Executive Order Number 29
Governor's Task Force on Prescription Drug and Heroin Abuse
Minutes of the Treatment Workgroup
December 5, 2014
Dumbarton Library
Henrico, Virginia

Co-Chairs
Delegate John O'Bannon, M.D.
Jennifer Lee, M.D., Deputy Secretary, Health and Human Resources

Members Present:
Chuck Adcock
Jan Brown
Lillian Chamberlain
Duffy Ferguson
Nancy Finch
Chief Mary Gavin
Cynthia Kirkwood, PharmD
Deputy Secretary Jennifer Lee, M.D.
Mary McMasters, M.D.
Delegate John O'Bannon, M.D.
Dana Schrad
Patricia Shaw
Art Van Zee, M.D.
Senator Jennifer Wexton

Members Absent
Jaime Areizaga-Soto
Debra Ferguson, Ph.D.
Diane Strickland
Hughes Melton, M.D.
Sheriff Gabe Morgan

Staff
Mellie Randall
Holly Mortlock

Guests
Lindsay M. Walton, J.D.

Call to Order and Introductions

Delegate O'Bannon called the meeting to order and asked workgroup members to introduce themselves. He welcomed Dr. McMasters, who is an addictionologist practicing in Fishersville, and who was a member of Virginia's National Governors Association Policy Team on prescription drug abuse. Delegate O'Bannon also announced that Hughes Melton, M.D., had also been appointed to the workgroup and that Dr. Ait-Daoud had been transferred to the Education Workgroup.

Ms. Randall provided an overview of the agenda.

Medication-Assisted Treatment for Opioid Addiction

At the request of the chairs, Dr. Van Zee provided an overview of buprenorphine as a medication for opioid addiction. (See Attachment 1). He made the point that addiction is a disease with a broad spectrum; there is a clinical difference between a young adult who has used OxyContin for

18 months and a person who has used heroin for many years, and that these individuals will need to be treated differently. He explained the difference between tolerance, which is a physiological phenomenon that could be experienced by any person who was exposed to opioids for a period of time, and addiction, which is a specific disorder that causes individuals to continue use despite obvious harm to themselves.

He explained that detoxing individuals off of opioids was generally ineffective and that there was universal agreement that using medication such as buprenorphine and methadone, in conjunction with psychological therapy, was the most effective method of treating opioid addiction.

He said that duration of treatment was most effective over a period of years; if the person is taken off the medication prematurely, he will likely relapse. Most studies indicate that only about 10 to 20 percent can be successfully withdrawn from medication and remain abstinent from drug use. Use of these medications has many benefits including: reduced mortality; reduced use of illicit drugs; reduced criminal activity; reduced exposure to risk factors for diseases such as HIV and hepatitis C; and increased pro-social behaviors such as employment and improved social and family relationships.

Dr. Van Zee explained that there are several brand names for buprenorphine and buprenorphine/naloxone. When the physician is "inducting" the patient (determining the appropriate dose), he uses buprenorphine which attaches directly to opioid receptors and partially prevents other opioids from reaching the receptors. He explained the process of dose determination. Once the appropriate dosing level is reached, the physician switches to a formulation that includes naloxone, which blocks access of any opioid to the opioid receptor so that the individual cannot experience the euphoric effects of an opioid if he decides to use one. Brand names for buprenorphine are Subutex and medication with naloxone is Suboxone, Zubsolv and Bunavail. The medication comes in a film that is dissolved under the tongue. However, if the patient is a pregnant woman, she is treated with buprenorphine alone, as the effects of naloxone on fetal development are not known. The infant, when born, has to be withdrawn from the medication, however, treatment for the pregnant woman helps her to stabilize during pregnancy, reduces use of illicit drugs which would cause potentially more harm to the infant and reduces exposure to other risk factors which could also harm the fetus

Buprenorphine is an expensive medication and the cost is dependent on the strength of the dose and the manufacturer, ranging from $120 to $400 per month for the medication alone.

Because buprenorphine can be prescribed by physicians in private practice, it has become very commercialized; some physicians have developed very lucrative practices based solely on buprenorphine cash practices. There are concerns that some physicians do not adequately monitor their patients who may be diverting their medication for cash used to buy illicit drugs. Also, some physicians do not make psychological help or case management available to their patients.

In summary, Dr. Van Zee stressed that medication assisted treatment for individuals addicted to opioids can help them live normal lives by removing the brain-based craving, eliminating the

need to use illegal opioids to satisfy the craving, reducing exposure to life threatening illness often associated with drug use such as HIV or hepatitis C, reducing the risk of opioid overdose, improving social functioning with work and family, and improving life expectancy.

Dr. O'Bannon asked how long individuals need to stay on medication. Dr. McMasters and Jan Brown agreed that medication is very effective at controlling cravings and that the person needed to stay on the medication until he or she had developed other methods for coping with cravings. Dr. Van Zee indicated that some individuals may need to take medication, even at a very low dose, for the rest of their lives.

Dr. Van Zee also discussed legislation introduced to the US Senate by Senator Edward Markey that would lift the cap of 100 patients that one physician can treat with buprenorphine in certain cases and asked that the workgroup consider recommending that Virginia's Congressional delegation support the bill. (See Attachment 2)

At the request of the chairs, Chuck Adcock provided a presentation on methadone as a treatment for opioid addiction. (See Attachment 3). He said that its use started about 70 years ago and focused on the poor and those involved with the criminal justice system, and that its dissemination paralleled the develop of the 12-Step movement, but that they were mutually exclusive because the 12 Step philosophy insisted that participants be "drug-free," including methadone and psychotropic medications as well He said that methadone was perceived as a medication used for individuals who were not serious about recovery, in contrast to 12 Step programs that were spiritual and focused on internal change. Mr. Adcock compared medication-assisted treatment to individuals who develop diabetes and are put on insulin; sometimes they are able to make lifestyle changes that will allow them to no longer take insulin. He said that methadone is most effective when used as a maintenance medication; studies indicate that most people will relapse to illicit drug use if they are detoxed from methadone.

He said that methadone clinics have been the "step-child" of treatment for many years, but that the increased problem with abuse of prescription pain medication had resulted in a shift in attitudes about the use of medication-assisted treatment, including methadone. The wave of prescription pain medication abuse had affected more affluent families and had brought younger individuals to methadone clinics seeking treatment because psychotherapy alone was ineffective. Buprenorphine became available as the prescription drug problem was emerging and was initially seen as a medication used transiently; it was also believed that buprenorphine could not be abused and would not be diverted. It was an attractive medication for the middle-class to use because it could be obtained at a physician's office instead of a clinic. However, it was soon discovered that long-term maintenance with buprenorphine was much more effective.

While individuals cannot overdose on Suboxone (buprenorphine and naloxone), some individuals will try to "use over Suboxone," but since the naloxone blocks the euphoric effect of the street opiate, the person ends up experiencing respiratory depression without ever feeling "high" and can potentially overdose. He said that buprenorphine worked well for individuals who are compliant and disciplined enough to take medication daily as prescribed. Methadone works well for individuals who need structure and have difficulty with compliance because they

have to report to a clinic on a regular basis, provide a urine sample for analysis, interact with staff, etc.

He expressed concern that buprenorphine is sometimes used to detoxify individuals who have a very limited history of opioid addiction, and then it becomes necessary for them to continue maintenance medication, when they could have possibly been detoxified without buprenorphine or other opiate replacement. He believes that medication assisted treatment should be an option for treatment after other options have failed. However, he indicated that those started on opioid replacement treatment (medication) now will continue for many years.

Delegate O'Bannon indicated that the medical establishment's emphasis on pain management had had the unintended consequence of exposing individuals to opiate pain medications and increasing access to opiates in the community.

Mr. Adcock said that for many years, methadone clinics were found only in the inner city and that it was a profit driven business. Originally buprenorphine was marketed as a medication exclusively for detoxification, but that practitioners found that it wasn't effective unless it was also used for maintenance, for at least some period of time, until the person no longer felt the craving. He said that buprenorphine works well with counseling and that his organization, the Family Counseling Center for Recovery, now refers individuals for whom buprenorphine is indicated out of its system.

In describing how methadone is administered, he said that individuals are assessed, specifically for their level of use, and that federal regulations specify that initial doses be limited to between 30-40 mg per day. The physician observes, with the patient, how effective that dose is with regard to controlling cravings and withdrawal symptoms while also observing for how alert the patient can stay while on the dose. The dose is adjusted until the person achieves maximum functioning and there is no euphoria or craving. The medication is administered as a liquid formulation that the patient drinks in front of clinic staff. The medication is dispensed by an electric pump under the supervision of a pharmacists into a small bottle labeled with each patient's name. Methadone patients have regular interactions with nurses and counselors. Clinics are regulated by the DEA, the Substance Abuse and Mental Health Services Administration, JCAHO or CARF, the Board of Pharmacy and DBHDS. Clinics are required to provide supportive counseling and other services in addition to medication, and the medication is difficult to divert, because it is liquid. Even when patients are stabilized and are permitted to take a supply of medication home, the daily dose is dispensed in individually measured and sealed bottles for each daily dose, so it is easy to see of a dose has been tampered.

The cost of methadone is about $12-$15 per day. Mr. Adcock said that there were issues with insurance payment for methadone treatment. Technically the medication is covered, but because there are so many other costs associated with providing the medication due to federal regulations, it is very difficult to get the treatment covered. Ms. Chamberlain said that some of the patients treated at the Norfolk CSB clinic file a claim annually and are able to get reimbursed.

Mr. Adcock said that as prescription drug abuse wanes, heroin addiction is increasing; he expects that heroin addiction will continue to increase for the next five years. He stressed that medication-assisted treatment should not be the first intervention offered to a person seeking treatment for opioid addiction but that there was considerable financial incentive for private, for-profit providers to use MAT. He also described how patients are cleared to begin taking medication home – that they must have weekly urine toxicology tests that show no drug use. However, he indicated that federal regulations do not require that clinics test for THC (the active substance in marijuana). Once the patient begins taking the medication home, he is subject to "call backs" in which he must bring the medication back in to be checked. It is dispensed as a daily dose in a sealed bottle, so it is easy to tell if a person is using more medication than he is prescribed. He said the cost was about $12-$15 per day, and that his organization also provides individual sessions on a weekly basis and access to acupuncture on a daily basis.

He believes that the group of individuals currently becoming addicted will require long-term medication assisted treatment as they are transitioning from prescription pain medication, which is now harder to access due to implementation of the Prescription Monitoring Program, to heroin, and may use heroin for a long period of time before accessing treatment. He pointed out that methadone treatment has become big business. When Bain Capital owned CRC, they earned $0.27 on every dollar of investment and had just sold CRC off at a large profit. He said that where previous generations had experimented with beer and pot, now youth go from Percocet to heroin. He believes that as marijuana becomes decriminalized in the US, the cartels that used to distribute marijuana will switch to heroin, a drug that had been limited to impoverished sectors of the population but which is now affecting the middle class. He said that he would like to see medication assisted treatment be available to participants in drug courts and to individuals who are incarcerated in local jails.

There was some discussion about the physiological basis of craving and whether or not it is "psychological"; the group discussed and understood that craving is a brain-based physiological component of addiction that medication can address.

Ms. Chamberlain pointed out that the rates and structure for Medicaid reimbursement needs to be revisited; the reimbursement rate for treatment is lower than the rate for case management but requires a higher level of credential.

Mr. Adcock made some suggestions that would increase access to medication assisted treatment.

1. Set-up public/private partnerships between private clinics and CSBs that would allow the private company to operate under the umbrella of a CSB. This would allow the capacity to ebb and flow as demand dictated so that individuals could get treatment when they needed it without a big capital outlay by the CSB.
2. Drug courts should allow individuals to utilize medication assisted treatment.
3. The organization conducting the assessment should not be the same as the system providing care. If a person seeks services from a methadone clinic, most often the clinic will treat him with methadone even if before he has tried to address the addiction with therapy. Medication assisted treatment should be available but it should be reserved for

those who have not been successful at other forms of treatment, because once started, the person will need to continue it for a long time.

4. Many people are able to achieve long-term sobriety without medication after participating in a good jail-based treatment program; more jail-based treatment programs need to be available.
5. The industry is very profit driven and managers lose their jobs if the census dips, so there is no incentive for clinics to detox their patients even when they could be detoxed.
6. Clinics provide minimal case-management and counseling services because these services are time intensive and therefore costly to the industry. More emphasis needs to be placed on these services.
7. Other medications, such as naltrexone/Vivitrol should be available at the methadone clinic sites and should be used prior to putting patients on opiate replacement therapy.
8. Medicaid reimbursement for methadone should be bundled; because it is heavily regulated, it would be difficult to abuse the rates, and would make it easier for providers to bill.
9. Make access to the Prescription Monitoring Program available for probation and parole officers.
10. Increase access to professional education about addiction, such as the ADERP program at VCU.

Ms. Randall then reviewed the steps that are required to establish a methadone clinic in Virginia and said that it could easily take between 12-18 months. She said that DBHDS was beginning to examine if there were internal processes that could be streamlined without reducing oversight or quality. The steps, which she distributed in a handout to the workgroup members present, are as follows:

1- Applicant submits an initial application to DBHDS - Office of Licensing (OL);
2- The OL has 15 days to notify local government and the local community services board (CSB);
3- Within 30 days of receiving notice from the applicant, the local government and the CSB shall submit to the Commissioner comments on the proposed application (half-mile rule and any relevant local ordinances);
4- The applicant sends Policies and Procedures to DBHDS - OL; the Policies and Procedures are reviewed by DBHDS- OL with technical assistance from DBHDS – Office of Substance Abuse Services (OSAS). DBHDS communicates concerns to the applicant; this may involve considerable communication between DBHDS -OL and the applicant, and could take as long as six months.
5- Concurrently, the applicant presents to local human rights committee, which meets quarterly.
6- Once the Policies and Procedures have been preliminarily approved, they are then sent to the local Senior License Specialist who has final approval. Once approved, the Senior Licensing Staff to visit the program site.

7- The applicant notifies (through separate, respective applications) the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Agency (DEA), and the Virginia Board of Pharmacy of its intent to operate.
8- The Board of Pharmacy visits the site.
9- The DEA approves the application, pending licensing by DBHDS.
10- DBHDS – OL issues a license, and the Board of Pharmacy & the DEA issue approval. The DEA communicates with SAMHSA which contacts DBHDS - OSAS for signature of approval.
11- Within about two weeks of SAMHSA receiving DBHDS-OSAS approval, SAMHSA provides certification for the program to order the forms that the program must use to order methadone.
12- The whole process takes approximately one year to complete.

Delegate O'Bannon asked if Virginia had enough OTPs (methadone clinics). Ms. Randall said that the issue was access to any treatment and that OTPs were not well distributed around the state. Also, she indicated that some CSB staff lack knowledge about MAT and are subject to the same stigma as the general public in their attitudes towards MAT. Also, CSBs have difficulty accessing physicians who are knowledgeable about addiction, much less MAT. Ms. Chamberlain said that CSBs lack funding to expand access to MAT.

Overview of the Mental Health Parity and Addiction Act of 2008

In deference to time, the members agreed to postpone an in-depth discussion of parity for another meeting. Delegate O'Bannon said that he had been in contact with the Bureau of Insurance at the State Corporation Commission and that its staff had promised to check on the status of implementation of the legislation.

Discussion of Initial Recommendations to the Task Force

Delegate O'Bannon asked each member to provide no more than three recommendations for consideration.

Art Van Zee, M.D.:

(1) Support Senator Markey's Legislation related to the provision of buprenorphine to treat opioid addiction
(2) In order to expand access to treatment, additional funds will be needed; explore the use of the Tobacco Indemnification Fund to support treatment services in the southwestern part of the state because it has been disproportionately affected.
(3) Explore using resources garnered through asset forfeiture to support treatment. Ms. Schrad pointed out that this would be difficult as the federal government controls assets forfeited to it in federal cases and the state system is modeled after the federal system.
(4) Use the PMP to profile "outlier" prescribers for review by the Board of Medicine

Nancy Finch:

(1) Bring back SABRE (Substance Abuse Rehabilitation and Education), a specific fund briefly available in early 2000's, that was dedicated to supporting treatment for young nonviolent offenders.
(2) If marijuana is legalized, any tax revenues that result should be dedicated to treatment.
(3) Expand Medicaid eligibility and make sure that coverage for substance abuse treatment is addressed.

Duffy Ferguson:

(1) Assure that providers of medication-assisted treatment are utilizing best practices that include case management to help individuals access other needed wrap-around services.
(2) Provide services to adolescents in settings that are part of their natural system

Dana Schrad:

(1) Provide more treatment to individuals while they are incarcerated in local jails, as this is often a critical point in their lives.
(2) Fund drug courts to provide intensive supervision for their participants

[Dr. McMasters and Mr. Adcock reinforced the point that coerced treatment that provides close supervision and evidence-based practices is just as effective as voluntary treatment; Ms. Finch suggested that the workgroup provide information about the cost-effectiveness of treatment.]

Lillian Chamberlain:

(1) Require health insurance plans to provide adequate coverage for treatment including MAT
(2) Enhance relationships between CSBs and other treatment providers with local community corrections and state Probation and Parole to include access to MAT, with the result that these organizations will be less "siloed"

Jan Brown:

(1) Provide access to MAT with counseling and other supports
(2) Improve the knowledge base of the workforce at CSBs regarding use of MAT

Chief Mary Gavin:

Chief Gavin said that she had been impressed by the family stories in the New Jersey report that had been distributed to workgroup members and suggested that the Virginia report include similar information. She also said that she is concerned about how easy heroin is to get.

(1) Increase access to jail-based treatment
(2) To reduce stigma among law enforcement, provide education for law-enforcement regarding addiction being a brain-based disease

Senator Jennifer Wexler:

(1) Increase opportunities for jail-based treatment and increase opportunities for diversion from jail, especially where overdose incidents are concerned.

Senator Wexler went on to say that jail is not a good place to detox and that pre-trial is not currently equipped to address treatment needs. The six to eight weeks between arrest and arraignment could be used to provide intensive supervision and treatment.

(2) Allow state and local probation officers to access the PMP for the clients under their supervision.
(3) Allow individuals with charges such as theft and prostitution that are related to their drug use to access drug treatment courts

Delegate John O'Bannon:

(1) Expand use of the PMP
(2) Expand use of naloxone administered by lay rescuers to statewide; allow first responders to carry and use naloxone; and provide criminal immunity for individuals who call 911 in the course of reporting an overdose
(3) Address discrepancies in Medicaid related to reimbursing providers for substance abuse treatment services.

Dr. Kirkwood:

(1) Require pharmacists to check the PMP before dispensing at-risk medication
(2) Examine the use of a "lock-in" program for Medicaid recipients (restricts Medicaid beneficiaries to one prescriber for at-risk medications)

Chuck Adcock:

Mr. Adcock said that more funding is necessary for access to treatment to improve.
(1) Explore forming partnerships between private and public sector providers and require private OTPs to dedicate a certain proportion of their treatment to indigent care
(2) Expand access to naloxone
(3) Explore how peer-providers can be utilized in the criminal justice system and how peers could connect individuals to treatment in overdose situations
(4) Mandate use of the PMP

Mary McMasters, M.D.

(1) Establish and enforce a standard of care for buprenorphine
(2) Have board certified addictionologists teach in public university medical schools.

Patricia Shaw:

(1) Fund drug courts; only 14 of the drug courts receive funding
(2) Provide education and training to the medical profession about how to provide medical treatment for individuals with addiction (e.g., pain management).

Deputy Secretary Jennifer Lee, M.D.:

(1) Provide education for physicians already in practice about pain management and identifying individuals at risk of developing addiction

Dr. Lee pointed out that the executive order that established the task force also required that some metrics for success be identified; this might be numbers of individuals receiving treatment and some measure of availability, such as a ratio of providers to population.

Mellie Randall:

(1) Improve the knowledge of the CSB workforce about how to treat opioid addiction.

Wrap-Up and Next Steps

The next meeting of the whole task force is December 16 at the Patrick Henry Building in Richmond. The workgroups will meet on that day prior to the task force meeting and will receive a notice.

Delegate O'Bannon adjourned the meeting.