**Executive Order Number 29**
**Governor's Task Force on Prescription Drug and Heroin Abuse**
**Minutes of the Treatment Workgroup**
**March 19, 2015**
**Patrick Henry Building**
**10:00 A.M.**

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

**Members Present:**
Chuck Adcock
Jaime Areizaga-Soto
Jan Brown
Nancy Finch
Cynthia Kirkwood, PharmD
Deputy Secretary Jennifer Lee, M.D.
Hughes Melton, M.D.
Sheriff Gabe Morgan
Delegate John O'Bannon, M.D.
Patricia Shaw
Art Van Zee, M.D.
Senator Jennifer Wexton

**Members Absent**
Lillian Chamberlain
Chief Mary Gavin
Mary McMasters, M.D.
Debra Ferguson, Ph.D.
Duffy Ferguson
Diane Strickland
Dana Schrad

**Staff**
Mellie Randall
Holly Mortlock

**Guests**

**Welcome and Introductions**
Dr. Lee convened the meeting at 10:00. After introductions, she reviewed the agenda which was approved by the workgroup.

**Review of Legislation**
Dr. Lee reviewed legislation related to the Task Force that had been introduced in the 2015 Session of the General Assembly. (Attached).

HB1458 introduced by Delegate O'Bannon, was passed. This bill makes access to naloxone administered by lay rescuers available statewide. It builds on a pilot currently administered by DBHDS (REVIVE!) that has been implemented in metropolitan Richmond and the far southwestern part of the state. The bill provides civil immunity for prescribers, lay rescuers, law enforcement and firefighters and allows pharmacists to dispense naloxone under a protocol to be developed by the Virginia Department of Health. Dr. Lee explained that the pilot had identified that having to have a licensed prescriber write the prescription had been found to be a barrier in the pilot project as it not only added an extra step and time to the process but also added expense for the lay rescuer. Ms. Randall displayed the kit that lay rescuers receive after they have been training and explained the components of the kit. She also said that the cost of naloxone had doubled since the pilot had begun in June 2014. She explained that the naloxone used in the pilot

was dispensed in a pre-filled syringe to which a mucosal atomizer device (part of the kit) was attached so that the medication could be administered nasally. She said that this formulation of naloxone is not approved by the FDA to be administered nasally but that most lay-administered naloxone projects use the nasal method with good results. She said that one naloxone product had been approved by the FDA in an auto-administration device but that it was extremely expensive, and that another product was in the FDA pipeline that would be manufactured with the nasal spray device already attached, but that the price was, as yet, unknown.

HB1810 protects data collected by the Prescription Monitoring Program (PMP) from being subpoenaed for use in a civil action, such as divorce proceedings or child custody cases. In addition, this protection is required for the Virginia to participate in interoperability (data sharing) agreements with PMPs in other states.

HB1841 builds on legislation introduced (but failed) last year that tied registration to use the PMP with biannual licensure renewal. This bill, which was passed, provides for mass registration for all licensed prescribers without waiting for licensure renewal. The bill also requires pharmacists to register so that they can query the PMP when they are filling prescriptions. Finally, the bill requires prescribers to check the PMP if they are writing a prescription for a scheduled medication that will be used longer than 90 days.

HB 1738 passed and was introduced by Delegate Hodges, a member of the Task Force. It requires hospices to notify the pharmacist of record when a patient dies. Delegate Hodges, who is a pharmacist, introduced this legislation to prevent other people from attempting to refill prescriptions of deceased individuals. It will be enforced by the Virginia Department of Health in the process of licensing hospices.

HB1500 (Carr) passed and provides an affirmative defense to individuals who report overdoses to emergency medical services or the police and stay with the victim until emergency services arrives. This legislation came about because many individuals who witness overdoses are afraid to call emergency services for fear of being prosecuted and convicted of possession of an illegal drug or paraphernalia. This bill provides a defense for individuals who report overdoses and stay with the victim.

Several bills related to the Task Force failed. These include HJ622, introduced by Sen. Herring, which called for a study of treatment services necessary to divert individuals from jail. The bill failed due to lack of funding.

SB1035, introduced by Senator Wexton, proposed to make distribution of a Schedule I or II drug that resulted in death within 48 hours eligible for prosecution as second degree murder unless the distribution without consideration or distributed without intent to induce addiction or dependence. The bill died in the Finance Committee.

**Medication Assisted Treatment (MAT)**
Dr. Lee reflected that the workgroup had spent considerable time learning about how medication assisted treatment using either methadone, buprenorphine or naltrexone, in conjunction with counseling and support services, is the evidence-based approach to treating opioid addiction.

Dr. Lee asked the workgroup to consider whether to recommend to the full task force that it adopt or endorse a general statement in support of MAT. This idea was proposed by a member of the full task force, Don Flattery, who felt that an "abstinence only" approach and insistence by a treatment center that they detox his son from Suboxone may have contributed to his relapse and ultimate death.

Ms. Randall suggested that the workgroup consider the National Association of State Alcohol and Drug Abuse Directors (NASADAD) policy statement on MAT. After reviewing the statement, Dr. Lee asked members of the workgroup to consider whether or not to recommend that the full task force adopt the state adopt this statement in whole or in part, or to develop its own position statement. Sheriff Morgan said that he supported the statement with reservations due to ongoing problems with diversion of buprenorphine. He said that some prescribers are not providing adequate counseling.

Dr. Melton said that prescribers tend to fall into two groups; either they are prescribing too high a dose of buprenorphine or they stop prescribing abruptly, leading the addicted person to return to using opioids illegally.

Dr. Van Zee indicated that some physicians prescribe too high a dose and the patients divert what they don't use so that they can afford to continue to get the prescription. Dr. Melton said that in some cases, buprenorphine has become the fast food industry of substance abuse treatment. He said that in some cases, these practices are not even owned by physicians but by nonmedical entrepreneurs who hire physicians to prescribe buprenorphine. He said that in some cases, the business owners mislead the physicians about the counseling and supports that the business is offering the patients.

Ms. Randall pointed out that unlike methadone clinics, which are regulated by multiple federal and state agencies, buprenorphine by design is administered in a physician's office and is prescribed with very little oversight unless the physician has drawn the attention of the DEA. She suggested that the Task Force ask the Board of Medicine to address the issue. Dr. Melton suggested that prescribers would respond to standards of care, even if they were not regulatory. He also suggested that focusing on the owners of the business or the business license of these prescribers might provide leverage.

Mr. Adcock expressed concern that methadone clinics were located in clusters without regard to need. Dr. Lee wondered whether utilizing Certificate of Public Need for methadone and buprenorphine might help address this. Ms. Randall indicated that it would be difficult to apply COPN to buprenorphine as it was prescribed as a part of private physician practices. She said that there is not a complete list of physicians who are waivered to prescribe buprenorphine; the SAMHSA list is voluntary.

Dr. Van Zee expressed support for standards of care for buprenorphine that included appropriate dosing.

Delegate O'Bannon indicated applying COPN could get very complicated but that the PMP would be a resource. He suggested that the Boards of Medicine and Pharmacy could identify outliers if standards of practice were developed. The standards would focus on treatment supports and appropriate dosing.

Ms. Shaw indicated that many drug treatment courts have not permitted medication assisted treatment, however, federal grants are now requiring access to MAT and the National Association of Drug Treatment Courts has issued a statement in support of MAT.

Dr. Lee highlighted the concluding paragraph of the NASADAD statement and asked if the workgroup members could support that particular segment of the policy statement. The workgroup agreed to endorse the statement.

Mr. Adcock pointed out that even national treatment programs, such as Hazelden, that had been traditionally abstinence oriented, were now utilizing MAT.

Dr. Van Zee shared that some insurance plans require physicians to submit tapering plans.

Dr. Melton said that Standards of Care could take two approaches: to establish requirements or to make statements to encourage physicians to adhere to standards.

Mr. Areizaga-Soto thanked Delegate O'Bannon for his work on HB1458.

Dr. Lee said that she would discuss with Dr. Brown (Director of the Department of Health Professions) the development of standards of care for the use of buprenorphine to treat addiction.

Delegate O'Bannon suggested that the strategy focus on education, promoting standards of care, and use of the PMP to monitor buprenorphine prescriptions. He suggested that Reckitt Benckiser, the initial manufacturer of buprenorphine (Subutex® and Suboxone®) be engaged to possibly help support education of prescribers.

**Insurance Parity**

Ms. Randall introduced Holly Mortlock, Director of Policy, DBHDS, and said that she had helped her develop the presentation (attached ) explaining the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008. The regulations pertaining to this legislation were finally promulgated in 2013. There was considerable discussion about the difficulty of understanding the regulations. The underlying principle of the legislation is that if a health plan is covering certain types of physical health care, it must provide the same type of behavioral health care. Although MHPAEA does not mandate behavioral (mental health and substance use disorder) benefits, behavioral health care is included as one of the ten essential health benefits in the legislation. Ms. Mortlock pointed out the Delegate O'Bannon had introduced legislation (HB1747) that required plans operating in Virginia to comply with MHPAEA; requires that group and individual plans provide mental health and substance use disorder benefits; requires

that these benefits be offered in parity with benefits for medical/surgical services, even where those requirements would not otherwise directly apply; and requires the Bureau of Insurance to develop reporting requirements addressing denied claims, complaints and appeals and compile them into an annual report.

**Recommendations to the Task Force**
As the Task Force needs to complete its work by the end of June, Dr. Lee suggested that the workgroup begin drafting its recommendations for consideration (attached). The workgroup will continue to review and refine these at its next meeting.

**Adjournment**
Dr. O'Bannon adjourned the meeting at noon.

Respectfully submitted,

Mellie Randall

## Prescription Drug and Heroin Abuse Task Force Bill Tracker

| Bill Number | Patron | Summary | Committee | Docket Time |
|---|---|---|---|---|
| **HB1458**[1] | O'Bannon | Naloxone administration in cases of opiate overdose. Authority for trained lay people, law enforcement, firefighters to possess and administer. No liability for proper administration. Pharmacists can dispense w/o Rx but according to standard protocol | House Committee on Health, Welfare and Institutions | •Jan. 29; Reported from Health, Welfare and Institutions with substitute 22-Y 0-N<br>•Jan. 30; First reading<br>•Feb. 2; Second reading<br>•Feb. 3; Third reading and passed House Block Vote (98-Y 0-N)<br>•Feb.4; Constitutional Reading Dispensed, Referred to Senate Committee on Education and Health |
| **HB1810** | Herring | Prescription Monitoring Program information not available for subpoenas | House Committee for Courts of Justice; Civil Law Subcommittee | •Jan. 26; Subcommittee Recommended Reporting (10-Y 0-N)<br>•Feb. 4; Courts of Justice Reported (20-Y 0-N)<br>•Feb. 6; First reading<br>•Feb. 9; Second reading and engrossed<br>•Feb. 10; Third reading and passed House Block Vote (100-Y 0-N) |
| **HB1841** | Herring | Prescription Monitoring Program registration requirement for dispensers and prescribers | House Committee on Education and Health | •Jan. 22; Subcommitee Recommended Reporting with Amendments (10-Y 0-N)<br>•Jan. 27; HWI Committee Reported with Substitute (22-Y 0-N)<br>•Jan. 28; First reading<br>•Jan. 29; Second reading, engrossed by house<br>•Jan. 30; Third reading and passed House Block Vote (96-Y 0-N) |

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| | | | | •Feb. 2; Constitutional Reading Dispensed, referred to Senate Committee on Education and Health |
| **HB1738** | Hodges | Requiring hospices licensed by VDH or exempt from licensure to notify pharmacies that dispensed drugs to hospice patients for pain management of the patient's death within 24 hours. | House Committee on Health, Welfare and Institutions; HWI Subcommittee #1 | •Jan. 26; Subcommittee Recommended Reporting with Amendments (11-Y 0-N)<br>•Jan. 29; Reported from HWI with substitute (22-Y 0-N)<br>•Jan. 30; First reading<br>•Feb.2; Second reading, engrossed by House<br>•Feb. 3; Third reading, passed House Block Vote (98-Y 0-N)<br>•Feb. 4; Constitutional reading dispensed, Referred to Senate Committee on Education and Health |
| **HJ622** | Herring | Study of diversion programs for certain drug offenders | House Committee on Rules | •Jan. 29; Recommended laying on the table by voice vote |
| **SB1035** | Wexton | Establishing 5-40 year penalty for felony homicide in violation of a felony drug offense. | Senate Committee of Courts of Justice | •Jan. 26; Committee Reported from Courts of Justice with Substitute (14-Y 0-N), Rereferred to Finance<br>•Feb. 3; 9 am in Senate Room B |
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| [1] **(Related Bill)** HB1732 | Hodges | Dispensing and administration of naloxone or other opioid antagonists | House Committee for Courts of Justice; Civil Law Subcommittee | •Feb. 4; Stricken from docket by Courts of Justice by voice vote |
| HB1833 | Gilbert | Naloxone administration by law-enforcement officers | House Committee for Courts of Justice; Civil Law Subcommittee | •Feb. 4; Subcommittee Recommended Reporting (10-Y 0-N)<br>•Feb. 6; Reported from |

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| | | | | Courts of Justice with amendments (22-Y 0-N)<br>•Feb. 7; First reading<br>•Feb. 9; Second reading, Committee amendments agreed to, Engrossed to House as amended<br>•Feb. 10; Third reading and Passed House Block Vote (100-Y 0-N) |
| HB1647 | Miller | Reporting of medical aid or treatment for drug overdoses | House Committee for Courts of Justice; Criminal Law Subcommittee | • Feb. 4; Subcommittee Recommended laying on the table by voice vote. |

NASADAD

## National Association of State Alcohol and Drug Abuse Directors, Inc.
## Consensus Statement on the Use of Medications in Treatment of Substance Use Disorders

Numerous studies have shown the effectiveness of including medication in the treatment of some individuals with substance use disorders. For years, there has been limited use of medications for the treatment of substance dependence. Today, however, public and private health insurance plans are including (or at least considering) coverage of medication services along with psychosocial interventions for treatment of substance use disorders. A growing body of research substantiates that the use of FDA-approved medications can play an important role in the treatment of substance use disorders, especially for people with alcohol, opioid, or nicotine dependence, with continued research being done on medications for other substance use disorders. These studies demonstrate the efficacy of treating addiction as a chronic disease.

A review of current standards and principles of effective treatment demonstrates that:

- Dependence on alcohol and drugs is a complex but treatable disease that affects brain function and behavior.[1]
- No one treatment protocol is appropriate for everyone.[2]
- For some individuals, use of medication is recommended as a recovery tool.[3]
- Where clinically appropriate, use of medication as a recovery resource should be utilized as an adjunct to other treatment services.
- Medications such as methadone, buprenorphine, and naltrexone (both oral and extended release injection) have been shown to reduce opioid use; and naltrexone, disulfiram, and acamprosate have been shown to be effective in the treatment of alcohol dependence. The appropriate use of these medications allows individuals to experience sustained recovery from opioid and alcohol dependence, including through long-term management using medication maintenance. They should be made available to individuals who could benefit from them.[4][5][6][7][8]
- It is recommended that any medication assisted treatment be combined with psychosocial and behavioral strategies that are clinically matched to the severity of the individual's addiction.
- Longitudinal studies show that treatment initiated in the criminal justice system and continued in the community garners lasting reductions in criminal activity and drug abuse. This includes medication-assisted treatment (e.g., methadone, buprenorphine/naloxone, and injectable naltrexone) for some prisoners with opioid dependence.[9]

Additionally, the National Quality Forum's "National Voluntary Consensus Standards for the Treatment of Substance Use Conditions: Evidence-Based Treatment Practices (p.VII)"[10] recommends that pharmacotherapy should be made available to all adult patients diagnosed with opioid dependence, alcohol dependence, and nicotine dependence, as long as there are not medical contraindications.

Finally, the American Society for Addiction Medicine (ASAM) has taken an affirmative position on the use of medications for the treatment of alcohol use disorders in their ASAM Patient Placement Criteria: Supplement on Pharmacotherapies for Alcohol Use Disorders.[11]

**Conclusion:** Individuals seeking treatment for substance use disorders should be educated about all treatment options, including the use of medications, so that they may make informed decisions about their care. For some people, medication will be unnecessary. For others, it may be a helpful tool for recovery. For still others, medication will be a crucial component of treatment without which the prognosis for recovery is very poor. In all cases, the use of addiction medications should be considered and supported as a viable treatment strategy in conjunction with other evidenced based practices and as a path to recovery for individuals struggling with substance use disorders. In addition, NASADAD recommends that public and private health insurance plans cover medications for the treatment of opioid, alcohol, and nicotine dependence.

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[1] NIDA (2009). Principles of drug addiction treatment: A research-based guide (2nd ed.). Retrieved from http://www.drugabuse.gov/publications/principles-drug-addiction-treatment
[2] NIDA (2009). Principles of drug addiction treatment: A research-based guide (2nd ed.).
[3] NIDA (2009). Principles of drug addiction treatment: A research-based guide (2nd ed.).
[4] NIDA (2009). Principles of drug addiction treatment: A research-based guide (2nd ed.).
[5] Center for Substance Abuse Treatment. *Incorporating Alcohol Pharmacotherapies Into Medical Practice*. Treatment Improvement Protocol (TIP) Series 49. HHS Publication No. (SMA) 12-4380. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2009.
[6] Substance Abuse and Mental Health Services Administration. (2012). An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People With Opioid Dependence. Advisory, Volume 11, Issue 1.
[7] McNicholas, L. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction: A treatment improvement protocol (TIP 40). Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, 2004.
[8] Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 05-4048. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.
[9] NIDA (2010). Addiction and the criminal justice system. Retrieved from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=22
[10] National Quality Forum (2007). National voluntary consensus standards for the treatment of substance use conditions: Evidence-based treatment practices. Retrieved from http://www.rwjf.org/files/research/nqrconsensusreport2007.pdf
[11] American Society of Addiction Medicine (2010). ASAM patient placement criteria: Supplement on pharmacotherapies for Alcohol Use Disorders.

Virginia Department of Behavioral Health & Developmental Services

# Mental Health Parity and Addiction Equity Act of 2008

Presentation to the
Treatment Workgroup of the
Governor's Task Force on Heroin and Prescription Drug Abuse

Mellie Randall
Director
Office of Substance Abuse Services

March 19, 2015

# BACKGROUND

- Mental Health Parity Act (1996)
- Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA, 2008)
- Patient Protection and Affordable Care Act (2010)

# REGULATORY ACTION

- MHPAEA regulations ~ November 2013
  - Covers group health plans med/surg benefits and MH/SUD benefits
  - Insurance offering health insurance for MH or SUD benefits with group plan AND individual health coverage

# Regulatory Action

## Exemptions

- "Small employers" ~ 50 or fewer OR employers of 100 employees for non-Federal governmental plans. Exception: Fully-insured group plans must comply with MHPAEA
- Self-funded non-Federal governmental plans can "opt-out."

# Regulatory Action

MHPAEA includes behavioral health (MH & SUD) services as one of the ten essential health benefits but does not mandate benefits

# Classification of Benefits

- Emergency Care
- Prescription Drugs
- Inpatient, in-network
- Outpatient, in-network
- Inpatient, out-of-network
- Outpatient, out-of-network

# Classification of Benefits

- Intermediate care must be consistent between med/surg and MH/SUD and placed in the same classification for both.
- If MH/SUD are provided in any classification, it must be provided in every classification in which med/surg benefits are provided
- Classifications can be subdivided (e.g., outpatient could include 1:1 and IOP)
- In-network classifications can also be subdivided if the plan has multiple network tiers if the tiers are based on reasonable factors without regard to med/surg or MH/SUD.
- Cannot classify based on generalist/specialist.

# Financial Requirements and Quantitative Treatment Limitations

Financial requirements and quantitative treatment limitations cannot be not more restrictive than predominant requirements or limitations applied to substantially all medical surgical benefits.

Cannot be more restrictive for MH/SUD in any classification than to med/surg

# Definitions and Examples

- Quantitative Treatment Limitations:
  - Limit on the amount of service
- Nonquantitative Treatment Limitation:
  - Medical management standards
    - Medical appropriateness
    - Medical necessity
  - Formulary
  - Provider standards
  - Methods for determining fees
  - Fail first policies
  - Exclusion due to failure to complete treatment

# Financial Requirements and Quantitative Treatment Limitations

- Predominant financial requirement
- Substantially all
  - Applies to at least 2/3 of all med/surg benefits in that classification
- Group health plans cannot accumulate requirements or limitations separately in a classification.

# Nonquantitative Treatment Limitations (NQTLs)

- Must be the same for both med/surg and MH/SUD
  - Medical management standards
  - Formulary
  - Provider standards to participate in a network (including rates)
  - Method for determining Usual and Customary and Reasonable Charge
  - "Fail first" policy
  - Exclusion due to failure to complete treatment
  - Coverage restrictions that limit the scope or duration of benefits

# Availability of Plan Information Required To Be Available

- Criteria for medical necessity determinations for MH/SUD benefits
- Reason for denial of reimbursement or payment for services for MH/SUD
- Reasonable access to and free copies of all documents, records other information relevant to claim

# MHPAEA and State Mandates

State insurance laws requiring parity or mandating coverage for MH/SUD benefits is not pre-empted unless a barrier to MHPAEA

# MHPAEA and State Mandates

## Enforcement

- State insurance commission – primary for group and individual
- U.S. Health and Human Services – secondary
  - If state not enforcing
  - With nongovernmental plans
- U.S. Dept of Labor – group health
- IRS - employers and church plans

# Mental Health Parity in Virginia

- Virginia mental health parity law
  - §38.2-3412.1 Coverage for mental health and substance abuse services
  - §38.2-3412.1:01 Coverage for biologically based mental illness

# Mental Health Parity in Virginia

- House Bill 1747 (2015) – Health insurance; mental health parity (Del. O'Bannon)
  - Conforms state requirements to provisions of MHPAEA (2008)
  - Requires that group and individual plans provide MH/SUD benefits
  - Requires that MH/SUD benefits be in parity with med/surg even where those requirements would not otherwise directly apply
  - Requires the Bureau of Insurance (SCC) to develop reporting requirements and compile into annual report
    - Denied claims
    - Complaints
    - Appeals

# Next Steps?