JOINT COMMISSION ON HEALTH CARE

# 2017 ANNUAL REPORT

COMMONWEALTH OF VIRGINIA
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# 2017 Annual Report
# Joint Commission on Health Care

To the Governor and the
General Assembly of Virginia

## Report Document #197

Commonwealth of Virginia
Richmond
2018

# JOINT COMMISSION ON HEALTH CARE

Senator Rosalyn R. Dance, Chair

Delegate T Scott Garrett, Vice Chair

June 20, 2018

The Honorable Ralph Northam
Governor of Virginia
Patrick Henry Building, 3rd Floor
1111 East Broad Street
Richmond, Virginia 23219

Members of the Virginia General Assembly
Pocahontas Building
Richmond, Virginia 23219

Dear Governor Northam and Members of the General Assembly:

Pursuant to the provisions of the *Code of Virginia* Title 30, Chapter 18 establishing the Joint Commission on Health Care and setting forth its purpose, I have the honor of submitting herewith the Annual Report for the calendar year ending December 31, 2017.

This report includes a summary of the Joint Commission's activities including legislative recommendations to the 2018 Session of the General Assembly. In addition, staff studies are submitted as written reports and made available on the Reports to the General Assembly and the Joint Commission on Health Care websites.

Respectfully submitted,

Rosalyn R. Dance

Michele L. Chesser, Ph.D., Executive Director
Joint Commission on Health Care
P.O. Box 1322/Richmond, Virginia 23218

# Joint Commission on Health Care

## Legislative Members

The Honorable David L. Bulova
The Honorable Benjamin L. Cline
The Honorable T. Scott Garrett
The Honorable Patrick A. Hope
The Honorable Riley E. Ingram
The Honorable Kaye Kory
The Honorable John M. O'Bannon III
The Honorable Christopher K. Peace
The Honorable Christopher P. Stolle
The Honorable Roslyn C. Tyler

The Honorable Charles W. Carrico, Sr., Chair
The Honorable Rosalyn R. Dance, Vice Chair
The Honorable George L. Barker
The Honorable Siobhan S. Dunnavant
The Honorable John S. Edwards
The Honorable L. Louise Lucas
The Honorable Glen H. Sturtevant, Jr.
The Honorable David R. Suetterlein

## Ex Officio Member

The Honorable William A. Hazel, Jr.
Secretary of Health and Human Resources

# Commission Staff

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Executive Director

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Senior Health Policy Analyst

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# Preface

The Joint Commission on Health Care (JCHC), a standing commission of the General Assembly, was established in 1992 to continue the work of the Commission on Health Care for All Virginians. *Code of Virginia*, Title 30, Chapter 18, states in part: "The purpose of the Commission is to study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services. In so doing, the Commission shall endeavor to ensure that the Commonwealth as provider, financier, and regulator adopts the most cost effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care." The Joint Commission's sunset date was extended to July 1, 2022 during the 2017 General Assembly Session (Senate Bill 1043 and House Bill 1736).

The Joint Commission on Health Care is comprised of 18 legislative members, eight members of the Senate appointed by the Senate Committee on Rules and 10 members of the House of Delegates appointed by the Speaker of the House.

Senator Charles W. Carrico, Sr. served as Chair and Senator Rosalyn R. Dance served as Vice Chair in 2017. Senator Siobhan S. Dunnavant and Delegate T. Scott Garrett served as Co-Chairs of the Behavioral Health Care Subcommittee and Senator George L. Barker and Delegate Christopher P. Stolle served as Co-Chairs of the Healthy Living/Health Services Subcommittee.

Delegate John M. O'Bannon III is not returning in 2018 and the Commission would like to thank him for his invaluable and dedicated service. He represented the 73rd District in the Virginia House of Delegates from 2000 to 2017. He was appointed to the JCHC in 2004 and served as Vice Chair from 2012 to 2013 and as Chair from 2014 to 2015. Delegate O'Bannon also was a longstanding and active member of both the Behavioral Health Care and the Healthy Living/Health Services subcommittees. In fact, he served as Chair of the Long Term Care and Medicaid Reform subcommittee from 2006 to 2007 and then continued as a Co-Chair from 2008 to 2011 as it transitioned to the Healthy Living/Health Services subcommittee. He introduced a number of bills on behalf of JCHC that were enacted including: HB 2511 (2005) which expanded Virginia's panel for newborn screening to include additional disorders; HB 343 (2012) established the All-Payer Claims Database system; HB 1751 (2017) expanding the mission of the Virginia Foundation for Healthy Youth. Delegate O'Bannon's knowledge and experience as a physician has been very beneficial in the Commission's consideration of health care issues.

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# Activities

In keeping with its statutory mandate, the Joint Commission received reports; completed studies; considered comments from public and private organizations, advocates, industry representatives, citizens and other interested parties; and introduced legislation to advance the quality of health and health care services in the Commonwealth.

## Joint Commission on Health Care

The full Commission met five times in 2017. These meetings were held in Senate Room 3 of the Capitol Building on May 23th and August 22nd and in the Pocahontas Building on September 19th, October 17th and November 9th. Meeting materials (including agendas, presentations, handouts and minutes) are posted on the JCHC website at http://jchc.virginia.gov. Eleven staff reports were presented during the 2017 Joint Commission meetings.

- Medical Use of Cannabis and Health Effects of Cannabis
- Sustainability of Virginia's Prescription Monitoring Program
- Development of Life-Sustaining Treatment Guidelines
- Heroin Use in Virginia
- Should Medigap Policies Be Provided for Medicare Recipients Under 65 Years of Age in Virginia?
- Staffing Ratio Requirements for Assisted Living Facilities in Virginia
- Creation of a Registry of Abuse or Neglect Cases for the Building Independence, Family and Individual Supports, and Community Living Waiver Programs in Virginia
- Quality of Health Care Services in Virginia Jails and Prisons, and Impact of Requiring Community Services Boards to Provide Mental Health Services in Jails, Interim Report (2-year study)
- Options for Increasing the Use of Telemental Health Services in Virginia, Interim Report (2-year study)
- Prevalence and Risks of ADHD Medications in Virginia, Interim Report (2-year study)
- Medical Aid-in-Dying in Virginia, Interim Report (2-year study)

In addition to the staff reports, members received reports and heard presentations from a number of guest presenters. Their PowerPoint presentations are available to view on the JCHC website meetings page. The following are the reports presented to JCHC members.

Marissa Levine, Commissioner of the Department of Health, gave a presentation on the Department's Plan for Well Being, including the foundational concepts of the plan, contributions of factors affecting health, community infrastructure model of health improvement, and insights from plan implementation.

Jack Barber, Interim Commissioner of the Department of Behavioral Health and Developmental Services (DBHDS), presented an Update on the Department's activities and initiatives. He discussed the Virginia Center for Behavioral Rehabilitation, jails, workforce shortages, oversight processes and behavioral health state spending. He also mentioned hospital discharge challenges and what is being done to fix those issues. Lastly he spoke about structural updates that need to be done to state hospitals due to the age of the buildings.

Steve Herrick, Director of Health Services for the Department of Corrections (DOC), presented on the requirements of the DOC and the actions taken or planned to address them.

Mellie Randall, Substance Use Disorder Policy Director for the DBHDS, gave an overview of the State Targeted Response to the Opioid Crisis Grant awarded to Virginia for the provision of opioid prevention and recovery services.

Debbie Oswalt, Executive Director of the Virginia Health Care Foundation, gave a presentation, "25 Years of Productive Partnerships," in recognition of the Foundation's 25th anniversary. She explained the mission and accomplishments of the Foundation, such as helping to provide health services to 700,000 uninsured and medically underserved Commonwealth residents.

Michael Lundberg, Executive Director of VHI, presented the organization's Annual Report and Strategic Plan. He explained the different reports that can be accessed on their website and who may benefit from reading them. He also discussed ConnectVirginia HIE, Emergency Department Care Coordination Program (EDCCP), All Payer Claims Database (APCD), healthcare reform efforts and the sources of VHI revenues.

Andrew Mitchell, JCHC Senior Health Policy Analyst, presented the results of the Life-Sustaining Treatment Guidelines Work Group that was created by a 2016 JCHC approved policy option (see Executive Summaries below for additional information).

# Behavioral Health Care Subcommittee

The Behavioral Health Care Subcommittee met on October 17th, 2017. Sarah Stanton and David Cotter, attorneys from the Division of Legislative Services, gave an Update on the Joint Subcommittee to Study Mental Health Services in the 21st Century, including the activities and recommendations of each of the Subcommittee's work groups.

**BHC Subcommittee**
Senator Siobhan S. Dunnavant, Co- Chair

Delegate T. Scott Garrett, Co-Co-Chair

Senator George L. Barker
Senator Charles W. Carrico, Sr.
Senator Rosalyn R. Dance
Senator John S. Edwards
Senator L. Louise Lucas
Senator David R. Suetterlein

Delegate David L. Bulova
Delegate Patrick A. Hope
Delegate Riley E. Ingram
Delegate Kaye Kory
Delegate John M. O'Bannon III
Delegate Christopher K. Peace
Delegate Christopher P. Stolle
Delegate Roslyn C. Tyler

Will Frank, Director of Legislative Affairs at DBHDS, and Shannon Dion, Director of Policy and Legislative Affairs at the Virginia Department of Criminal Justice Services, presented on the Alternative Transportation Study. They discussed the language of HB 1426 (Garrett)/SB 1221 (Barker) and the membership of the corresponding work group charged with creating an alternative transportation model. They then explained the work group's meetings and recommendations.

Patti Goodall, Manager of the Brain Injury Services Coordination Unit, Division for Community Living, Department for Aging and Rehabilitative Services, presented the Brain Injury Interagency Report. She spoke about the request that was received from JCHC to develop and implement a program for improving services for individuals with traumatic brain injury and she explained the goals of the implementation team created to meet the request.

Several members of the Minnesota Multistate Contracting Alliance gave an overview of their organization. They discussed ways in which their organization is saving money for many agencies in Virginia, and other states, on pharmaceutical and medical supplies.

# Healthy Living/Health Services Subcommittee

The Healthy Living/Health Services Subcommittee met on August 22nd. There was one staff presentation that provided an interim report on the medical-aid-in-dying two-year study. The presentation is available on the JCHC website on the Meetings page (see Executive Summaries below for additional information).

**HLHS Subcommittee**
Senator George L. Barker, Co-Chair

Delegate Christopher P. Stolle, Co- Chair

Senator Charles W. Carrico, Sr.
Senator Rosalyn R. Dance
Senator Siobhan S. Dunnavant
Senator John S. Edwards
Senator L. Louise Lucas
Senator David R. Suetterlein

Delegate David L. Bulova
Delegate T. Scott Garrett
Delegate Patrick A. Hope
Delegate Riley E. Ingram
Delegate Kaye Kory
Delegate Christopher K. Peace
Delegate Roslyn C. Tyler

Dawn Traver, Director of Waiver Operations in the Division of Developmental Services at DBHDS, gave an update on the three redesigned Developmental Disability Waivers. The presentation included an explanation of the number of waiver slots available, how they are being changed, and the number of individuals on the wait list for waiver services.

Kathy Wibberly, Director of the Mid-Atlantic Telehealth Resource Center at the University of Virginia Center for Telehealth, gave a presentation on the Telehealth Pilot Program. She introduced a two-year pilot project for Teleheath services and listed 5 core elements needed for the success of the project.

# Staff Endeavors

In 2017, JCHC staff engaged in a range of additional activities such as the following:

Memberships:

Children's Health Insurance Program Advisory Committee (CHIPAC)

CHIPAC Executive Committee

Early Periodic Screening Diagnosis and Treatment (EPSDT) two-year project to assess the EPSDT benefit in Virginia, develop a blueprint for program improvements and work with stakeholders to identify how it can be used to improve child health and wellness.

GME (Graduate Medical Education) Advisory Group

Presentations and Conferences:

Presentation on the quality of health care in Virginia jails and prisons to the Joint Subcommittee to Study Mental Health Services in the 21st Century

Annual Health Law Legislative Update and Extravaganza presentation

LAN Fall Summit on Payment Reform in Washington D.C.

Mid-Atlantic Telehealth Resource Center (MATRC) Summit in Leesburg, Virginia

National Cannabis Summit in Denver, Colorado

Courses Taught:

HCPR 601, Introduction to Health Policy, in the Department of Health Behavior and Policy at Virginia Commonwealth University

HCPR 692, Applied Health Policy Research, in the Department of Health Behavior and Policy at Virginia Commonwealth University

Meetings Attended:

Brain Injury Council

Broadband Advisory Council

Geriatric Mental Health Partnership

Health Insurance Reform Commission

Joint Subcommittee to Study Mental Health Services in the 21st Century

Substance Abuse Services Council

Virginia Disability Commission

Virginia Commission for Health Innovation

Two JCHC staff toured the Virginia Commonwealth University Health Services Secure Unit in which current offenders in Virginia's correctional system can receive inpatient care.

Finally, staff helped Virginians (or legislators contacting the JCHC on behalf of a constituent) with questions or problems regarding the following issues: high insurance premiums, maternity care at a local health department, brain injury information, and barrier crimes.

# Executive Summaries

During 2017, Commission staff conducted studies in response to mandates or requests from the General Assembly or from the Joint Commission on Health Care membership. In keeping with the Commission's statutory mandate, the following studies were completed.

## Medical Use and Health Effects of Cannabis

### Study Mandate

In 2017, the House Courts of Justice requested by letter that the JCHC study the therapeutic and detrimental effects of THC-A and CBD oils, and HJR 578 (Delegate Marshall) requested that the JCHC examine existing data on the health effects of cannabis. HJR 578 was left in the House Committee on Rules with the understanding that JCHC would consider conducting the study.

### Background

Currently 31 states have approved the use of cannabis products for medical purposes (Medical Marijuana Laws [MML] states), with nine of those states additionally permitting use of cannabis for non-medical reasons (Recreational Marijuana Law [RML] states). Sixteen states permit the restricted use of cannabinoids in extract form (Cannabinoid Oil Law [COL] states). Four states do not permit any form of cannabis use.

**Figure 1. State Laws on Medical and Non-Medical Use of Cannabis**

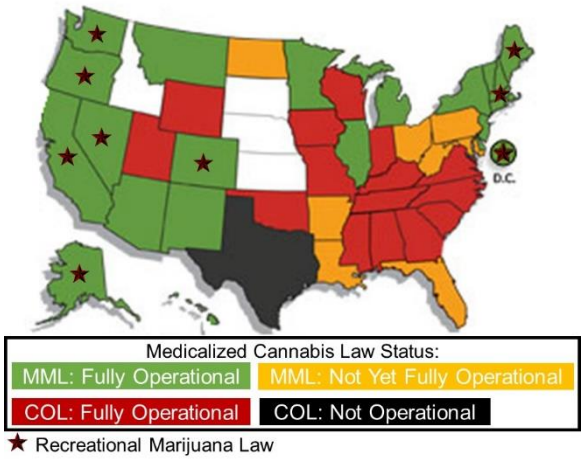
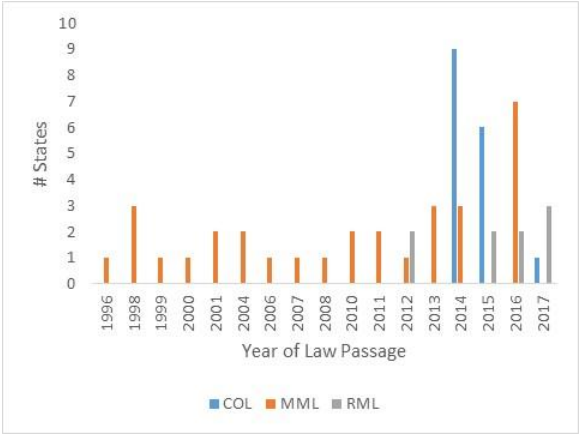



**Figure 2. Year of Passage of COLs, MMLs, and RMLs**




COL: Cannabinoid Oil Law; MML: Medical Marijuana Law; RML: Recreational Marijuana Law

Source: adapted from (National Organization for the Reform of Marijuana Laws (NORML) 2017a)

# Medical Use of Cannabis

Psychoactivity of THC-A and CBD Oils

Because neither THC-A nor CBD are "intoxicating", they are traditionally considered non-psychoactive.[1] However, THC-A readily decarboxylates (i.e. changes) into THC – the primary psychoactive (intoxicating) substance in cannabis (Russo & Marcu 2016). Due to decarboxylation, the maximum potential percentage THC for any cannabis product is defined as the sum of the total percentage THC and a fraction (approximately 90 percent) of the percentage of THC-A. Since Virginia Code permits a maximum of 5 percent THC in either THC-A or CBD oil, the following scenarios are possible.

- Psychoactive effects of CBD oil will be limited to psychoactive effects from 5 percent THC if THC is defined as maximum potential THC (if not, processors could add additional THC-A). In Virginia, the Department of Health Professions (DHP) has indicated that it will define THC in CBD oil as maximum potential THC.
- Psychoactive effects of THC-A oil may exceed psychoactive effects from 5 percent THC if THC-A decarboxylates into THC at the processing and/or consumption stages. For instance, if the percentage of THC-A in a THC-A oil is 15 percent and the level of THC is 5 percent *and* THC-A is fully decarboxylated into THC, that THC-A oil could contain up to 18 percent maximum potential THC.

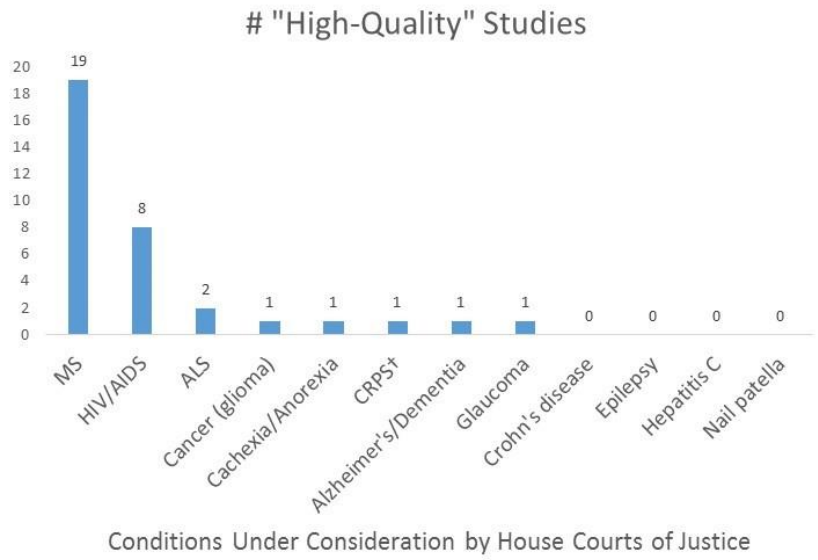
There are several conditions under which it can decarboxylate into THC, either on the producer's or consumer's end. On the production side, research indicates that THC-A is prone to decarboxylation under varying storage conditions (e.g., a half-life of 35 days at room temperature in sunlight) (Lindholst 2010; McPartland et al. 2017). On the consumer side, it is not difficult for consumers of THC-A oil products to promote decarboxylation of THC-A into THC, such as through cooking or baking (Sutton 2017).

There are regulatory steps that could be considered for both processors and consumers to avoid decarboxylation of THC-A into THC. For processors, these include requiring cold storage of THC-A to ensure stability and stability testing overseen by the Department of Health Professions (DHP). For consumers, these include regulations on the acceptable manner by which to consume THC-A oil. such as a prohibition on heating of THC-A oil by patients who can otherwise legally invoke an affirmative defense in the use of these oils. To this end, three MML states – Louisiana, Ohio and Pennsylvania - statutorily prohibit the smoking of medical cannabis.

[1] Note that CBD interacts directly with the CB1 cannabinoid receptor in therapeutically relevant ways and there is evidence that it attenuates THC's psychoactive effects.

Therapeutic Effects of Cannabis for Medical Use

**Figure 3. Research Quality of Cannabis Studies**




Source: National Academies of Sciences Engineering and Medicine, 2017

The strength of the evidence base on therapeutic effects of THC and CBD is highly limited, and even more so for THC-A. Of "high-quality" studies examining therapeutic effects of cannabinoids and reviewed recently by the National Academies (National Academies of Sciences Engineering and Medicine 2017), the vast majority relates to four conditions: chronic pain, nausea/vomiting (associated with chemotherapy), Multiple Sclerosis (MS) and HIV/AIDS (see Figure 3). Among the 12 conditions/symptoms on which the House Courts of Justice specifically requested information, studies are highly limited, with 60 percent assessing therapeutic effects of THC and/or CBD, around one-quarter (23 percent) assessing effects of synthetic THC, around one-fifth (20 percent) assessing effects of cannabis flower, and none assessing effects of THC-A.

Available evidence from this review indicates that only one of the 12 conditions under consideration by the House Courts of Justice – patient-reported MS symptoms – has strong evidence of therapeutic effects. Conversely, there is insufficient evidence to support or refute the existence of an association of effectiveness for ALS, cachexia, cancers and epilepsy. There is limited evidence of effectiveness in treating clinician-measured MS symptoms and appetite or weight loss associated with HIV/AIDS; and limited evidence that cannabis is ineffective in treating glaucoma and dementia.

Detrimental Effects of THC and CBD

The majority of evidence on detrimental effects of cannabinoids relates to therapeutic products containing THC alone or THC combined with CBD. On the one hand, two reviews have found CBD to be generally well-tolerated and safe at high doses and with chronic use (Iffland & Grotenhermen 2017; Bergamaschi et al. 2011). On the other, CBD and/or THC have been associated with both serious and non-serious Adverse Events (AEs) (Wang et al. 2008; Whiting et al. 2015). Additionally, although cannabis does not appear to be contra-indicated for other drugs, according to the Colorado Department of Public Health and Environment (2016), cannabis can interact with other drugs, resulting in amplified or attenuated effects for either cannabis or the other drugs. There is little to no evidence on THC-A related to tolerability, AEs or drug interactions.

Regulatory steps that can be considered to address AEs and drug interactions include the following.

- Establishing standardized procedures for documenting and reporting of AEs by dispensers, practitioners and/or patients, as is practiced in some MML states. In Virginia, DHP has not instituted such procedures.
- Making use of the Prescription Monitoring Program (PMP). DHP administrative regulations require that dispensers of THC-A and CBD oils query the PMP at the time of dispensing, which could help identify and prevent interactions with drugs. However, there is no accompanying requirement that pharmacists log dispensing information about THC-A and CBD oils into the PMP at the time of dispensing since they are not scheduled in Virginia as a II-IV substance. The lack of requirement to enter dispensing information is likely to limit the utility of querying the PMP.

Detrimental effects of CBD and THC-A oils could also result from inactive ingredients in the oils (e.g., use of peanut oil as carrier oil, for those with peanut allergies). While most other MML and COL states permitting sale of medical cannabis products require labeling of inactive ingredients, such as type of excipient oil(s), or presence of additives, DHP requires only that active ingredients be listed.

Qualifying Conditions for Cannabis for Medical Use

Across the US, around 850,000 patients are registered to use medical marijuana, with around two-thirds of patients in MML states registered for its use to treat pain.[2] All but two MML and COL states list specific medical conditions or symptoms for which cannabis may be recommended by physicians (e.g., over 25 states list pain as an eligible condition). However, for the majority of the most commonly listed qualifying conditions, the evidence base on the therapeutic effect of cannabis is highly limited.

[2] Data drawn from State websites.

Among the 31 MML states, four (California; Washington, DC; Florida and Massachusetts) permit physicians to make recommendations for conditions that are not explicitly listed in Code. Two place some restrictions on physician determination of additional qualifying conditions (e.g., in Florida, cannabis may be recommended for "[m]edical conditions of the same kind or class [as the enumerated list]") while two leave relatively unrestricted discretion to the physician (e.g., in Massachusetts, cannabis may be recommended for "other conditions as determined in writing by a qualifying patient's physician"). Additionally, one COL State (Wisconsin) allows physicians to provide certification for CBD oil for any medical condition.

Around 70 percent of MML states delegate authority to agencies overseeing medical marijuana programs to consider the addition of new conditions to those approved in Code; and the remaining 30 percent require a strictly legislative process. Among the 20 states with a model of delegated authority to approve new conditions, all use a petition-based process to consider new conditions and most (65 percent) make use of an advisory body to review petitions and make recommendations to the overseeing authority. Wide variations exist related to advisory body membership composition, size, appointment authority, etc.[3] Additionally, one of the 16 CBD oil states (Iowa) uses a delegated authority model, with recommendations for adding conditions made by an advisory council.

## Health Effects of Cannabis Use

Adverse Associations of Cannabis Use

Adverse associations between non-medical cannabis use and health outcomes were recently reviewed by 1) the National Academies as part of their comprehensive systematic review on cannabis (National Academies of Sciences Engineering and Medicine 2017), 2) a systematic review by the Colorado Department of Health (Colorado Department of Public Health and Environment (CDPHE) 2016), and 3) an expert review by the World Health Organization (World Health Organization (WHO) 2016). Of almost 50 health/social outcomes reviewed and most relevant to this study, the evidence base was determined to be limited or too insufficient to draw conclusions for the majority (56 to 66 percent, depending on the review). The following tables summarize findings from those reviews. Themes that are emerging in research on cannabis and health include 1) certain populations may be at highest risk for adverse health outcomes, such as adolescents and individuals with genetic pre-disposition to psychotic disorders; 2) the nature of cannabis and ways in which it is consumed is rapidly evolving, making it unclear the degree to which findings from previous studies apply to the cannabis products used today; and 3) available evidence on health "impacts" of cannabis use relates to *associations* with health outcomes as there are many reasons why determining causation remains highly limited.

[3] One State (Minnesota) requires that determinations to add new conditions by the program's executive agency be submitted to the State legislature and adopted unless the legislature provides otherwise

**Adverse Associations of Cannabis Use**
**Strong/Moderate Evidence in at Least 2 of the 3 Reviews**

| Category | Outcome | Evidence Level†: | |
|---|---|---|---|
| | | Strong | Moderate |
| Mental Health | Development of schizophrenia, other psychoses (dose-response relationship; highest risk in frequent users) | CO; NA; WHO; CO | |
| | Development of problem use/cannabis use disorder (among certain users) | CO; NA; WHO | |
| | Development of Substance Use Disorders | CO | CO; NA |
| | Cognitive function (acute effects of cannabis use) | CO; WHO; NA | |
| Physical Health | Motor vehicle crashes | CO; NA; WHO | |
| | Worsened: respiratory symptoms; chronic bronchitis | CO; NA; WHO | |
| | Overdose pediatric injuries (where cannabis is legalized) | CO | NA |
| | Lung cancer (*no association*) | | CO; NA |

CO = CDPHE review; NA = National Academies review; WHO = World Health Organization review
† For the CO review, strength of evidence depended on particular conditions or substances; for the WHO review, there were methodological differences in assessment of strength of evidence

**Adverse Associations of Cannabis Use**
**Limited/Insufficient Evidence in at Least 2 of the 3 Reviews**

| Category | Outcome | Evidence Level: | |
|---|---|---|---|
| | | Limited | Insufficient†† |
| Mental Health | Maternal cannabis use and child's: academic achievement (decreased); delinquency | CO | NA |
| | Maternal cannabis use and child's psychosis | | CO; NA |
| | Bipolar disorder: development | NA | CO |
| Physical Health | AMI (short-term triggering of) | CO; NA; WHO | |
| | Cancers (various) | CO; WHO; NA | |
| | Testicular tumors | CO; NA; WHO | |
| | Chronic Obstructive Pulmonary Disease | NA; WHO; CO | |
| | Maternal pregnancy complications | CO; NA | |
| | Maternal cannabis use and SIDS | CO | NA |
| | Mortality | | CO; NA |
| | Asthma | | CO; NA |
| | Occupational accidents/injuries | CO | NA |

CO = CDPHE review; NA = National Academies review; WHO = World Health Organization review
† Insufficient evidence to support or refute existence of associations
†† For the CO review, strength of evidence depended on particular conditions or substances; for the WHO review, there were methodological differences in assessment of strength of evidence

In terms of adverse associations between cannabis use and specific health conditions identified in HJR 578, there is mixed or unclear evidence on several, including the following.

- Maternal cannabis use: while there is evidence that smoked cannabis use during pregnancy is linked to newborn lower birth weight and one review found moderate evidence of decreased offspring IQ, no adverse outcomes on neonatal development have

been found. Studies do not support an effect of cannabis exposure on overall cognitive function (although there is more consistent evidence of adverse outcomes for adolescents, including increased delinquency, greater cigarette and cannabis use, and increased mental health symptoms) and it is difficult to attribute the outcomes to prenatal exposure (Colorado Department of Public Health and Environment [CDPHE] 2016; National Academies of Sciences Engineering and Medicine 2017).

- Long-term cognitive function: there are indications that greater cannabis exposure is associated with decreased long-term cognitive function; however, causal inference and generalizability are limited (Levine et al. 2016).
- Brain development: while brain imaging studies have found structural differences between early-onset cannabis users and non-users, causal relationships with cannabis and permanency of differences have not been established, and there is limited or insufficient evidence that cannabis use is associated with long-term outcomes (e.g., academic degree-earning; income) (Meier et al. 2017).
- As a "gateway" to other substances: cannabis use is associated with later illicit drug use; however, the order of drug initiation may not be a major factor in developing a substance use disorder, and associations between cannabis use and illicit drug use may reflect underlying, shared liabilities (e.g., predisposition towards addiction) (Mayet et al. 2015; Secades-Villa et al. 2015).

## Cannabis Legalization and Decriminalization

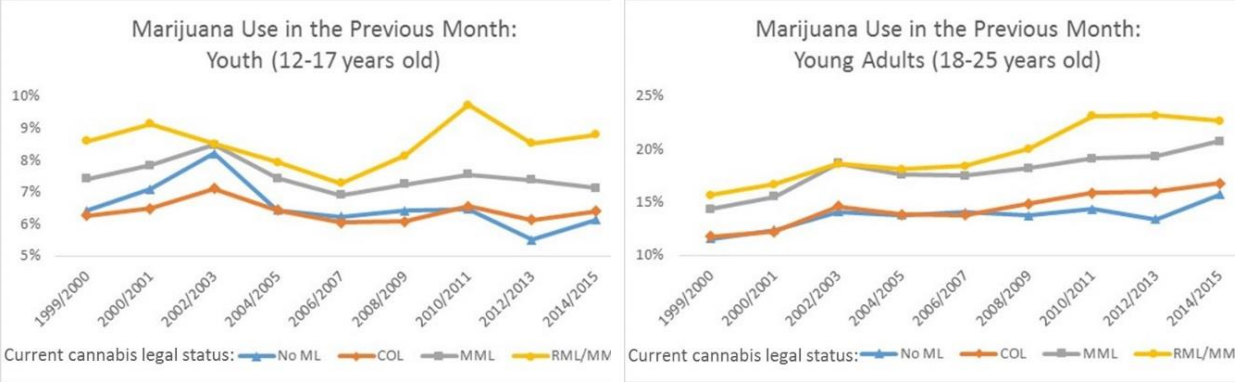
Recurring themes that emerge in research on the status of states' cannabis laws and cannabis use, age of cannabis initiation and impaired driving include the following.

- Levels of use in MML and RML states are higher today – and have generally been higher since 1999 – compared to COL states and states that do not permit any form of cannabis use.
- Changes over time for young adults appear to trend differently – generally upward – from changes over time for youth, which are generally flat or trend downward.
- Research on how passage of cannabis laws are related to changes in cannabis use, age of cannabis initiation and impaired driving is still emerging and often provides an unclear picture.

Cannabis Use

Between 1999 and 2015, *youth* use of marijuana appears to have remained relatively similar across time, with levels in current RML and/or MML states generally higher – in most cases even prior to passage of those states' laws – than in states that currently have CBD oil laws or do not permit any cannabis use. Over the same time period, *young adult* use of marijuana has increased overall, and has been consistently higher in current RML and/or MML states – in most cases even prior to passage of those states' laws – than in states that currently have CBD oil laws or do not permit any cannabis use.

**Trends in age of cannabis use**




Source: (Substance Abuse and Mental Health Services Administration (SAMHSA) n.d.)

In terms of associations between passage of medical marijuana laws (MMLs) and recreational marijuana laws (RMLs) and changes in cannabis use, researchers have indicated the following results (Anderson 2015; Cerdá et al. 2017; Cerdá et al. 2012; Choo et al. 2013)(Johnson et al. 2016; Hasin et al. 2015; Hasin et al. 2017; Lynne-Landsman et al. 2013)(Martins et al. 2015; Pacula et al. 2014; Stolzenberg et al. 2015)(Wall et al. 2016; Wall et al. 2011; Wen et al. 2015)(Williams et al. 2017).

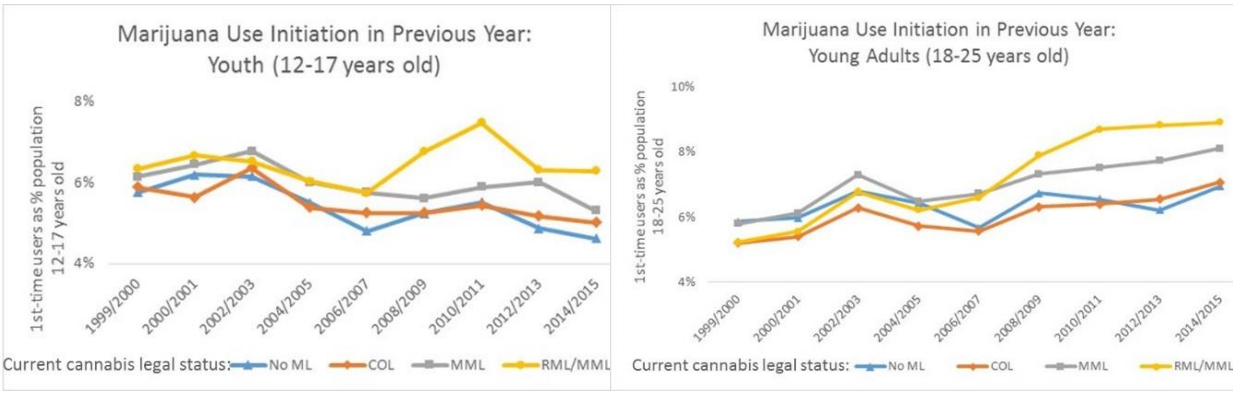
- For MMLs, most research has *not* found increased cannabis use among *youth* after MML enactment even if youth's perceptions of marijuana's risk of harm has declined. Conversely, there is greater evidence of increased *adult* use after passage of MML.
- For RMLs, there is a smaller evidence base, representing an area for further research.
- In either MML or RML contexts, passage of these laws may be affecting high-risk and heaviest users the most.

*Age of Initiation*

Since 1999, the percentage of youth initiating marijuana use has decreased overall – with the exception of RML states – and has been generally higher in current RML and/or MML states – in most cases even prior to passage of those states' laws – than in states that currently have CBD oil laws or do not permit any cannabis use. Since 1999, the percentage of young adults initiating marijuana use at this age has increased overall, particularly in RML states, and has been generally higher in current MML states – in most cases even prior to passage of those states' laws – than in states that currently have CBD oil laws or do not permit any cannabis use.

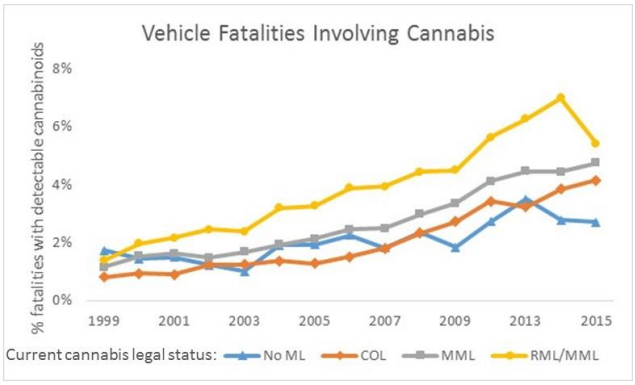
While research on associations between age of initiation of cannabis use and the passage of cannabis laws is not as extensive as research on use, two studies have found earlier age of initiation after passage of cannabis laws, although the magnitude may be modest and earlier age of initiation may represent increased experimentation with cannabis rather than ongoing use (Wen et al. 2015; Borodovsky et al. 2015; Williams et al. 2017). As with many other areas of study, the limited research hampers ability to draw firm conclusions.

**Trends in Age of Cannabis Initiation**




Source: Substance Abuse and Mental Health Services Administration (SAMHSA) n.d.

Impaired Driving




While there is strong evidence that cannabis use is associated with increased motor vehicle accidents, assessing associations between passage of cannabis laws and changes in impaired driving is limited by a variety of data limitations (e.g., blood concentrations of THC may or may not reflect actual impairment, and data routinely collected nationally on driving accidents have several known limitations) (Watson & Mann 2015; Romano et al. 2016). The evidence base on associations between either passage of MMLs or RMLs and changes in impaired driving is mixed. Increased presence of cannabinoids in fatal crashes has been found in MML states relative to other states, but other research suggests MMLs and dispensaries are associated with reduced fatalities (Aydelotte et al. 2017; Masten & Guenzburger 2013)(Pollini et al. n.d.; Santaella-Tenorio et al. 2016). In the RML context, there is evidence of increased collisions by around 3 percent in three RML states (Colorado, Oregon and Washington) compared to non-RML states, but no changes in crash fatality rates three years after legalization (Salomonsen-Sautel et al. 2014; Insurance Institute for Highway Safety (IIHS) & Highway Loss Data Institute 2017).

## Methods Used by States and Other Countries to Limit Illicit Cannabis Use

In the US, legal penalties and funding of prevention and treatment services are two common methods used. Two states with among the lowest reported use of marijuana have internal possession laws, meaning that evidence of having used marijuana can incur legal penalties, not just possessing marijuana. A second approach adopted by some MML states is to tax medical marijuana and earmark a certain percentage of revenue for drug abuse prevention, counseling

and treatment services. Internationally, the impact of specific methods on cannabis use (e.g., zero tolerance, drug courts) is often not clear (Mansson 2017; Home Office 2014).

| Level of Past Year Marijuana Use | Lowest Offense | | | Highest Offense | |
|---|---|---|---|---|---|
| | Avg. Allowable limit† | Avg. Min. Incarceration | Avg. Min. Fine | Avg. Max. Incarceration | Avg. Max. Fine |
| 10 Lowest-Use States | 1.35 oz | 168 days | $1,505 | 25 years | $115,325 |
| 10 Highest-Use States | 1.67 oz | 0.2 days | $1,035 | 4.25 years | $69,010 |

† Allowable limit refers to maximum quantity allowable to remain at lowest level of offense; Source: (National Organization for the Reform of Marijuana Laws (NORML) 2017b)

## Actions Taken by the Joint Commission on Health Care

During the Joint Commission's 2017 Decision Matrix meeting, JCHC members voted to take action on two policy options. The first requests that the Department of Health Professions amend administrative code by requiring THC-A oil processors to ensure that the percentage of THC remains within 10 percent of the level measured for labeling under 18 VAC 110-60-290 and establishing a stability testing schedule for THC-A oil processors. The second approved option amends the Code of Virginia to allow physician recommendation for any condition determined by the physician to benefit from THC-A or CBD oil.

## Legislative Action

Senator Dunnavant and Delegate Cline introduced companion bills on behalf of the JCHC (SB 726 and HB 1251, respectively), both of which were enacted with amendments in the 2018 Acts of Assembly.

**SB 726 and HB 1251: CBD oil and THC-A oil; certification for use; dispensing.** Provides that a practitioner may issue a written certification for the use of cannabidiol (CBD) oil or THC-A oil for the treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy. The bill increases the supply of CBD oil or THC-A oil a pharmaceutical processor may dispense from a 30-day supply to a 90-day supply. The bill reduces the minimum amount of cannabidiol or tetrahydrocannabinol acid per milliliter for a dilution of the Cannabis plant to fall under the definition of CBD oil or THC-A oil, respectively. As introduced, this bill was a recommendation of the Joint Commission on Health Care. The bill contains an emergency clause

Senator Dunnavant also introduced SB 330 which was enacted with amendments in the 2018 Acts of the Assembly.

**SB 330: CBD and THC-A oil**. Adds cannabidiol oil (CBD oil) or THC-A oil to the list of covered substances the dispensing of which must be reported to the Prescription Monitoring Program. The bill requires a practitioner, prior to issuing a written certification for CBD oil or THC-A oil to a patient, to request information from the Director of the Department of Health Professions for the purpose of determining what other covered substances have been dispensed to the patient. The bill requires the Board of Pharmacy to (i) promulgate regulations that include a process for registering CBD oil and THC-A oil products and (ii) require an applicant for a pharmaceutical processor permit to submit to fingerprinting and provide personal descriptive information to be forwarded through the Central Criminal Records Exchange to the Federal Bureau of Investigation for a criminal history record search. The bill requires a pharmacist or pharmacy technician, prior to the initial dispensing of each written certification, to (a) make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; (b) view a current photo identification of the patient, parent, or legal guardian; and (c) verify current board registration of the practitioner and the corresponding patient, parent, or legal guardian. The bill requires that, prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent view the current written certification; a current photo identification of the patient, parent, or legal guardian; and the current board registration issued to the patient, parent, or legal guardian. Finally, the bill requires a pharmaceutical processor to ensure that the percentage of tetrahydrocannabinol in any THC-A oil on site is within 10 percent of the level of tetrahydrocannabinol measured for labeling and to establish a stability testing schedule of THC-A oil. As introduced, this bill was a recommendation of the Joint Commission on Health Care.

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# Sustainability of the Prescription Monitoring Program

In 2017, Senator Carrico, Sr. requested via SJR 285 that the Joint Commission on Health Care study the sustainability of the Prescription Monitoring Program (PMP) and identify potential funding sources for its future operation. SJR 285 was left in the Senate Committee on Rules with the understanding that the study would be considered by the JCHC members at the May 23, 2017 work plan meeting.

## Background

According to the Department of Health Professions (DHP), the goal of the PMP is to promote appropriate use of controlled substances for legitimate medical purposes – including deterrence of misuse, abuse and diversion of controlled substances – by helping prescribers and pharmacists make safe prescribing and dispensing decisions, identifying patients for risk of overdose, monitoring patient compliance with treatment plan, and reducing illicit use of Controlled Substances. Virginia's PMP was initiated in 2002 as a pilot program in Southwest Virginia and expanded Statewide on the basis of $20M in funding received by Virginia from a federal court settlement agreement with The Purdue Frederick Company.

The PMP tracks all Schedule II-IV controlled substances dispensed as well as drugs of concern. Users required to register with the PMP include providers from four Boards (Medicine, Nursing, Optometry and Dentistry) and the Board of Pharmacy. Dispensers are required to report filled prescriptions within 24 hours, and prescribers must query the PMP in selected circumstances. Virginia's PMP has a relatively high percentage of users registered to use the PMP compared to other states, reflecting automatic user registration at time of license renewal.

Workflow integration is a key DHP programmatic priority for the PMP. The current PMP platform requires users to step out of their usual workflow – such as an Electronic Health Record – to log into the PMP platform, and does not provide patient-level analytics that might aid in ensuring safe prescribing and dispensing decisions. The current PMP platform will be referred to as "basic functionality". By contrast, "enhanced functionality" involves workflow integration, with PMP data integrated into the user workflow and analytical clinical tools provided, such as patient risk scores. Studies from other states indicate that a lack of workflow integration has been found to be a barrier to use of Prescription Drug Monitoring Programs (PDMPs) (Poon et al. 2016; Blum et al. 2015). Purdue Pharma is currently supporting the integration of up to 18,000 users and 400 pharmacies through a $3.1M grant. After the grant ends, DHP estimates a cost of $1.5M to $2M annually to integrate all PMP users in the Commonwealth.

While the PMP routinely collects data on the number of users and characteristics of prescriptions, PMP data are not routinely combined with other data sources for analysis (e.g., overdose deaths). As a result, the PMP has limited ability to assess impact on prescribing and dispensing practices through routine program data. The PMP's relatively limited use of analytics to evaluate the impact of the program in relation to its goals appears to be similar to that of other

states in terms of use of program data. An exception is Tennessee, which conducts relatively sophisticated analyses that combine PMP data with other patient-level databases to perform epidemiological analyses and report findings to the State. While use of programmatic data to assess impact remains limited, academic research indicates that PDMP implementation may be related to changes in a variety of provider and patient behaviors and health outcomes – such as prescribing of controlled substances and drug overdose/mortality (Ali et al. 2016; Baehren et al. 2009; Bao et al. 2016)(Delcher et al. 2014; Haegerich et al. 2013; Li et al. 2014)(Rutkow et al. 2015; Patrick et al. 2016)(Rasubala et al. 2015; Yarbrough 2017). However, methodological challenges limit the ability to attribute changes in outcomes to use of PDMPs.

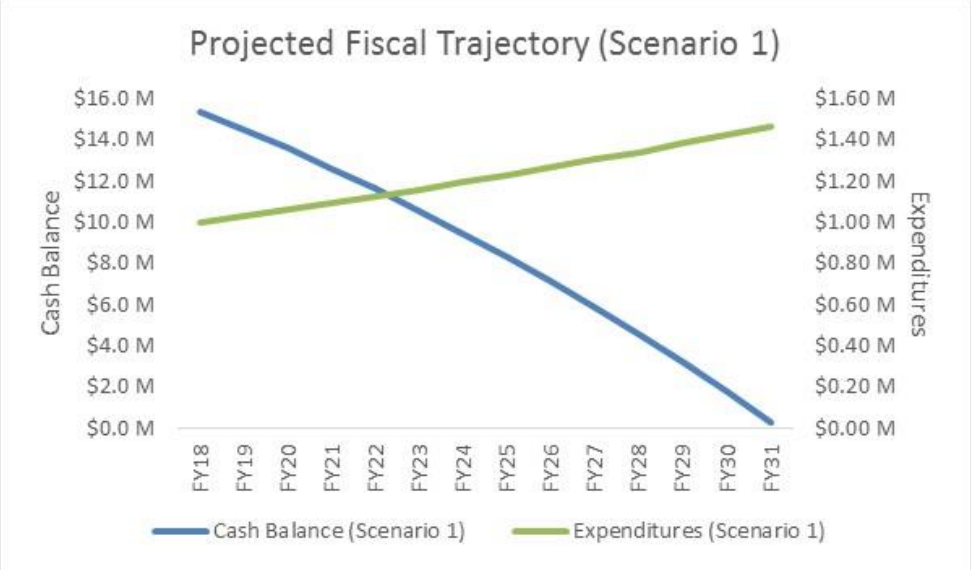
## PMP funding

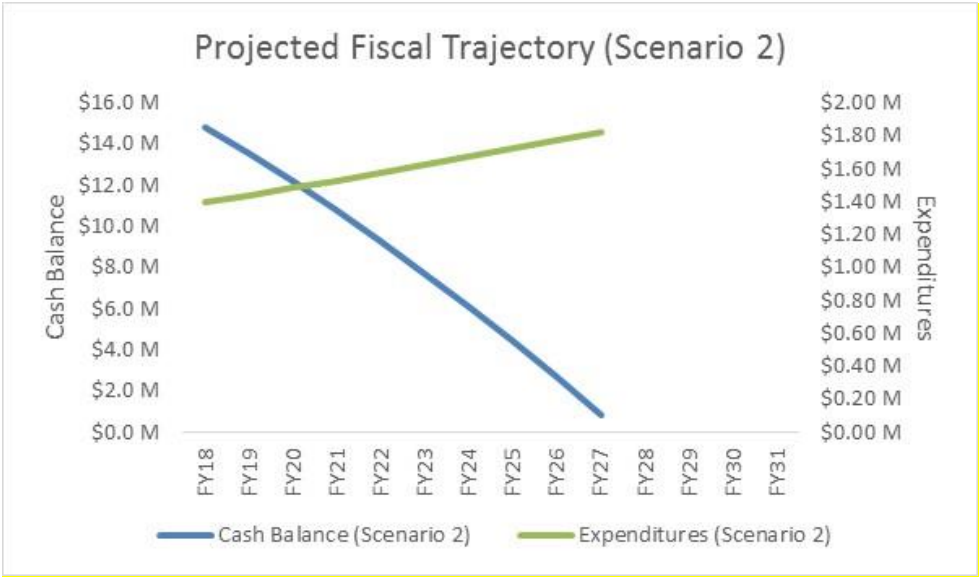
The PMP's current annual budget is around $875,000, which is expected to climb to at least $1M by FY18. As indicated in the table below, the Purdue Frederick Company court settlement agreement funds support basic functionality, while there are currently additional sources of funds supporting time-limited initiatives.

**Current PMP Funding Sources**

| Basic functionality | | Additional Initiatives | |
|---|---|---|---|
| Purpose | Source | Purpose/amount | Source |
| PMP operational costs | Remaining funds in Purdue Frederick Company court settlement agreement | Prescriber reports ($50,000 for 2 years) | VDH |
| | | Advanced analytics ($30,000 for 2 years) | VDH |
| | | Strategic planning/resource allocation ($130,000 for 1 year) | DBHDS |
| | | Integration of up to 18,000 users/400 pharmacies ($3.1M for 2 years) | Purdue Pharma LP |

The current reserves of the Purdue Frederick Company court settlement agreement funds are approximately $16M. Going forward, the PMP projects that the remaining settlement agreement funds will be run down between 2027 and 2031 to support basic functionality. The longer expenditure trajectory until 2031 assumes that expenditures beginning in FY18 are $1M, with annual increases due to inflation thereafter. The shorter expenditure trajectory assumes that expenditures beginning in FY18 will be somewhat higher than current expenditures – for example if future legislative requirements for the PMP require a higher level of resources than currently are needed, with increases thereafter for inflation.




## Sustainable Funding Models

Nationally, around one-half of states finance their PDMPs in whole or in part with fees assessed on users, including health professional licensing fees, controlled substances registration fees, or through regulatory Board funds. Another 20 percent use General Funds, and the rest, including Virginia, rely on other sources. The following analytic framework was used to inform recommendations for sustainable funding options.

- Sustainability should focus on both maintaining benefits of current PMP use, and maximizing potential benefits that would accrue from increased PMP use by users.
- The focus should be on funding options that do not incur additional costs to the Commonwealth.

- The Commonwealth, PMP users and beneficiaries all may appropriately have roles to play in sustaining the PMP, either in terms of basic functionality or enhanced functionality.
- Sustainability may require a transition period to allow stakeholders to adjust to a longer-term funding model.

Model 1: Health Professional Licensing Fees

Use of professional licensing fees to support PDMPs is one of the most common models used by states. Where possible to quantify the annual dollar amount of those fees used to support their states PDMPs, most were $20 annually or less (ranging from $3 to $40). Based on the number of providers and dispensers required to register with the PMP – just under 79,000 – and DHP's estimates of program costs for basic PMP functionality over the next 5 years, an annual fee increase of $13 - $19 would be anticipated to support basic PMP functionality. As a point of reference, current license fee renewal levels for Virginia physicians and pharmacists – the two professions that make up 71 percent of users required to register with the PMP in Virginia – are 3rd–lowest and at the median, respectively, compared to neighboring states.

Model 2: Controlled Substances Sales Tax

Across the US, only Illinois currently taxes prescription medicines, and in Virginia in 2014, the Joint Subcommittee on Tax Preferences recommended continued exemption of prescription medicines. In 2011, it was estimated that tax exemptions for controlled substances resulted in approximately $32M in foregone revenue that year. Based on estimated sales of controlled substances in 2011 (the latest year for which sales data are available), a retail sales tax of 0.013 to 0.026 percent would raise approximately $1M - $2M. A flat point-of-sales tax could be an alternative approach to a retail sales tax. Based on the volume of controlled substances dispensed in 2016 (13,847,223 controlled substances tracked by the PMP were dispensed), a flat point-of-sale controlled substances tax of $0.08 to $0.14 would raise approximately $1M to $2M. The Virginia Department of Taxation (VATAX) anticipates a one-time cost of around $83,400 and annual costs of around $21,600 to administer either tax.

Model 3: Health Insurance Premium Assessment

This model would be administered by Virginia's State Corporation Commission's (SCC) Bureau of Insurance, which currently assesses premiums on several types of insurers to support four funds. While the Bureau of Insurance regulates health insurers, the Bureau's regulatory scope extends only to the fully-insured markets – which covers an estimated 30 percent of health insurance policies in the State. A premium assessment would therefore apply only to policyholders in those markets. The remaining 70 percent of health insurance policies are self-insured policies regulated by the US Department of Labor and would not be subject to an assessment by the Bureau of Insurance. Based on premiums collected in 2016, an assessment of 0.01 - 0.02 percent on total health insurance premiums for policies regulated by the Virginia Bureau of Insurance would raise approximately $1M - $2M. As context, if the premium

assessment were spread evenly across policyholders, this would equate to between $1 and $2 per policy per year.

Summary of Models 1 – 3

A comparison of funding models is presented in the table below. As an example, each of the following would generate enough revenue to support low-end estimates of annual basic PMP functionality expenditures over the next 5 years (i.e., $1.06M):

- a $14 increase in health professional license fee; OR
- a controlled substances sales tax of 0.014 percent of retail price or $0.07 flat point-of-sale; OR
- a health insurance premium assessment of 0.011%.

**Comparison of Funding Models**

| Funding Source | Amount Needed to Support PMP Functionality | | | | | |
|---|---|---|---|---|---|---|
| | Basic alone* | | Enhanced alone** | | Basic + Enhanced | |
| | Low end ($1.06M) | High end ($1.49M) | Low end ($1.5M) | High end ($2M) | Low end ($2.56M) | High end ($3.49M) |
| Licensing fee increase | $14 | $19 | $19 | $25 | $33 | $44 |
| Controlled Substances sales tax | | | | | | |
| % retail price | 0.014% | 0.02% | 0.02% | 0.026% | 0.036% | 0.046% |
| Flat point-of-sale | $0.08 | $0.11 | $0.11 | $0.14 | $0.19 | $0.25 |
| Health insurance premium assessment | | | | | | |
| % total premium | 0.011% | 0.015% | 0.015% | 0.02% | 0.025% | 0.035% |
| Average $ / policy*** | $0.95 | $1.32 | $1.34 | $1.78 | $2.29 | $3.10 |

* Based on projected FY18-FY22 average ** Based on estimates for FY19 *** Informational only

Sustainability plan

Because an abrupt model transition in PMP funding might disrupt or deter use of the PMP and create barriers in achieving the PMP's goals, a sequenced sustainability plan can be considered

with the goal of ensuring both sustainable funding and increased use of the PMP. Characterized in the table below is an illustrative sustainability plan intended to maximize ongoing and future use/benefits of Virginia's PMP while ensuring its long-term financing. To summarize that sustainability plan:

- basic functionality costs would be supported through Model 1, 2 and/or 3;
- Purdue Frederick Company court settlement agreement funds would be used for a limited period of time to support integration (i.e., enhanced functionality) for all PMP users; and
- at a predetermined time, health systems, hospitals, practices, etc. would absorb the cost of supporting workflow integration either in part (Short-term Phase) or in whole (Long-term Phase).

**Illustrative Sustainability Plan**

<table>
<tr><th rowspan="2">Phase</th><th colspan="2">Revenue Source for PMP Functionality</th><th rowspan="2"># Years</th><th rowspan="2">Notes</th></tr>
<tr><th>Basic</th><th>Enhanced</th></tr>
<tr><td>Short-term</td><td rowspan="3">• License fees<br>AND/OR<br>• Tax on Controlled Substances<br>AND/OR<br>• Health insurance premium assessment</td><td>• DHP at 100%</td><td>• 2-3 years</td><td>• Enhanced functionality supported by DHP using Purdue Frederick Company court settlement agreement funds<br>• Begins when Purdue Pharma LP $3.1M integration grant funds spent (anticipated end FY18)</td></tr>
<tr><td>Medium-term</td><td>• DHP at 50%; health systems / hospitals / provider practices at 50%</td><td>• 2-4 years</td><td>• 50% enhanced functionality supported by DHP using court settlement agreement funds<br>• Ends when court settlement agreement funds reach pre-determined floor (e.g., $5M)</td></tr>
<tr><td>Long-term</td><td>• Health systems / hospitals / provider practices at 100%</td><td>• Indefinite</td><td>• Remaining court settlement agreement funds allocated by DHP to respond to program needs</td></tr>
</table>

## Actions Taken by the Joint Commission on Health Care

JCHC members voted to take no action.

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# Development of Life-Sustaining Treatment Guidelines

Virginia Code §54.1-2990 regulates physician actions if a physician refuses to provide health care requested by/for a patient because the physician determines the requested treatment to be medically or ethically inappropriate. However, while the Code provides a 14-day timeframe for transferring the patient to a different provider in cases of unresolved conflict, §54.1-2990 does not address situations in which 14 days pass and the conflict remains unresolved and/or the patient is unable to be transferred. During the 2015 General Assembly, Delegate Stolle introduced HB 2153 to amend §54.1-2990 to include the language that "the physician may cease to provide care that he has determined to be medically or ethically inappropriate." HB 2153 was tabled in the House Health, Welfare and Institutions Committee by voice vote, and in 2016, Delegate Stolle requested that the JCHC study the current legal and regulatory environment on life-prolonging care, focusing on legal/regulatory requirements regarding disagreements over medical appropriateness of life-prolonging care; how other states address this issue, including how patients can pursue desired treatments and how providers are protected from providing medically inappropriate treatment; and recommendations for legislative changes clarifying actions after the current legal time period for patient transfer (14 days) has passed and the patient is unable to be transferred. The 2016 JCHC staff study resulted in an approved policy option to include in the 2017 JCHC work plan that staff form a work group to continue and extend discussions initiated by a work group formed during the initial study and focus on preventing/improving outcomes of treatment decision conflict in Virginia, and staff is to report back to the JCHC in 2017.

## Background[4]

When a patient is in need of life-sustaining treatment to remain alive, treatment decision making conflicts between patients – or, as in almost all cases involving life-sustaining treatment decisions, an incapacitated patient's agent – and providers are not uncommon. One driver of treatment decision making conflict occurs if a patient/patient's agent requests life-sustaining treatment(s) that a physician believes to be inappropriate. While a patient's/patient agent's right to refuse treatment options offered by clinicians is well-established in common law, Constitutional law and statutory documents, a patient's/patient agent's right to demand any available treatment has not been similarly established. As a result, treatment decision conflicts are thought to arise in up to 50 percent of the Intensive Care Unit (ICU) setting admissions, and are regularly identified as the single biggest ethical dilemma facing North American hospitals.

Many physicians and health care institutions follow a number of process steps to prevent treatment decision conflicts before they occur, such as through clarifying goals with patients, or resolving conflicts once they arise by, for example, convening ethics committee consultations,

[4] This section draws from: Mitchell (2016). "Development of Life-Sustaining Treatment Guidelines" Presentation at: Joint Commission on Health Care meeting, September 7, 2016.

obtaining additional medical opinions and/or engaging institutional resources (e.g., palliative care specialists; patient advocates). While it is estimated that consensus is reached in the vast majority (over 95 percent) of cases of treatment decision conflict, many hospital and physician stakeholders in Virginia have expressed a desire for greater clarity in allowable physician actions for the minority of cases that remain unresolved.

## Virginia's Health Care Decisions Act in Comparison to other States' Statutes Governing Health Care Decisions[5]

Virginia's "Health Care Decisions Act" (§§54.1-2981-2993) regulates several aspects of patient decision making relevant to this study, including procedures relating to Advance Directives (e.g. their construction, form, and revocation), duties/authorities of a patient's agent as well as physicians, procedures if a physician refuses to honor an Advance Directive or health care decision, judicial review of decisions, and immunities. While the Health Care Decisions Act applies to any treatment decision, it is particularly relevant in the context of life-sustaining treatment decisions.

Under the Health Care Decisions Act, Virginia is one of 15 states that allows physicians/facilities to decline to follow health care directives for treatments that would be medically ineffective, inappropriate and/or contrary to generally accepted health care standards. Eleven of the 15 states, including Virginia, do not define "medically" or "ethically" inappropriate treatment. Virginia is also one of the majority of states that specifies only two basic process measures to resolve treatment decision conflicts that may result: the physician must make a reasonable effort to inform the patient of reasons for refusing to provide treatment (32 states) and transfer the patient to another physician (46 states) – and one of 25 states to explicitly mandate continued provision of requested life-sustaining treatment while a transfer is sought. However, similar to most other states, if a transfer is unable to be effected, Virginia Code does not directly address allowable provider actions or legal consequences for withdrawing/withholding requested treatment. By contrast, three states permit a physician to refuse to provide treatment if transfer is unsuccessful – either unconditionally or if certain process measures are taken – while one State takes the opposite track by mandating continued provision of requested treatment if transfer is unsuccessful.

The following are three other aspects of health care decisions relevant to treatment decision making conflicts.

1. Artificially administered nutrition and hydration: Even though artificially administered nutrition and hydration is considered by the medical practice and in case law to be equivalent to any medical treatment, it is often viewed by the general public as different from other medical treatments, requiring different or specific standards regulating its use.

[5] This section draws from: Mitchell (2016). "Development of Life-Sustaining Treatment Guidelines" Presentation at: Joint Commission on Health Care meeting, September 7, 2016.

Virginia is one of 18 states to include artificially administered nutrition and hydration in its definition of life-sustaining care, compared to 4 states that exclude artificially administered nutrition and hydration from their definition and 18 states that do not reference artificially administered nutrition and hydration one way or the other. Three states mandate continued provision of artificially administered nutrition and hydration throughout a treatment decision conflict resolution process, while the remainder of states (including Virginia) do not specifically reference artificially administered nutrition and hydration.

2. Judicial recourse/review of physician treatment decisions: Virginia is one of 15 states to identify a process for judicial recourse/review specific to the context of care provided under the Health Care Decisions Act, compared to 23 states that do not explicitly reference a process. Virginia is not one of six states to identify a judicial review process specific to the context of treatment decision conflict/patient transfers.
3. Non-discrimination in physician treatment decisions: Some stakeholders in Virginia and nationally have concerns that clinicians determining the appropriateness of life-sustaining treatment will discriminate against vulnerable populations, such as the disabled or elderly, by placing a lower valuation on expected benefits for those patients and/or a higher valuation on expected repercussions/ineffectiveness compared to other patients. There are four states, not including Virginia, that reference non-discrimination or disabilities in the context of life-sustaining treatment.

The Texas Advance Directives Act is the most detailed and comprehensive State Statute to address treatment decision conflicts between patients and physicians and an instructive model to inform potential revisions to Virginia Statute. Originally enacted in 1999, its primary features are standardized facility-level conflict resolution processes including review of physician decision by third-party ethics or medical committee; provision of information on the decision review process (written description, advance notice of meeting time, copy of registry list of providers willing to accept transfer/assist in locating provider); patient/patient agent's entitlements (attend review meeting, receive written explanation of decision/relevant portion of medical record); facility role in attempting patient transfer ("reasonable effort") and required health care pending transfer (life sustaining treatment, comfort care); patient responsibility for costs of transfer; ability of physician/health facility to cease life-sustaining treatment after 10 days, with exception of artificially administered nutrition/hydration considered ordinary care (exceptions specified for cases of artificially administered nutrition/hydration considered extraordinary care); judicial review of physician decision is limited to extending the 10-day time period if there is a "reasonable expectation" that another physician/facility will accept the patient and honor the treatment request; and exclusion of home and community support services facilities from conflict resolution process/requirements.

## 2017 Work Group Activities

Building on the participation of stakeholders for the 2016 study, work group participants included stakeholders representing providers, patients and legal counsel, and State agencies. The following is the list of entities represented in the work group.

- Bon Secours Health System
- Carilion Clinic
- Department of Aging and Rehabilitative Services
- Department of Health Professions
- disAbility Law Center of Virginia
- Inova
- LeadingAge
- LifeNet Health
- Mary Washington Health Care
- Medical Society of Virginia
- Riverside Health System
- Sentara Healthcare
- The Arc of Northern Virginia
- The Family Foundation
- University of Virginia Health System
- Virginia Association for Hospices & Palliative Care
- Virginia Association of Centers for Independent Living
- Virginia Association of Health Plans
- Virginia Catholic Conference
- Virginia Commonwealth University Health System
- Virginia Department of Health
- Virginia Health Care Association
- Virginia Hospital and Healthcare Association
- Virginia Nurses Association
- Virginia Society for Human Life
- Virginia Trial Lawyers Association

The work group identified three work streams on which to focus: 1) literature/data on contextual factors surrounding disputes, 2) data on the frequency and characteristics of disputes in Virginia, and 3) continued revisions to § 54.1-2990 to increase statutory clarity on resolution of disputes.

Contextual Factors Surrounding Disputes

To better understand why decision making conflict arises – and, as a result, understand how it might be prevented or addressed - information was gathered from the literature on contextual factors surrounding cases of decision making conflict over life-sustaining care. Briefly, it was found that around one-third of deaths in the US occur in hospitals, with the vast majority (80 percent) directly relating to decisions to withhold or withdraw life-sustaining treatment (Angus et al., 2004; Prendergast & Luce, 1997; Azoulay et al., 2009; Cook et al., 1995; Sprung et al., 2014). Conflicts between clinicians and families over these treatment decisions arise frequently (e.g. 22 to 48 percent of ICU admissions) – and are a primary focus of ethical consultations (50 percent), although it is estimated that consensus is reached in the vast majority (95 percent) (Studdert, et al., 2003; Breen, et al., 2001; Pope, 2013; Swetz, Crowley, Hook, & Mueller, 2007).

Common factors associated with treatment decisions disputes between patients/families and providers include different goals of care, differences in interpretation of likelihood of success, and distrust in patient/family-provider relationship (Azoulay et al., 2009). These factors relate to fundamentally different perspectives of patients and providers. The most frequent sources of

conflict related to treatment decision disputes in end of life care include a lack of psychological support for families, sub-optimal facility decision making processes, and perceived disregard for family and patient preferences (Abbott et al (2001); Azoulay et al., 2009). These sources reflect issues that may be addressed through improved processes and flows of information to patients' families, such as improved hospital processes, better acknowledgment of family preferences and increased opportunity to discuss treatment with family (McDonagh et al., 2004; Schuster et al., 2014).

On the provider side, there is a body of literature documenting the effect that conflictual situations have on providers in terms of moral distress. Among nurses and physicians, prolonged aggressive treatment when the patient's prognosis is poor has been identified as the most common cause of moral distress. This type of distress is positively correlated with intention to leave a position and, at any given time, 10-25 percent of clinicians are considering leaving their position due to it (Allen et al., 2013; Hamric & Blackhall, 2007; Whitehead et al,. 2015). In Virginia, the UVA Health System has conducted over 75 consults in the past 10 years related to moral distress, with 40 percent relating to end-of-life situations or treatment decision conflicts. While these situations almost certainly exact a toll on patient family members as well, the literature exploring that is much more limited (Hamric et al., 2017).

Frequency and Characteristics of Disputes in Virginia

A survey was developed to quantify and characterize instances of life-sustaining treatment disputes between patients/families and providers. Data were collected from health systems operating acute care hospitals in Virginia and 84 percent (16/19) of health systems had a representative respond to the survey, representing 90 percent (66/73) of general acute care hospitals in Virginia. Fifty-six percent of health systems surveyed (9/16) have a written, formalized process for handling situations of intractable treatment decision conflict between the health care team and patients/families/surrogate decision makers which explicitly indicates how patients/family members/patient agents are able to participate in the process. Of the 8 health systems surveyed without a written, formalized process, all but one of the health system representatives see a need for such a process; however, the majority (5/8) of health systems have not established such a process due to lack of legislative clarity.

Among health systems with a process for handling situations of intractable treatment decision conflict, over 40 cases went through the process in the last 12 months. Across all 40 cases, 38 percent were resolved because the health care team and the patient or patient's agent came to consensus, 27 percent were resolved because the patient died, consistent with national literature 5 percent resulted in withholding or withdrawing life-sustaining treatment over patients' family's objections, 2 percent were resolved because the patient was transferred to another facility or physician, and none involved litigation. Among health systems without a formalized process, three estimated that they would see five to ten cases per year and three indicated that they would see ten to twenty cases per year. In part because of the perceived value of these findings to

workgroup participants, multiple workgroup participants expressed a desire to build off of the knowledge gained in this survey to more routinely collect data going forward.

Continued Revisions to § 54.1-2990

In reviewing § 54.1-2990 of Virginia Code, the work group determined the following guiding principles. The group would build off of the revisions drafted in 2016 as part of the "Development of Life-Sustaining Treatment Guidelines" study. Continuing to obtain input from all stakeholders, they would address concerns and, in particular, work through safeguards for both the patient and provider that do not exist in the current Statute language. In several ways, these safeguards address contextual sources of conflict between families and providers described earlier and address the fundamental incompleteness and imbalance in § 54.1-2990, specifically that this section should outline a complete process governing decisions to withdraw or withhold life-sustaining treatment, and, importantly, provide clarity about an endpoint to this process. They would reflect principles of due process, which relates to providing safeguards to both patients and providers, such as the opportunity to have assistance of counsel, a neutral/independent decision maker, meaningful appellate review, notice, written statement of decision, and criteria to guide decision.

The following is the proposed revisions to § 54.1-2990 by the work group:

§ 54.1-2990. Medically unnecessary treatment not required; procedure when physician refuses to comply with an advance directive or a designated person's treatment decision; mercy killing or euthanasia prohibited

Nothing in this article shall be construed to require a physician to prescribe or render health care to a patient that the physician determines to be medically or ethically inappropriate. *The physician, using reasonable medical judgment in determining the medical or ethical appropriateness of treatment, shall base his determination solely on the patient's medical condition, not the patient's age or other demographic status, disability, or diagnosis of Persistent Vegetative State (PVS), except to the extent that the patient's age or other demographic status, disability, or diagnosis of Persistent Vegetative State (PVS) relate to the patient's medical condition.*

~~However, i~~*I*n such a case *that the physician determines health care to be medically or ethically inappropriate,* if the physician's determination is contrary to the request of the patient, the terms of a patient's advance directive, the decision of an agent or person authorized to make decisions pursuant to § 54.1-2986~~, or a Durable Do Not Resuscitate Order,~~ the *policies of the hospital in which the patient is receiving health care will be followed.*

Policies of the hospital that is equipped to provide life-sustaining treatment shall be documented and shall include, at a minimum, the following steps:

(1) Rendering of a second medical opinion;

(2) Review of the physician's determination by an interdisciplinary medical review committee, followed by issuance of its own determination on the appropriateness of requested treatment. The patient, agent or person authorized to make medical decisions pursuant to § 54.1-2986 will be afforded reasonable opportunity to participate in the medical review committee meeting;

(3) Written explanation of the decision reached during the medical review committee review process that will be included in the patient's medical record

If the patient, agent or person authorized to make medical decisions pursuant to § 54.1-2986 requests life-sustaining treatment that the attending physician determines to be medically or ethically inappropriate, the physician or physician's designee shall document his decision in the patient's medical record and make a reasonable effort to provide ~~inform~~, in writing, to the patient or the patient's agent or person with decision-making authority pursuant to § 54.1-2986: the physician's ~~of such~~ determination and the reasons for the determination~~.~~, and; a copy of the hospital policies pursuant to this section.

The hospital in which the patient is receiving health care shall make reasonable efforts to inform the patient or the patient's agent or person authorized to make decisions pursuant to § 54.1-2986, in writing: that the patient has the right under § 32.1-127.1:03 to obtain a copy of the patient's medical record; that the patient may obtain on his or her own behalf independent medical opinion; that under this section, the patient has the right to participate in the medical review committee meeting and may be accompanied by any trusted advisor to assist the patient, patient's agent, or person authorized to make decisions pursuant to § 54.1-2986 in understanding the proceedings, deliberations, and decision of the medical review committee; and that neither hospital policies and procedures nor any requirement of this section shall preclude the patient, patient's agent, or person authorized to make decisions pursuant to § 54.1-2986 from obtaining legal counsel to represent the patient or from seeking other remedies available at law; provided, however, that the patient or his or her legal counsel must provide a formal notice of such intention to the chief executive officer of the hospital prior to the date fourteen days following documentation of the decision of the physician in the patient's medical record.

~~If the conflict remains unresolved, the physician shall make a reasonable effort to transfer the patient to~~*If* another physician *or facility* ~~who~~ is willing to comply with the request of the patient, the terms of the advance directive, the decision of an agent or person authorized to make decisions pursuant to § 54.1-2986~~, or a Durable Do Not Resuscitate Order~~. *the physician currently attending the patient shall cooperate in transferring the patient to the second physician or facility.* The physician shall provide the patient or his agent or person with decision-making authority pursuant to § 54.1-2986 a reasonable time of not less than fourteen days *after documentation of the decision of the physician pursuant to this section in the patient's medical record* to effect such transfer. During this period, the physician shall*:* continue to provide any life-sustaining care *treatment* to the patient which is reasonably available to such physician, as requested by the patient or his agent or person with decision-making authority pursuant to § 54.1-2986*. The hospital in which the patient is receiving health care shall facilitate prompt*

*access to medical records related to the treatment received by the patient in the facility pursuant to § 32.1-127.1:03.*

If, at the end of the 14-day period, the policies of the hospital in which the patient is receiving health care have been followed and the physician has been unable to transfer the patient to another physician who is willing to comply with the request of the patient, the terms of the advance directive, the decision of the agent or person authorized to make decisions pursuant to § 54.1-2986 despite reasonable efforts, the physician may cease to provide the treatment that the physician has determined to be medically or ethically inappropriate.

However, artificially administered nutrition and hydration: must be provided if, based on the physician's reasonable medical judgment, removal of artificially administered nutrition and hydration would be the sole mechanism that would hasten the patient's death; may be withdrawn or withheld if, based on the physician's reasonable medical judgment, providing artificially administered nutrition and hydration would:

(1) hasten the patient's death;

(2) be harmful or medically ineffective in prolonging life; or

(3) be contrary to the patient's or surrogate's clearly documented desire not to receive artificially administered nutrition or hydration.

In all cases, care directed toward the patient's pain and comfort shall be provided.

A health care provider who abides by the duties and requirements of § 54.1-2990 shall be presumed to have complied with the standard of care as set forth in § 8.01-581.20, absent clear and convincing evidence of gross negligence or willful misconduct by such health care provider. A health care provider who abides by the duties and obligations of § 54.1-2990 shall not be subject to criminal prosecution related to such actions or inactions and shall not be subject to disciplinary or regulatory enforcement actions by any health regulatory board related to such actions or inactions, absent gross negligence or willful misconduct. Any health care provider or person who provides information to any medical review committee, board, group or other entity providing a medical or ethics review pursuant to § 54.1-2990, or makes any finding, opinion, or conclusion as part of such entity shall be immune from civil liability for any act done for, or any utterance or communication made to, such entity unless such act, utterance or communication was the result for gross negligence or willful misconduct. For purposes of this section, health care provider shall have the same meaning as defined in § 8.01-581.1.

B. For purposes of this section, "life-sustaining ~~care~~*treatment*" means any ongoing health care that utilizes mechanical or other artificial means to sustain, restore or supplant a spontaneous vital function~~, including hydration, nutrition, maintenance medication, and cardiopulmonary resuscitation.~~

C. Nothing in this section shall require the provision of health care that the physician is physically or legally unable to provide, or health care that the physician is physically or legally unable to provide without thereby denying the same health care to another patient.

D. Nothing in this article shall be construed to condone, authorize or approve mercy killing or euthanasia, or to permit any affirmative or deliberate act or omission to end life other than to permit the natural process of dying.

## Actions Taken by the Joint Commission on Health Care

During the November 2017 decision matrix meeting, JCHC members voted to take no action.

## Legislative Action

During the 2018 General Assembly Session, JCHC members Delegate Stolle and Senator Edwards introduced companion bills (HB 226 and SB 222) to establish a process whereby a physician may cease to provide health care that has been determined to be medically or ethically inappropriate for a patient. After amendments, both bills were passed and enacted.

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# Heroin Use in Virginia

## Study Mandate

In 2017, Delegate Marshall requested via House Joint Resolution 597 that the Joint Commission on Health Care study heroin use in Virginia including the rates of use, reasons why individuals become addicted, what other illegal substances individuals who overdose on heroin may have also used, initiatives underway in Virginia to address heroin addiction and overdose, the impact of state and federal laws on the availability of naloxone, the cost of naloxone and how often it has been used, and JCHC recommendations for improving the Commonwealth's response to the heroin crisis. The resolution was tabled in House Rules committee with the understanding that the JCHC would consider conducting the study.

## Background

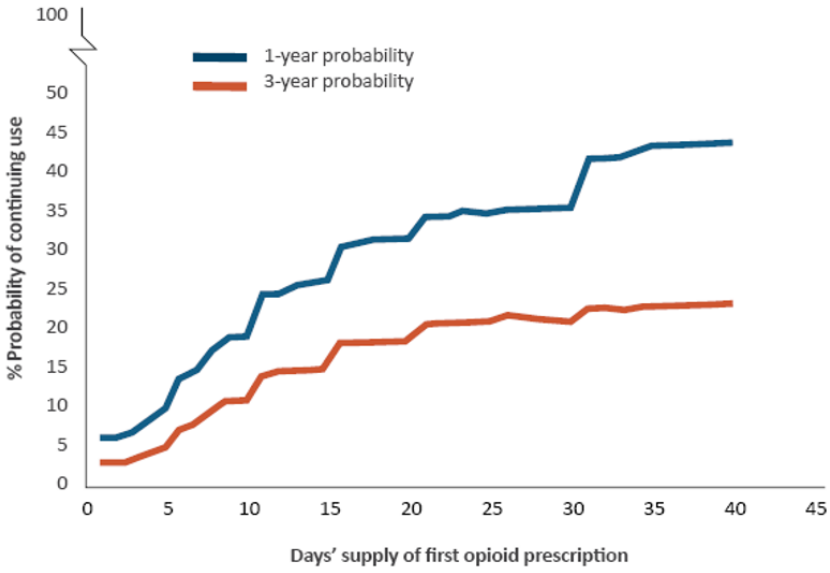
Heroin is in the same class of drugs as opium, morphine, methadone and prescription opioid pain medicine. The misuse of prescription opioid pain medicine is considered one of the major contributors to the increase in heroin use and overdose fatalities. This report focused on heroin and includes discussions about prescription opioid pain medicine as necessary.

## National Information

In the U.S., deaths from drug overdose involving heroin tripled from 8 percent in 2010 to 25 percent in 2015. The number of people indicating heroin use on the National Survey on Drug Use and Health (NSDUH) increased by 150 percent from 2007 (207,000) to 2013 (517,000). The increase in use was found to be greatest among white men between the ages of 18 and 25 (Harris 2015).

**Probability of Continued Opioid Use After One and Three Years**

By number of days' supply of the first opioid prescription, 2006–2015




*Source: Centers for Disease Control and Prevention, 2017*

During the 1960s, 82 percent of heroin users seeking treatment reported using heroin as their first opioid; by 2010 the percent flipped, 75 percent of heroin users seeking treatment reported using prescription pain medicine first (Millman 2014). From 2002 to 2013 the percent of heroin users with opioid pain reliever abuse or dependence more than doubled from 20.7 to 45.2 percent. In 2013, 59 percent of the heroin deaths involved one other drug; marijuana, cocaine and/or prescription opioid pain relievers (Jones 2014; CDC 2015).

## Why Heroin

Heroin has the same effect on the brain and body as prescription opioid pain medicine (i.e. OxyContin and Vicodin). A complex chain of events related to pain-relief, intense euphoria and cravings for more are triggered from the drugs. CDC data indicate that the longer a prescription opioid is prescribed the higher the probability that the person will continue to use the drugs. As tolerance to prescription opioids increases individuals seek stronger and less costly drugs, and heroin is less costly and more potent than prescription opioid pain medicine. According to the CDC, people who use opioid pain medicine are 40-times more likely to be addicted to heroin. Addiction, however, is highly individualistic with genetics accounting for 35 to 40 percent of risk (CDC 2017; Volkow and McLellan 2016; Compton et al 2016).

## Overdose and Naloxone

Heroin overdoses can occur at any time. Signs may include loss of consciousness; unresponsiveness; inability to talk; shallow, erratic breath or no breathing; skin color turning blue; slow, erratic or no heartbeat; and gurgle or choking sounds – referred to as the 'death rattle'. Naloxone, when administered, reverses the effects of an overdose immediately sending a person into withdrawal. Naloxone wears off within 30 to 90 minutes while the effects of an opioid can last for much longer. Naloxone does not, and is not intended to, address addiction (Harm Reduction Coalition 2017; Volkow and McLellan 2016).

## State and Federal Laws for Naloxone

Naloxone is a prescription drug but it is not a controlled substance; it has no abuse potential. State laws regulate its distribution, use and Good Samaritan protections for those administering it. According to the Network for Public Health Law, all 50 states and the District of Columbia passed legislation designed to improve layperson naloxone access. Forty states and the District of Columbia passed overdose Good Samaritan laws. A recent study reported that the adoption of naloxone access and Good Samaritan laws are associated with a 9 to 11 percent decrease in opioid-related deaths in a state. The general assembly in Virginia passed legislation related to both the availability of naloxone and Good Samaritan laws starting in 2015 (NCSL 2017; Mattina 2017).

## The Cost of Naloxone

The price of naloxone varies. Insurance companies negotiate prices and often have built in rebates. For individuals, naloxone savings cards and coupons are available on the web. Many nonprofit and government agencies may receive naloxone at highly discounted rates and in some situations for free depending on the manufacturer. Kaleo, a Virginia based company, reports that people with insurance making less than $100,000, as well as uninsured people, pay nothing for the company's injector device.

Lowest Med - with coupon
Email: info@lowestmed.com
Naloxone HCL Spray / Evzio - Auto Injection

| Drug Store | Evzio - Auto Injection | | Narcan Spray | Generic Syringe | | Generic Vial | |
|---|---|---|---|---|---|---|---|
| | 0.4 MG (1 syringe) | 2 MG/0.4 ML (1 syringe) | 4 MG (2/pack) | 1 MG/2 ML (2 syringes) | 0.4 MG/ML (1 syringe) | 0.4 MG/ML (10ML - 1 vial) | 0.4 MG/ML (1 ML - 1 vial) |
| Rite Aid | $1,863.25 | $2,171.55 | $140.50 | $39.47 | $19.90 | $112.44 | $19.54 |
| Target | $1,891.43 | $2,145.95 | $136.25 | $53.72 | $19.65 | $109.84 | $22.01 |
| Smiths | $1,920.25 | $2,098.75 | $135.70 | $43.60 | $19.40 | $108.84 | $19.75 |
| Kmart | $1,941.40 | $2,122.00 | $138.40 | $41.87 | $23.30 | | $20.06 |
| Walmart | $1,962.07 | $2,144.77 | $135.07 | $42.71 | $18.47 | $111.01 | $18.82 |
| CVS | $1,965.50 | $2,147.20 | $141.00 | $50.89 | $23.47 | $109.84 | $25.06 |
| Walgreens | $1,988.56 | $2,173.36 | $138.13 | $42.47 | $22.10 | $109.34 | $12.18 |
| SHOPKO | | | | | $25.09 | | $25.09 |
| Average Price with Coupon | $1,933.21 | $2,143.37 | $137.86 | $44.96 | $21.42 | $110.22 | $20.31 |

RELATIONSHIP BETWEEN PRESCRIPTION-OPIOID AND HEROIN USE

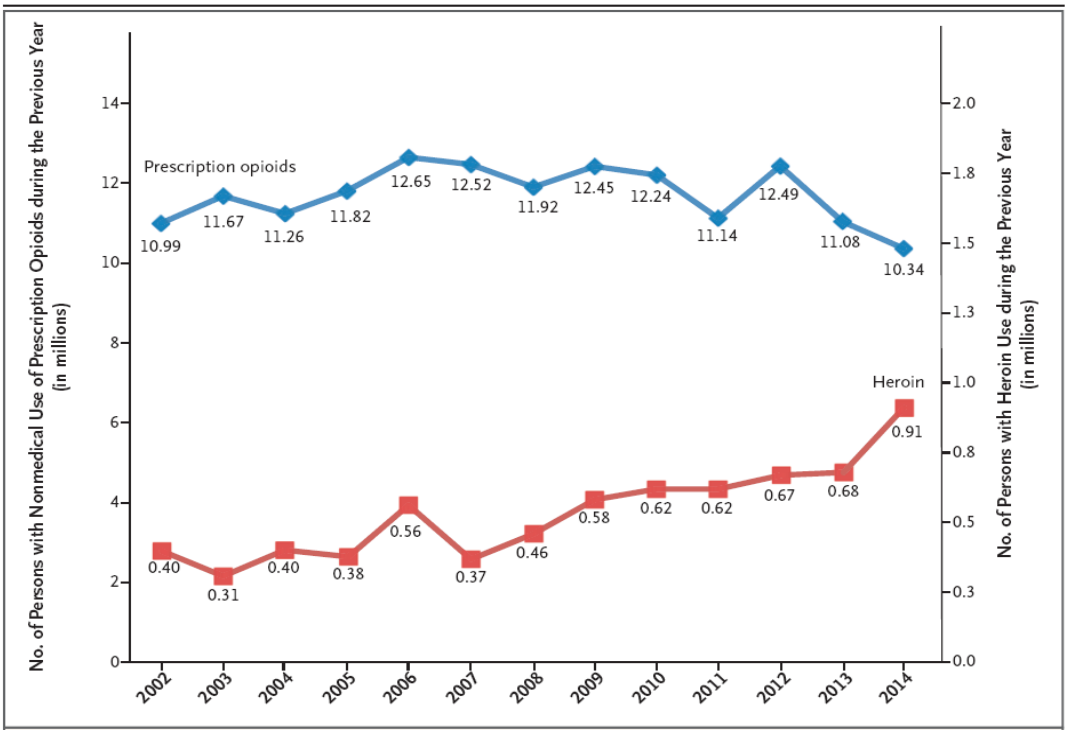



**Figure 2. Nonmedical Use of Prescription Opioids and Heroin during the Previous Year among Noninstitutionalized Persons 12 Years of Age or Older, 2002–2014.**
Data are from the Center for Behavioral Health Statistics and Quality.[2]

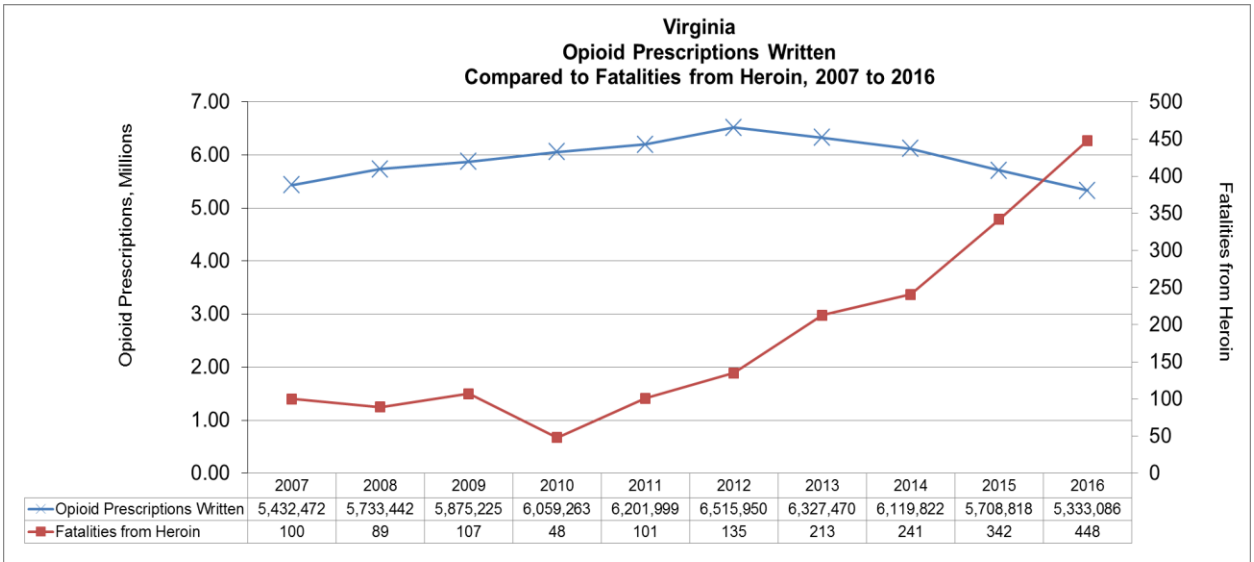
## Actions that May Be Impacting Heroin Use and Overdose

Beginning in 2010 the federal government began to recognize the growing problem of prescription drug abuse. Increased enforcement of federal dispensing laws, a five-year goal to reduce prescription drug abuse, and other guidance on prescribing and dispensing of controlled substances encouraged states and the medical community to address the issue. By 2017, 22 states, including Virginia, passed laws related to limiting the number of days certain opioid prescriptions can be prescribed. The number of days varies by state from 3 to 4 days (Kentucky and Minnesota) to 14 days (Nevada) and are either in state code or by agency regulation as directed by state code (Compton et al 2016). National research on the impact of federal actions to reduce the dispensing and use of prescription pain medicine coupled with state laws and regulations related to limiting opioid prescriptions indicates that these policies may unintentionally be contributing to increases in heroin use and overdose.

## The Next Emerging Crisis: Synthetic Fentanyl

Fentanyl is a synthetic opioid pain reliever often given to people with advanced cancer. The drug is 50 to 100 times more powerful than morphine and, in the illegal market, is often mixed with heroin and/or cocaine as a combination product. Due to its powerful nature, reversing an overdose involving fentanyl may require multiple doses of naloxone (CDC 2017).

# Virginia Information




| | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|---|---|---|---|---|
| Opioid Prescriptions Written | 5,432,472 | 5,733,442 | 5,875,225 | 6,059,263 | 6,201,999 | 6,515,950 | 6,327,470 | 6,119,822 | 5,708,818 | 5,333,086 |
| Fatalities from Heroin | 100 | 89 | 107 | 48 | 101 | 135 | 213 | 241 | 342 | 448 |

Source: Opioid prescription drug rates: CDC Prescribing Rate Maps (https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html)
Center for Behavioral Health Statistics and Quality. (2016). Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/
Fatalities from Heroin: Virginia Department of Health, Office of Chief Medical Examiner
* Estimate: state population times the national percent of heroin users as determined by the National Survey of Drug Use and Health Surveys , 2015
Prepared by JCHC

According to the 2014-2015 National Survey of Drug Use and Health Surveys, 25,000 Virginians over the age of 12 used heroin in the last year; or approximately 0.3 percent of the state population. The survey reports that heroin use went from 0.2 to 0.3 percent of the U.S. population from 2007 to 2015.[6] According to the Virginia Office of the Chief Medical Examiner (OCME), fatal heroin overdoses often occur as the primary drug causing death, but more recently, fentanyl and/or fentanyl analogs in addition to heroin have caused fatal overdoses. Fatal heroin overdoses increased by 31.0 percent in 2016 when compared to 2015. OCME reports that in 2016, 57.4 percent of heroin deaths also included fentanyl (Bond 2016).[7]

Virginia state code authorized the Boards of Medicine and Dentistry to adopt regulations concerning the prescribing of opioids. Both Boards limit overall prescriptions per patient for acute pain to three months and require practitioners to prescribe the lowest doses possible within the manufacturer's guidelines. The Board of Medicine's regulations require health care practitioners to develop treatment plans for chronic pain management and establish informed consent agreements with patients, limit the number of days an opioid can be prescribed for acute pain to no more than 14 consecutive days and require practitioners to check the Prescription Monitoring Program (PMP) under certain circumstances before prescribing. The Board of Dentistry's regulations limit the number of consecutive days a dentist can write an opioid prescription to seven days. While it is too early to determine what the overall impact on heroin use and abuse may be, Virginia's data related to heroin deaths mirrors the national data

[6] Prior to the 2014-15 survey heroin use was included within the "illicit drug use" category of the survey report for each state and not uniquely identified.
[7] Re: Heroin Study. Kathrin Hobron (VDH, OCME). Email to Stephen Weiss. October 10, 2017.

indicating an increase in heroin fatalities coinciding with increased efforts to reduce prescription opioid drug abuse.[8]

## Lack of Data on Naloxone Use

As mentioned above, Virginia made naloxone available without a prescription beginning in 2015, with standing orders and a protocol first issued later the same year. Due to the newness of the availability of naloxone there is a lack of adequate and coordinated data on its dispensing and use in Virginia. Emergency Medical Services (EMS) is the only state agency collecting data and reporting on the use and administration of naloxone. In 2015, EMS administered naloxone 3,183 times; in 2016 the number increased to 4,315, a 35.6 percent increase over 2015. As of August 2017, naloxone was administered 3,186 times by EMS and may exceed 4,700 times by year's end, a 47.7 percent increase from 2015.

## Actions Virginia has Taken to Address the Opioid Crisis

- Governor's Task force on Prescription Drug and Opioid Abuse (created in 2014); continuing as the Governor's Executive Leadership Team on Opioids and Addiction (created December of 2016 to oversee the ongoing response to the crisis)
- State Health Commissioner declared the opioid addiction crisis a Public Health Emergency
- State Health Commissioner issued standing order for naloxone
- Legislative changes include the passage of 7 laws and 2 budget amendments addressing:
    - Expanded availability of naloxone
    - Broadened immunity from civil liability for the use of naloxone
    - Mandated e-prescribing to ensure that all opioid prescriptions are transmitted electronically by the year 2020
    - Peer recovery registration for Medicaid reimbursement
    - Naloxone dispensing by community organizations
    - Reports of substance-exposed infants to ensure treatment for mother and child if necessary
    - Harm reduction pilot programs at local health departments
    - Mandate to check the PMP for initial opioid prescription over 7 days
- Administration of federal grants to address opioid crisis
- Issuance of at least 11 regulatory actions related to pain management and addiction treatment
- Creation of a central webpage clearinghouse of information: VaAware - http://vaaware.com/

[8] Code of Virginia. § 54.1-2522.1. (https://law.lis.virginia.gov/vacode/54.1-2522.1)

## Conclusions

The Commonwealth response to the heroin crisis, including making naloxone available statewide, appears to be consistent with what other states have done/are doing. Other things the Commonwealth may want to explore include alternative ways of treating and caring for heroin addicts, such as reviewing options related to the opening of 'safe injection sites.' Supervised injection sites will help reduce the spread of HIV and hepatitis C among intravenous drug users, as well as provide locations where people can be directed into treatment, and prevent overdose death. In addition, data collection, coordination and reporting is an area that needs to be reviewed for all agencies involved in order to improve the programs and to identify and respond to emerging trends. Finally, the Governor's Task Force/Executive Leadership Team on Prescription Drug and Heroin Abuse is comprehensive, all-inclusive and has been studying the topic, making recommendations and overseeing the State's ongoing response to the crisis. The Task Force website is: https://www.dhp.virginia.gov/taskforce/.

## Actions Taken by the Joint Commission on Health Care

JCHC members approved a policy option to introduce legislation to amend the Code of Virginia by adding in § 2.2-200 a section to require that all Governor's Secretaries coordinate and identify data related to substance abuse that can be used to identify current and emerging substance abuse trends, and to develop local, regional and statewide plans to address the changing landscape as new substances are introduced to the Commonwealth. The section also would require that all state and local agencies, including local law enforcement agencies, government and non-government hospitals, Community Services Boards, and any other entities receiving public funds from the Commonwealth, provide such [substance abuse] data to the appropriate state agencies identified by the Governor's Secretaries.

## Legislative Action

Senator Edwards and Delegate Hope introduced companion bills (SB 459 and HB 816). SB 459 was incorporated into SB 580 patroned by Senator Hanger, along with Senators Barker, Carrico, Dunnavant and Edwards as incorporated chief co-patrons.

**SB 580: Data collection and dissemination; governance.** Amends the Government Data Collection and Dissemination Practices Act (§ 2.2-3800 et seq.) to facilitate the sharing of data among agencies of the Commonwealth and between the Commonwealth and political subdivisions. The bill creates the position of Chief Data Officer of the Commonwealth (CDO), housed in the office of the Secretary of Administration, to (i) develop guidelines regarding data usage, storage, and privacy and (ii) coordinate and oversee data sharing in the Commonwealth to promote the usage of data in improving the delivery of services. The bill also creates a temporary Data Sharing and Analytics Advisory Committee (Advisory Committee) to advise the CDO in the initial establishment of guidelines and best practices and to make recommendations to the Governor and General Assembly regarding a permanent data governance structure.

The bill directs the CDO and the Advisory Committee to focus their initial efforts on developing a project for the sharing, analysis, and dissemination at a state, regional, and local level of data related to substance abuse, with a focus on opioid addiction, abuse, and overdose.

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# Should Medigap Policies Be Provided for Medicare Recipients under 65 Years of Age in Virginia?

## Study Mandate

By letter to the Joint Commission on Health Care Chair, Senator Wagner, Chairman of the Senate Committee for Commerce and Labor, asked the JCHC to review issues related to access to Medigap policies for those who are disabled and under the age of 65. The request was approved by JCHC members during the May, 2017, work plan meeting.

## Background

Medigap is supplemental health insurance for people enrolled in fee-for-service Medicare Parts A (hospital coverage) and B (physician and ancillary medical services). The purpose of Medigap is to help beneficiaries pay for the out-of-pocket cost sharing expenses required by Medicare Parts A and B. In order to be eligible to enroll in Medicare under the age of 65 a person needs to be deemed disabled by the Social Security Administration. The data indicate that people under age 65 and enrolled in Medicare are often in poorer health and require more health care services than those age 65 and over.

Medigap supplemental insurance is sold to Medicare beneficiaries by private insurance companies. Federal law regulates the sale and provision of Medigap for Medicare beneficiaries age 65 and older but is silent for Medicare beneficiaries under the age of 65, leaving this segment of the Medigap market to be state regulated. Due to the poor health of Medicare beneficiaries under age 65, Medigap health insurance policies are not considered profitable by the health insurance industry. Therefore, private insurance companies do not offer Medigap supplemental insurance to Medicare beneficiaries under the age of 65 unless the state requires them to make the policies available. Thirty-three states currently require health insurance companies that sell Medigap to Medicare beneficiaries age 65 and over in their state to make at least one policy available to those under age 65.

The requirement for health insurance companies to sell Medigap supplemental health insurance to those under age 65 varies depending on the state. States have the authority and flexibility to limit the types of Medigap plans sold, regulate premiums charged, create different risk categories for those over and under age 65, and to exclude certain illnesses from coverage (i.e. end stage renal disease). Finally, availability of plans in any given area of a state is determined by the insurance carrier.

## Why Medicare Supplemental Insurance May be Needed

Medicare's out-of-pocket cost sharing requirements for Parts A and B do not include maximum out of pocket limits. Studies indicate that, on average, 27 percent of all Medicare beneficiaries spent 20 percent or more of their income on out-of-pocket expenses and premiums in 2016.

When premiums are excluded, a typical beneficiary spends an average of $3,024 per year and those with serious cognitive and/or physical impairments spend an average of more than three times as much out-of-pocket ($5,519) as those without chronic disease or disability ($1,549). Finally, high-need beneficiaries can spend well over $7,000 a year out-of-pocket to cover their health care needs. Some of the out-of-pocket spending is on services not covered by Medicare, i.e. dental, vision, hearing and long term care.[9]

Medicare beneficiaries have two other options to cover out-of-pocket expenses. The first option is to sign up with a Medicare Advantage (MA) health plan. MA health plans provide comprehensive coverage with low premiums and maximum out-of-pocket expense limits. MA plans are not offered everywhere and most Medicare beneficiaries (64 percent nationally and 78 percent in Virginia) do not enroll in them. The majority of MA plans operate as traditional HMOs. The HMOs require enrollees to receive primary care physician referrals for specialists, stay within the plan's provider network, and may require prior authorizations for select services. Studies find that people with complex health care needs due to illness and/or disability report problems gaining access to physicians, especially specialists, and some needed health care services.

The second option is to qualify for Medicaid or the Medicare Savings Program (MSP) administered by the state Medicaid program. Being deemed disabled by the Social Security Administration does not guarantee that a person will qualify for either Medicaid or MSP. Both programs require a Medicare beneficiary to meet income and asset requirements of the state and federal government.

Making Medigap available to Medicare beneficiaries in Virginia who are disabled and under age 65 is one way to make health care more stable, predictable and affordable for them. In addition, the availability of Medigap to this group may prevent some from having to "spend down" their income in order to qualify for Medicaid and/or the MSP program.

[9] Schoen M.S., Cathy. Medicare Beneficiaries' High Out-of-Pocket Costs: Cost Burdens by Income and Health Status. The Commonwealth Fund. Issue Brief. May 2017.

| Three State Comparison<br><br>Medigap Enrollment Data for those under age 65 | | | | |
|---|---|---|---|---|
| Description | Colorado | Maine | Tennessee | Total |
| Medicare beneficiaries under age 65 | 101,264 | 57,189 | 246,712 | 405,165 |
| Medigap policies sold to persons under age 65 | 11,296 | 2,558 | 4,833 | 18,687 |
| Percent < 65 years | 11.16% | 4.47% | 1.96% | 4.61% |

Medigap enrollment and premium data for those under age 65 provided by three states (CO,ME,TN) suggest that an average of 4.61 percent of Medicare beneficiaries in those states under age 65 have a Medigap policy. Using the average percent, a conservative estimate of the number of Medigap policies sold to Medicare beneficiaries under age 65 in Virginia may be 9,247. Premiums charged for the plans offered in the three states suggest that the average premium for someone under age 65 may be 2.5 to 3 times higher than the premiums for those age 65 and over.

| Description of Medigap Insurance Requirements for Medicare Beneficiaries Under Age 65 | | | | | |
|---|---|---|---|---|---|
| **State** | Premium Rating | Required Coverage | Plan Types Required | Enrollment Period | Rating Provisions |
| **Colorado** | Attained Age Rating | Disabled including ESRD | All plans offered to over 65 population | 6 months from first day of first month person enrolled in Part B | Plans may use the lowest premium for each plan; or based on formula in state law |
| **Maine** | Community Rating | Disabled including ESRD | All plans offered to over 65 population | 6 months from date of enrollment in Part B with a 90-day Special Enrollment Period | Same premium as all |
| **Tennessee** | Attained Age Rating | Disabled including ESRD | All plans offered to over 65 population | 6 months from date of enrollment in Part B; or 6 months after loss of Medicaid or MA | Premium rates may differ between over and under 65 provided the rates are based on sound actuarial principles |
| Sources: Kaiser Family Foundation. **https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8412-2.pdf**. AND American Health Insurance Plans (AHIP). Under age 65 disabled - Access to Medigap. May 2017. | | | | | |

One health insurance plan offers a Medigap policy for people under the age of 65 in Northern Virginia as part of a Washington DC metro area agreement related to Medigap. According to the Virginia Bureau of Insurance's website, the average cost of the premium is approximately $11,010 per year, which is 5.28 times higher than the average cost of a premium for a person age 65 and over ($2,085). In spite of the cost, the company reports 49 Medicare beneficiaries under the age of 65 in Northern Virginia purchased a policy, or 1.44 percent of the total number of Medigap policies sold by the company in Northern Virginia as of July 2017 (3,398). Finally, as noted above, each state includes different regulatory requirements for the sale of Medigap to those under age 65. The previous table displays the different features of each state.

## Conclusions

Thirty-three states currently require health insurance companies selling Medigap to those age 65 and older to also sell Medigap to those under age 65. Information from Colorado, Maine, Tennessee and Northern Virginia indicates that, when Medigap is available, there is a market for it. Insurance companies on their own, however, will not offer the policies, viewing this market as not profitable because Medicare beneficiaries under the age of 65 are disabled and; therefore, likely costlier than those age 65 and older.

## Actions Taken by the Joint Commission on Health Care

JCHC Members chose to take no action.

# Mandated Staffing Ratios in Assisted Living Facilities

Passed during the 2017 General Assembly session, Senate Joint Resolution 266 (Senator Dance) directed the Joint Commission on Health Care (JCHC) to identify and analyze current staff-to-resident ratio requirements for assisted living facilities (ALF) and special care units and make recommendations for changes to such ratio requirements that would lead to better care and quality of life for residents, including recommendations regarding the total number and type of staff required to meet the routine and special needs of all residents, the number of staff that must be awake and on duty during night shifts, and the number of staff who should accompany residents on trips away from the assisted living facility or special care unit. The resolution was passed by indefinitely in Senate Rules committee with the understanding that JCHC would consider conducting the study.

## Background

Assisted living facilities (ALF) are congregate home-like settings housing four or more adults who are aged, infirmed or disabled. They Provide 24/7 supervision and oversight of the physical and mental well-being of the individuals, housekeeping, meals, medication management, transportation, and other services. ALFs may not admit individuals whose care needs are greater than the ALF's ability to safely serve. No ALF in Virginia may admit individuals who are ventilator dependent, have some stage III and IV dermal ulcers, pose an imminent physical threat to themselves or to others, need continuous licensed nursing care, or have physical/mental health needs that cannot be met, as determined by the facility.

ALFs are varied in type and may be for-profit or not-for-profit; have various numbers of beds; may be affiliated with a faith-based organization; may be small, stand-alone operations, or they may be part of a local or national chain. ALFs may serve mixed populations (needing different levels of care) in the same unit, or they may be *continuing care communities* having several separate units providing different levels of care that residents may move through as their needs change (e.g., independent living, residential care, assisted living, memory care and skilled nursing).

Federal regulations prohibit Medicare and Medicaid from paying for ALF room and board costs. Most of the ALFs in Virginia serve residents who are private pay, while some also serve individuals who receive Auxiliary Grant (AG) funds. The AG is a state- and locally-funded grant program (80 percent state and 20 percent local funds) that contributes to room and board costs for individuals who meet income and other eligibility criteria. In addition to the AG, Virginia Medicaid pays a per diem rate of $49.50 (approximately $1,485 per month) to help pay for direct care services for persons living in ALFs who are enrolled in the Medicaid Alzheimer's Assisted Living Waiver. The Waiver will expire the end of June 2018 with no plans for renewal.

Individuals in the Alzheimer's Assisted Living Waiver will be moved to other Medicaid Home and Community-Based Services Waivers (such as the Elderly and Disabled with Consumer

Direction Waiver), but ALFs will no longer receive the Medicaid direct care services per diem payment for these individuals. According to DMAS, this change effects approximately twenty individuals. DMAS staff reports that some ALFs have agreed to continue to serve Medicaid recipients with Alzheimer's Disease, despite the cessation of the per diem payment.

## Current Virginia ALF Regulation

The Department of Social Services (DSS) inspects and licenses ALFs, and inspections occur at least annually. Licenses may be granted for one to three years based on inspection results, and there is also a provisional six-month license for ALFs with significant issues which need to be addressed immediately. Each ALF resident must have an individualized service plan that is based on their needs and must be updated at least every 12 months. Current Virginia law does not mandate a staff-to-resident ratio in most instances, but it does specify the minimum number of staff that must be on duty over-night and in units that serve residents with special needs, such as memory care. In addition:

- facilities must have a written staffing plan that specifies the number and type of staff required to meet the direct care needs of their residents;
- ALFs must have written back-up plans for when regular staffing plans cannot be met;
- ALFs must report safety incidents to DSS within a day of occurrence;
- Virginia regulations specify the training required of individuals who provide direct care services;
- Virginia regulations require that each room have a call signal system for residents to use when they need immediate attention; and
- residents may wear remote signaling devices when they are not in their rooms

in ALFs without call buttons, and staff must check on each resident at least once per hour overnight and keep a log documenting when checks were made.

Virginia requires that ALFs specify a method to determine and document staffing needs but does not specify the method – each ALF may develop their own method for determining and documenting staffing needs. Documentation based on the method is reviewed when DSS performs inspections and responds to complaints. Several ALF administrators expressed that staffing needs in ALFs can change frequently, depending on changing resident needs and turnover in resident populations. They stressed that requiring a fixed staff-to-resident ratio would be inefficient, result in over-staffing and under-staffing at times due to needs based on *patient-centered care plans* (e.g., many residents need assistance with bathing and desire to bathe around the same time of day) and could lack the flexibility needed to provide adequate care.

## Staffing and Salaries

The 2013 National Center of Assisted Living survey reported that over half of ALF employees consisted of nursing staff. Certified Nurse Assistants (CNAs) represented a third of all nursing staff, and 27 percent were resident caregivers or non-certified nursing assistants. The turnover

rate among nursing staff was 24 percent overall, and 206 of the responding ALFs reported that they had a combined total of over 1,000 nursing staff vacancies.

According to the Bureau of Labor Statistics, the nationwide mean hourly wage for nursing assistants in 2016 was $13.29. In Virginia, the mean hourly wage was $12.52 ($0.77 below national mean), and in the District of Columbia it was $16.05. Staff turnover is a constant challenge. One Virginia ALF administrator reported that, although they provide free on-site CNA training, many CNA staff members leave the facility after several months to work for individuals in their homes. Another Virginia ALF administrator reported that adding 3 more staff would raise costs by $2,490 per resident per year.

## Monitoring Limitations

DSS does not currently have automated reporting capabilities to track inspection results and violations. Creating reports to monitor performance is currently a manual process that draws on data from several separate files is time consuming and dependent on institutional knowledge. In fact, LeadingAge (a statewide organization representing not-for-profit ALFs) creates summary reports of their member facilities' inspection findings which they provide to DSS. Additional resources for DSS are needed in order to create reports that can be easily produced on a regular basis to help identify problems and track trends over time and persist despite agency staff turnover.

## Costs and Reimbursement

Genworth Financial estimated that in 2019, the median cost of assisted living in Virginia will be approximately $4,300 per month[10]. The current AG monthly rate (approximately $1,220) covers about 28 percent of the projected 2019 monthly cost. Resident SSI income (except for a small monthly personal needs allowance) goes towards the monthly ALF payment, and the AG pays the difference between the amount that the resident pays and the AG rate (see example below). ALF administrators report that they must carefully manage their mix of AG to private paid residents, mix of level of need, and mix of unit types, in order to ensure adequate cash flow to remain viable. One non-profit ALF that serves a majority of residents whose fee is paid through the AG reported that they generally end each year with an operating deficit of approximately $400,000 to $500,000. The religious organization with which they are affiliated fills the funding gap. According to DSS staff, ALFs serving AG recipients have closed due to inadequate funding, and small ALFs are particularly vulnerable. Further, they report that placing individuals receiving the AG has become increasingly difficult, resulting in individuals being placed further away from their families.

[10] https://www.genworth.com/about-us/industry-expertise/cost-of-care.html.

State General Funds Allocated for Auxiliary Grants

SFY 2011 = $23,152,956; SFY 2012 = $20,739,804

SFY 2016 = $21,898,969; SFY 2017 = $21,398,969

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Monthly Auxiliary Grant Rate

SFY 2012 = $1,112 SFY 2017 = $1,221

Genworth Financial Median Monthly Assisted Living Costs[3]

2016 = $3,950 2019 Projected = $4,316

Sources: Department for Aging and Rehabilitation Services Annual Report 2013 and Department for Aging and Rehabilitation Services Annual Report

Example: Current AG Rate = $1,221 per month

**Resident payment:** ($735 SSI – $81 PNA) = **$656**

Auxiliary Grant payment: ($1,221 - $656) = $565

*The current maximum SSI payment is $735

## Recent Developments

An ALF stakeholder workgroup led by DSS is in the process of developing a new tool to help ALFs better determine staffing requirements. The tool is modeled on one used in Oregon modified to reflect Virginia needs. The tool will be pilot-tested in Virginia facilities that range in size, acuity mix, affiliation status and region. Results from the pilot tool will be compared to those determined by the current tools to help determine efficacy. It is expected that the new tool will be available in 2018 but its use will be voluntary; ALFs may still choose their current method to determine and document staffing needs.

In addition, DSS led a multi-year effort of stakeholders to update Virginia regulations dealing with ALFs. The new regulation package was signed by Governor McAuliffe in the summer of 2017 and included revised language increasing staff training on cognitive impairment, increased supervision of medication aides, increased administrator staffing, fall risk ratings for all residents, increased incentives for employment of full-time licensed health care professionals, and additional requirements for signaling devices and awake overnight staff. DSS staff and ALF administrators expressed the preference for allowing time for the new regulations to be implemented and their results evaluated before considering changes mandating staffing ratios.

## Review of Literature and Other States

According to the 2016 National Center for Assisted Living Regulatory Review, ten states specify staff-to-resident ratios in ALFs (Georgia, Idaho, Indiana, Maine, Mississippi, Missouri, Michigan, New Mexico, North Carolina, and South Carolina). Two of these states (Nevada and North Carolina) only specify ratios in special care units. In states that do not specify staff ratios, staff levels must be sufficient to meet resident needs and ensure safety, and the ALF must have a written staffing plan and demonstrate how their staffing system works. This is similar to Virginia's requirements.

The literature review findings suggest that specifying staffing ratios may result in a loss of staffing flexibility with increased costs but little or no gain in quality, due to the frequent changes in need at facilities. As noted above, resident turnover results in differing staffing needs, based upon the current mix of resident's needs and their desire for the timing of activities requiring assistance during the day. Some hours may be more staff-intensive (e.g., due to the need for assistance with bathing, toileting, dressing) than other times of the day despite the same number of residents. Set staff-to-resident ratios could result in both overstaffing and understaffing at times. Findings also included that increasing direct care staff may result in a reduction of other categories of staff (e.g., housekeeping) with no increase in quality.

## Actions Taken by the Joint Commission on Health Care

At the JCHC *Decision Matrix* meeting held in November 2017, the members approved a policy option to raise Auxiliary Grant rates and one requesting that the Secretary of Health and Human Resources direct the Department of Social Services to field a request for information to enhance data reporting capabilities. The Deputy Commissioner of Health and Human Resources was present at the meeting and the JCHC Chair obtained his agreement to act on this request.

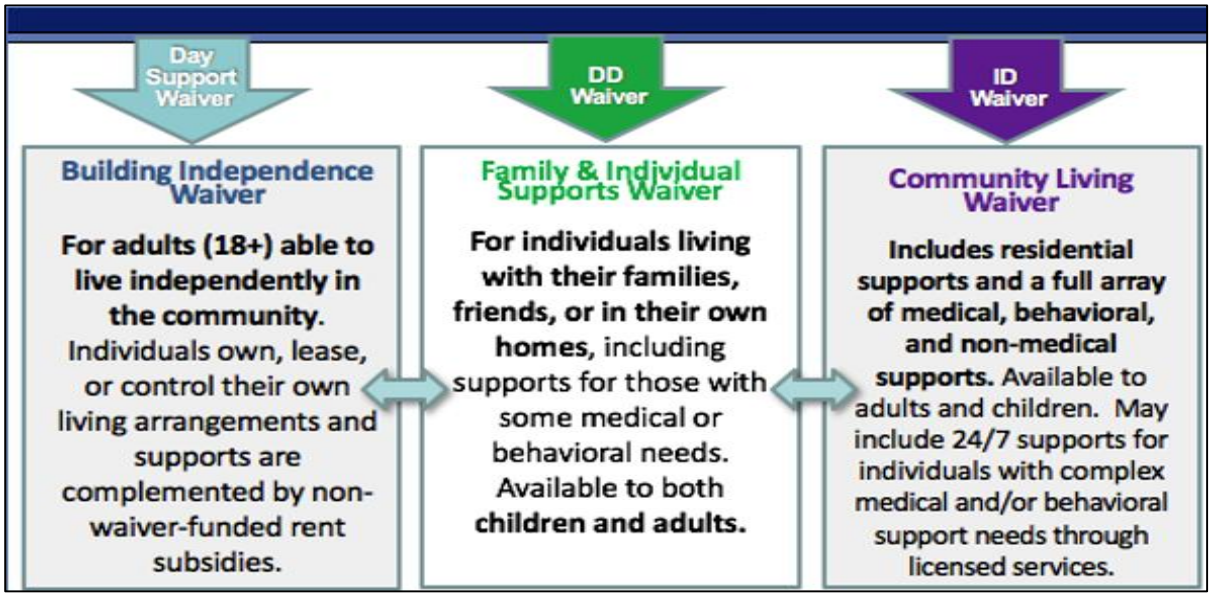
## Legislative Action

During the 2018 General Assembly session, Senator Rosalyn Dance introduced a budget amendment, Senate Bill 30 Item 343 #1s, to increase the Auxiliary Grant rate by $50 per month (for a total request of $2,280,000) in the first year of the biennium and an additional $100 per month in the second year (for a total request of $4,560,000), and Delegate Roslyn C. Tyler introduced a companion bill (House Bill 30 Item 343 #1h). The final budget did not include the budget amendment, but did maintain additional funds for the Auxiliary Grant provided in the Governor's introduced budget.

# The Creation of a Registry of Cases of Abuse and Neglect of Individuals Enrolled in the *Building Independence, Family and Individual Supports* and *Community Living* Medicaid Home and Community-Based Services and Supports Waivers

In 2017, the Joint Commission on Health Care (JCHC) received a letter of request from Delegates T. Scott Garrett, R. Steven Landes, John M. O'Bannon III and Chris P. Stolle asking the Commission to study the issue of abuse and neglect by service providers in three waiver programs. Specifically, JCHC was asked to identify costs of, and necessary statutory, regulatory and policy changes needed, to establish a registry of cases of complaints of abuse and neglect against direct service professionals (DSP) serving individuals enrolled in three Medicaid Home and Community-Based Services and Supports (HCBSS) waivers: Building Independence, Family and Individual Supports, and Community Living. Individuals in the three waivers include children and adults with developmental and intellectual disabilities (DD/ID). The waiver programs are operated jointly by the Department of Medical Assistance Services (DMAS) and the Department of Behavioral Health and Developmental Services (DBHDS).

## Background




Waiver services include in-home residential support services, personal care, respite care, skilled nursing, day support, pre-vocational services, therapeutic consultation, crisis stabilization, and companion care. Waiver services may be delivered in the home or other non-institutional setting and may be managed by an organization or, in the Consumer Directed model, by the enrollee or a family member. The variety of available services means that many Direct Service Professionals (DSPs) may come in contact with an enrollee.

## Abuse, Neglect, and Exploitation

The definitions of abuse and neglect are specified in the *Code of Virginia* (Title 63.2 Chapter 1 Section § 63.2-100) and include physical, emotional, and financial trespasses. Physical abuse is defined as intentional bodily injury such as slapping, choking, shoving, and poisoning. Sexual abuse is non-consensual or unwanted sexual contact. Mental/emotional abuse is defined as deliberately causing mental/emotional pain. Exploitation occurs when resources or income of adults are illegally or improperly used for another person's gain. Neglect is defined as when a person, through action or inaction, deprives an individual of care necessary to maintain health. Finally, self-neglect is defined as when adults fail to provide for themselves and jeopardize their health.

According to the Bureau of Justice Statistics (2016), individuals with a disability are victimized at higher rates than individuals without a disability, persons with cognitive disabilities have the highest rate of victimization, and the majority of perpetrators are known by the victim. Individuals with DD/ID may be particularly vulnerable to crimes involving interpersonal violence, such as physical or sexual assault, because as a population, regardless of age or gender, they are often the least able to recognize danger, the least able to protect themselves, likely to feel dependent on their abusers, and are the least able to obtain assistance within the criminal justice system.

## Mandated Reporting and Virginia Workplace Laws

Legally mandated reporters include health service providers, guardians, home care workers, law enforcement officers, teachers, athletic coaches and others (see the *Code of Virginia* § 63.2-1606). Failure to report may result in fines of up to $1,000.

Several Virginia state agencies have responsibilities for receiving, investigating and disposing of reported complaints.

1. The Department of Social Services (DSS) is responsible for complaints involving children through Child Protective Services (CPS). DSS maintains a central registry of founded cases and responds to requests for a search of the central registry.
2. The Department for Aging and Rehabilitative Services (DARS) is responsible for complaints involving adults through Adult Protective Services (APS). DARS delegates the responsibility of receiving and investigating reports to local Departments of Social Services (LDSS). The Virginia Department of Social Services (VDSS) maintains the DARS data platform, although DARS controls permission to access the database.
3. The Department of Behavioral Health and Developmental Services (DBHDS) is responsible for complaints involving individuals in the three waivers through the Office of Human Rights (OHR). The OHR maintains the Comprehensive Human Rights Information System (CHRIS).
4. The Department of Health Professions (DHP) receives complaints involving individuals licensed through their agency.

Only the DHP database is public-facing and CHRIS data that is made public must be in a format in which all information identifying a provider (perpetrator) or an individual receiving services has been removed. There is no cross-agency access to non-public databases.

After investigating reports by the appropriate agency, cases receive a disposition of either *founded/substantiated*, where the preponderance of the evidence supported the claim, or *unfounded/unsubstantiated* where the preponderance of the evidence did not support the claim. A disposition of unfounded/unsubstantiated may not always mean that abuse, neglect or exploitation did not occur – only that there was insufficient evidence to support the allegation.

## Case Information

Reports of abuse and neglect of children that are unfounded are maintained separately from founded cases and are only accessible to LDSS staff. Unfounded cases are purged after one year if there are no subsequent complaints, or after two years, if requested by the person alleged of committing abuse or neglect. Records must be retained for up to an additional two years if requested in writing by the person who is the subject (alleged perpetrator) of such complaint or report. The subject of an unfounded report or complaint who believes that such report or complaint was made in bad faith or with malicious intent may petition the circuit court for the release to such person of the records of the investigation or family assessment.

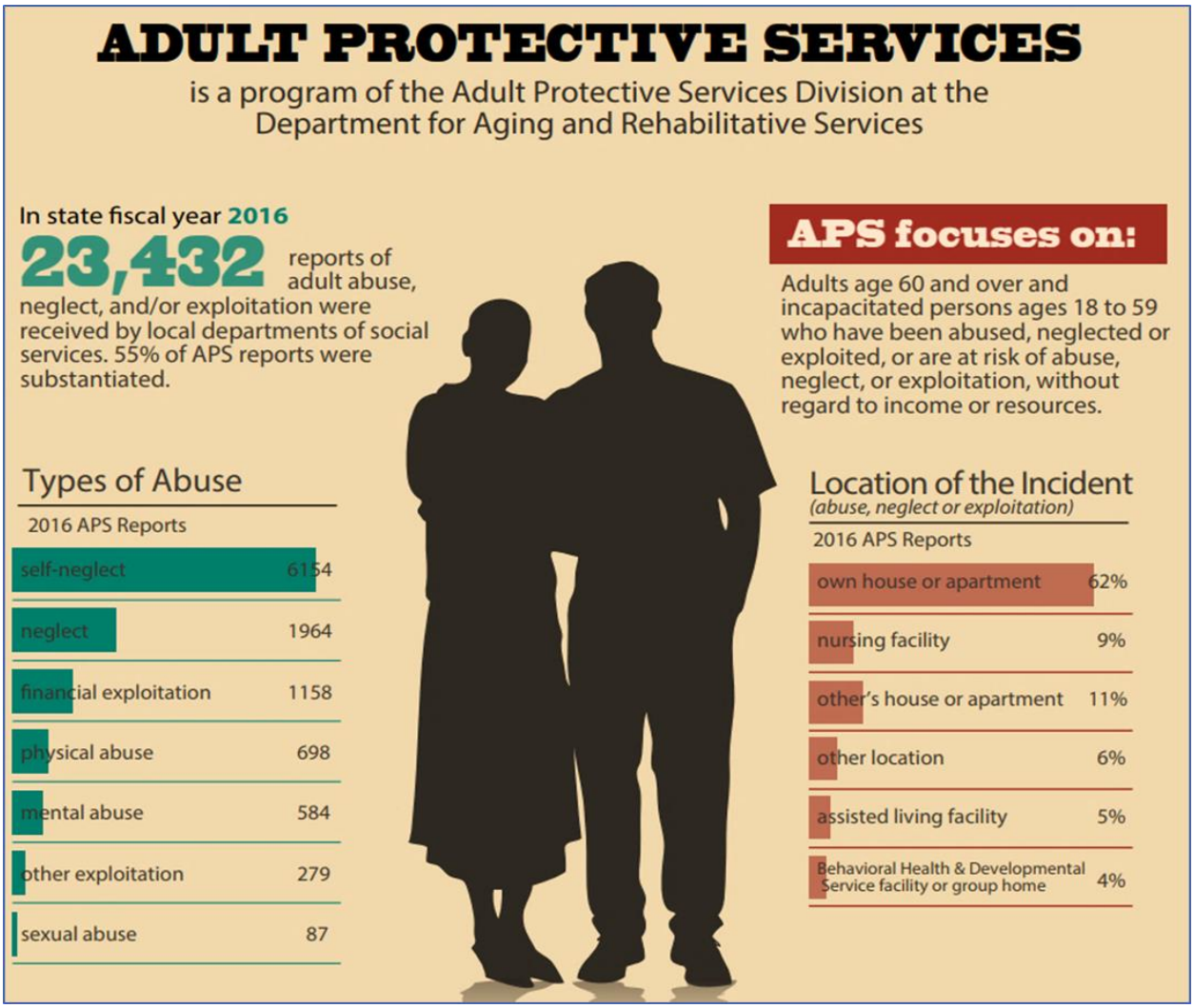
The Virginia Child Abuse and Neglect Central Registry contains the names of individuals identified as an abuser or neglector in founded child abuse and/or neglect investigations conducted in the state of Virginia. The findings are made by CPS staff in each LDSS and are maintained by the VDSS. Virginia mandates the VDSS to respond to requests for a search of the database made by local departments, local school boards, and governing boards or administrators of accredited private schools.

The DBHDS OHR administers the Comprehensive Human Rights Information System (CHRIS) in which allegations of abuse, neglect and exploitation are submitted. CHRIS has a licensed provider search capacity that can be accessed by specified individuals with certain roles, including OHR staff, advocates, Community Services Boards (CSBs), private providers, waiver staff and providers, the Office of Licensing, Local Licensing Providers, and Licensing Specialists. CHRIS information and statistical data is made available to the public in a format from which all information identifying a provider (perpetrator) or an individual receiving services has been removed. Lastly, the DHP maintains a searchable database of licensed providers with findings of facts and conclusions of law.

The DSS maintains the DARS platforms for LDSS staff to enter adult protective services (APS) cases, but DARS controls permission to access the database. Disclosure of information on adult cases can be made under a court order or when there is a legitimate interest to agencies, providers, guardians, attorneys, responsible family members, or others. According to the most recent DARS annual report, in SFY 2016 there were over 23,000 reports of adult abuse, neglect and exploitation of which 55 percent were substantiated or founded (DARS 2017). Therefore, it

may be possible that some providers who in fact committed abuse, neglect or exploitation continue to put waiver participants at risk because the preponderance of evidence did not support a complaint and potential employers do not have access to the unfounded complaint record, which in some cases has been purged.

Additionally, the *Code of Virginia* delineates the type of information that may be revealed by a past employer to a prospective employer and offers some protection from civil liability when the information disclosed is truthful and disclosed without malignant intent (§ 8.01-46-1). (The Code prohibits employers from willfully and maliciously preventing a past employee from obtaining employment [§ 40.1-27]). Despite protections against civil liability, employers may be reluctant to disclose negative information about a past employee's job performance. One possible solution to this problem may be found in Title 15.2 Chapter 17 of the *Code of Virginia* which provides immunity from civil liability to any sheriff, chief of police, director or chief executive of any agency or department employing deputy sheriffs, law-enforcement officers, the Director of the Department of Criminal Justice Services or his designee and jail officers for disclosing information on job performance of former deputy sheriffs, law-enforcement officers, or jail officers. A similar law may be introduced to provide immunity for employers of waiver services providers.



## Review of Other States

A review of other states found that none have public-facing registries of complaints for which no investigation has occurred or disposition determined. Some states have registries of founded/substantiated reports that are disability-specific and allow online searches. The cost of developing and maintaining such a registry is difficult to determine. Ohio created an Abuser Registry of founded/substantiated cases to be used during background checks and received a non-competitive CMS three-year grant under the Nationwide Program for National Background Checks for Direct Patient Access Employees of Long Term Care Facilities and Providers authorized by the Accountable Care Act. Other states use different types of methods to help ensure the safety of individuals receiving services. One state requires letters of reference from two past employers for direct care applicants and one state requires that applicants sign a consent to allow past employers to disclose information to potential employers.

## Actions Taken by the Joint Commission on Health Care

Members approved a policy option to introduce legislation to mandate that candidates seeking employment as direct care providers to waiver enrollees sign a consent to allow prospective employers to contact previous employers.

## Legislative Action

HB 813 (Delegate Hope), amended and enacted, "directs the Department of Behavioral Health and Developmental Services, in conjunction with the Department for Aging and Rehabilitative Services, the Department of Medical Assistance Services, the Department of Social Services, the Virginia Association of Community Services Boards, the Virginia Network of Private Providers, and other relevant provider organizations and stakeholders, to convene a work group in support of the Joint Commission on Health Care's efforts to improve the quality of the Commonwealth's direct support professional workforce and, if necessary, develop recommendations for policy changes to increase the transparency of the employment history of direct support professional job candidates. Recommendations are to be reported to the Joint Commission on Health Care by October 1, 2018."

## Additional Reference Information

Bureau of Justice. Crime Against Persons with Disabilities, 2009-2014 Statistical Tables. November 2016. https://www.bjs.gov/content/pub/pdf/capd0914st_sum.pdf

DMAS (Department of Medical Assistance Services). Individual and Family Developmental Disabilities Support Waiver Services Manual. Chapter 2, Provider Participation Requirements. 2017

DARS (Department for Aging and Rehabilitative Services), Adult Protective Services Division. SFY 2017 Annual Report. https://www.vadars.org/publications.htm#annualreports

# Quality of Health Care Services in Virginia Jails and Prisons, and Impact of Requiring Community Services Boards to Provide Mental Health Services in Jails, Interim Report

This is an interim report of a two-year study concerning health care services provided in jails and prisons based on resolutions that did not pass out of House Rules committee but were approved by the JCHC members at the May 23, 2017 Work Plan Meeting. The resolutions that the study is based on are HJR 616 (Delegate O'Bannon) mandating a study of the quality of health care services in jails and prisons and HJR 779 (Delegate Holcomb) mandating a study of jails to determine whether to require Community Services Boards (CSBs) to provide mental health services in jails and the impact of such requirement, including the costs and benefits.

By law the Virginia Department of Corrections (VADOC) and the local and regional jails are required to provide adequate health care to incarcerated offenders (U.S. Const. Amend. VIII; §53.1-32, and § 53.1-126 Code of Virginia). The only requirement in the Virginia Code is that the purchase of "medicine" by jails and regional jails be at the lowest prices reasonably possible.[11] Access to adequate health care, not quality health care, was defined by the United States Supreme Court in 1976. The court's definition was limited to access to care provided at the same level as the "community standard" with a full range of services. The court identified three rights to health care for incarcerated offenders: access to care, care that is ordered by a health care professional, and the right to professional medical judgment. [12]

## Existing Legislative Studies on Mental Health Services in the Jails

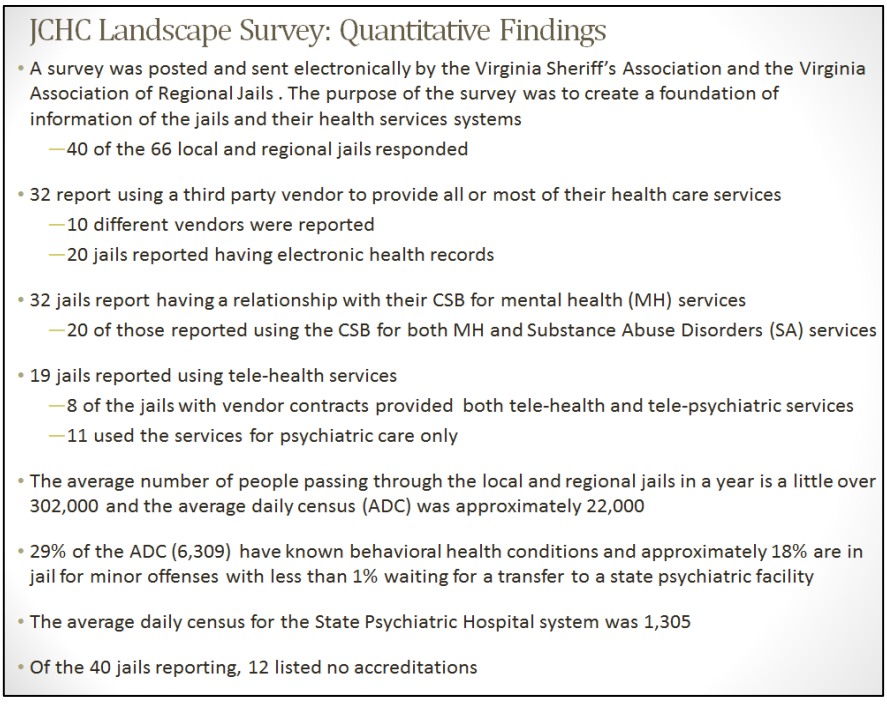
Currently, the Virginia General Assembly is studying care provided to offenders with a mental illness and/or substance use disorder through the Joint Subcommittee to Study Mental Health Services in the 21st Century. The study has produced a variety of recommendations that are in the process of being implemented. Some of the recommendations include designating a validated screening tool for mental health to be used by all jails and regional jails; use of jail diversion programs for the mentally ill; the creation of a discharge planning process for jails and regional jails to use; and improving the linkages between the jails, regional jails and community services such as Medicaid. In addition, the Virginia Department of Criminal Justice implemented six Jail Mental Health Pilot Grants across the Commonwealth. The purpose of the grants is to create comprehensive best-practice programs for offenders with mental illness that will provide comprehensive, evidence based services.

[11] Code of Virginia § 53.1-126
[12] Estelle v. Gamble, 429 U.S. 97, 97 S.Ct. 285, 1976

## Survey of Jails

As part of the interim report, JCHC conducted a landscape survey of the jails and regional jails to determine how health care services were delivered; whether they were delivered through a third party vendor and what level of services were being delivered. The interim report also included basic statistics and data compiled from the Virginia Medical Examiner's Office, the Virginia Department of Corrections and the Virginia Compensation Board. The interim report determined that there was a lack of knowledge at the state level about third party-vendor contracts between the jails and regional jails. The vendor contracts are not reviewed or collected by the state and while the Virginia Department of Risk Management (DRM) indicated that they provide liability insurance coverage to jails and prisons there was uncertainty over who was paying for medical liability insurance when vendor contracts were being used. In addition, the Board of Corrections jail standards are focused on policies and procedures, not the quality or delivery, of health care services. Finally, the interim report found that while a variety of avenues exist for a person in custody to file an official complaint related to health care services the system of collecting and maintaining the complaints is uncoordinated and not maintained electronically.

A significant issue arose during the initial review of jails and regional jails involving data sharing between them and the Community Services Boards (CSB).[13] The lack of data sharing included discussions about the meaning and intent of the federal Health Insurance Portability and Accountability Act (HIPPA). HIPPA includes a "lawful custody exception" in 45CFR 164.512 that allows all jails and CSBs to exchange information. Only a few jails and CSBs are doing so through memorandums of understanding. A legal opinion from the Attorney General providing clarification to all of the jails and CSBs regarding HIPPA may

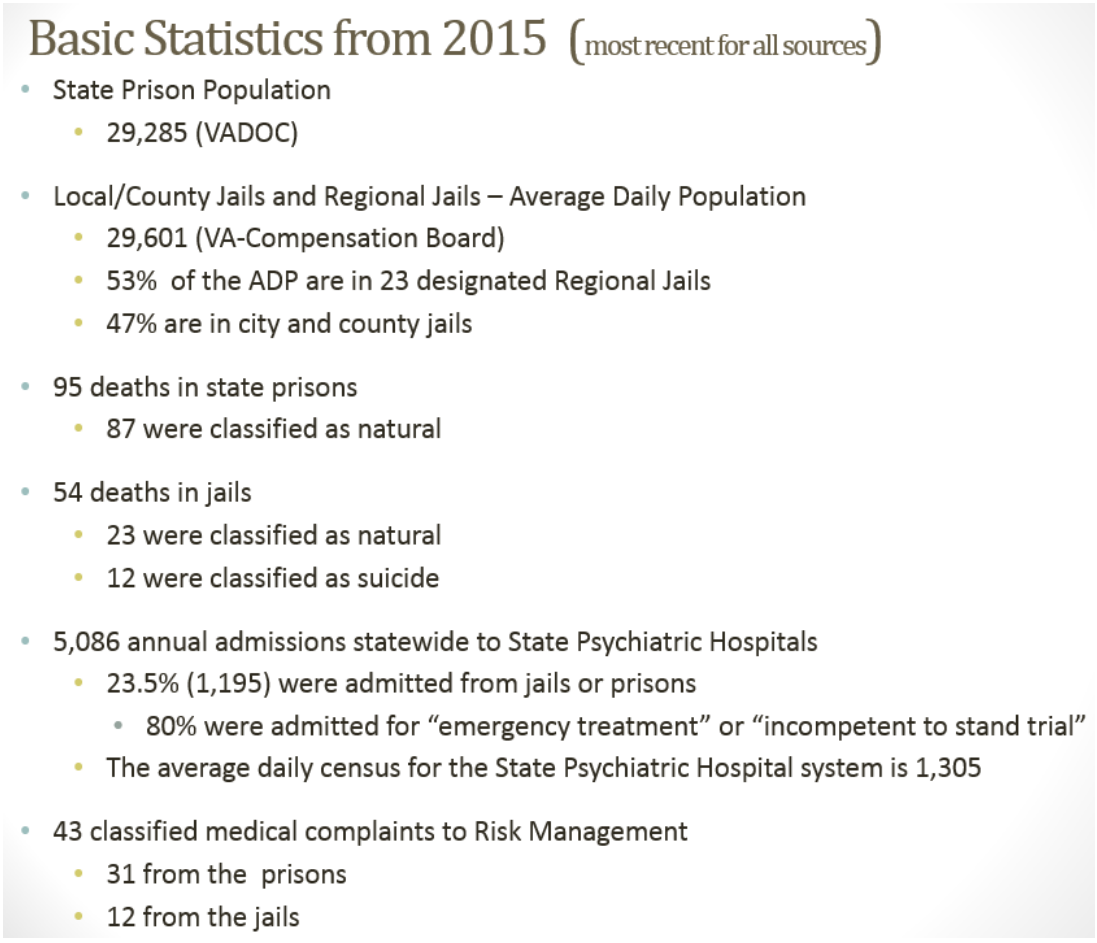



[13] Community Service Boards (CSB) are the designated entities that provide community mental health services across the state.

facilitate the necessary and important data sharing by providing local entities with one universal opinion on how to apply the federal privacy rules and laws.

## Other Preliminary Findings

Other preliminary findings from the initial review and interim report included a lack of confidence in the data being collected and reported by the State Compensation Board through its annual Jail Mental Health Survey. The data included in the report is not audited for accuracy. In addition, while tele-psychiatry in the jails and regional jails was being used it did not appear to be used to the fullest extent possible. The JCHC survey found 19 of 39 jails reported using a form of tele-health/tele-psychiatry. The Compensation Board data from the Annual Jail Mental Health Survey showed 17 of 66 jails reported some level of medical consultations in 2016 through video with only 6 using tele-psychiatry for CSB mental health prescreening for temporary detention orders. Finally, the Chief Medical Examiner's Office indicated a need to implement a Fatality Review process for inmate deaths. A fatality review process, it was suggested, could provide information on system wide gaps related to inmate health care.[14]




[14] The Virginia General Assembly authorized the Board of Corrections to establish a fatality review program during the 2017 legislative session (SB 1063, Code of Virginia § 53.1-2, 53.1-5, and 53.1-127)

## Actions Taken by the Joint Commission on Health Care

No action was taken; policy options will be included in the final report to be presented in 2018.

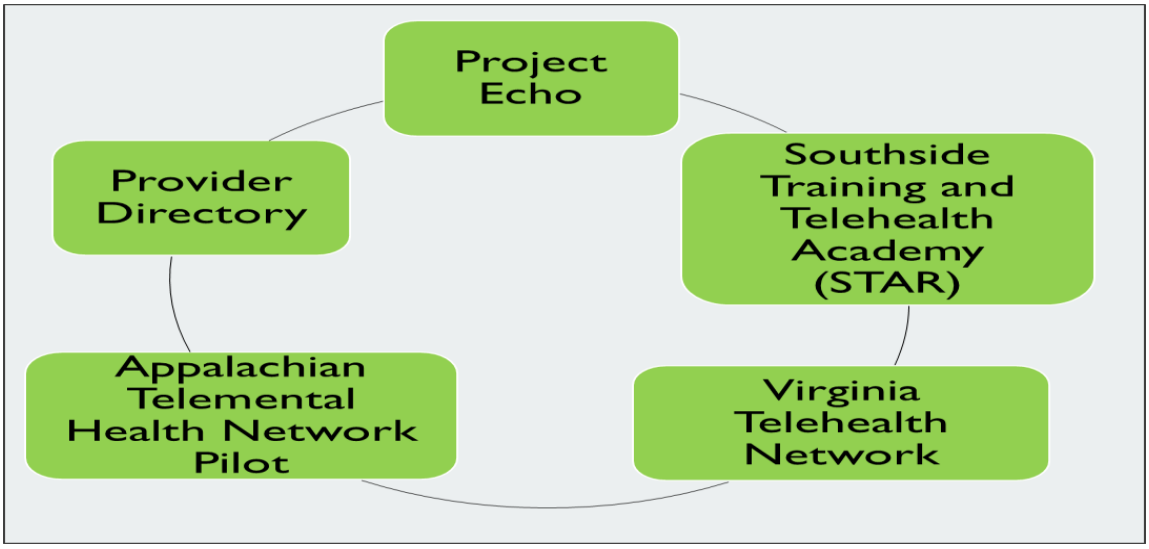
# Options for Increasing the Use of Telemental Health Services in the Commonwealth, Interim Report

HB1500 Item 30 #1c directed the Joint Commission on Health Care (JCHC) to study options for increasing the use of telemental health services in the Commonwealth, specifically the issues and recommendations set forth in the report of the Telemental Health Work Group of the Services System Structure and Financing Work Group of the Joint Subcommittee Studying Mental Health Services in the 21st Century.

## Background

The Joint Subcommittee Studying Mental Health Services in the 21st Century formed several work groups to deal with specific aspects of mental health services delivery, including a work group to identify barriers to, and make recommendations for, expanding the use of telemental health in the Commonwealth. The work group identified six categories of barriers (provider, workforce, financial, client/patient, policy, and preventive care) to expanding telemental health services. In addition, the work group identified twenty-nine options and twelve recommendations to address the barriers.

The interim JCHC report focused on several of the work group recommendations that are either in progress and need new resources, involve budget amendments and/or involve issues that can be addressed in the 2018 General Assembly (GA) session. These recommendations work together to educate providers on how to establish a telehealth practice; educate primary care providers on assessing, managing and referring patients to specialists; expand the number of specialists available to individuals living in health professional shortage areas; and streamline psychiatric contracting by the Community Services Boards (CSB). The activities include the following.



## Project ECHO®

Many primary care providers are not trained to treat patients with behavioral/substance use disorders and may feel uncomfortable managing such patients. As a result, primary care providers may wish to refer patients with complex issues to specialists; however, there is a lack of specialists to whom patients can be referred. Primary care providers need resources to help manage and/or refer patients appropriately. Project ECHO fosters knowledge sharing, collaboration, and building the confidence and capacity of providers to appropriately manage patients in the primary care setting and/or refer them to specialists.

Project ECHO began at the University of New Mexico (UNM) in response to the Hepatitis C epidemic that was occurring within a mostly rural state with many underserved areas. The project was then expanded to treat substance use, behavioral health, and many chronic health conditions. It employs a collaborative practice model using the *spoke and hub* system that links expert specialist teams at an academic 'hub' with primary care clinicians in local communities – the 'spokes' of the model. Project ECHO sessions allow for a team of specialists to consult on de-identified patient cases via video conferencing with primary care and other providers across the state. Sessions also include a didactic section on pre-determined topics (including medication assisted treatment for substance use) and continuing medical education credits are available. Providers can participate over computers and smart phones.

The Virginia Department of Health received a one-year grant from the Substance Abuse and Mental Health Services Administration (SAMHSA) for a pilot Project ECHO program in Virginia which is co-administered by the Virginia Department of Medical Assistance Services (DMAS). The Project ECHO pilot is scheduled to launch in early 2018 and includes three hubs at the University of Virginia (UVa), Virginia Commonwealth University (VCU) and Virginia Tech/Carilion. Hubs will oversee curriculum development and the rotation of specialists as well as provide administrative support and other resources. Virginia agency staff received training on Project ECHO at the University of New Mexico in the Summer of 2017. The University of New Mexico also provides the free software used for Project ECHO and will assist in evaluating the results of the Virginia pilot.

Ongoing funding is needed to maintain and expand the program beyond the one-year pilot period and to add other sites and subject areas. The Work Group estimated that $300,000 per year, for three years, is required to maintain and expand Project ECHO in the Commonwealth. Funds would be used for office space and administrative costs, payment to hub providers, technology, equipment and connectivity fees. The Work Group recommends that General Funds in the above amount be allocated for Project ECHO. As with all of the programs discussed in this report, Project ECHO is expected to be financially sustainable without General Funds after the initial three years.

## Southside Training and Telehealth Academy (STAR)

STAR is a partnership of the University of Virginia Center for Telehealth and the New College Institute located in Martinsville, Virginia. The New College Institute (NCI) is a state-funded educational entity that provides access to bachelor's degree completion programs, master's degrees, teacher endorsement programs, teacher recertification courses, and other resources through partnerships with colleges and universities. The STAR Telehealth programs are low cost and include training for providers, technology professionals, and telehealth presenters who help facilitate telehealth visits, as well as training on protecting personal health information (see Figure 2). The STAR platform, website and content were created in 2012 and are outdated and need to be refreshed. The Work Group estimates that it would take $100,000 to update STAR and recommends that General Funds be allocated for this purpose.

**Figure 2: STAR Training Topics**

- Board Certified Telemental Health Provider training for mental health professionals includes:
  - Crisis Management
  - Settings and Care Coordination
  - Direct-to-Consumer legal and ethical requirements
  - Orienting Clients
  - Choosing and Using Technology
- Certified Telemedicine Clinical Presenter training
  - Telemedicine Essentials
  - Live Video/Store, Foreword, Remote Monitoring
  - Consultation Protocols
  - Video Conferencing Etiquette & Record Keeping

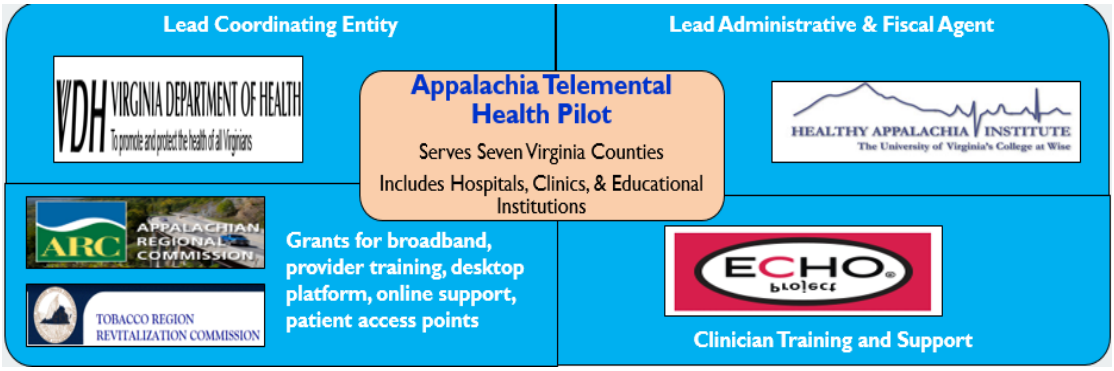
- Certified Telehealth Coordinator/Technical Professional
  - Technology Used & Live Interaction Visit
  - The Telehealth Coordinator and Team
  - Clinical Basics and Working with the Presenter
  - Remote Patient Monitoring
- HIPPA training
  - Purpose of HIPAA & HIPAA Standards
  - Identifying Breach Scenarios
  - How to be HIPAA Compliant
  - Business Associates Agreements
  - Penalties and Fines Related to Breaches
  - Role of HIPAA Audits

(Source: http://www.startelehealth.org/certificates-and-credentials)

## Appalachia Telehealth Network Pilot

The Appalachia Telehealth Network Pilot would involve several organizations including the Virginia Department of Health (VDH) which would be the lead coordinating agency and has already begun work on Project ECHO, Appalachian Regional Commission (ARC), the Tobacco Region Revitalization Commission (TRRC), and the Healthy Appalachia Institute at the University of Virginia in Wise, Virginia which would administer the program and serve as the fiscal agent (see Figure 3).

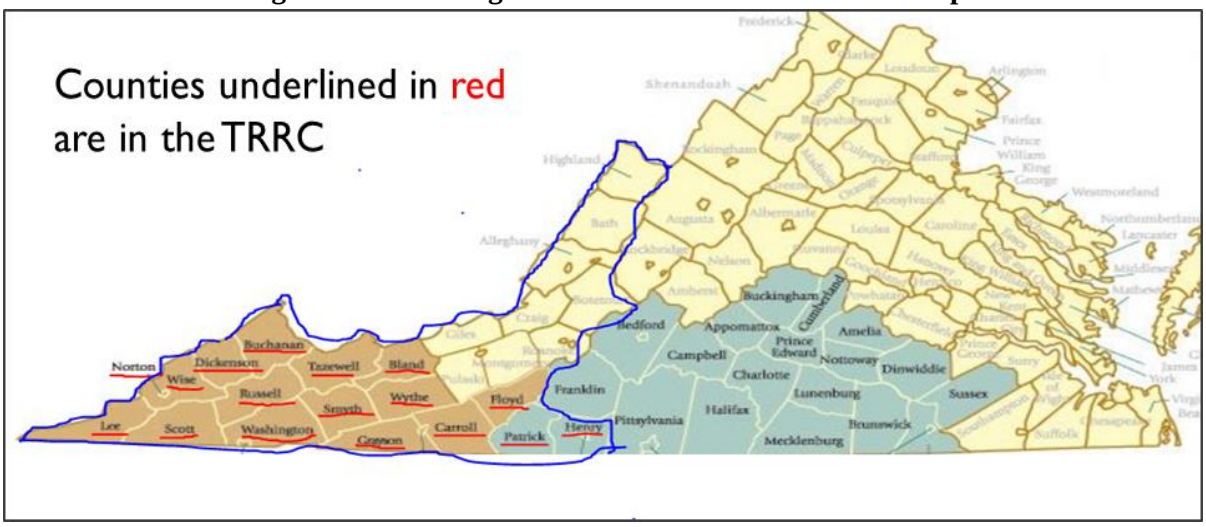
**Figure 3: Appalachia Telemental Health Pilot**




The goals of the recommended pilot are to expand and enhance access to quality affordable mental health services in Appalachia, allowing for efficient, early and accurate diagnoses while reducing travel time and costs. The pilot would create an online database of network providers to allow for shared feedback on technology, equipment, trainings, and certifications; and to provide a support community for providers across Appalachia. The pilot would also establish an on-line referral network (discussed below) that will allow providers to post information about specialty and state licenses, enable patients to identify providers with open appointments, and display patient ratings of providers and patient satisfaction.

The Appalachian Telemental Health Network would be composed of a regional broadband health network using an interoperable, standards-based system to allow for multiple vendor platforms. The pilot would assess broadband infrastructure throughout the region to close gaps; develop partnerships with regional providers, clinics, hospitals, public health institutes and institutes of higher education; and explore innovation through the development and testing of new technologies. In the Fall of 2017, the Work Group released *Next Steps for Expanding Access to Mental Health Services in Virginia: Priority Recommendations of the Telemental Health Work Group on Policy Development,* in which they estimated that $650,000 per year for three years would be required for the pilot and recommended that General Funds be appropriated for this purpose. The Work Group also noted that General Funds appropriated for any of the recommendations included in the report may be used to leverage Appalachian Regional Commission and Tobacco Region Revitalization Commission grants, both of which require matching funds. As administrative lead, the Healthy Appalachian Institute would apply for funding from the ARC and TRRC.

**Figure 4: Appalachian Regional Commission and Virginia Tobacco Region Revitalization Commission Footprints**




## Telemental Health Provider Directory

Another Work Group recommendation is for the General Assembly to allocate funds to the Virginia Telehealth Network to be used to implement a state-wide telemental health provider directory and website that could be accessed by individuals needing treatment who live in areas without appropriate providers. It is envisioned that the content of the directory would be limited to providers licensed and living in Virginia. Providers could receive technical and management training through STAR Telehealth Certification Trainings.

Additional ongoing funding may be required for sustainability but could come from a variety of sources (e.g., private/public partnerships). General Fund dollars would go to establishing and maintaining a directory of active providers to provide telehealth services to areas with health care professional shortages. The Work Group recommends that $50,000 annually, for three years, be allocated for this purpose.

## Other Recommendations

In addition to the above recommendations, the Work Group recommended that the JCHC conduct a study on the feasibility of statewide contracting for tele-psychiatric services by the Community Services Boards. Currently, the CSBs are each responsible for individual contracting, which the Work Group believes may be inefficient, particularly in light of the fact that CSBs serve urban, rural, and suburban areas with some CSBs requiring several full-time equivalent psychiatric staff, while others may only require a few hours per month. They envision that the Virginia Department of Behavioral Health and Developmental Services (DBHDS) function as a central contracting agent for all CSBs statewide.

## Conclusion

The Work Group made twelve recommendations to expand telemental health in the Commonwealth, and a budget amendment (HB1500 Item 30 #1c) mandated that the JCHC report on the recommendations. Several of the recommendations fit together synergistically to address access issues in Southwestern Virginia and statewide, and if implemented could help address the opioid crisis, especially in the southwest part of the state. Activities include provider training and support – both clinical support and technical support; training in how to administer a telemental health program, training for telehealth office support staff, establishing an on-line provider directory, software and hardware, provider capacity evaluation, and evaluation of the programs put in place. In total, the Work Group estimates that $1,100,000 of state General Funds per year for three years would be required to implement the recommendations. State General Funds could be leveraged as a match for ARC and TRRC grants. The final JCHC report on this issue will address progress achieved between this interim report and November 2018, as well as other Work Group recommendations.

## Actions Taken by the Joint Commission on Health Care

No action was taken; policy options will be included in the final report to be presented in 2018.

# ADHD Prevalence and Risks of ADHD Medication in Virginia, Interim Report

HB1500, Item 30(A), mandated that Joint Commission on Health Care (JCHC) identify methods to a) raise awareness of health/addiction risks of Attention Deficit Hyperactivity Disorder (ADHD) medication use; b) 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"; c) used by other states/countries to limit antipsychotic use; and d) identify the incidence/prevalence of prescribing anti-psychotics for off-label use. The budget language states that the results should be reported by the JCHC to the Chairmen of the House Appropriations and Senate Finance Committees no later than November 30, 2018.

## Background

Terms and Definitions

Psychotropic/psychiatric medications are psychoactive medications that change brain function and result in alterations in perception, mood, consciousness or behavior. Antipsychotic medications are a subset of psychotropic medications. There are two types of antipsychotic medications, typical and atypical, that are FDA-approved medications for various mental disorders (e.g., schizophrenia). Off label use of a medicine is use outside scope of marketing authorization from the Food and Drug Administration (FDA) with respect to the disorder being treated, patient demographics (e.g., age), and/or prescribed dosage/route of administration (Wittich et al. 2012). "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient" (FDA 2017).

Misuse/non-medical use of a drug is use for a purpose other than intended (e.g., performance enhancement). Abuse is consumption of a drug in harmful amounts. Dependence is a physical need for a drug and addiction is the combined physical/psychological need for a drug (Clemow et al. (2017).

ADHD Diagnosis

There are no clinical markers or lab tests for ADHD and it is diagnosed through a psychological assessment. In the US, a diagnosis is made on the basis of criteria specified in the DSM, including evidence of impairment in more than one setting (based on information from multiple informants like parents, teachers and other adults in the child's life) and ruling out other conditions that may have similar symptoms to ADHD (American Psychiatric Association, 2012). DSM criteria have evolved with all five editions of the DSM expanding the ADHD diagnostic eligibility each time. Diagnosis of ADHD may vary in other countries such that some countries (e.g., UK) have historically relied on more restrictive ICD-based hyperkinetic disorder diagnosis

while other countries rely on symptomology alone (vs. requiring evidence of impairment in the daily environment) (Thomas et al 2015; Visser et al 2015).

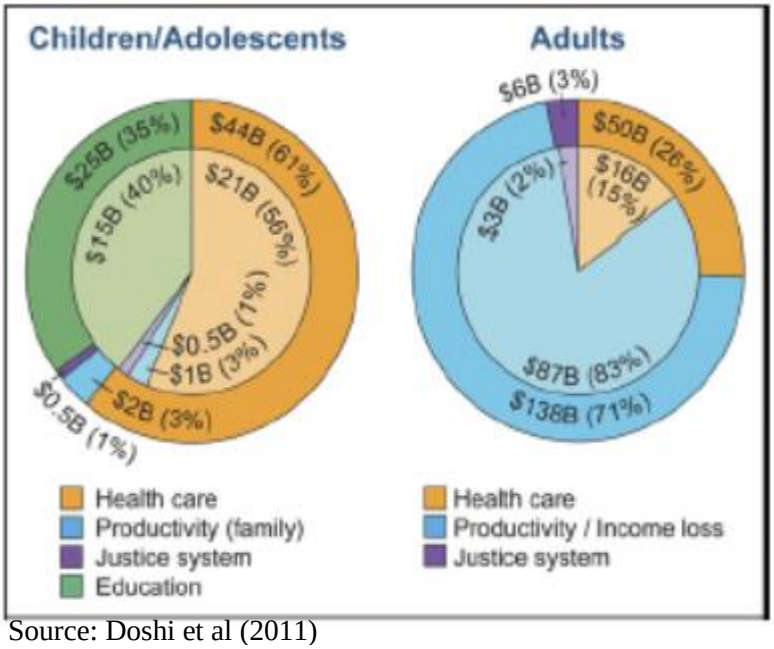
| | Current diagnostic criteria (DSM-5): | Examples: |
|---|---|---|
| | •6+ symptoms of inattention (≥6 month duration) AND/OR | •Has difficulty remaining focused during lengthy reading |
| | •6+ symptoms (>=6 month duration) of Hyperactivity and impulsivity | •Often fidgets with or taps hands or feet or squirms in seat |
| **AND** | •Several symptoms present: before 12 years old; in >1 setting | •At home, in school |
| **AND** | •Symptoms clearly interfere with/reduce quality of functioning | •Social, academic, occupational |
| **AND** | •Symptoms do not occur exclusively during course of schizophrenia/psychotic disorder and are not another mental disorder | •Mood/anxiety/personality disorder; substance intoxication/withdrawal |

ADHD Epidemiology-National Prevalence

In the US, ADHD is the most diagnosed neurodevelopmental disorder among youth. Estimates vary both by source of reported diagnosis, parent reports vs. administrative claims records, as well as within certain populations. The exact reasons for variations in reported prevalence of ADHD are unknown; however, there appear to be several drivers including demographic and potentially cultural differences among states resulting in wide variations in diagnosis; several schooling-related factors; and diagnostic factors. The "No Child Left Behind" law was associated with a 5.5 percentage point increase in ADHD diagnosis (from 10 to 15.5 percent) prevalence among low-income youth populations in states without existing school accountability laws. This association dissipated by 2011 as states transitioned to the "Race to the Top" law (Hinshaw & Scheffler 2014). Some evidence that laws limiting school personnel recommendation of psychotropic medications and/or eliminating psychotropic medication use from school-level decisions associated with lower diagnostic prevalence compared to no law (by 0.5 to 1 percent per year) (Hinshaw & Scheffler 2014). Multi-country evidence that children born just before school cut-off dates are 30 to 60 percent more likely to be diagnosed with ADHD/receive psychostimulants compared to those born after cut-off dates (Merten et al. 2017). The evolving DSM criteria has resulted in a two percent increase in the number of children meeting criteria for ADHD using the DSM-5 vs. DSM-4 criteria (McKeown et al. 2015). The rates of diagnosis also are influenced by how the DSM criteria are used. Diagnoses can be reduced by 50 percent when full criteria are rigorously applied (Thomas et al 2015). As will be highlighted later in this report, ADHD is associated with a high incidence of concurrent mental and behavioral disorders for which psychotropic medications are often prescribed.

While there are wide variations in estimates of ADHD symptom persistence into adulthood, evidence suggests a number of adverse impacts in terms of health, academic achievement, employment and criminality. These include decreased life expectancy and increased mortality

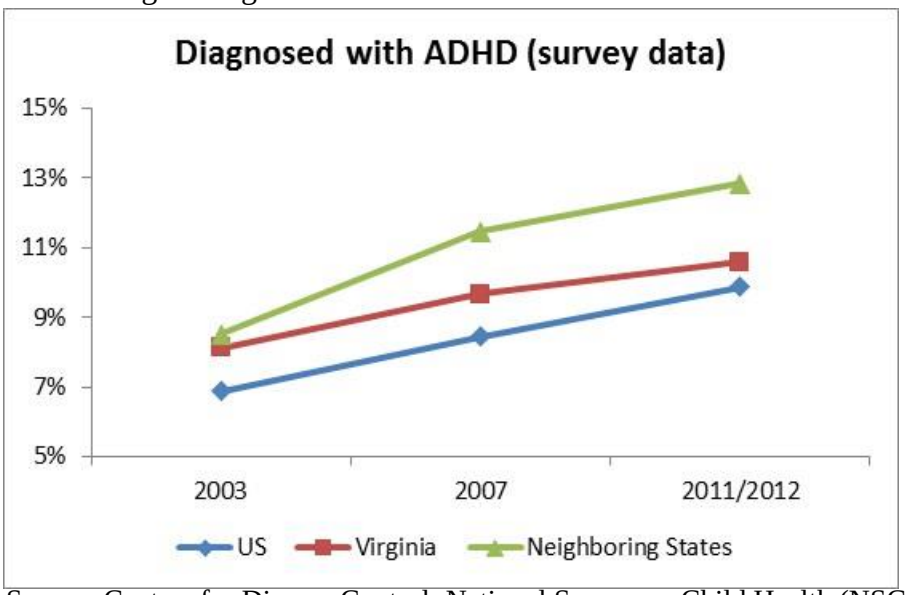
risk – likely in large part to increased risk of accidents – as well as adverse social outcomes in terms of schooling, employment and criminality (Cortese et al. 2015; Curry et al. 2017; Dalsgaard, Østergaard, et al. 2014; Dalsgaard et al. 2013; Erskine et al. 2015; Fletcher 2014; Mohr-Jensen & Steinhausen 2015; Nigg 2012). For the US as a whole, it is estimated that childhood ADHD imposes costs of over $140 - $265B (Doshi et al. 2011; Hinshaw & Scheffler 2014). Direct health care costs predominate in childhood years, while costs to economic productivity dominate among adults.




Source: Doshi et al (2011)

ADHD Epidemiology-Prevalence in Virginia

The following chart indicates the prevalence of ADHD in the general population (2003-2012) in Virginia relative to neighboring states and the U.S. overall.




Source: Centers for Disease Control: National Survey on Child Health (NSCH)

In Virginia, estimated prevalence from survey data collected from parents indicates increased prevalence over time, which reflects national trends but also appears to be lower than that of neighboring states. Health insurance data from both the commercial markets and Medicaid MCOs indicate slightly lower diagnostic prevalence among 2014/2015 enrollees compared to the most recent survey data from 2011. Specifically, 6.9-7.8 percent of individuals age 19 or less and 3.3 percent of individuals over age 19 had a diagnosis of ADHD in 2014/2015 in the commercial health insurance market (Virginia Health Information 2017).[15] In the Medicaid MCOs, 7.9 percent of children age 4-17 years old and 3.3 percent of adults age 18-25 were considered to have ADHD in 2014 (Hofford 2015).

One of the study components is related to prevalence of ADHD in schools. Information on ADHD prevalence is gathered in part via two federal laws that provide students diagnosed with disabilities eligibility for educational accommodations through Individualized Education Plans (IEPs) or "Section 504" plans. While there are federal reporting requirements for OHIs and disability designations more broadly, there is no direct measure of ADHD currently collected by the Virginia Department of Education. Between 2002 and 2017, the percentage of students designated with an OHI disability in Virginia increased from 1.7 to 2.6 percent (Virginia Department of Education); however, without ADHD-specific data, it is unknown the degree to which ADHD has played a role in the increase of OHI designations over time.

ADHD Treatment

There are two main treatment options for individuals with ADHD: pharmacological treatments and psychological interventions. In terms of ADHD medication, stimulants – which target norepinephrine and dopamine referenced earlier – constitute the majority of 1st-line medications, with non-stimulants often used in cases where stimulants are not effective or well-tolerated. There are also a variety of psychological intervention options, which can involve services for both children and their parents. In the U.S., the American Academy of Pediatrics (AAP) recommends behavior therapy first for children less than 6 years old, and ADHD medications first for those older than 6 years of age (Subcommittee on Attention Deficit/Hyperactivity Disorder, S.C.O.Q.I.A.M., 2011). Other countries, such as those in the United Kingdom, have different guidelines, especially for younger ages (Murphy et al. 2013). There are also other non-pharmacological interventions implemented for ADHD, such as nutrition-based interventions (e.g., elimination of food coloring, elimination of certain fats; limitation of food varieties), but these are not widely adopted. Nationally, up to three-quarters of children and adolescents diagnosed with ADHD receive medications – in particular stimulants – while rates of uptake of psychological services are substantially lower (Centers for Disease Control 2014).

In Virginia, the latest survey data from parental reports (2011/2012) suggest that the percentage of children and adolescents diagnosed with ADHD taking ADHD medication is in line with other

[15] Data represent 100% of individuals with fully insured policies and an estimated 50% of individuals with self-insured policies

states (Centers for Disease Control: National Survey on Child Health [NSCH]). More recent data from insured populations indicate that, between 2014 and 2015 in the commercial health insurance markets, just over one-half of individuals <20 years old who were diagnosed with ADHD were taking medication, somewhat lower than indicated in parental survey data. This equated to four percent of the total enrolled population in this age group. In the Medicaid population, around seven percent of enrolled individuals <18 years old were prescribed ADHD medications. Finally, according to DBHDS 2014-2017 data, approximately 2 percent of the population across all facilities were prescribed ADHD medication while 15 percent of children at the Commonwealth Center for Children were prescribed ADHD medication (DBHDS 2017). In the Community Services Boards (CSBs), between 2015 and 2017, 15–16 percent of individuals seeking any services had an ADHD diagnosis (DBHDS 2017a).

In terms of quality of ADHD treatment in the Commonwealth, for the Medicaid population, two recent reviews of the adherence of Medicaid providers to clinical practice guidelines suggest that there are areas of improvement (Magellan of Virginia 2017; Magellan of Virginia 2016). Assessment scores for ADHD diagnostic and therapeutic practices lagged behind those for three other behavioral health conditions reviewed. Examples of diagnostic practices not adhered to by many providers include reviewing findings from consultation with a psychiatrist or primary care physician when the provider was not a physician, and consideration of whether there had been partial remission of symptoms. On the other hand, two indicators of ADHD treatment quality drawn from the Healthcare Effectiveness Data and Information Set suggest that follow up for the MCO population during medication initiation and maintenance phases are in line or above the national average (see tables below) (DMAS 2017).

Magellan Clinical Practice Guideline (CPG) review of 139 patient records in 2015-2016*

| Assessment | CPG Provider Assessment Score <=3: Adherent; >3: Not Adherent | |
|---|---|---|
| | 2015 | 2016 |
| Suicide Risk | 2.5 | 1.1 |
| Major Depressive Disorder | 3.2 | 2.5 |
| Schizophrenia | 4.7 | 1.39 |
| ADHD | 6.8 | 6.6 |

Source: Magellan (2017); Magellan (2016)

Follow-up care for children 6-12 years old prescribed ADHD medication (2016) in MCOs

| Phase | Virginia | US average |
|---|---|---|
| Medication initiation | 44% | 42% |
| Medication continuation/maintenance | 56% | 52% |

Source: CHIPAC (2017)

* Records covered individuals receiving carved-out behavioral health services

ADHD Pharmacological Treatment Effectiveness

In the short term, there is consistent evidence both that ADHD medications reduce core symptomology, and that, when combined with psychotherapy, treatment improves a variety of outcomes, such as behavioral co-morbidities, academic achievement and social functioning (Chan 2016; Charach et al. 2011; Hinshaw & Scheffler 2014; Punja et al. 2015). However, it is worth noting that these findings have not gone unchallenged, with a recent meta-analysis assessing the strength of evidence as low, primarily because of funding connections between study authors and pharmaceutical companies (Storebø et al. 2014). In the long-term, some reviews have found benefits of ADHD medications on multiple long-term outcomes, but others have found that initial associations between ADHD medication use and improved outcomes dissipate over time (Arnold et al. 2015; Shaw et al. 2012; Storebø et al. 2014; Charach et al. 2011; Molina et al. 2009; Currie et al. 2014). It is unknown the degree to which diminished long-term effectiveness reflects medication efficacy, provider practices, or patient practices such as medication adherence.

ADHD Pharmacological Treatment Safety

Studies have found that most reported AEs are non-serious, such as GI pain (Storebø et al. 2014). However, it should be noted that follow up periods in these studies are typically short-term, and a recent review found that a large number of individuals drop out of studies on AEs, which may result in underestimation of AEs (Aagaard & Hansen 2011). Additionally, concerns have been raised that authors of studies assessing safety of ADHD medications have interests that may bias their results (Storebø et al. 2014). There is a strong body of evidence that stimulant use can cause short-term weight loss and slowed growth velocity, and mixed evidence on effects in the longer-term (For example, some studies have found growth catch-up associated with treatment cessation, while others have found persistent growth retardation) (Poulton et al. 2016; Powell et al. 2015; Faraone et al. 2007). There may be increased risk of CVD, although the magnitude of association is not well-established, due in part because CVD is a relatively rare event in study populations and power to detect risk differences is generally low (Dalsgaard, Kvist, et al. 2014; Hennissen et al. 2017; Schneider & Enenbach 2013; Westover & Halm 2012). On the other hand, there is a large body of evidence suggesting that stimulants are either not associated with or protective against both developing a substance use disorder and depression (Dalsgaard et al. 2013; Lee et al. 2015).

ADHD Stimulants and Non-Medical Use

Studies find non-medical use of stimulants in 3.4 to 9 percent of grade school and high school-age children, and between five and 35 percent of college age students, although the wide ranges may reflect uncertainties in the underlying self-reported data (Sweeney et al. 2013; Clemow 2016; Wilens et al. 2007). However, a sharp rise between 2005 and 2010 was also documented in terms of ED visits for the non-medical use of stimulants, with rates tripling during that time frame. The number of law enforcement cases in Virginia involving ADHD stimulants increased from 184 in 2000 to 1,089 in 2016 (Clemow & Walker 2014; Clemow 2017). However, while

ADHD stimulants have abuse potential, that potential is substantially reduced compared to illicit stimulants, and long-acting formulations further limit abuse potential (Clemow 2017). There is little evidence from the literature of misuse resulting in addiction to ADHD simulants.

Antipsychotic Medication Use

Use of atypical antipsychotics (AAPs) – which now constitute the vast majority of antipsychotics used – has grown substantially since the early 2000s, particularly in children and adolescent populations. Atypical antipsychotics are FDA-approved for a variety of mental health conditions. While ADHD is not one of those conditions, it is one of the most common mental health diagnoses among youth prescribed antipsychotics (Larson et al. 2011; van Hulzen et al. 2015). This finding may reflect a combination of elevated levels of co-occurrence of ADHD with FDA-indicated conditions for antipsychotics (e.g. major depressive disorder, bipolar mania, autism), off label use for a condition co-occurring with ADHD (e.g. aggression), and/or off label use for ADHD. Off-label use of Atypical Antipsychotics (AAPs) has increased over time (Sikirica et al. 2014). A significant percentage (e.g., 18-20 percent in the mid-2000s) of ADHD-diagnosed youth have been prescribed AAPs without a condition indicated for use (Birnbaum et al. 2013); however, more recent data on off label use of AAPs are limited.

In Virginia, data from insured populations indicate 5-6.4 percent of enrollees with an ADHD diagnosis were prescribed AAPs. Of particular relevance to this study, 2014-2015 data from the commercial health insurance market indicate that of all of the individuals prescribed AAPs, 31 percent did not have a FDA-indicated diagnosis for the prescribed AAP (Virginia Health Information 2017). It is possible that prevalence of off label prescriptions would be even higher if patient age and dosage level were also taken into consideration. Of the subset of enrollees prescribed AAPs who also had an ADHD diagnosis, 46 percent were prescribed AAPs off label. Medicaid data on off label prescribing of AAPs were not able to be analyzed for this report but will be part of the final report.

As with ADHD medications, there are also data on provider quality of care in regard to AAP prescribing. According to those data from 2016, children less than 18 years of age in Virginia MCOs had higher than national median use of multiple concurrent AAPs (2.66 percent versus 1.99 percent nationally), around average use of metabolic monitoring for side effects (29.8 versus 29.6 percent, respectively), and lower than national median rates of attempting psychosocial care before turning to AAPs (51.8 versus 60.4 percent, respectively) (DMAS 2017). A 2017 Agency for Health Research Quality (AHRQ) study assessed both effectiveness and harms of AAPs and found that they probably reduce conduct problems and aggression in children with ADHD and/or conduct disorders and there is moderate evidence of clinical benefit only for those unresponsive to stimulant medications for ADHD or have other behavioral disorders as the primary diagnosis. However, there may be increased risk of several adverse events or side effects, such as a higher risk of drug-induced movement disorder, total cholesterol, sedation/somnolescence or weight gain (AHRQ 2017).

## Actions Taken by the Joint Commission on Health Care

No action was taken; policy options will be included in the final report to be presented in 2018.

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# Medical Aid-in-Dying, Interim Report

Delegate Kaye Kory requested via letter that the Joint Commission on Health Care (JCHC) study the issue of Medical Aid-in-Dying (MAID). The delegate asked that the study include a review of states that currently authorize MAID and address the following questions. What has been the impact of informing patients about end-of-life options such as hospice care and palliative care? In current MAID states, how have health care systems, institutions and providers acted to implement the law? In current MAID states, have people been coerced to ingest end-of-life medication? Have any of the states enacted protections to discourage or prevent coercion? Has the implementation of the law impacted any state's health care costs? Using data from states that allow medical aid-in-dying, how many people would likely utilize medical aid-in-dying if it became law in Virginia? JCHC members approved the study during the Commission's May 23, 2017 work plan meeting.

## Background

Medical aid-in-dying, also known as physician assisted suicide or death with dignity, is defined in the literature as the ability of a patient to obtain a medication to end their life if they are competent, terminally ill, and over 18 years of age and/or the ability of a physician to prescribe a medication that will allow a competent, terminally ill individual over the age of 18 to end their life. Data from existing MAID states indicate that the majority of individuals who request MAID are white, college-educated, and dying of cancer.[16] The following tables provide additional information.

**Oregon: N=133 Washington: N=239 California: N=111 (In 6 months)**

**SEX** (Male)

- Oregon: 72 (54.1%) Washington: 120 (50%) California: 51 (45.9%)

**AGE**

| Oregon | | Washington | | California | |
|---|---|---|---|---|---|
| 18-54 | 8 (6.1%) | 18-44 | 6 (3%) | < 60 | 14 (12.6%) |
| 55-64 | 18 (13.5%) | 45-64 | 65 (27%) | 60-79 | 55 (49.5%) |
| 65-84 | 83 (62.4%) | 65-84 | 126 (53%) | 80-89 | 29 (26.1%) |
| 85 | 24 (18%) | 85 | 42 (18%) | 90 or > | 13 (11.7%) |

Note: Age categories differ for each state

**RACE / ETHNICITY**

| | Oregon | Washington | California |
|---|---|---|---|
| White | 127 (96.2%) | 232 (97%) | 102 (89.5%) |
| Black | 0 | . | 3 (2.6%) |
| Hispanic | 2 (1.5%) | . | 3 (2.6%) |
| Asian | 2 (1.5%) | . | 6 (5.3%) |

Source: Each state's 2016 Data Summary/Report

[16] Although a disproportionate number of individuals have ALS or some other neuromuscular disease as their terminal illness.

**Oregon: N=133 Washington: N=239 California: N=111 (In 6 months)**

Education

| | OR | WA |
|---|---|---|
| Less Than High School | 3.8% | 4% |
| High School Graduate | 17.4% | 27% |
| Some College | 28.8% | 35% |
| Baccalaureate or Higher | 50.0% | 32% |

| | CA |
|---|---|
| No High School Diploma | 5.4% |
| High School Diploma or GED | 22.5% |
| Some College, No Degree | 14.4% |
| Associate, Bachelor or Master Degree | 45.9% |
| Doctorate or Professional Degree | 11.7% |

Marital Status

| | OR | WA |
|---|---|---|
| Married | 47.0% | 43% |
| Widowed | 19.7% | 20% |
| Divorced | 27.3% | 27% |
| Domestic Partner | . | 1% |
| Never Married/Single | 6.1% | 7% |

Source: Each state's 2016 Data Summary/Report

**Underlying Illness, 2016**

**Oregon: N=133 Washington: N=239 California: N=111 (In 6 months)**

Oregon

| | |
|---|---|
| Cancer | 78.9% |
| ALS | 6.8% |
| Chronic Lower Respiratory Disease | 1.5% |
| Heart Disease | 6.8% |
| Other | 6.0% |

Washington

| | |
|---|---|
| Cancer | 77% |
| Neuro-degenerative Disease (including ALS) | 8% |
| Respiratory Disease (including COPD) | 8% |
| Heart Disease | 6% |
| Other | 2% |

California

| | |
|---|---|
| Cancer | 58.6% |
| Neuromuscular | 18% |
| Lung Respiratory Disease (non-cancer) | 6.3% |
| Heart Disease | 8.1% |
| Other | 9% |

Source: Each state's 2016 Data Summary/Report

Most private insurance pays for MAID medication and the physician visit. By law, federal funds cannot be used for a MAID prescription; therefore, Medicare and the VA cannot pay for the medication. Medicare enrollees, however, may use their private supplemental insurance to cover some of the costs and Medicaid can pay for MAID prescriptions out of a pot of state-only funds. As the tables below indicate, the majority of MAID individuals have government funded insurance, likely a result of the great majority of them being 65 years of age or older and; therefore, likely on Medicare.

## Insurance

**Oregon: N=133 Washington: N=239 California: N=111 (In 6 months)**

### Oregon

| | |
|---|---|
| Private | 26.3% |
| Medicare, Medicaid or Other Gov't | 61.7% |
| None | 0.01% |
| Unknown | 11.3% |

### Washington

| | |
|---|---|
| Private Only | 18% |
| Medicare, Medicaid Only | 46% |
| Combo of Private & Medicare/Medicaid | 17% |
| None | <1% |
| Unknown | 6% |
| Other (Including VA) | 11% |

### California

| | |
|---|---|
| Private | 18.9% |
| Medicare | 44.2% |
| Medicaid | 3.6% |
| Medicare/Medicaid (Dual Eligible) | 9.0% |
| Medicare/Medicaid & Private Supplemental Insurance | 11.7% |
| Has Insurance, but Type Unknown | 9.0% |
| None | 3.6% |

Source: Each state's 2016 Data Summary/Report

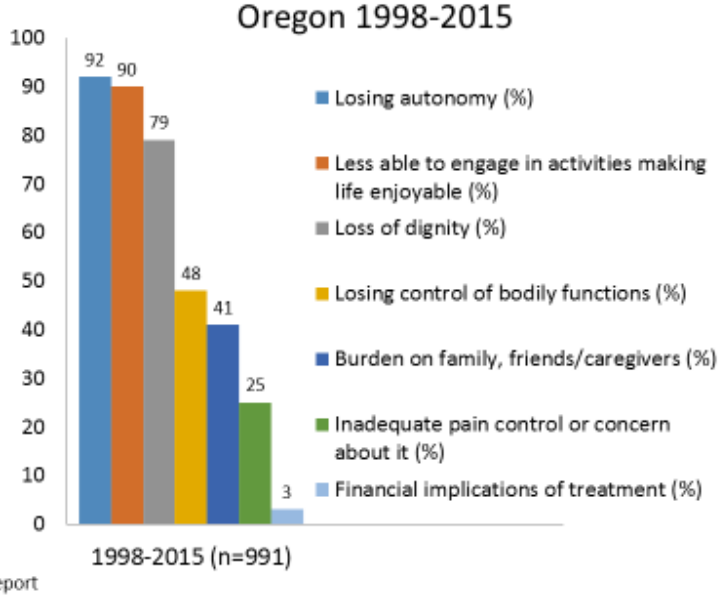
Often it is assumed that most terminally ill individuals who wish to use MAID do so because of physical pain. However, the most common concerns of individuals who have requested MAID are losing autonomy, being unable to engage in enjoyable activities, and loss of dignity. The great majority of the patients who ingested the MAID prescription did so at home (88.6 percent in OR; 88 percent in WA) and while enrolled in hospice care (88.7 percent in OR; 77 percent in WA; and 83.8 percent in CA).[17]

## MAID Patient Concerns

### Oregon & Washington 2016

| Reason Provided | OR % | WA % |
|---|---|---|
| Losing Autonomy | 89.5 | 87 |
| Unable to engage in enjoyable activities | 89.5 | 84 |
| Loss of dignity | 65.4 | 66 |
| Loss of bodily control | 36.8 | 43 |
| Burden on family | 48.9 | 51 |
| Concern about pain control | 35.3 | 41 |
| Financial implications of treatment | 5.3 | 8 |

### Oregon 1998-2015




Source: Oregon's and Washington's 2016 Data Summary/Report

[17] Source: Each state's 2016 Data Summary Report.

## Existing Virginia Statute

Current Virginia statute includes the following injunction against assisted suicide:

§ 8.01-622.1. Injunction against assisted suicide; damages; professional sanctions.

A. Any person who knowingly and intentionally, with the purpose of assisting another person to commit or attempt to commit suicide, (i) provides the physical means by which another person commits or attempts to commit suicide or (ii) participates in a physical act by which another person commits or attempts to commit suicide shall be liable for damages as provided in this section and may be enjoined from such acts.

B. A cause of action for injunctive relief against any person who is reasonably expected to assist or attempt to assist a suicide may be maintained by any person who is the spouse, parent, child, sibling or guardian of, or a current or former licensed health care provider of, the person who would commit suicide; by an attorney for the Commonwealth with appropriate jurisdiction; or by the Attorney General. The injunction shall prevent the person from assisting any suicide in the Commonwealth.

C. A spouse, parent, child or sibling of a person who commits or attempts to commit suicide may recover compensatory and punitive damages in a civil action from any person who provided the physical means for the suicide or attempted suicide or who participated in a physical act by which the other person committed or attempted to commit suicide.

D. A licensed health care provider who assists or attempts to assist a suicide shall be considered to have engaged in unprofessional conduct for which his certificate or license to provide health care services in the Commonwealth shall be suspended or revoked by the licensing authority.

E. Nothing in this section shall be construed to limit or conflict with § 54.1-2971.01 or the Health Care Decisions Act (§ 54.1-2981 et seq.). This section shall not apply to a licensed health care provider who (i) administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort and without intent to cause death, even if the medication or procedure may hasten or increase the risk of death, or (ii) withholds or withdraws life-prolonging procedures as defined in § 54.1-2982. This section shall not apply to any person who properly administers a legally prescribed medication without intent to cause death, even if the medication may hasten or increase the risk of death.

F. For purposes of this section:

"Licensed health care provider" means a physician, surgeon, podiatrist, osteopath, osteopathic physician and surgeon, physician assistant, nurse, dentist or pharmacist licensed under the laws of this Commonwealth.

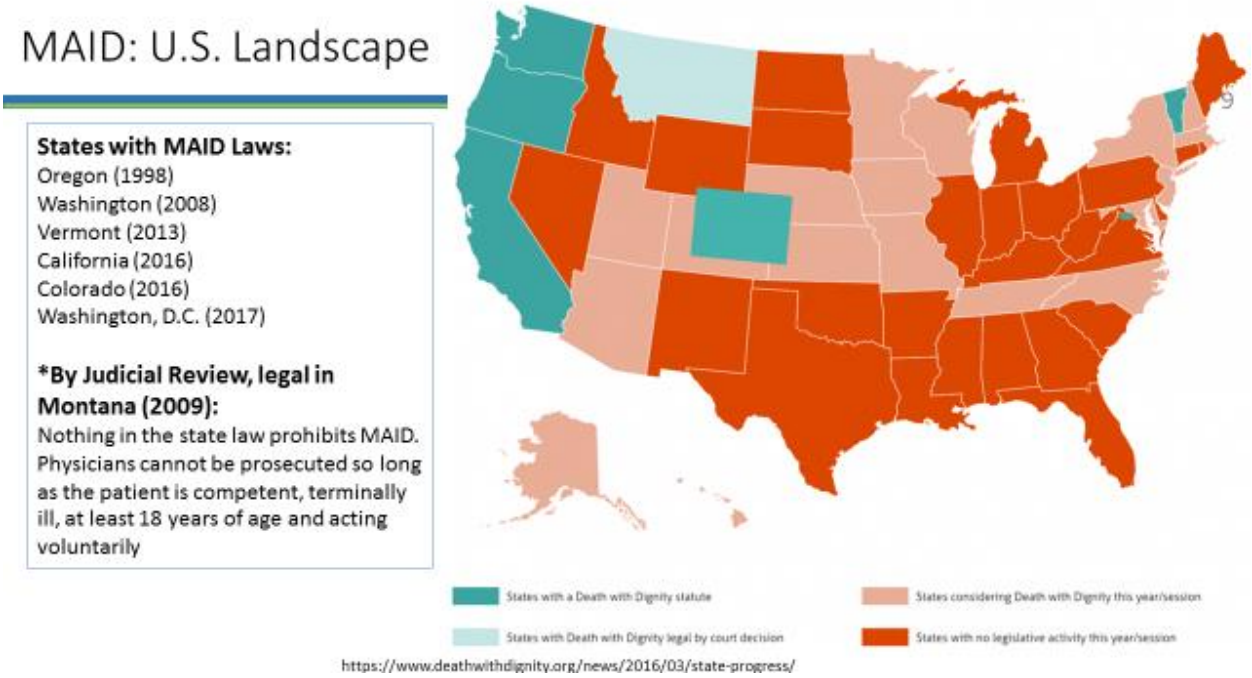
"Suicide" means the act or instance of taking one's own life voluntarily and intentionally.

1998, c. 624; 2015, c. 710.

(Emphasis added)

## Existing Medical Aid-in-Dying States[18]

In 2017, there were six states, and the District of Columbia, with laws allowing MAID[19].




https://www.deathwithdignity.org/news/2016/03/state-progress/

Oregon was the first state to legalize MAID and the states/D.C. that followed utilized Oregon's statute as a blueprint (excluding Montana in which MAID is legal by Judicial Review). Generally, existing MAID statutes include the following.

Eligibility Criteria:

- Adult, 18 years of age and older
- Resident of the state
- Suffer from a terminal illness
- Able to self-administer the medication

Requires physician provide the following to the patient:

1. Diagnosis with prognosis
2. Range of options including palliative care and hospice care
3. Risks and probable death from prescription

Process:

- Attending and consulting physicians determine and agree that the patient suffers from a terminal disease with less than six months to live.
- Patient must provide 2 voluntary oral requests no less than 15 days apart.
- Patient must provide a signed written request (form provided) for the medication, co-signed by 2 witnesses
- Physician to provide prescription at least 15 days after the initial oral request and at least 48 hours after the signed request.
- Before providing the prescription, the physician must confirm the patient has not rescinded the request and remind the patient that the patient is not required to ingest the medication.
- If either physician believe the patient is suffering from depression or any behavioral health condition that may be impacting their choice, they are to refer the patient to a psychiatrist before proceeding.
- For prescription: After obtaining patient approval, attending physician calls pharmacy to alert pharmacist of the prescription to be filled and sends the written prescription through specified means.
- When ingesting, patient must self-administer the medication.

[18] Please note that states with failed MAID legislation and/or that passed anti-MAID laws will be discussed in the final report in 2018.

[19] In April, 2018 Hawaii's Governor signed into law the "Our Care, Our Choice Act," making it the seventh state to legalize MAID. The law will go into effect January 1, 2019.

Oregon Statute[20]

Oregon's law requires the patient to be a resident of the state, determined by the attending physician to have a terminal disease, and voluntarily express a wish to die. The attending physician, to ensure that the patient is making an informed decision, shall inform the patient of his or her medical diagnosis and prognosis; the potential risks associated with taking the medication to be prescribed; the probable result of taking the medication to be prescribed; and the feasible alternatives, including, but not limited to, comfort care, hospice care and pain control. A consulting physician also must examine the patient and relevant medical records and confirm, in writing, the attending physician's diagnosis that the patient is suffering from a terminal disease, and verify that the patient is capable, is acting voluntarily and has made an informed decision.

If either physician believes the patient may have a mental health disorder (including depression) causing impaired judgement, the physician may refer the patient for counseling. Medication can only be prescribed if the counselor determines that the patient does not have impaired judgement resulting from a mental health condition. The patient must provide to the attending physician two oral requests no less than 15 days apart, and a written request witnessed by two people. The prescription cannot be provided less than 15 days from initial oral request and less than 48 hours after written request. Witnesses must attest that to the best of their knowledge the patient is capable, acting voluntarily, and is not being coerced to sign the request. One of the witnesses must be a person who is not a relative of the patient by blood, marriage or adoption; a person who at the time the request is signed would be entitled to any portion of the estate of the qualified patient upon death under any will or by operation of law; or an owner, operator or employee of a health care facility where the qualified patient is receiving medical treatment or is a resident. The patient's attending physician at the time the request is signed shall not be a witness. If the patient is in a long term care facility at the time the written request is made, one of the witnesses shall be an individual designated by the facility and having the qualifications specified by the Department of Human Services.

The attending physician also must adhere to the following requirements. Immediately prior to writing the prescription for medication, he/she must verify again that the patient is making an informed decision. The physician also is required to recommend the patient notify next of kin; counsel the patient about the importance of having another person present when the medication is consumed and of not taking the medication in a public place (e.g. a hotel room, park)[21]; and inform the patient that he or she has an opportunity to rescind the request at any time and in any manner, and offer the patient an opportunity to rescind at the end of the 15-day waiting period. The physician may dispense medications directly if he/she is registered as a dispensing physician

[20] Note: All of this section is pulled from Oregon's statute, 127.800 §1.01 through 127.995.

[21] The statute states that any governmental entity that incurs costs resulting from a person terminating his or her life in a public place shall have a claim against the estate of the person to recover such costs and reasonable attorney fees related to enforcing the claim.

or, with the patient's consent, contact a pharmacist and inform the pharmacist of the prescription and deliver the written prescription personally or by mail to the pharmacist, who will dispense the medications to either the patient, the attending physician or an expressly identified agent of the patient. Finally, the attending physician must document all steps of the MAID process in the patient's medical record and fill-out and submit to the Center for Health Statistics required forms when medicine was prescribed (including the dispensing record) and after death. (The Department of Human Services is required to generate and make publically available an annual statistical report of information.) The cause of death on the death certificate should be the terminal illness.

*Immunities and Opting-Out*

No one can be punished for choosing to participate or not participate in MAID. Participation in MAID is voluntary. If a health care provider is unable or unwilling to carry out a patient's request the physician can transfer the patient to a new provider (which includes a new physician or new facility). However, a provider (facility/health care system) may prohibit another provider (physician) from participating in MAID on the premises of the prohibiting provider if the prohibiting provider has notified the health care provider of the prohibiting provider's policy regarding participating in MAID. If the provider engages in MAID, he/she can receive sanctions within the context of the facility/health care system. Suspension or termination of staff membership or privileges due to prohibited participation in MAID is not reportable under ORS 441.820 and cannot be the sole basis for a report of unprofessional or dishonorable conduct under ORS 677.415 (2) or (3). A health care provider can participate in MAID while acting outside the course and scope of the provider's capacity as an employee or independent contractor; and a patient can contract with his or her attending physician and consulting physician to act outside the course and scope of the provider's capacity as an employee or independent contractor of the sanctioning health care provider.

*Effect on Construction of Wills, Contracts or Statutes*

The law also states that no provision in a contract that would affect whether a person engages in MAID shall be valid. The sale, procurement, issuance or rate of life, health, or accident insurance shall not be effected by MAID. In addition, ending one's life utilizing MAID shall not have an effect upon a life, health, or accident insurance or annuity policy. A request by a qualified individual to an attending physician to provide an aid-in-dying drug shall not provide the sole basis for the appointment of a guardian or conservator.

Nothing in the statute can be construed to authorize a physician or any other person to end a patient's life by lethal injection, mercy killing or active euthanasia. Actions taken in accordance with this statute shall not, for any purpose, constitute suicide, assisted suicide, mercy killing or homicide, under the law. Engaging in coercion or fraud in order to compel a person to engage in MAID is a class A felony.

Statutes: What Other MAID States Have Done Differently[22]

While Oregon's statute was used as a blueprint, the subsequent MAID states did make the following changes.

**CA:** The attending physician, consulting physician, or mental health specialist shall not be related to the individual by blood, marriage, registered domestic partnership, or adoption, or be entitled to a portion of the individual's estate upon death.

**VT:** The attending physician must inform the patient, *in writing*, of their diagnosis, prognosis and range of treatment options including hospice and palliative care.

**DC:** The attending physician must inform the patient of the availability of supportive counseling to address the range of possible psychological and emotional stress involved with the end stages of life.

**CO:** The attending physician must confirm no coercion or undue influence by having a private conversation with the patient.

**CA, CO:** As part of informed decision, the attending physician must state the possibility that the patient may choose to obtain the medication but not take it.

**VT, CA, CO**: Statute does NOT include the following: If the patient is in a long term care facility at the time the written request is made, one of the witnesses shall be an individual designated by the facility and having the qualifications specified by the Department of Human Services.

**CA:** The attending physician shall give the patient the final attestation form, with the instruction that the form be filled out and executed by the patient within 48 hours prior to taking the medication.

**CA:** A person is not liable if hs/she assisted the patient by preparing the medication so long as the person did not assist with the ingestion of the drug.

**CA:** Patients are instructed to keep the medication in a safe and secure location until the time that the qualified individual will ingest it.

**CA, WA, VT, CO:** Language includes rules for safe disposal of unused medications.

[22] Sources: California statute-Division 1 of the Health and Safety code, Part 1.85 § 443 through 443.22b; Colorado statute-§ 1, 25-48-101 through 25-48-123; D.C. Act 21-577, "Death with Dignity Act of 2016"; Vermont statute-Chapter 113 § 5281 through § 5290; Washington statute-70.245.010 through 70.245.010.

**CA:** Actions taken in compliance with MAID statute shall not constitute neglect or elder abuse for any purpose of law.

**CO:** An individual utilizing MAID and on Medicaid shall not have their benefits denied or altered.

**CA:** Patient level data shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding.

**VT:** Language does not require statistics to be collected for public use.

**CA:** Prohibits an insurance carrier from providing any information in communications made to an individual about the availability of an aid-in-dying drug absent a request by the individual or his or her attending physician at the behest of the individual. The bill would also prohibit any communication from containing both the denial of treatment and information as to the availability of aid-in-dying drug coverage.

**DC:** The death certificate will state the terminal disease as cause of death, but the Office of the Chief Medical Examiner shall review each death involving a qualified patient who ingests a covered medication and, if warranted by the review, may conduct an investigation.

**DC:** Mayor shall issue rules to specify the recommended methods by which a patient may notify first responders of his or her intent to ingest a medication; and establish training opportunities for the medical community to learn about the use of covered medications by patients, including best practices for prescribing the medication.

## MAID Outcomes in Oregon and Washington

Data compiled by Oregon and Washington state government officials indicate that not all of the individuals prescribed MAID medications die from ingesting them. As the two Oregon figures below indicate, some individuals who received the prescription died from other causes, most likely their illness, and the outcome of others is unknown (some of whom will be recorded in the subsequent year). Note that in the longitudinal table, for 2016, the 133 MAID deaths include 19 from the previous year that were not included in the total number of prescription recipients (e.g. 204) because they received their prescription the year before.

**Oregon DWDA Prescription Recipients and Deaths by Year, 1998-2016 (As of January 23, 2017)**

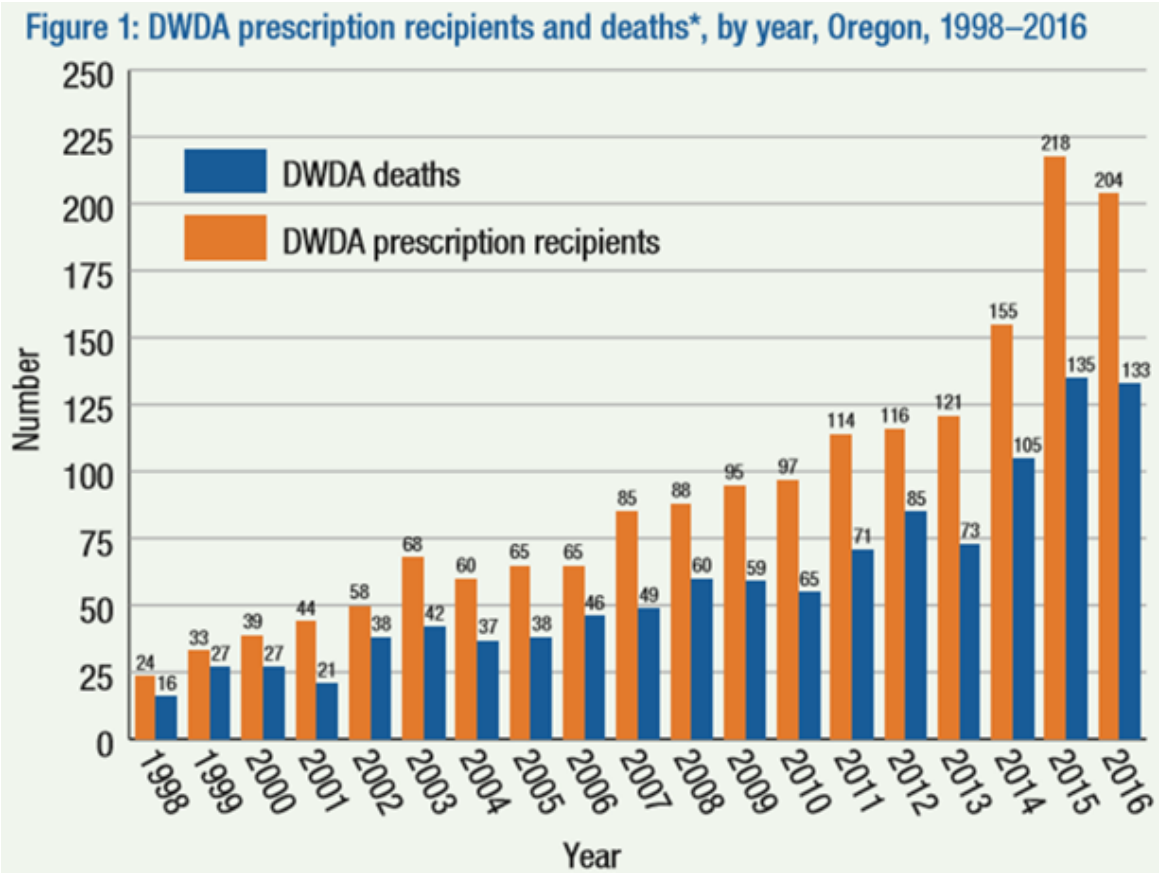
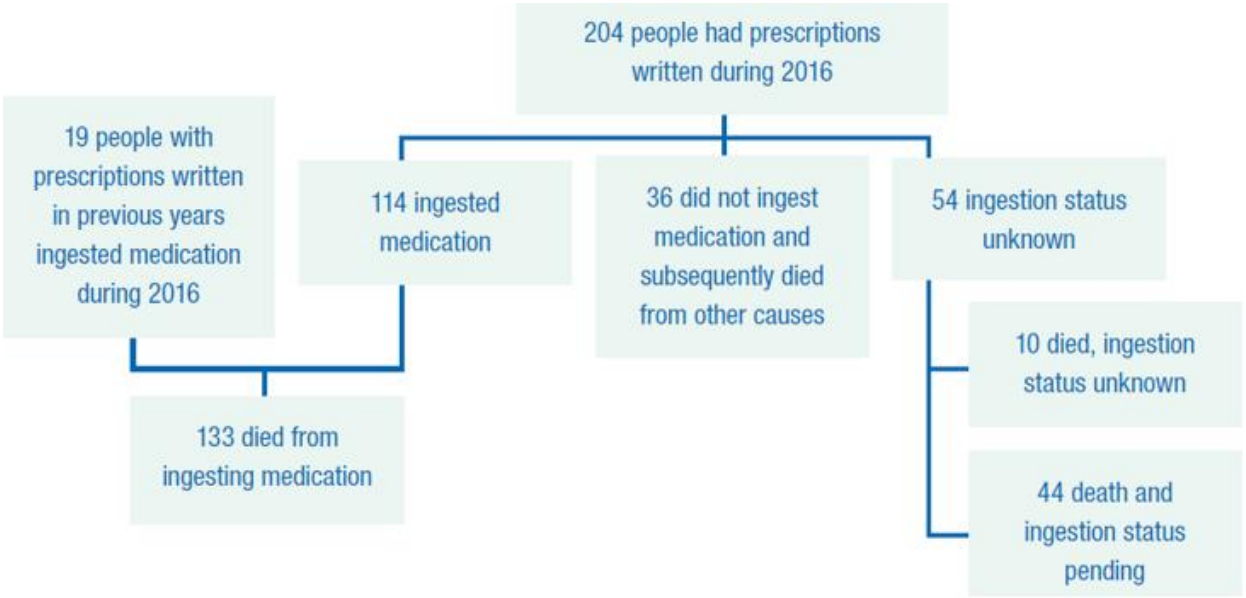



**Chart of Outcomes from Oregon DWDA 2016 Data Summary**



The following are data on MAID outcomes in the state of Washington.

**Washington MAID Utilization Rates**

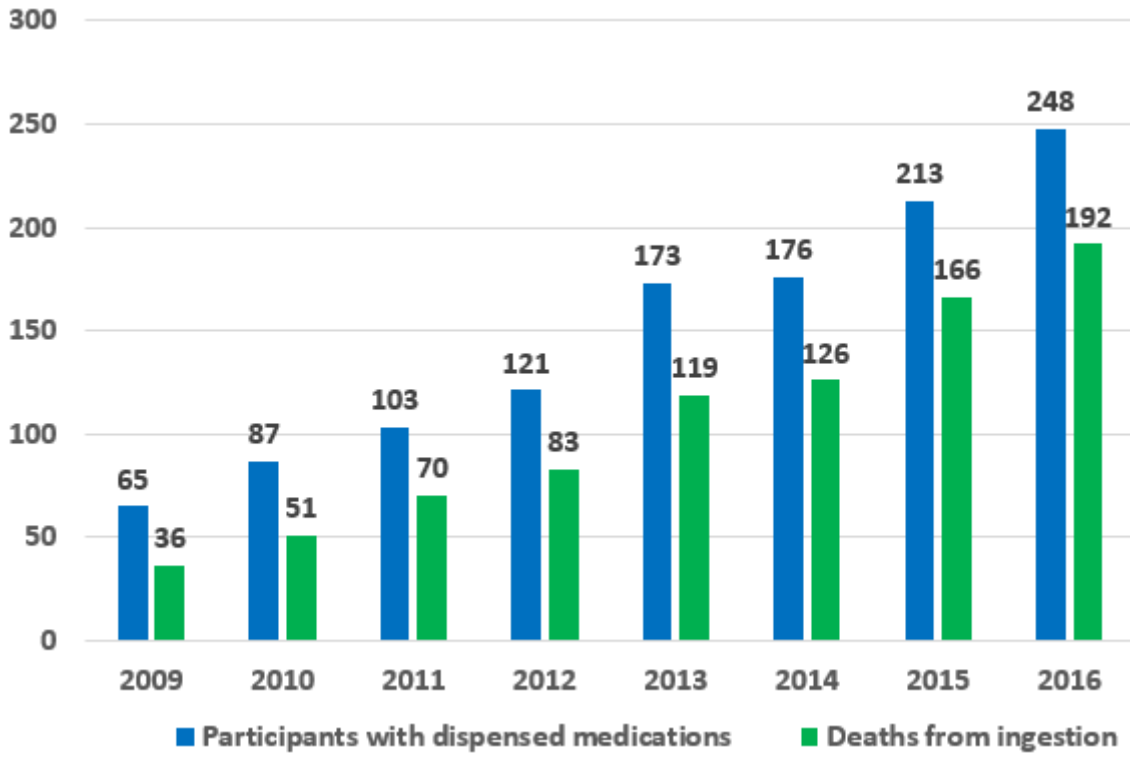
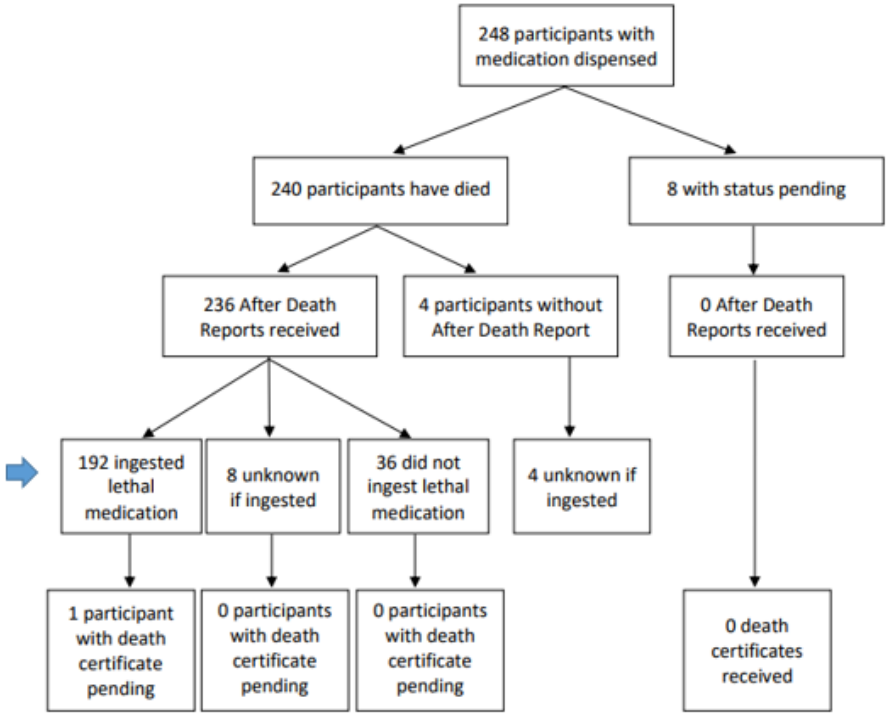



**Chart of Outcomes from Washington DWDA 2016 Data Summary**

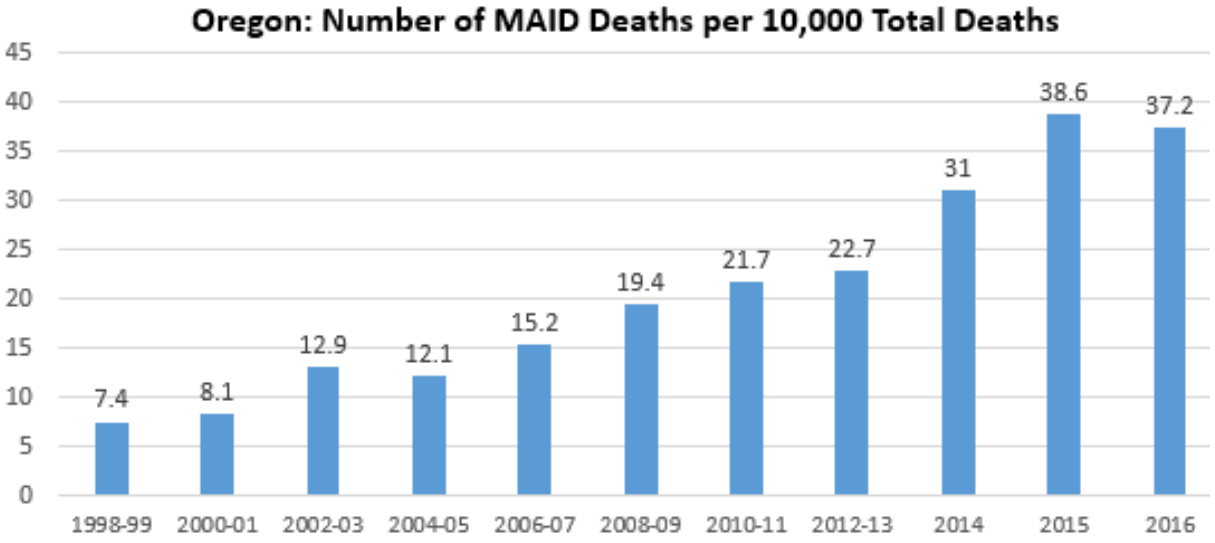



Source: http://www.doh.wa.gov/portals/1/Documents/Pubs/422109-DeathWithDignityAct2016.pdf

## Estimating MAID Utilization in Virginia[23]

For Oregon and Washington (states for which there is trend data), the number of people who died due to MAID medication has remained below 200 individuals. Specifically, in Oregon there were 37.2 MAID deaths per 10,000 total deaths in 2016 (i.e. less than 1 percent of all deaths). The death rate in California was 13.5 per 10,000 total deaths.[24] Based on this information, if MAID were to be legalized in Virginia it is likely that the number of people requesting MAID would be quite small for the first few years, gradually increasing to approximately 242 individuals dying from MAID medications.

- Oregon: 37.2 / 10,000 = .00372 percent of all deaths
- Virginia[25]: .00372 x 65,000 (total deaths in 2015) = 241.8




Data compiled from Oregon's annual DWDA data summaries, 1998-2016

[23] Sources: Oregon, Washington and California data summaries/reports; and for Virginia death data: http://vaperforms.virginia.gov/indicators/healthfamily/mortalityLongevity.php

[24] The rate includes 11 individuals who were prescribed medications in 2016 and died from ingesting the drugs in 2017. It does not include 128 (out of 577) individuals who were prescribed medications in 2017 but their outcome was still undetermined at the time of the annual report.

[25] Most recent data available.

## MAID Study Work Group

A work group was created to discuss Medical Aid-in-Dying and consider components of the statute that will be one of the policy options. The following individuals/organizations were invited to participate:

- ALS Association
- American Cancer Society
- American Lung Association
- Anthem
- Bon Secours
- Capital Caring
- Carilion
- Compassion and Choices
- DARS
- DBHDS
- DHP
- DisAbility Law Center
- DMAS
- Family Foundation
- HCA Healthcare Virginia
- INOVA
- Mary Washington Healthcare
- Medical Society of Virginia
- NAMI
- Office of the Secretary of Health and Human Resources
- Riverside Health System
- Robert Misbin, MD
- Senior Navigator
- Sentara
- Social Worker, Diane Kane
- Society for Critical Care Medicine
- The Arc of Virginia
- University of Virginia
- Virginia Association of Health Plans
- Virginia Commonwealth University Health System
- VDH
- Virginia Association of Health Plans
- Virginia Association for Hospices and Palliative Care
- Virginia Catholic Conference
- Virginia Centers for Independent Living
- Virginia Health Care Association
- Virginia Hospital and Healthcare Association
- Virginia Nurses Association
- Virginia Public Access Project
- Virginia Society for Human Life
- Virginia Trial Lawyer Association

In 2017, the work group had two meetings, on July 25 and August 25, with additional meetings planned for 2018. The work group has discussed the many issue areas associated with medical-aid-in-dying including philosophical, ethical, legal, policy, and statutory.

## Actions Taken by the Joint Commission on Health Care

No action was taken; policy options will be included in the final report to be presented in 2018.

# Meeting Agendas 2017

## Joint Commission on Health Care

| | |
|---|---|
| May 23, 2017 | **Call to Order**<br>Senator Charles W. Carrico, Sr., Chair<br>**Discussion of 2017 Work Plan Proposal**<br>Michele L Chesser, Ph.D.<br>Executive Director, Joint Commission on Health Care |
| August 22, 2017 | **VDH Update on the Plan for Well Being**<br>Marissa Levine, M.D.<br>Commissioner of Health, VDH<br>**Overview of the State Targeted Response to the Opioid Crisis Grant Awarded to Virginia**<br>Mellie Randall<br>Substance Use Disorder Policy Director, DBHDS<br>**Staff Report: Options for Increasing Telemental Health Services in Virginia**<br>Paula R. Margolis, Ph.D., MPH<br>Senior Health Policy Analyst<br>**Staff Report: Should Medigap Policies Be Provided for Medicare Recipients Under 65 Years of Age in Virginia**<br>Stephen Weiss, MPA<br>Senior Health Policy Analyst |
| September 19, 2017 (AM) | **Update from the Virginia Health Care Foundation**<br>Debbie Oswalt<br>Executive Director, Virginia Health Care Foundation<br>**Life-Sustaining Treatment Guidelines Working Group Report**<br>Andrew Mitchell, Sc.D.<br>Senior Health Policy Analyst<br>**Staff Report: Staffing Ratio Requirements for Assisted Liing Facilities in Virginia**<br>Paula R. Margolis, Ph.D., MPH<br>Senior Health Policy Analyst<br>**Staff Report: Quality of Health Care Services in Virginia Jails and Prisons, and Impact of Requiring Community Service Boards to Provide Mental Health Services in Jails (Interim Report)**<br>Stephen Weiss, MPA<br>Senior Health Policy Analyst |

| | |
|---|---|
| September 19, 2017 (PM) | **Update on the Department of Behavioral Health and Developmental Services' activities and initiatives including mental health in jails (HB 1996), hospital census, STEP-VA (same-day access), and the Department of Justice settlement agreement regarding Virginia training centers**<br>Jack Barber, M.D.<br>Interim Commissioner, DBHDS<br><br>**Report from the Virginia Department of Corrections on its review of policy options from the 2016 Medical Care Provided in State Prisons- Study of the Costs**<br>Steve Herrick, Ph.D.<br>Director, Office of Health Services at Virginia Department of Corrections<br><br>**Staff Report: Sustainability of Virginia's Prescription Monitoring Program**<br>Andrew Mitchell, Sc.D.<br>Senior Health Policy Analyst<br><br>**Staff Report: Prevalence and Risks of ADHD Medications in Virginia**<br>Andrew Mitchell, Sc.D.<br>Senior Health Policy Analyst |
| October 17, 2017 | **VHI Annual Report and Strategic Plan**<br>Michael Lundberg<br>Executive Director, VHI<br>**Staff Report: Heroin Use in Virginia**<br>Stephen Weiss, MPA<br>Senior Health Policy Analyst<br><br>**Staff Report: Creation of a Registry of Abuse or Neglect Cases for the Building Independence, Family and Individual Supports, and Community Living Waiver Programs in Virginia**<br>Paula R. Margolis, Ph.D., MPH<br>Senior Health Policy Analyst<br><br>**Staff Report: Medical Use and Health Effects of Cannabis**<br>Andrew Mitchell, Sc.D.<br>Senior Health Policy Analyst |
| November 21, 2017 | **Call to Order and Recognition of Departing Member**<br>Senator Charles W. Carrico, Sr., Chair<br><br>**Overview of Agenda**<br>Michele Chesser, Ph.D.<br>Executive Director<br><br>**Decision Matrix**<br>Study-overviews, with Public Comment Results, and Review of Policy Options<br>JCHC Staff |

## Behavioral Health Care Subcommittee

October 17, 2017

**Update from the Mental Health Services in the Commonwealth in the 21st Century Subcommittee**
Sarah Stanton and David Cotter
Senior Attorneys, Division of Legislative Services

**Presentation on the Alternative Transportation Study (HB1426)**
Shannon Dion
Director of Policy and Legislative Affairs, Department of Criminal Justice Services
Will Frank
Director of Legislative Affairs, Department of Behavioral and Developmental Services

**Report from the Brain Injury Interagency Implementation Team**
Patti Goodall
Director of Brain Injury Services Coordination Unit, Department of Aging and Rehabilitative Services

**Overview of the Minnesota Multistate Contracting Alliance for Pharmacy**
Jeff Schimeno
Senior Account Executive for East Region, Minnesota Multistate Contracting Alliance for Pharmacy

## Healthy Living/Health Services Subcommittee

August 22, 2017

**Telehealth Technology-Enabled Patient Care Teams**
Kathy Wibberly, Ph.D.
Director of Mid-Atlantic Telehealth Resource Center, UVA Center for Telehealth

**My Life My Community (ID/DD) Medicaid Waiver Redesign**
Dawn Traver
Director of Waiver Operations, DBHDS

**Staff Report: Should Medical Aid-in-Ding be legal in Virginia? (Interim Report)**
Michele L Chesser, Ph.D.
Executive Director, Joint Commission on Health Care

# Statutory Authority

§ 30-168. (Expires July 1, 2022) Joint Commission on Health Care; purpose.

The Joint Commission on Health Care (the Commission) is established in the legislative branch of state government. The purpose of the Commission is to study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services. In so doing, the Commission shall endeavor to ensure that the Commonwealth as provider, financier, and regulator adopts the most cost-effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care. Further, the Commission shall encourage the development of uniform policies and services to ensure the availability of quality, affordable and accessible health services and provide a forum for continuing the review and study of programs and services.

The Commission may make recommendations and coordinate the proposals and recommendations of all commissions and agencies as to legislation affecting the provision and delivery of health care.

For the purposes of this chapter, "health care" shall include behavioral health care.

(1992, cc. 799, 818, §§ 9-311, 9-312, 9-314; 2001, c. 844; 2003, c. 633.)

30-168.1. (Expires July 1, 2022) Membership; terms; vacancies; chairman and vice-chairman; quorum; meetings.

The Commission shall consist of 18 legislative members. Members shall be appointed as follows: eight members of the Senate, to be appointed by the Senate Committee on Rules; and 10 members of the House of Delegates, of whom three shall be members of the House Committee on Health, Welfare and Institutions, to be appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates.

Members of the Commission shall serve terms coincident with their terms of office. Members may be reappointed. Appointments to fill vacancies, other than by expiration of a term, shall be for the unexpired terms. Vacancies shall be filled in the same manner as the original appointments.

The Commission shall elect a chairman and vice-chairman from among its membership. A majority of the members shall constitute a quorum. The meetings of the Commission shall be held at the call of the chairman or whenever the majority of the members so request.

No recommendation of the Commission shall be adopted if a majority of the Senate members or a majority of the House members appointed to the Commission (i) vote against the recommendation and (ii) vote for the recommendation to fail notwithstanding the majority vote of the Commission.

(2003, c. 633; 2005, c. 758.)

**§ 30-168.2. (Expires July 1, 2022) Compensation; expenses.**

Members of the Commission shall receive such compensation as provided in § 30-19.12. All members shall be reimbursed for reasonable and necessary expenses incurred in the performance of their duties as provided in §§ 2.2-2813 and 2.2-2825. Funding for the costs of compensation and expenses of the members shall be provided by the Joint Commission on Health Care.

(2003, c. 633.)

**§ 30-168.3. (Expires July 1, 2022) Powers and duties of the Commission.**

The Commission shall have the following powers and duties:

1. To study and gather information and data to accomplish its purposes as set forth in § 30-168;

2. To study the operations, management, jurisdiction, powers and interrelationships of any department, board, bureau, commission, authority or other agency with any direct responsibility for the provision and delivery of health care in the Commonwealth;

3. To examine matters relating to health care services in other states and to consult and exchange information with officers and agencies of other states with respect to health service problems of mutual concern;

4. To maintain offices and hold meetings and functions at any place within the Commonwealth that it deems necessary;

5. To invite other interested parties to sit with the Commission and participate in its deliberations;

6. To appoint a special task force from among the members of the Commission to study and make recommendations on issues related to behavioral health care to the full Commission; and

7. To report its recommendations to the General Assembly and the Governor annually and to make such interim reports as it deems advisable or as may be required by the General Assembly and the Governor.

(2003, c. 633.)

**§ 30-168.4. (Expires July 1, 2022) Staffing.**

The Commission may appoint, employ, and remove an executive director and such other persons as it deems necessary, and determine their duties and fix their salaries or compensation within the amounts appropriated therefor. The Commission may also employ experts who have special knowledge of the issues before it. All agencies of the Commonwealth shall provide assistance to the Commission, upon request.

(2003, c. 633.)

§ 30-168.5. (Expires July 1, 2022) Chairman's executive summary of activity and work of the Commission.

The chairman of the Commission shall submit to the General Assembly and the Governor an annual executive summary of the interim activity and work of the Commission no later than the first day of each regular session of the General Assembly. The executive summary shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

(2003, c. 633.)

**§ 30-169. Repealed by Acts 2003, c. 633, cl. 2.**

§ 30-169.1. (Expires July 1, 2022) Cooperation of other state agencies and political subdivisions.

The Commission may request and shall receive from every department, division, board, bureau, commission, authority or other agency created by the Commonwealth, or to which the Commonwealth is party, or from any political subdivision of the Commonwealth, cooperation and assistance in the performance of its duties.
(2004, c296.)

**§ 30-170. (Expires July 1, 2022) Sunset.**
The provisions of this chapter shall expire on July 1, 2022.
(1992, cc. 799, 818, § 9-316; 1996, c. 772; 2001, cc. 187, 844; 2006, cc. 113, 178; 2009, c. 707; 2011, cc. 501, 607.)

2014, cc. 280, 518.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