ADHD Prevalence and Risks of ADHD Medications in Virginia Final Report

Joint Commission on Health Care
June 15, 2018 Meeting

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Study Mandate

HB1500, Item 30(A), requested that JCHC identify methods:

1. To raise awareness of health/addiction risks of Attention Deficit Hyperactivity Disorder (ADHD) medication use
2. To compile/track statistics on Virginia school children diagnosed with ADHD or other categories such as “specific learning disabilities, other health impairment, multiple disorder, and emotional disturbances”
3. Used by other states/countries to limit antipsychotic use
4. To identify the incidence/prevalence of prescribing anti-psychotics for off-label use

The analysis shall be reported by the JCHC to the Chairmen of the House Appropriations and Senate Finance Committees no later than November 30, 2018

Interim Report Summary – ADHD

- Variations in prevalence of ADHD across countries, States and populations likely reflect a combination of inherent differences, differing diagnostic criteria – including multiple changes over time in the DSM criteria – and schooling factors.
- Untreated ADHD is associated with sizeable adverse impacts to individuals and society.
- While there is consistent evidence that 1st-line ADHD medication treatment reduces ADHD symptoms in the short-term, its longer-term effectiveness is not as well-established. Additionally, there is well-documented evidence that ADHD stimulant use can have adverse short-term health side effects, but implications on longer-term health is more uncertain.
- Data from Virginia suggest that ADHD prevalence and medication use are largely in line with national trends.
- Misuse of ADHD stimulants may be sizeable among some populations (e.g., college-aged individuals), although there is little evidence of addiction to stimulants.

Interim Report Summary – Antipsychotics

- Conditions for which atypical antipsychotics (AAPs) are FDA-approved co-occur at elevated rates with ADHD, and ADHD is one of the most common mental health diagnoses among youth prescribed AAPs.
- Off label use of AAPs has increased over time, and there is evidence that a significant percentage of ADHD-diagnosed youth (e.g., 20%) are prescribed AAPs off label.
- Concerns since the 2000s have been raised in the US about the use of AAPs among foster populations. Recent quality data from Virginia suggest that practices are favorable compared to the general Medicaid population (e.g., lower multiple concurrent antipsychotic use).

ADHD and AAP Data in insured populations – Virginia

- ADHD
  - Diagnosed prevalence (commercial health insurance/Medicaid populations): 7% - 8% of individuals <20 (3% of individuals 20+)
  - ADHD medication treatment (commercial health insurance/Medicaid populations): 4% - 7% of enrolled individuals <20 years old were prescribed ADHD medication (1% - 2% of adults 20+)
- Off label use of AAPs*
  - Commercial health insurance markets: Of the approximately 29,000 individuals prescribed AAPs (2014-2015), 31% did not have a FDA-indicated diagnosis for the prescribed AAP
  - Medicaid population: Of approximately 69,000 individuals prescribed AAPs (2015-2017), 56% did not have a FDA-indicated diagnosis for the prescribed AAP

* Data relate to all individuals prescribed AAPs, not just individuals diagnosed with ADHD

Virginia ADHD Diagnosis Policies – DOE

- Virginia Code §22.1-298.1 requires completion of study in ADHD to obtain an initial teacher licensure
  - DOE has added ADHD content to professional studies requirements for both school personnel and education programs
- Virginia Code §22.1-298.4 mandates that DOE, in collaboration with SCHEV, require all teacher preparation programs offered at public institutions of higher education to convey information on the identification of students at risk for learning disabilities, including ADHD
  - DOE plans to require documentation about inclusion of the competencies

Virginia ADHD & Psychotropic Medication Policies – DOE

- School personnel are permitted to administer prescription medicines – including psychotropic medications – to students
- Virginia Code §22.1-274.3 requires DOE to develop and implement policies prohibiting school personnel from recommending the use of psychotropic medications for students
  - Almost all Virginia school divisions have documented/written policies
  - Nationally, 4 other States have similar policies (CT, CO, OR, TX)

Virginia ADHD & Psychotropic Medication Policies – DMAS

- Service Authorizations (SAs) for psychotropic medications are required for fee-for-service (FFS) population
  - ADHD medications/stimulants: children outside of FDA-approved age range; adults 18+
  - Antipsychotics: children <18 years old
    - Medication must be prescribed by a psychiatrist/neurologist or prescriber must supply proof of a psychiatric consultation
    - Member must be participating in a behavioral management program
    - SA Duration: 6 months
- SA requirements for Managed Care Organization (MCO) population are consistent with FFS requirements
- Under Medallion 4.0, MCO health plans are required to adopt the FFS Preferred Drug List, including accompanying SA requirements (“Common Core Formulary”)

Virginia ADHD & Psychotropic Medication Policies – DSS

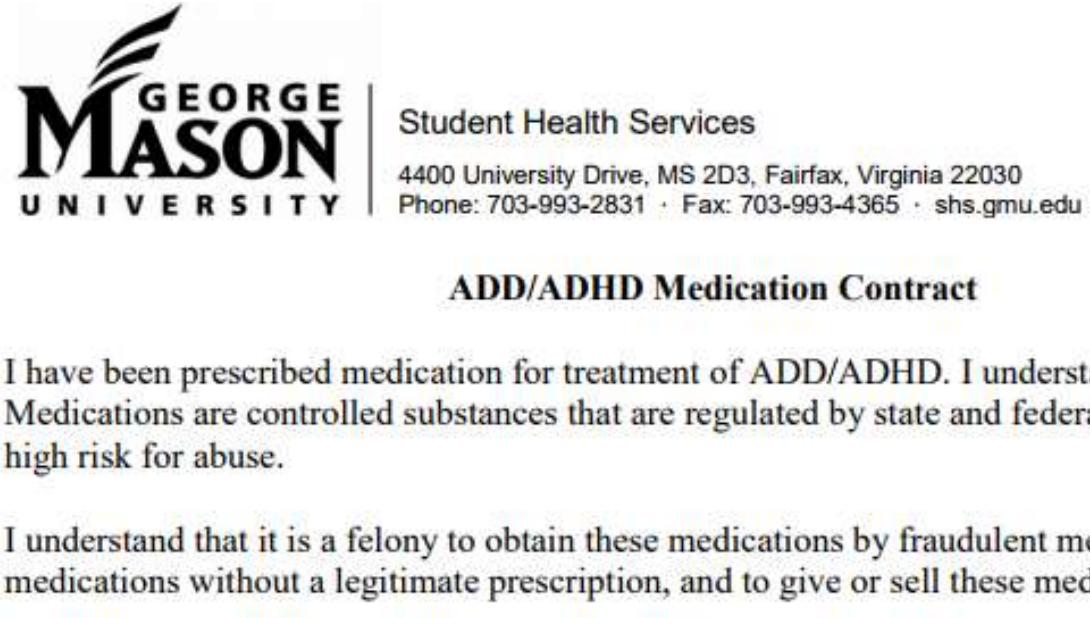
- In recent years, DSS has increased monitoring of psychotropic prescribing practices for foster youth by:
  - Working with DMAS to increase level of medical oversight and implement review process to monitor off label use of psychotropic/AAPs for children
  - Raising awareness of issue among caseworkers (e.g., e-learning on psychotropic medications; screening tools for trauma) and modification of case worker database in 2016 to track foster youth medical/prescription history
    - However, data are currently entered manually by caseworkers and not synchronized with DMAS data

Methods to Raise Awareness of ADHD Medications Risks/Addiction Potential

- General public
  - FDA safety communications on ADHD medications (e.g., “Permanent loss of skin color may occur” (2015))
  - FDA label (“black box”) warnings on ADHD medications:
    - E.g., Amphetamines: have a high potential for abuse; administration for prolonged periods of time may lead to drug dependence and must be avoided; misuse may cause sudden death/serious cardiovascular adverse events

Methods to Raise Awareness of ADHD Medications Risks/Addiction Potential (2)

- Providers
  - Insurer guidelines to prescribers (e.g., provision of information on FDA black box warnings)
- College/University setting
  - ADHD Medication Contract. For example:



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ADD/ADHD Medication Contract

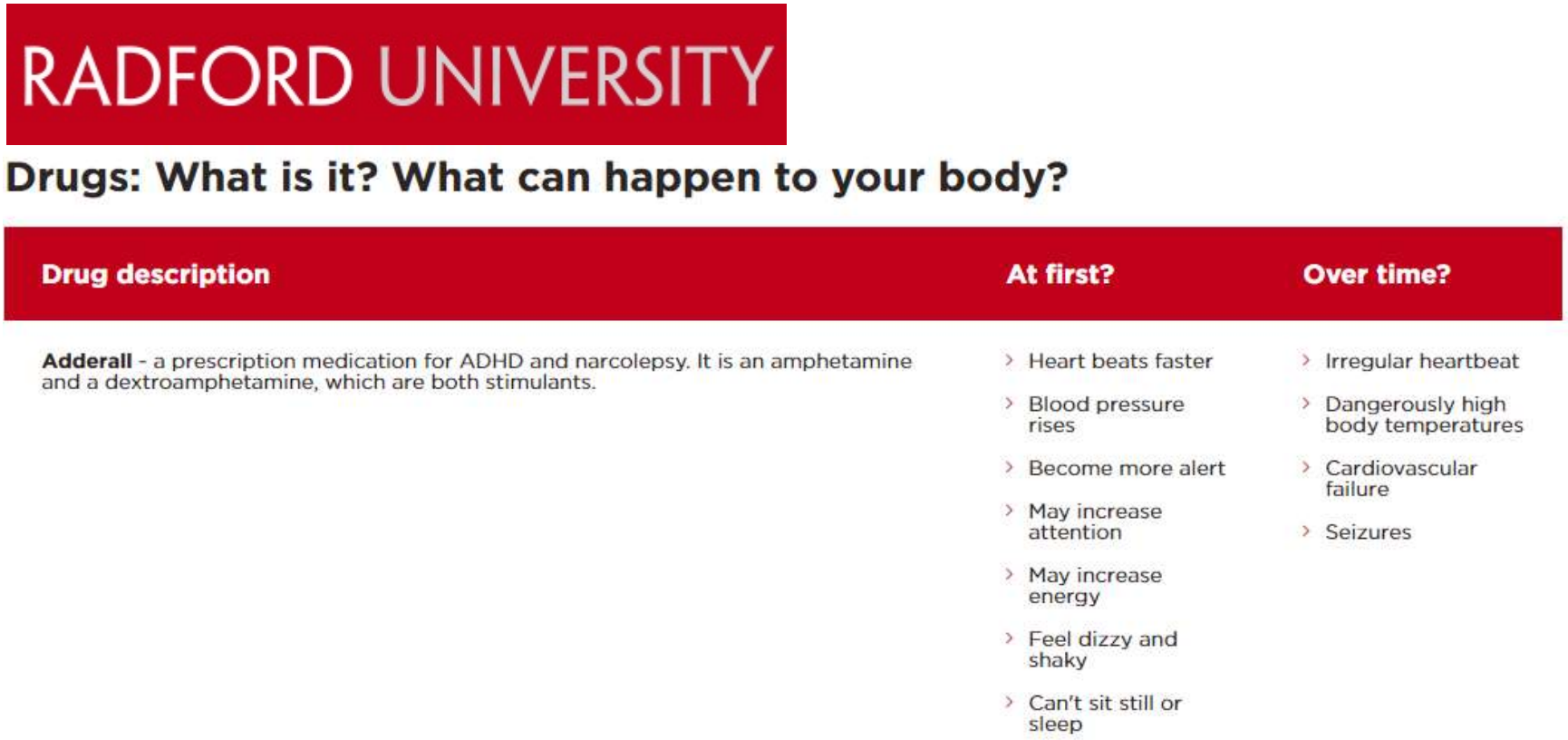
I have been prescribed medication for treatment of ADD/ADHD. I understand that ADD/ADHD Medications are controlled substances that are regulated by state and federal law because of their high risk for abuse.

I understand that it is a felony to obtain these medications by fraudulent means, to possess these medications without a legitimate prescription, and to give or sell these medications to others.

Source: https://shs.gmu.edu/wp-content/uploads/2013/07/ADD-ADHD-Contract-2.pdf

Methods to Raise Awareness of ADHD Medications Risks/Addiction Potential (3)

- College/University setting
  - Information on drug risks. For example:



RADFORD UNIVERSITY

Drugs: What is it? What can happen to your body?

Drug description	At first?	Over time?
Adderall - a prescription medication for ADHD and narcolepsy. It is an amphetamine and a dextroamphetamine, which are both stimulants.	› Heart beats faster › Blood pressure rises › Become more alert › May increase attention › May increase energy › Feel dizzy and shaky › Can't sit still or sleep	› Irregular heartbeat › Dangerously high body temperatures › Cardiovascular failure › Seizures

Source: https://www.radford.edu/content/saves/home/substance-abuse/drug-use.html

Methods to Track ADHD Diagnosis Statistics in Schools

- Some States collect statistics on ADHD diagnoses through data collection collaborations between State health and education agencies. However:
  - Data collection methods vary between States/school divisions within States, with most relying on parent-reported information provided in IEPs, Section 504 plans and/or school entrance forms
  - Data consistency and/or quality are unknown
- Virginia's DOE estimates that establishing an ADHD diagnosis data collection system for Virginia public school children:
  - Would incur a one-time investment cost of $2.9M and annual recurrent costs of $81.2K
  - Would be operational in 2 years and be able to produce reports in 3 years
  - Would encounter similar data quality/consistency uncertainties as in other States

Methods to Identify Off-label Prescribing of Antipsychotics for ADHD

- Diagnosis is not required on pharmaceutical claims, making it difficult to track off-label prescribing of AAPs with certainty
- Due to methodological challenges, DMAS has not been able to endorse a methodology that would be able to produce public use information in tracking off label prescribing of AAPs based on claims data

Methods Used by Other States/Countries to Limit Antipsychotic Use

- Nationally, common methods to limit/ensure appropriate use of AAPs and/or ADHD medications

Method	Use in Virginia
• Service authorization (SA)	• Used for both ADHD and AAPs • DMAS' current antipsychotic SA does not collect information on metabolic monitoring
• Provider peer review	• Used on case-by-case basis for FFS/MCO populations
• Drug Utilization Review (DUR)	• DUR Board meets quarterly • AAP report reviewed

- Globally, little information exists on methods to limit use of AAPs or stimulants. However, in France, it is reported that a psychiatrist must be the provider to initiate medications for ADHD.

Policy Options

Study Mandate Component	Policy Option(s)
N/A	Option 1: Take No Action
Raise awareness of ADHD medication risks	Option 2: By letter from the JCHC Chair, request the governing board of each four-year public institution of higher education to: • Require ADHD stimulant medication contracts of any student prescribed ADHD stimulants by the institution, and; • Develop and implement policies that result in the provision of written information to students about the potential risks of stimulant use
Track statistics on Virginia school children diagnosed with ADHD	Option 3: Introduce a budget amendment of $2.98M for SFY 2020 for DOE to establish an ADHD diagnosis data collection system for Virginia public school children

Policy Options (2)

Study Mandate Component	Policy Option(s)
Methods to limit antipsychotic use for ADHD	Option 4: By letter of the JCHC Chair, request that DMAS and DSS convene a stakeholder group to identify methods to ensure that DSS data on antipsychotic and other prescription medications currently being prescribed to foster populations are accurate and up-to-date Option 5: By letter of the JCHC Chair, request that DMAS require documentation of metabolic monitoring in the service authorization form for antipsychotics for children <18 years old, including documentation of: baseline and routine monitoring of weight or body mass index (BMI); waist circumference; blood pressure; fasting glucose; fasting lipid panel; and Extrapyramidal Symptoms (EPS) using Abnormal Involuntary Movement Scale (AIMS)
Methods to track off label prescribing of antipsychotics	Option 6: By letter of the JCHC Chair, request that DMAS cost out an appropriate methodology to track off label prescribing of AAPs among FFS beneficiaries – and determine required contract modifications with contracted health plans to track off label prescribing of AAPs among MCO beneficiaries – with the Department reporting back to the Commission with a proposed implementation plan by October, 2019

Public Comment

Written public comments on the proposed options may be submitted to JCHC by close of business on July 11, 2018.

Comments may be submitted via:

- E-mail: jchcpubliccomments@jchc.virginia.gov
- Fax: 804-786-5538
- Mail: Joint Commission on Health Care
  P.O. Box 1322
  Richmond, Virginia 23218

Comments will be provided to Commission members and summarized before they vote on the policy options during the JCHC's November 7th decision matrix meeting.

(All public comments are subject to FOIA release of records)

Appendix: Additional Detail

Methods to Track ADHD Diagnosis Statistics in Schools

- Examples of States that collect statistics on ADHD diagnoses through data collection collaborations between State health and education agencies:
  - Tennessee: annual Health Services reports draw ADHD diagnosis data from local school division database systems
  - Connecticut: annual Health Services Program Information Surveys draw ADHD diagnosis data from local school division database systems from provider orders, children's assessments, and other methods that vary by school division
  - North Carolina: Annual School Health Services Surveys collect data on students actively receiving some level of health services from the school nurse

Methods Used by Other States/Countries to Limit Antipsychotic Use

- Common methods to limit/ensure appropriate use of AAPs and/or ADHD medications include:
  - Prior/service authorization: Medication pre-approval form that requires prescribers to provide information that allows the payer to check appropriateness of requested medication.
  - Peer review: process for manual clinician review/consultation of prior authorization requests
  - Drug Utilization Review (DUR) Program: 2-phase process conducted by all State Medicaid agencies
    - Prospective DUR: electronic monitoring system screens prescription drug claims to identify potential problems (e.g., therapeutic duplication, incorrect treatment dosage/duration, clinical misuse)
    - Retrospective DUR: ongoing/periodic examination of claims data
    - On an annual basis, states are required to report on their state's prescribing habits

Virginia ADHD & Psychotropic Medication Policies – DMAS

- Fee-for-Service (FFS) population
  - ADHD medications/stimulants Service Authorization (SA):
    - Required for: children outside of FDA-approved age range; adults 18+
    - SA Duration: 1 year
  - Antipsychotics: Service Authorization (SA) required for children <18 years old
    - Medication must be prescribed by a psychiatrist/neurologist or prescriber must supply proof of a psychiatric consultation
    - Member must be participating in a behavioral management program
    - SA Duration: 6 months
- Managed Care Organization (MCO) population
  - ADHD medications
    - Most health plan requirements are consistent with FFS
  - Antipsychotics
    - Aligned with FFS requirements, except SA duration is 1 year (ages 6 – 17) after initial 6-month SA approval

Methods to Raise Awareness of ADHD Medications Risks/Addiction Potential

- General public
  - FDA safety communications on ADHD medications:
    - Permanent loss of skin color may occur (2015)
    - Methylphenidate may in rare instances cause prolonged/painful erections (2013)
    - Studies have not shown increased risk of serious cardiovascular adverse events (CVD) in adults (2011)
    - Manufacturers should develop patient Medication Guides to alert patients to possible CVD/psychiatric symptoms risks (2007)
  - FDA label ("black box") warnings on ADHD medications:
    - Amphetamines: have a high potential for abuse; administration for prolonged periods of time may lead to drug dependence and must be avoided; misuse may cause sudden death/serious cardiovascular adverse events (since 2005)
    - Methylphenidates: should be given cautiously to patients with a history of drug dependence or alcoholism; chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior; frank psychotic episodes can occur, especially with parenteral abuse (since 2001)
    - Strattera (non-stimulant): Increased risk of suicidal ideation in children or adolescents (since 2006)

Citations

Slide 5

- Virginia Health Information (commercial insurance data)
- Department of Medical Assistance Services (Medicaid data)

Slide 10

- U.S. Food & Drug Administration. Information about Medications Used to Treat Attention-Deficit/Hyperactivity Disorder (ADHD). https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm283449.htm

Slide 15

- Zito, J. et al. 2008. A three-country comparison of psychotropic medication prevalence in youth. *Child Adolesc Psychiatry Ment Health*, 2(1):26.