

Provider Eligibility Criteria VIVITROL® for Addicted Offenders

The 2014 Florida Legislature appropriated \$1 million in recurring General Revenue funds and \$2 million in non-recurring funds to provide extended-release injectable naltrexone (VIVITROL®) to treat alcohol and opioid addicted offenders in community-based drug treatment programs. These funds were appropriated to the Office of the State Court Administrator (OSCA) who has contracted with the Florida Alcohol and Drug Abuse Association (FADAA) to establish a program enabling providers to access this medication. The funds will reimburse providers for VIVITROL screening, assessment, and medication administration at the following rate:

- Naltrexone Screening/Medication Education - Unit Price \$150
- Naltrexone Assessment (Physical Examination, Lab Work) - Unit Price \$540
- Administration of Medication (Medication Management, Medication Administration, Lab Work, and Medication) - Unit Price \$1,331

With dedicated resources made available by the Legislature to access this medication, there is an opportunity for providers to expand their clinical and medical protocols to use VIVITROL. FADAA has established a grant process for the selection of eligible providers and for the allocation and distribution of the funds.

If you are interested in accessing these funds to utilize VIVITROL as part of your agency's clinical protocol, you must meet the following eligibility criteria and complete and submit an on-line application, and upon approval enter into a Memorandum of Agreement (MOA) with FADAA. The electronic application is available at: <http://www.fadaa.org/vivitrol/vivitrol.php>

Your organization must have, or must establish prior to acceptance as a provider in the VIVITROL project, the following:

- 1) A current Florida license as a substance abuse provider pursuant to s.397.401, Florida Statutes.
- 2) A formally adopted medical protocol for assessment and administration of VIVITROL. (FADAA has an acceptable protocol available on the website at: [FADAA Medical Protocol](#))
- 3) Documentation of training for the provider's medical and clinical staff on the FDA-approved prescribing instructions, exceptions, and exclusions for use of VIVITROL.
- 4) If applicable, documentation of the number of individuals receiving VIVITROL through your organization in the past two years, the funding source for this medication, and the referral source for the clients.
- 5) Documentation that your organization has a history of working with drug offenders, including but not limited to, drug court and other problem solving court offenders, and the number of court referred offenders your agency has served in the past two years.
- 6) Documentation that your organization has the appropriate health care practitioners on your staff or under contract to:
 - a. evaluate individuals for the appropriate use of VIVITROL, including the ability to conduct medical baseline evaluations and required lab work to detect all

- contraindications for administering the medication;
 - b. prescribe the medication (physician);
 - c. store and dispense the medication following approved FDA guidelines;
 - d. administer the medication following FDA guidelines;
 - e. medically monitor the use of VIVITROL;
 - f. conduct a clinical assessment and develop a treatment plan incorporating VIVITROL.
- 7) Documentation that your organization's medical director/physician is licensed in Florida and has at least one of the following credentials or experience level:
- a. Certification in Addiction Medicine.
 - b. Active in Addiction Medicine Fellowships.
 - c. Psychiatrist with a certificate in Addiction.
 - d. Training in the administration of VIVITROL.
- 8) Documentation that you have the refrigeration needed to store VIVITROL at a temperature between 2-8 degrees Celsius or 36-46 degrees Fahrenheit.
- 9) Documentation that your agency has the capacity to detox or refer a client for detox services and to monitor them or have them monitored for 7-10 days of abstinence following detox prior to placing them on VIVITROL.
- 10) Documentation of insurance coverage for all actions of your organization related to the services provided pursuant to the administration of VIVITROL in the minimum amount of \$1,000,000.00 per occurrence and \$3,000,000.00, aggregate.
- 11) Your agency must agree to perform the following services/activities prior to being accepted as a participant in the VIVITROL project. Use the [online application link](#) to affirm your commitment to meet these criteria.
- a. Provide VIVITROL as an adjunct to, and in coordination with, behavioral health treatment, including individual and/or group counseling as determined through the appropriate provider.
 - b. Screen individuals to establish both legal and medical qualifications for individuals to receive VIVITROL through this program;
 - c. Administer VIVITROL qualified individuals;
 - d. Establish local program goals and submit specific reports to FADAA for OSCA which include:
 - i. Monthly medication inventory reports for VIVITROL including (Number of doses on hand at the beginning of each month (-)less the number administered (+)plus the number received from the designated specialty pharmacy (=) equals the number of doses on hand at the end of the month;
 - ii. monthly client data program activities and outcomes reports. Data will include, but may not be limited to:
 - 1. Number of clients screened and educated on the use, benefits, and risks of VIVITROL;
 - 2. Number of clients assessed (received physical exam and/or lab work) for use of VIVITROL;
 - 3. Number of clients who received one or more doses of VIVITROL;

- 4. Number of clients screened, educated, and/or assessed who did not receive one or more doses of VIVITROL and reason for not receiving;
 - iii. Demographics of individuals served (first, middle, and last name; date of birth; race; ethnicity; gender; social security number; state identification number; Florida Department of Corrections number, if applicable; county with court jurisdiction of case; current charge(s); court case number; type of problem-solving court, if applicable; alcohol or opioid as drug of choice; and current treatment modality, including outpatient, inpatient, and/or aftercare).
 - iv. Client outcomes including, urge to drink and/or use opiates; number days in the month that client drank or used opiates; number of admissions to inpatient treatment; number of days client participated in treatment (treatment retention); increase or decrease in observed or reported symptoms; and changes in social and occupational functioning.
 - v. Number of clients who received at least one dose of VIVITROL and completed the prescribed course of treatment with the total number of doses received by client;
 - vi. Number of clients who received at least one dose of VIVITROL and did not complete the prescribed course of treatment with the total number of doses received by client;
 - vii. Average number of doses for alcohol users and average number of doses for opioid users; and
 - e. Assign and submit to FADAA a de-identified client number for reporting purposes.
- 12) Providers must submit a projection of the annual number of offender treatment referrals you anticipate receiving from the local court system and the projected number of these individuals who would be appropriate for medication assisted treatment using VIVITROL;
 - 13) Establish a relationship and execute a contract with Besse Medical, 9075 Centre Point Drive, Suite 140, West Chester, OH 45069, to request and receive VIVITROL directly for the services provided under this agreement. www.besse.com/
 - 14) Comply with all applicable federal, state and local laws, rules and regulations, including, but not limited to those laws and regulations enforced by the Food and Drug Administration, the Drug Enforcement Administration, and state laws regarding pharmaceutical standards and administration of medications, specifically.
 - 15) Agree to an on-site monitoring visit from FADAA and/or OSCA representatives to determine provider compliance with all requirements under the FADAA MOA at a date/time that is convenient for both parties.
 - 16) The invoice for reimbursement of Provider expenses must include the name of the Provider, types of services provided, number of units for each service type, the unit cost for each service type, and the total number of clients served during the month. Back-up documentation to be included with the invoice must include proof of Contractor (FADAA) payment to the Provider and a copy of the Provider invoice submitted to the Contractor for reimbursement.
 - 17) Comply with the Florida Single Audit Requirements which are:
 - a. The Provider, as a recipient of state funds, will comply with the Florida Single Audit Act, Section 215 .97, Florida Statutes.
 - b. In the event that the Provider expends a total amount of State awards equal to or in excess of \$500,000 in the Contractor's fiscal year, the Provider must have a

State single or project-specific audit for such fiscal year in accordance with section 215.97, Florida Statutes, and applicable rules of the Department of Financial Services and the Auditor General. Applicable rules of the Department of Financial Services, the Auditor General, and other information pertaining to the Florida Single Audit Act can be found at <https://apps.fldfs.com/fsaa/>

- c. The Catalog of State Financial Assistance establishes that state funds are awarded to the Contractor through the State Courts System, Office of the State Courts Administrator. The Catalog of State Financial Assistance number for this funding will be provided by the OSCA to the Contractor when the number is assigned and provided to the OSCA. Information from the Catalog can be found at: <https://apps.fldfs.com/fsaa/searchCatalog.aspx>.
 - d. In determining the State awards expended in its fiscal year, the Contractor shall consider all sources of State awards, including State funds received from the State Courts System, except that State awards received by a non-state entity for Federal program matching requirements shall be excluded from consideration.
- 18) The Provider shall ensure that the audit complies with the requirements of section 215.97(8), Florida Statutes, and the State Projects Compliance Supplement. The State Projects Compliance Supplement A is available from the Department of Financial Services at <https://apps.fldfs.com/fsaa/>. Compliance includes submission of a reporting package as defined by section 215.97(2)(e), Florida Statutes.
 - 19) If the Provider expends less than \$500,000 in State awards in its fiscal year, an audit conducted in accordance with the provisions of section 215.97, Florida Statutes, is not required. Audit costs may not be charged to state projects when the Provider expends less than \$500,000 in State awards.
 - 20) Unless prohibited by law, the cost of an audit required by s. 215.97, Florida Statutes, is an allowable charge to a state project. However, charges to state projects should be limited to those incremental costs incurred by the Provider as a result of the audit requirements of section 215.97, Florida Statutes in relation to other audit requirements. The Contractor should allocate the incremental costs to all state projects for which it expended state financial assistance.
 - 21) The Provider shall submit copies of reporting packages required by section 215.97, Florida Statutes, within 10 days of receipt of the audit findings, to each of the following:
 - a. The OSCA at the following address:

Jennifer Grandal
Senior Court Operations Consultant
Supreme Court Building 500 South Duval Street
Tallahassee, FL 32399-1900
 - b. The Auditor General at the following address:

State of Florida Auditor General
Room 574, Claude Pepper Building
111 West Madison Street Tallahassee, FL 32302-1450
 - 22) The Provider shall retain sufficient records demonstrating compliance with the terms of this agreement for a period of five (5) years from the date the audit report is issued, and shall allow

- the OSCA access to such records upon request. The contractor shall ensure that audit working papers are made available to the OSCA upon request for a period of five (5) years from the date the audit report is issued, unless extended in writing by the OSCA.
- 23) Pursuant to section 215.97, Florida Statutes, the OSCA, the Florida Supreme Court Inspector General, the Auditor General and other state officials may conduct additional audits or evaluations of state financial assistance provided to the Contractor under this Agreement.
 - 24) Allow public access to all documents, papers, letters or other material made or received by the Provider in conjunction with the project unless the Records are exempt from disclosure pursuant to Ch. 397.501, F.S., applicable federal confidentiality regulations, and s. [119.07\(1\)](#), F. S. and s. 24(a), Art. I of the State Constitution.
 - 25) Indemnify and defend the Florida Alcohol and Drug Abuse Association against any claims related to the improper administration of VIVITROL due to the actions of the provider, their officers, agents and employees, including but not limited to claims for any forms of negligence or damages by recipients of the medication and/or claims of improper billing or administrative practices.
 - 26) Agree to respond appropriately to protect the privacy of individuals and all confidential information obtained or created by the Provider during the course of its performance under this Agreement.
 - 27) Ensure that state funding provided through this project is the payer of last resort.
 - 28) Comply with the Americans with Disabilities Act, the Civil Rights Act of 1964, as amended, the Florida Civil Rights Act of 1992 and any other federal or state law that prohibits discrimination based on race, color, national origin, religion, sex, age, marital status, or disability.