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November 2, 2017

The Honorable Brian Moran
Secretary of Public Safety and Homeland Security
P.O. Box 1475
Richmond, VA 23218

The Honorable William A. Hazel, Jr.
Secretary of Health and Human Resources
P.O. Box 1475
Richmond, VA 23218

The Honorable Thomas K. Norment, Jr
Co-Chairman, Senate Finance Committee
P.O. Box 6205
Williamsburg, VA 23188

The Honorable Emmett W. Hanger, Jr.
Co-Chairman, Senate Finance Committee
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The Honorable S. Chris Jones, Chairman
House Appropriations Committee
P.O. Box 5059
Suffolk, VA 23435

The Honorable Robert B. Bell, Chairman
Virginia State Crime Commission
1111 East Broad Street, Suite B036
Richmond, VA 23219

Mr. Daniel Timberlake, Director
Department of Planning and Budget
1111 East Broad Street, Room 5040
Richmond, VA 23219

Re: Report Pursuant to Item 40, Paragraphs H (5) and (7)
2017 Appropriation Act

Dear Gentlemen:

Item 40.H.5 of the 2017 Appropriation Act requires the Executive Secretary of the Supreme Court of Virginia to report the results of two substance abuse treatment pilot programs at the Norfolk Adult Drug Court and the Henrico County Adult Drug Court utilizing non-narcotic, non-addictive, long-acting, injectable prescription drug treatment regimens.

In addition, Item 40.H.7 of the 2017 Appropriation Act was added appropriating $50,000 during FY 2018 to support a substance abuse treatment program at the Bristol Adult Drug Court utilizing non-narcotic, non-addictive, long-acting, injectable prescription drug treatment regimens, and the Executive Secretary was directed to include the results of this pilot program in its report pursuant to Item 40.H.5.

Please find enclosed the required report addressing these budget items. If you have any questions about the report, please do not hesitate to contact me.

With best wishes, I am

Very truly yours,

Karl R. Hade (by EMM)

Karl R. Hade

Enclosure

VIRGINIA DRUG TREATMENT COURTS: SUBSTANCE USE TREATMENT PILOTS

October 1, 2017

Office of the Executive Secretary

Supreme Court of Virginia

PREFACE

The Virginia 2016-2018 State Budget (Items 40 H. #5 & #7), *see* Appendix A, directs the Office of the Executive Secretary (OES) of the Supreme Court of Virginia to report the results of stakeholders review recommendations for expansion of the pilot program to other drug courts and of the pilot programs in Henrico, Norfolk and Bristol to the Secretaries of Public Safety and Homeland Security and Health and Human Resources, the Director of the Department of Planning and Budget, and the Chairmen of House Appropriations and Senate Finance Committees. This report reflects the report due October 1, 2017.

I. Background: Need/Problem/Desire Addressed by Initiative

Beginning in 2015, drug courts applying for federal funding pursuant to the Adult Drug Court Discretionary Grant Program needed to attest in writing that they will not deny otherwise eligible candidates access to the program because of a candidate's use of an FDA-approved medication for the treatment of a substance use disorder, and they will not require participants to discontinue such medications as a condition of graduating from the program (U.S. Department of Justice, 2015). The grant language creates a difficult-to-rebut presumption that medication-assisted treatment (MAT) will be permitted if it is prescribed lawfully by a licensed medical practitioner who has personally examined the participant and determined that the medication is appropriate to treat the disorder. The MAT attestation applies only to drug courts receiving Bureau of Justice Assistance or Substance Abuse Mental Health Services Administration (SAMHSA) funding.

Drug courts often operate on an abstinence-based philosophy for drug use and have frequently discovered that a participant has been misusing or abusing medication or diverting medication for unauthorized purposes. Some drug courts programs believe that MAT is a substitution of one drug for another and not recovery-based.

The recommendation in this report for the Vivitrol pilot sites supports the Governor's Task Force on Prescription Drug and Heroin Abuse Treatment Workgroup recommendation to "Explore ways to enhance medication-assisted treatment (MAT) through CSBs, Drug Treatment Courts, and jail-based treatment." The Task Force further reported that "fewer than half of the CSBs currently utilize medication to assist treatment for individuals seeking recovery from opioid addiction." Barriers to providing MAT include limited funding, lack of access to a qualified physician or opiate treatment program, and lack of staff knowledge about how medication can assist in recovery. Judges may also not be aware of the critical role that MAT can play in helping drug treatment court participants achieve success and instead insist on a "drug-free" model that is not supported by evidence. In addition, most drug treatment courts are not adequately funded to provide medication. Sheriffs and jail administrators also lack up-to-date information, access to qualified physicians and funding to support necessary staff and purchase medication." The treatment workgroup offered additional recommendations related to the lack of access to treatment for drug addiction in Virginia noting it as a major barrier to overcoming prescription opioid and heroin abuse, misuse and overuse.

2016 Legislative Initiatives from the Governor's Task Force included the following:

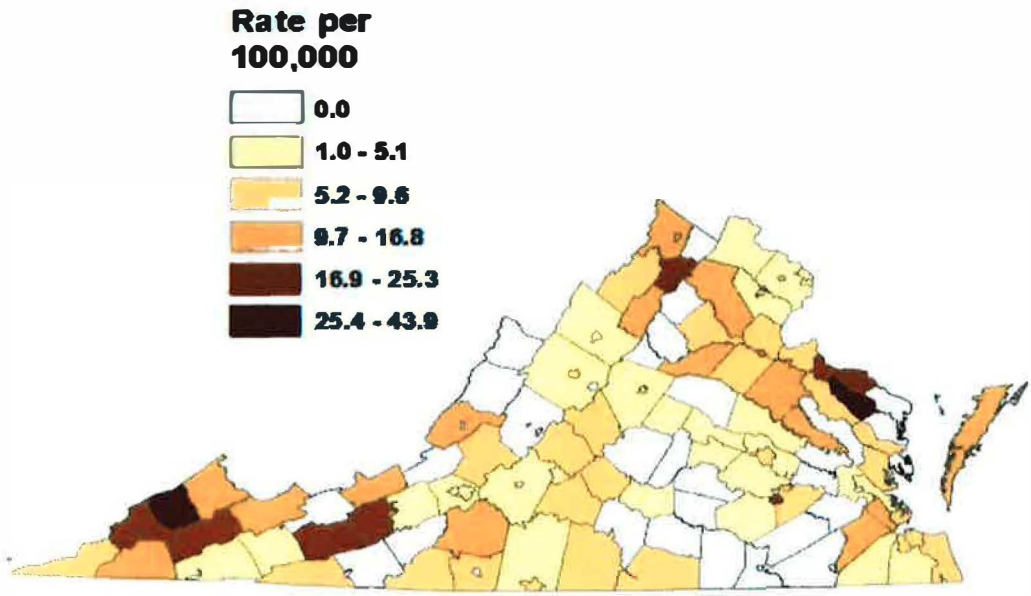
- Mandates Continuing Medical Education for providers regarding proper prescribing, addiction, and treatment –CHAP0447
- Reduces dispenser reporting time from 7 days to 24 hours, allows clinical consultation with pharmacists regarding patient history, and place copy of PMP report in patients' medical history – CHAP0309
- Sends unsolicited reports on egregious prescribing/dispensing behavior to agency enforcement –CHAP0098
- Requires query of PMP for all opioid prescriptions over 14 days –CHAP0113
- Provides certification for substance abuse peer support –CHAP0094

Programmatic/Policy Initiatives

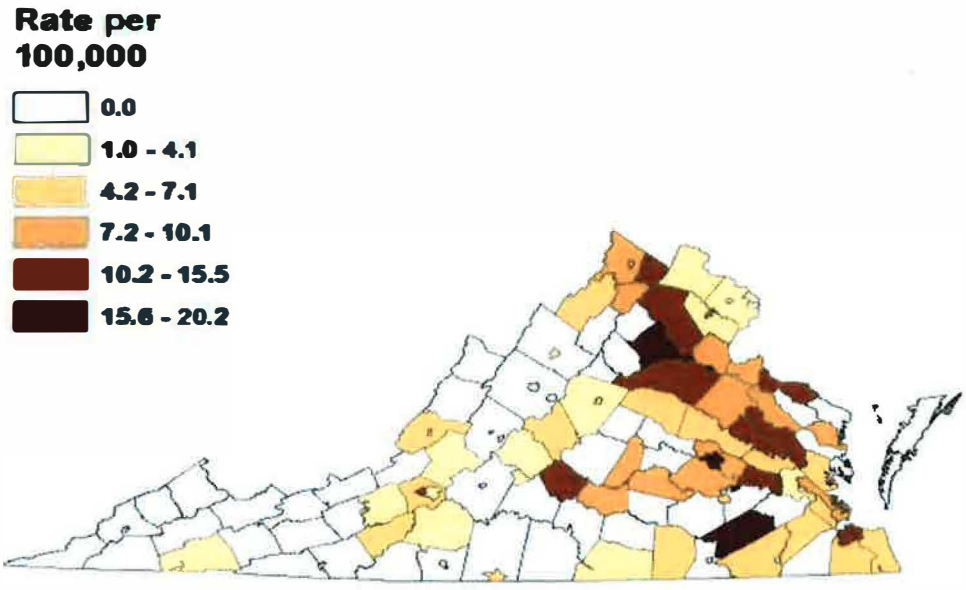
- Enhancing Medicaid Substance Use Disorder benefit in state budget
- Expanding short-term detox to 15 days for all Medicaid members
- Expanding short-term residential treatment up to 30 days for all members
- Increasing reimbursement for currently covered Medicaid SA services
- Adding coverage for peer supports
- Adding SA care coordinators at Medicaid MCOs
- Adding provider education, training, and recruitment for MAT
- VAaware.com website

The Virginia Department of Health Office of the Chief Medical Examiner produced data maps to report the rate of fatal heroin and other prescription opioid overdoses. The 2016 data maps are provided below. Additionally, the Vivitrol pilot sites should be selected based on data indicating the highest rate of overdose by heroin and opioid prescription occur. It important to note that the current pilot site locations are not where the data indicates the highest need for this intervention.

Rate of Fatal Heroin Overdoses by Locality of Overdose, 2016



Rate of Fatal Prescription Opioid (Excluding Fentanyl) Overdoses by Locality of Overdose, 2016



Naltrexone with the brand name Vivitrol® was approved by the FDA in 2006 for alcohol dependence and in 2010 for the prevention of relapse of opioid dependence after detoxification. As a physician-prescribed clinician-administered injectable medication, it may be covered under

a Medicaid plan's pharmacy benefit or medical benefit unlike either the generic tablet form of Naltrexone or the various formulations of buprenorphine, which are almost always covered as outpatient pharmacy benefits. If listed under medical benefits as an injectable similar to certain cancer medications, the prescribing physician must first "buy and bill" the medication in order to be reimbursed by Medicaid or other health plans.

Unlike methadone or buprenorphine, Naltrexone is not a controlled substance; and since it is injected, there are no concerns about misuse or diversion. Furthermore, prescribers do not require any special training or certification, other than learning how to appropriately inject the medication in their offices. Another difference about Naltrexone is that it is a specialty pharmaceutical which must be administered by a health care provider. As it is not a self-administered specialty pharmaceutical, it is typically covered as a medical benefit with implications for the patient in terms of co-payments for office-based injection.

The Vivitrol prescribing information on file at Alkermes, Inc., notes Vivitrol is naltrexone for extended-release injectable suspension, the only non-addictive, once-monthly medication available used with counseling to treat opioid and alcohol dependence. It continues to list the attributes and important safety information of Vivitrol as: "Non-addictive, Has no street value, Opioid antagonist, Requires detox, Non-Narcotic, Once-monthly injectable, Used with counseling and Administered by healthcare professional. ***Important safety information for patients and prescriber:*** Vivitrol is indicated for:

- Prevention of relapse to opioid dependence, following opioid detoxification
- Treatment of alcohol

The Substance Abuse and Mental Health Services Administration (SAMHSA) defines Naltrexone as "a medication approved by the FDA to treat opioid use disorders and alcohol use disorders. The injectable extended-release form of the drug (Vivitrol) is administered at 380mg intramuscular once a month. Naltrexone can be prescribed by any health care provider who is licensed to prescribe medications. To reduce the risk of precipitated withdrawal, patients are warned to abstain from illegal opioids and opioid medication for a minimum of 7-10 days before starting Naltrexone." (SAMHSA)

SAMHSA continues to warn that if a person relapses and uses the problem drug, Naltrexone prevents the feeling of getting high. Individuals using Naltrexone should not use any other opioids or illicit drugs; drink alcohol; or take sedatives, tranquilizers, or other drugs.

Patients on Naltrexone may have reduced tolerance to opioids and may be unaware of their potential sensitivity to the same, or lower, doses of opioids that they used to take. If patients who are treated with Naltrexone relapse after a period of abstinence, it is possible that the dosage of opioid that was previously used may have life-threatening consequences, including respiratory arrest and circulatory collapse."

II. Status of Implementation

Information entered into the Drug Court Database administered by the Office of the Executive Secretary generates the following information related to each of the local drug courts selected for the Vivitrol pilot sites' regarding their participants' reported drug of choice.

Drugs of Choice *As reported by drug court participants at time of program entry*		
	FY16	**FY17**
Bristol Adult Drug Court	**12.5% Opiates** 31.25% Marijuana 25% Meth	**12.5% Opiates** 31.25% Marijuana 25% Meth
Henrico Adult Drug Court	**67% Opiates**	**67% Opiates**
Norfolk Adult Drug Court	**53% Opiates**	**53% Opiates**

The Vivitrol® pilot funds will be administered by the Office of the Executive Secretary to the two drug courts, Norfolk and Henrico Adult Treatment Courts, using a grant process. Each drug court completed a grant application process that included the following:

- A detailed description of the program
- A copy of the policy & procedures manual for the pilot
- Compliance with the Medication Guide provided by the Vivitrol® manufacturer

The **Norfolk Adult Drug Treatment Court** intent is to use the funds to enhance their community services board's Opioid Treatment Program (OTP) using Vivitrol®. The program currently only offers Methadone. The OTP staff includes professionals with medical, clinical and administrative expertise. Patients receive individually prescribed medication from a licensed medical practitioner and routinely meet with a primary counselor and attend clinic groups. Drug screens are used as a clinical tool to modify treatment approaches and interventions. Patients and

their families receive education about substance addiction. Norfolk's program uses 100% of their funds in the 'supplies and other' category for the medication. The program estimates the cost of Vivitrol® at $1,000 per injection/dose. As of September 2017, Norfolk used $28,000 to serve four (4) participants on Vivitrol. There are no outcome or success measures because no participants enrolled in the pilot have graduated yet.

The **Henrico Adult Drug Treatment Court** did not spend any of their FY2017 allotted funds. They started their first participant on this Vivitrol pilot late June 2017. The related expenses will be applied to the FY2018 grant funds. The Henrico County Drug Court Vivitrol Pilot Program target population for the Vivitrol pilot will be active participants in Henrico Drug Court that have demonstrated an inability to abstain from opiate and/or alcohol use. This target population would have received interventions for their continued non-compliance; extra treatment sessions, essays, additional AA/NA meetings, and possible short jail sentences. After those interventions, if a participant continues to test positive for opiates and/or alcohol; the participant would be referred to complete the detox protocol at the Henrico County Jail. The participant will receive the first Vivitrol injection in the Henrico County Jail from the jail medical staff. The jail medical staff completed in-service training provided by Alkermes on April 4 and April 7, 2017. The Henrico Jail medical staff will provide all subsequent injections. Participants will be admitted to the Henrico County Jail for the purpose of receiving the monthly Vivitrol injection. The participant will be immediately released upon completion of the injection. The participants will be expected to remain in the Vivitrol pilot for six months. If applicable, the participant would be allowed to graduate from the Drug Court while still on Vivitrol.

The **Bristol Adult Drug Treatment Court** Vivitrol pilot description and grant application have not been received by OES at the time of this report.

III. Recommendation

As part of the Governor's Task Force on Prescription Drug and Heroin Abuse work, the treatment workgroup provided the following recommendation - Explore ways to enhance medication-assisted treatment (MAT) through CSBs, Drug Treatment Courts, and jail-based treatment. We continue to support this recommendation.

Funds for medication-assisted treatment options should be made available to the treatment providers serving drug courts. It is the role of a competent, properly licensed physician to

determine, based on the best available information, what regimen is most likely to be successful for a given patient. It is also the responsibility of a physician to explain this decision-making process to nonmedical persons, including the patient, the patient's loved ones, and third-party payers. Duly trained treatment professionals provide the counseling and other treatment services correlating with the medical treatment. Failing to consider scientific evidence when making decisions about MAT falls short of best practice standards (NADCP, 2013, 2015) and may under some circumstances amount to an abuse of judicial discretion. Additionally, we recommend the Vivitrol pilot sites be selected in compliance with the greatest need as indicated by the data maps of heroin and prescription drug overdose as reported by the Virginia Department of Health Office of the Chief Medical Examiner.

The task force recommendation includes, "fewer than half of the Community Services Boards (CSBs) currently utilize medication to assist treatment for individuals seeking recovery from opioid addiction." Barriers to providing MAT include limited funding, lack of access to a qualified physician or opiate treatment program, and lack of staff knowledge about how medication can assist recovery. Judges and their drug court teams may benefit from education regarding the critical role that MAT can play in helping drug treatment court participants achieve recovery. Additional funding would be needed as most Drug Treatment Courts are not adequately funded, and do not have funds to provide medication. Sheriffs and jail administrators could benefit from up-to-date information, access to qualified physicians, and funding to support necessary staff and to purchase medication.

To implement this recommendation, the following steps should be taken -

- Virginia Department of Behavioral Health & Developmental Services (DBHDS) collaborates with the Substance Abuse Council of the Virginia Association of Community Services Boards (CSBs) to develop and provide training and technical assistance to CSB staff and contract agencies about evidence-based methods of treating opioid addiction and successful methods of implementing MAT in their treatment systems. Necessary resources and infrastructure will be identified.
- DBHDS collaborates with the Office of the Executive Secretary, Supreme Court of Virginia Drug and its Statewide Drug Court Advisory committee, and the Virginia Association of Drug Treatment Courts (VADTC) to develop information, training and technical assistance to improve the use of MAT in drug treatment courts.

- DBHDS collaborates with the Substance Abuse Council of the Virginia Association of Community Services Boards, the Virginia Sheriffs' Association and the Department of Criminal Justice Services (DCJS) to explore methods of increasing access to medication-assisted treatment for individuals incarcerated in local jails."

The extended-release form of Naltrexone has only been FDA-approved since 2010 and research on results is limited. There is some evidence that the extended-release form may partially ameliorate the problem of prescription persistence that affects the oral version and improve compliance with Naltrexone therapy, as the medication remains active for 30 days with a single injection (Baser et al., 2011).

Both the oral and extended-release formulations of Naltrexone have been associated with patient deaths due to accidental overdoses of opioids while taking one or other of the medications (Deguisto, Shakeshaft, Ritter, O'Brien, & Mattick, 2004). In many cases, overdosing may be due to the blocking effect of Naltrexone, with relapsing patients taking large amounts of opioids to try to overcome the blockage (Substance Abuse and Mental Health Services Administration, 2009; Kleber, 2007). In addition, patients treated with extended-release Naltrexone may have reduced tolerance to opioids and be unaware of their potential sensitivity to the same, or lower, doses that they used to take of opioids. For such patients who relapse after a period of abstinence, the dosages of opioids previously used may have life-threatening consequences, including respiratory arrest and circulatory collapse (Alkermes, Inc., 2013; SAMHSA, 2013) Patients undergoing Naltrexone therapy should be clearly cautioned about these dangers.

Injection site reactions have been reported for extended-release Naltrexone. Treatment guidelines emphasize that extended-release Naltrexone must be injected only intramuscularly and never intravenously, subcutaneously, or into fatty tissues, using the kit included with the medication (Substance Abuse and Mental Health Services Administration, 2013).

Contraindications of Naltrexone include physiological dependence on opioids. Those currently physiologically dependent on opioids should be offered detoxification treatment or be referred to specialist services. Patients must have been fully withdrawn from all opioids before considering therapy with Naltrexone. Other contraindications include acute hepatitis or liver\ failure, as Naltrexone can be hepatotoxic in high doses. In view of its hepatotoxic effects, its use

in patients with active liver disease must be carefully considered, with doses causing hepatic injury being at most fivefold of those that appear to be safe (TIP 49).

While there are no clear recommended guidelines for the duration of Naltrexone therapy, 6 to 12 months is probably a minimum in most cases. Naltrexone can be stopped abruptly without withdrawal symptoms, but before discontinuing this medication, a careful clinical evaluation of the risk for relapse should be conducted (Kleber, 2007).

Appendix A

Virginia 2016-2018 State Budget (Items 40 H. #5):

5. Included in this item is $100,000 the first year and $100,000 the second year from the general fund to support two substance abuse treatment pilot programs at the Norfolk Adult Drug Court and the Henrico County Adult Drug Court utilizing non-narcotic, non-addictive, long-acting, injectable prescription drug treatment regimens. The Norfolk and Henrico County Adult Drug Courts shall utilize these resources to support pilot program medication, provider fees, counseling, and patient monitoring. The Executive Secretary of the Supreme Court shall report the results of the pilot program, as well as recommendations for expansion of the pilot program to other drug courts, to the Secretaries of Public Safety and Homeland Security and Health and Human Resources, the Director of the Department of Planning and Budget, the Chairman of the Virginia State Crime Commission, and the Chairmen of the House Appropriations and Senate Finance Committees by October 1 each year of the pilot program. The Norfolk and Henrico County Adult Drug Courts shall provide all necessary information to the Office of the Executive Secretary to conduct such an evaluation.

Virginia 2018 State Budget (Items 40 H. #7):

7. Included in this item is $50,000 the second year from the general fund to support a substance abuse treatment pilot program at the Bristol Adult Drug Court utilizing non-narcotic, non-addictive, long-acting, injectable prescription drug treatment regimens. The Bristol Adult Drug Court shall utilize these resources to support pilot program medication, provider fees, counseling, and patient monitoring. The Executive Secretary of the Supreme Court shall include the results of this pilot program in its report pursuant to Item 40.H.5. The Bristol Adult Drug Court Program shall provide all necessary information to the Office of the Executive Secretary to conduct this evaluation.

Appendix B

For additional specific information for the non-narcotic, non-addictive, long acting, injectable prescription drug please consult the following brief guide made available through SAMHSA.

Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide
http://store.samhsa.gov/product/Clinical-Use-of-Extended-Release-Injectable-Naltrexone-in-theTreatment-of-Opioid-Use-Disorder-A-Brief-Guide/SMA14-4892R

References

Alkermes, Inc. Medication guide. Revised November 2010, VIV993B). Waltham, MA: Alkermes, 2013. [Accessed at http://www.vivitrol.com/Content/pdf/medication_guide.pdf

Alkermes, Inc, Data on File. Data as of April 2017. Vivitrol (Naltrexone for extended-release injectable suspension) and the Criminal Justice System Brochure.

Baser, O., Chalk, M., Fiellin, D. A., & Gastfriend, D. R. (2011). Cost and utilization outcomes of opioid dependence treatments. *The American Journal of Managed Care*, *17*(8), S235-S248.

Degiusto, E., Shakeshaft, A., Ritter, A., O'Brien, S., & Mattic, R. P. Serious adverse events in the Australian National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD). *Addiction*, *99*(4), 450-460.

Kleber, H. D. (2007). Pharmacologic treatments for opioid dependence: detoxification and maintenance options. [Review]. *Dialogues in Clinical Neuroscience, 9*(4), 455-470.

Legal Action Center. (2009). Know your rights: Rights for individuals on medication-assisted treatment (HHS Publication No. [SMA] 09-4449]. Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration.

Marlowe, D.B., Hardin, C.D., & Fox, C.L. (2016). Painting the current picture: A national report on drug courts and other problem solving courts in the United States. Alexandria, VA: National Drug Court Institute.

National Association of Drug Court Professionals. (2013). Adult Drug Court best practice standards (Vol. I). Alexandria, VA: Author. Retrieved from http://www.nadcp.org/sites/default/files/nadcp/AdultDrugCourtBestPracticeStandards.pdf

National Association of Drug Court Professionals. (2015). Adult Drug Court best practice standards (Vol. II). Alexandria, VA: Author. Retrieved from http://www.ndcrc.org/sites/default/files/adult_drug_court_best_practice_standards_volume_ii.pdf

SAMHSA, Center for Substance Abuse Treatment, 2009, *Incorporating alcohol pharmacotherapies Into medical practice (TIP 49)*.

Substance Abuse and Mental Health Services Administration (SAMHSA). (2011). Medication-Assisted Treatment for Opioid Addiction: 2010 State Profiles (HHS Publication No. SMA-11-4643). Rockville, MD: Substance Abuse and Mental Health Services Administration.

Substance Abuse and Mental Health Services Administration. (2012). An introduction to extended release injectable naltrexone for the treatment of people with opioid dependence. SAMHSA Advisory, 11(1), 1–8. Retrieved from http://store.samhsa.gov/shin/content/SMA12-4682/SMA12-4682.pdf

U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance. (2015). Adult Drug Court Discretionary Grant Program FY 2015 Competitive Grant Announcement (OMB No. 1121-0329). Retrieved from https://www.bja.gov/Funding/15DrugCourtSol.pdf

http://www.vdh.virginia.gov/medical-examiner/forensic-epidemiology

Vivitrol [prescribing information]. Waltham, MA: Alkermes, Inc; 2015.