JANUARY 2015 Board Mtg.

New Mexico Regulation and Licensing Department
BOARDS AND COMMISSIONS DIVISION
Board of Pharmacy
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WAIVER REQUEST FORM

"Waive/waivers" means to refrain from pressing or enforcing compliance with certain regulations for the specified period of time, provided the health, safety, or welfare of patients and staff are not in danger. Waivers are issued at the sole discretion of the New Mexico Board of Pharmacy.
16.19.32.7 NMAC

You Must Provide the Following Information for Waiver Consideration
(per regulation 16.19.32.8 NMAC). Also Provide Any Relevant Supporting Documentation.

Licensee name: Turquoise Lodge Hospital

Address of Business: 5901 Zuni SE, Albuquerque, NM 87108

Type of Business: State Drug and Alcohol Detox / Rehab specialty Hospital

Pharmacy Board License Number: PH0002143

Reason for Waiver Request:

See Attached

Affected New Mexico Administrative Code Citation: 16.19.7.9 F

Expected Public Benefit As a Result of the Waiver:

See Attached

Name of Pharmacist in Charge/Consultant Pharmacist: Joel Villarreal RPh.

Date: 11/21/14

Waivers granted by the board are limited to use by the party and business specified in the waiver document. Waivers must be publicly displayed in proximity to the facility's current registration or license. All waivers will be subject to review and reconsideration.

Turquoise Lodge Hospital Waiver Request

Reason for Waiver Request:

Turquoise Lodge is currently teamed up with the National Institute of Drug Addiction (NIDA) in order to compare two medications; extended-release naltrexone (XR-NTX, Vivitrol) and buprenorphine/naloxone (BUP-NX, Suboxone). Both medications are approved by the US FDA (United States Food and Drug Administration) for this purpose. Vivitrol is the newer of the two drugs, and we are interested in comparing it to Suboxone over 6 months (24 weeks) of treatment. The Vivitrol will be given on site at Turquoise Lodge Hospital; however Suboxone would be dispensed to patient's on an outpatient basis, which would require a Retail License. We are requesting a waiver to dispense this medication to individuals in this study as outpatients. Turquoise Lodge does not intend to accept no more than 20 patients in the suboxone arm of this study and the study would end early 2016.

Expected Public Benefit As A Result of the Waiver:

Treatment for opioid dependence often involves medication, either to help with short-term detoxification, or to help prevent relapse over a longer period. Many people relapse after short-term treatment, so it is often recommended that people remain on medication for long periods, several months to many years.

The study is a NIDA Clinical Trials Network (CTN) multi-site trial comparing the effectiveness of the two drugs (Vivitrol and Suboxone) to prevent relapse to opioid use and addiction. Participants who qualify for participation and are consented to participate and will be randomized into either of the two groups and receive 6 months of treatment, that include frequent Medical Management (MM) and research follow up visits (weekly for 24 weeks) during the treatment phase. They will continue to be followed up for two additional research follow-up visits after that (at weeks 28 and 36 from baseline). Participants will also have the opportunity to attend weekly group counseling sessions, if they so choose and will be compensated for their time and effort in the participation of the research study visits. All study-related visits are conducted in a highly confidential and private in an effort to protect the participant's privacy.

After the six-month (24 weeks) treatment phase of the study, we will help participants seek similar treatment in the community. Related purposes of the study are to understand whether there are genetic or hereditary differences in how individuals respond to these medications and the economic costs and benefits of the two treatments.