



## LICENSING ALERT

Anna Marie Sossong  
Deputy Secretary for Quality Assurance

A handwritten signature in black ink, appearing to read 'Anna Marie Sossong', written over a large, stylized circular flourish.

May 2012

Division of Drug and Alcohol Program Licensure  
Licensing Alert 03-12

**(Replaces Licensing Alert and Attachment 01-08)**

### USE OF BUPRENORPHINE NONRESIDENTIAL 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.

However, due to the waiver of regulations through the exception process, safety issues were identified. To address these safety concerns, the Workgroup reconvened to review the

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regulations and discuss improved patient safety and which regulations initially waived for outpatient facilities may nevertheless be necessary.

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)).

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

**Those outpatient facilities that have already received an exception on the use of buprenorphine in a nonresidential facility need not apply for another exception. However, they will be held accountable to the new requirements outlined in this Alert.**

A licensed facility that desires to commence using buprenorphine in a nonresidential setting may submit a request, along with documentation of governing body approval, for an exception from the requirements of Chapter 715. 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 the physician or physicians.
- 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, 711.87 and 711.97). 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.

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Following is a listing of the applicable Chapter 715 regulations for nonresidential facilities for which compliance is required:

### **Nonresidential Facilities**

**715.6(a)(1)(i)-(iii) Physician staffing.** All facilities ordering or prescribing buprenorphine for its patients must have a qualified medical director to oversee the medical services of the program.

**715.9(a)(1)-(4) Intake.** Patients must meet minimum criteria for admission to a narcotic treatment program and it is the responsibility solely of the physician to diagnose and admit a patient after a face-to-face examination.

**715.10(a)-(f) Pregnant patients.** Prenatal care is critically important for patients abusing addictive substances, and it is the responsibility of a narcotic treatment program to facilitate this care.

**715.13(a)-(b) Patient identification.** Patients must be accurately identified prior to the administration of a narcotic medication.

**715.14(a) Urine testing.** Urine testing must be conducted on a regular basis to monitor patient use and progress in treatment and to prevent diversion.

**715.15(a)-(b) Medication dosage.** It is the responsibility of the narcotic treatment program physician to determine dosage and schedule, and to ensure that dosage levels are reviewed regularly.

**715.19(1)-(3) Psychotherapy services.** Psychotherapy services must be provided to all patients on an ongoing basis (2.5 hours per month the first two years, 1 hour per month the third and fourth year, 1 hour every two months after four years).

**715.21(1)-(2) Patient termination.** Involuntary terminations shall occur only when all other efforts to retain the patient have failed. Patients shall receive a detoxification of at least seven days or be transferred to another facility.

**715.28(a)(1)-(10) Unusual incidents.** Facilities must be prepared for unusual incidents and make reports to the appropriate authorities in a timely manner.

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:

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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. 03-12, 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
Nonresidential Detoxification (not to exceed 90 days)		
Nonresidential 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

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**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, 711.87, and 711.97 (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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