal medication order.

The facility needs a written protocol to detail who (e.g., minimum of a registered nurse) can complete the assessment. Also within the protocol, the program should state which instruments will be used for the various parts of the evaluation and what scores on the various instruments would make a patient eligible or ineligible for an immediate buprenorphine order. The physician must co-sign the various assessments when he signs the verbal order.

A form request for exception to 28 Pa. Code Chapter 715 is attached to this Licensing Alert. Requests for the exception to 28 Pa. Code Chapter 715 referred to herein, along with the required documentation and governing body approval must be forwarded to the following address:

Pennsylvania Department of Health
Bureau of Community Program Licensure and Certification
Division of Drug and Alcohol Program Licensure
132 Kline Plaza, Suite A
Harrisburg, PA 17104

Questions regarding this Licensing Alert may be directed to the Division of Drug and Alcohol Program Licensure at 717-783-8675.

Attachment

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**PENNSYLVANIA DEPARTMENT OF HEALTH
BUREAU OF COMMUNITY PROGRAM LICENSURE AND
CERTIFICATION
DIVISION OF DRUG AND ALCOHOL PROGRAM LICENSURE
Exception Request (28 Pa. Code Chapter 715)/Buprenorphine**

Name of Facility (Facility): _____

Facility Address: _____

Facility Mailing Address (if different): _____

Facility Number : _____

Facility Director: _____

Pursuant to the Department of Health, Bureau of Community Program Licensure and Certification, Division of Drug and Alcohol Program Licensure Licensing Alert No. 04-12, issued May 2012, and 28 Pa. Code §§ 701.11, 709.4 and 711.4 (as applicable), the above facility requests an exception to the requirements of 28 Pa. Code Chapter 715, for purposes of using buprenorphine in the detoxification and/or maintenance treatment of persons with opioid dependency for the following activities:

ACTIVITY	LENGTH OF TREATMENT	MAXIMUM CAPACITY
Residential Detoxification		
Residential Maintenance		

The physicians listed below are employed and/or contracted with the facility to provide buprenorphine detoxification and/or maintenance treatment. A copy of the current DEA Registration or CSAT approval of physician for prescribing and administering buprenorphine must be included for each physician named below:

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The Facility understands that the Department will review the Facility's policies and procedures during the next and future annual licensure surveys to determine compliance with applicable regulations including those that relate to medication control in 28 Pa. Code §§ 709.32, 711.58, 711.66 (as applicable) and Chapter 715, and that the Facility's current policies and procedures may require revision based on the granting of this exception.

Signed: _____
(Facility Director)

Print Facility Director Name: _____

Date: _____

Please submit request for exception to:

**Pennsylvania Department of Health
Bureau of Community Program Licensure and Certification
Division of Drug and Alcohol Program Licensure
132 Kline Plaza, Suite A
Harrisburg, PA 17104**

Questions regarding this request for exception may be directed to the Division of Drug and Alcohol Program Licensure at the above address or at (717) 783-8675.

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