



LICENSING ALERT

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Division of Drug and Alcohol Program Licensure
Licensing Alert 03-11

USE OF NON-NARCOTIC DRUGS IN DRUG AND ALCOHOL NON-RESIDENTIAL TREATMENT FACILITIES (VIVITROL)

The U.S. Food and Drug Administration recently approved the use of Vivitrol as a monthly injection to treat addiction to opioids. Vivitrol was previously approved in 2006 for the treatment of alcohol dependence.

Use of Vivitrol in a drug and alcohol treatment project licensed by the Department of Health (Department) is considered an "other chemotherapy approach" to treatment. The Department's regulations relating to drug and alcohol treatment projects define "Other Chemotherapy approach" as:

A treatment approach that includes chemotherapy using a primary medication for other than detoxification purposes. The term implies continued doses of medication. If a client receives only short-term medication for temporary symptomatic relief, the client is entered under the drug free or the detoxification approach, as appropriate. See 28 Pa. Code § 701.1

Drugs used or administered in other chemotherapy approach treatment in a non-residential drug and alcohol facility which are not classified as narcotics do not require approval under the Department's 28 Pa. Code Chapter 715, Narcotic Treatment Program regulations. However, a project shall notify the Division of Drug and Alcohol Program Licensure (Division) prior to any change in activity or treatment offered by the project, including the addition of an "other chemotherapy approach" to treatment, so that the project's license/certificate of compliance can accurately reflect the activities and treatment offered by the project. See 28 Pa. Code § 709.14(a) and (b)(4).

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The project is not required to go through the formal application process, but should submit a written notification to the Division, seeking to add the other chemotherapy approach to the project's license/certificate of compliance. This notification should identify the activity to which this approach is being added, the maximum number of clients that can be served under this activity/approach and a current staff roster of counselors/counselor assistants and hours worked per week. Upon confirmation that all the required information has been submitted by the project, the project will receive an updated license/certificate of compliance.

Written notification seeking to add Vivitrol as an other chemotherapy approach to the activities and treatment identified on the project's license/certificate of compliance shall be submitted to:

Pennsylvania Department of Health
Division of Drug and Alcohol Program Licensure
132-A Kline Plaza
Harrisburg, PA 17104

The project shall continue to maintain the appropriate client to counselor ratios as outlined in the staffing regulations and comply with all other licensing regulations. Policies and procedures should also be revised as necessary to ensure compliance with the Department's regulations and the delivery of proper treatment, particularly in the following areas:

- 28 Pa. Code §§ 709.83(a)(5) and 709.93(a)(2) Medication records. There should be a record of the dose, medication and name of the prescribing physician. Note that there is no equivalent regulation in the health care facility regulations (Chapter 711).
- 28 Pa. Code §§ 709.32(c)(1)-(7) or 711.87(a)(1)-(7) and/or 711.97(a)(1)-(7) Medication control. If medication is stored on site, either in the client's name or as part of the physician's stock, then this entire section applies and will be reviewed for policy and procedures along with documentation.

Questions on this Alert may be directed to the Division of Drug and Alcohol Program Licensure, telephone 717-783-8675.

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